THE QUEST FOR STEM CELL SCIENCE REGULATION IN MEXICO: ETHICAL, LEGAL AND RELIGIOUS CONTROVERSIES

Thesis submitted in fulfilment of the degree of Doctor in Bioethics and Medical Jurisprudence

By

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LIST OF CONTENTS

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DEDICATION

For my beloved best friends and parents
Alma Rosa Arellano Rafael & Ernesto Octavio Medina Lopéz
with deep gratitude for their constant encouragement

To my adored siblings and niece
Alma Judith, Ernesto Octavio & Alma Valeria.
Without your teasing, jokes, tenderness and words
this would not have been possible

With profound respect and unlimited love
to my grandmother, "Mamá Chuy"

And

Specially dedicated to the memory and constant example
of persistence of my treasured grandmother and grandfather
Maria Isabel Rafael Sanchez†
Primitivo Medina Lopéz

ABSTRACT

THE UNIVERSITY OF MANCHESTER
MARÍA DE JESÚS MEDINA ARELLANO
PHD IN BIOETHICS AND MEDICAL JURISPRUDENCE
THE QUEST FOR STEM CELL SCIENCE REGULATION IN MEXICO: ETHICAL, LEGAL AND RELIGIOUS CONTROVERSIES
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Many countries in Latin America, for cultural, religious and regulatory reasons, have struggled and failed to appear as competent players in the global bio-economy of emerging technologies in the biosciences field. This investigation takes Mexico as a country case study to map out the factors hampering the development of the governance of emergent biomedical biotechnologies in this context, particularly that applied to stem cell science.

This research aims to contextualise and portray prevailing ethical, legal, political and religious concerns regarding stem cell research in this context. Exploring the debates in these arenas, it seeks to elucidate the perceptions of key stakeholders and to appraise critically the divergences and convergences among the actors who currently shape the debate and who may have significant influence on the creation of any legislative framework in the area. It explores whether it is feasible to draw on the approach taken to stem cell science and tissue regulation in the United Kingdom, in order to illuminate the way forward for governing stem cell research and its clinical applications in Mexico. It also aims to evaluate the risks posed by the persistent lack of regulation in this scientific field, since Mexico appears to be an ideal destination for stem cell tourism among Latin American countries.

Drawing on empirical data gathered from prominent Mexican stakeholders in the stem cell issue, this research elucidates the key themes influencing the debate which need to be addressed in detail in order to prepare the ground for the effective governance of stem cell science and its clinical applications. By detailing the emergent themes and providing reflexive explanations of the elements influencing the views of all the actors in this arena, this thesis aims to provide ethical, empirical and normative proposals to be translated by policymakers into purposive regulation of biomedical innovations. Thus, it delineates two main features of the debate over stem cell science regulation in Mexico and shows the urgent need to create a legal framework to deal with problematic situations provoked by the legal vacuum in this area: a) the legal inertia preponderant in the Federal Congress, which is mainly caused by the constant lobbying of politicians by the Roman Catholic hierarchy to endorse prohibitive policies in sensitive areas, such as sexual matters, reproduction and stem cell science; b) the increasing phenomenon of stem cell tourism in the country, requiring the adoption of ethical and legal measures to avoid potential physical and financial harm to desperate patients who seek stem cell treatments.

In conclusion, I argue that it is plausible to advance a permissive model of governance for the area of stem cell science. This thesis is supported by the evidence gathered from stakeholders' opinions, added to the data emanating from the analysis of the country case study. As a result, it is possible to propose as an initial strategy the adoption of significant regulatory features of the paradigmatic system of governance which applies in the United Kingdom.

The law is up to date as of 19 June 2012.

DECLARATION

No portion of the work referred to in this doctoral work has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

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_____ ***20 June 2012***

María de Jesús Medina Arellano

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THE AUTHOR

María de Jesús Medina Arellano is a qualified lawyer who graduated from the Autonomous University of Nayarit (UAN), Mexico in 2004. After finishing her degree she decided to move to Mexico City to carry on her master's studies in the Philosophy of Law. In January 2008 she graduated with the equivalent of an MPhil (with honours) from the Postgraduate Law Division at the National Autonomous University of Mexico (UNAM). During her postgraduate degree she focused on the emerging paradigm of Health Law and Human Rights in Mexico. In December 2008 she was recognised as the Young Academic Talent of the Year, an award granted by the Nayarit Government in Mexico. In 2010, she was awarded the UNAM-Alfonso Caso silver medal for outstanding achievement, as the best postgraduate student of the 2008 class in the area of social sciences. She was a recipient of a graduate 'excellence grant' to pursue her master's and doctoral studies from the Mexican Council for Science and Technology and Ministry of Education (CONACYT)/ Ministry of Education (SEP) and the Autonomous University of NAYARIT (UAN). She was also granted the University of Manchester ORS award and School of Law contribution to tuition fees for the second and third year of her PhD in Bioethics and Medical Jurisprudence. Her research interests are currently focused on the bioethical and legal governance of emerging technologies and innovations, as well as the role of human dignity in these discussions.

Presentations

As work in progress, some parts of this thesis were exposed, the first as a poster presentation and the rest in oral format, at the following academic meetings:

- International Conference on Human Rights and Biomedicine, organised by the Erasmus Observatory of Health LAW, University of Rotterdam, The Netherlands, December 2008:
  The principle of Human Dignity in Human Embryonic Stem Cell Research (Part I: Introduction)
- Governance of New Technologies Conference, organised by the School of Law, University of Edinburgh, Scotland, March 2009:
  Human Dignity Among Divergent Legal Traditions and Regulations on Human Embryonic Stem Cell Research: Constructing an Operational Definition (Part I: Introduction)

- 4th Postgraduate Bioethics and Biolaw Conference, Queen´s Mary University, Belfast, Northern Ireland, June 2009:
  Stem Cell Regulation in Mexico: a Case of Bioethical Analysis Pending? (Paper I)
- Postgraduate Law Conference, School of Law, University of Manchester, September 2009:
  Abortion and Stem Cell Regulation in Mexico (Case Commentary)
- European Association of Health Law Conference, Royal College of Physicians, Edinburgh, Scotland, October 2009:
  Abortion and Human Embryonic Stem Cell Research in Mexico: Ethical, Legal and Political Conflicting Issues (Case Commentary)
- 60th Political Studies Association Annual Conference. Sixty Years of Political Studies: Achievements and Futures, Edinburgh, Scotland, March 2010:
  Stem Cell Politics in Mexico (Paper II)
- Conference of the International Association of Bioethics, organised by the National University of Singapore, Singapore, July-August 2010:
  Stem Cell Tourism in Mexico: No-Man´s Land (Paper III)

Papers

The substance of this doctoral thesis merged from 3 articles which have been published and accepted for publication:

1. Medina-Arellano MdJ, 'Stem Cell Regulation in Mexico: Current Debates and Future Challenges', *Studies in Ethics, Law and Technology* 5 (1) (2011) Article 2

2. Medina-Arellano MdJ, 'Contested Secularity: Stem Cell Governance in Mexico', *Science and Public Policy* 39 (3) (2012) 386-402

The third article has been submitted to the *Revista Red Latinoamericana y del Caribe de Bioética RedBioética/UNESCO:*

3. Medina Arellano MdJ, 'The Rise of Stem Cell Therapies in Mexico: Inadequate Regulation or Unsuccessful Oversight?' *(Submitted)*

A case commentary was also published as a part of the investigation conducted; this is also referenced in this thesis:

- Medina Arellano María de Jesús, 'Commentary: The Need for Balancing the Reproductive Rights of Women and the Unborn in the Mexican Courtroom', *Medical Law Review* 18 (3) (2010) 427-33

A Spanish version of the first article published 'Stem Cell Regulation in Mexico: Current Debates and Future Challenges', and it is referenced as follows:

- Medina Arellano MdJ, 'Ética, Derecho y Desarrollo: Desafíos para la Consolidación de la Regulación de las Células Troncales en México', in *Derecho, Instituciones y Desarrollo. Temas Selectos (Law, Institutions and Development. Selected Themes)* (Mexico: ITAM-PORRUA, 2012).

GLOSSARY

This glossary uses concepts, definitions and terms retrieved from the following databases, unless otherwise stated:

+ Harvard Stem Cell Institute glossary: http://www.hsci.harvard.edu/glossary

✚ The California Institute for Regenerative Medicine CIRM glossary, this information bank is also available in Spanish: http://www.cirm.ca.gov/Stem_Cell_Basics

✚✚ The Canadian Stem Cell Network *Réseau de cellules souches* 'Stem Cell School' glossary: http://www.stemcellschool.org/glossary.html#P

* The EuroStemCell glossary: http://www.eurostemcell.org/stem-cell-glossary

** The Human Fertilisation & Embryology Authority glossary: http://www.hfea.gov.uk/glossary_g.html

❖ The International Society for Cellular Therapy ISCT glossary: http://www.celltherapysociety.org/index.php?page=glossary

◆ The International Society for Stem Cell Research ISSCR glossary: http://www.isscr.org/Glossary_of_Stem_Cell_Related_Terms.htm

Adult stem cells (ASC)◆ - Stem cells found in different tissues of the developed, adult organism that remain in an undifferentiated, or unspecialized, state. These stem cells can give rise to specialized cell types of the tissue from which they came, i.e., a heart stem cell can give rise to a functional heart muscle cell, but it is still unclear whether they can give rise to all different cell types of the body.

Adverse event✚ - Any unintended and unfavourable sign, symptom, abnormality, or condition temporally associated with an intervention that may or may not have a causal relationship with the intervention, medical treatment, or procedure. Adverse reaction is a type of adverse event.

Adverse reaction✚ - A noxious and unintended response to the collection or infusion of any cellular therapy product for which there is a reasonable possibility that the cellular therapy product caused the response.

Affixed✚ - Attached in physical contact with the cellular therapy product container.

Allogeneic transplantation◆- Cell, tissue or organ transplants from one member of a species to a genetically different member of the same species.

Ancestor cell (*synonyms: precursor cell)** - General term for cell without self-renewal ability that contributes to tissue formation. In some cases it generates tissue stem cells.

Autologous transplantation◆- Cell, tissue or organ transplants from one individual back to the same individual. Such transplants do not include an immune response and are not rejected.

Assisted reproductive technologies (ART)** – The collective name for all techniques used artificially to assist women to carry children, including *in vitro* fertilisation and intra cytoplasmic sperm injection.

Available for distribution✚ - The time at which the cellular therapy product has been determined to meet all release criteria and may leave control of the facility.

Blastocyst◆ - A very early embryo consisting of approximately 150 cells. The blastocyst is a spherical cell mass produced by cleavage of the zygote (fertilized *(sic)* egg). It contains a fluid-filled cavity, a cluster of cells called the inner cell mass (from which embryonic stem cells are derived) and an outer layer of cells called the trophoblast (that forms the placenta).

Biotechnology✚✚ – The manipulation of organisms or their components to produce useful products.

Biobank† - A biobank may be defined as the long-term storage of biological samples for research or clinical purposes. In addition to storage facilities, a biobank may comprise a complete organization with biological samples, data, personnel, policies, and procedures for handling specimens and performing other services, such as the management of the database and the planning of scientific studies.

Bone marrow (BMW)✚ - The site of haematopoiesis or the generation of the cellular elements of the blood. A source of stem cells used for transplantation of the hematopoietic system. May be referred to as marrow. Proper FACT name is

† This definition is taken from Hallmans G and Vaught JB, 'Best Practices for Establising a Biobank', in Dillner J (Ed) *Methods in Biobanking* (Methods in Molecular Biology, Vol 675: Springer, 2011) 241-60 at 241.

Hematopoietic Progenitor Cells, Marrow or HPC-M. This terminology should be used in all relevant laboratory documents.

Bone marrow stromal cell◆ - Also known as mesenchymal stem cells, bone marrow stromal cells are a mixed population of cells derived from the non-blood forming fraction of bone marrow. Bone marrow stromal cells are capable of growth and differentiation into a number of different cell types including bone, cartilage and fat.

Cancer cell origin* - Precancerous cell that gives rise to a cancer stem cell. May be a mutated stem cell, or a progenitor cell that has acquired self-renewal capacity through mutation.

Cancer stem cell* - Self-renewing cell responsible for sustaining a cancer and for producing differentiated progeny that form the bulk of the cancer. Cancer stem cells identified in leukaemias and solid tumours are critical therapeutic targets.

Cancer-initiating cell* - Cell that can produce a new cancer upon transplantation. A key property of cancer stem cell.

Cell-based therapies* - Treatment in which stem cells are induced to differentiate into the specific cell type required to repair damaged or destroyed cells or tissues.

Cell culture* - The growth of cells in a laboratory dish for experimental research. The cells are grown in a solution, or medium, that contains nutrients and growth factors. Different factors can be added to the culture medium to initiate changes in cell behaviour.

Cell line◆- Cells that can be maintained and grown in culture and display an immortal or indefinite life span.

Cell nuclear replacement◆ - A technique in which an egg has its original nucleus removed and exchanged for the nucleus of a donor cell. The egg now has the same nuclear DNA, or genetic material, as the donor cell. Nuclear transfer is also referred to as somatic cell nuclear transfer (SCNT), as the donor cell is usually a somatic cell (that is, any cell of the body except sperm and egg cells).

Cell replacement therapy* - Reconstitution of tissue by functional incorporation of transplanted stem-cell progeny. Distinct from 'bystander' trophic, anti-inflammatory or immunomodulatory effects of introduced cells.

Cellular therapy✚ - The administration of products with the intent of providing effector cells in the treatment of disease or support of the other therapy.

Cellular therapy product✚ - Somatic cell-based product (e.g., mobilized hematopoietic progenitor cells, therapeutic cells, cord blood, pancreatic islets) that is procured from a donor and intended for processing and administration.

Cell type◆ - A specific subset of cells within the body, defined by their appearance, location and function.

i) **Adipocyte:** the functional cell type of fact, or adipose tissue, that is found throughout the body, particularly under the skin. Adipocytes store and synthesize fat for energy, thermal regulation and cushioning against mechanical shock.
ii) **Cardiomyocytes:** the functional muscle cell type of the heart that allows it to beat continuously and rhythmically.
iii) **Chondrocyte:** the functional cell type that makes cartilage for joints, ear canals, trachea, epiglottis, larynx, the discs between vertebrae and the ends of ribs.
iv) **Fibroblast:** a connective or support cell found within most tissues of the body. Fibroblasts provide an instructive support scaffold to help the functional cell types of a specific organ perform correctly.
v) **Hepatocyte:** the functional cell type of the liver that makes enzymes for detoxifying metabolic waste, destroying red blood cells and reclaiming their constituents, and the synthesis of proteins for the blood plasma.
vi) **Hematopoietic cell:** the functional cell type that makes blood. Hematopoietic cells are found within the bone marrow of adults. In the foetus, hematopoietic cells are found within the liver, spleen, bone marrow and support tissues surrounding the foetus in the womb.
vii) **Myocyte:** the functional cell type of muscles.
viii) **Neuron:** the functional cell type of the brain that is specialized in conducting impulses.
ix) **Osteoblast:** the functional cell type responsible for making bone.

x) **Islet cell:** the functional cell of the pancreas that is responsible for secreting insulin, glucogon, gastrin and somatostatin. Together, these molecules regulate a number of processes including carbohydrate and fat metabolism, blood glucose levels and acid secretions into the stomach.

Clinical translation* - The process of turning scientific knowledge into approved medical treatments, through a series of carefully controlled research and approval steps.

Clinical trial* - A research study in human subjects to answer specific questions about vaccines or new therapies or new ways of using known treatments. Clinical trials are used to determine whether new drugs or treatments are both safe and effective. Trials take place in four phases: Phase I tests a new drug or treatment in a small group; Phase II expands the study to a larger group of people; Phase III expands the study to an even larger group of people; and Phase IV takes place after the drug or treatment has been licensed and marketed.

Clone✚ - A strain of genetically identical cells descended in culture or *in vivo* from a single cell.

Cloning◆ - In biology, the process in which an organism produces one or more genetically identical copies of itself by asexual means. Cloning may occur by, for example, propagation or cuttings, as in the same case of plants; continual budding, as in the case of hydra; fission, as in the case of bacteria and protozoa; or parthenogenic asexual reproduction as in the case of aphids. The term also refers to creating multiple copies of a product such as a fragment of DNA. The term cloning can be applied to a group of cells undergoing replication by repetitive mitoses (cell divisions). In the case of higher order animals, such as mammals, nuclear transfer can be used to generate embryos with identical nuclear genetic material to an existing animal; the nuclear transfer embryo can be used either to derive embryonic stem cells or for reproductive purposes.

Clonal analysis* - Investigation of properties of single cells. Essential for formal demonstration of self-renewal and potency.

Collection✚ - Any procedure for harvesting cellular therapy products, including labelling, regardless of the technique or source.

Commitment* - Engagement in a programme leading to differentiation. For a stem cell, this means it no longer retains the ability to self-renew.

Cord blood✚ - The whole blood including hematopoietic progenitor cells, collected from placental and umbilical cord blood vessels after the umbilical cord has been clamped.

Cord blood bank✚ - Facility in which hematopoietic progenitor cells collected from the placental and umbilical cord blood vessels are processed, cryopreserved and/or stored. For purposes of FACT Standards, a Cord Blood Bank is considered a laboratory facility.

Cross match✚ - The reciprocal testing of serum and red blood cells from the intended donor and recipient of a blood transfusion to detect the presence of antibody to blood group antigens.

Cross-contamination✚ - Transfer of element(s) from one product, reagent, document or electronic record to another causing original, pure state to be compromised.

Cryopreservation✚ - The preservation of material in a frozen state. Human blood or bone marrow cryopreservation requires a cryoprotectant agent, usually dimethyl sulfoxide (DMSO), glycerol or a combination to prevent ice crystal formation and to maintain cell integrity during the freezing process.

Cytoplasm◆ - The part of the cell not including the nucleus.

Daughter cell* - One of the two or more cells formed in the division of a single cell.

Differentiation◆ - The process of development with an increase in the level of organization or complexity of a cell or tissue, accompanied with a more specialized function.

Distribution✚ - Any conveyance or shipment (including importation and exportation) of a cellular therapy product that has been determined to meet appropriate release criteria, whether or not such conveyance or shipment is entirely intrastate.

Distributor✚ - The establishment that determines that a product meets all release criteria (or releases a product under exception) and makes a cellular therapy product available for distribution. Includes distribution to another facility and distribution for administration.

Donor✚ - A person who is the source of cells or tissue for a cellular therapy product.

Ectoderm◆ - The outer of three germ layers of the early embryo that give rise in later development to the skin, cells of the amnion and chorion, nervous system, enamel of the teeth, lens of the eye and neural crest.

Egg, ovum or oocyte** - The gamete produced by females during their monthly cycle. The egg is also known as an oocyte.

Embryo◆ - The product of a fertilized egg, from the zygote until the foetal stage.

Embryoid bodies◆ - Spheroid colonies seen in culture produce by the growth of embryonic stem cells in suspension. Embryoid bodies are of mixed cell types, and the distribution and timing of the appearance of specific cell types corresponds to that observed within the embryo.

Embryonic germline cells◆ - Embryonic germline cells, also called EG cells, are pluripotent stem cells derived from the primitive germline cells (those cells that give rise to eggs and sperm). Their properties are similar to those of embryonic stem cells.

Embryonic stem cells (hESC) ◆ - Also called ES cells, embryonic stem cells are cells derived from the inner cell mass of developing blastocysts. An ES is self-renewing (can replicate itself), pluripotent (can form all cell types found in the body) and theoretically is immortal.

Endoderm◆ - The inner of three germ layers of the early embryo that give rise in later development to tissues such as the lungs, the intestine, the liver and the pancreas.

Errors✚ - Any unforeseen or unexpected deviations from applicable regulations, standards, or established specifications that may affect the safety, plurality, or potency of a cellular therapy product.

Ex vivo✚ - Outside the living body.

Fertilisation** - The penetration of an egg by a sperm and the formation of an embryo from this. Naturally fertilisation occurs in the woman's body (*in vivo*) but it can also occur in the laboratory (*in vitro*).

Foetus◆ - The stage in development from the end of the embryonic stage, 7-8 weeks after fertilization, to developed organism that ends at birth.

Fresh✚ - An unexpanded cellular therapy product that has never been cryopreserved. May also refer to products that are ex vivo expanded from previously frozen cells.

Fresh and frozen cycles** - In most cases, the eggs collected from a patient are mixed with her partners fresh sperm produce embryos within a few days. These fresh embryos are then transferred back to the patient. Where the patient's body is not ready to receive the embryos, or where an excess of embryos is available, these embryos may be cryogenically frozen for future use. Once thawed, these embryos are transferred to the patient as a frozen cycle.

Gamete** - The male and sperm or female egg which fuse together to form a zygote.

Gene manipulation✚ - The insertion of one or more exogenous genes into hematopoietic cells or other cell types.

Genome✚✚ – All of the genetic information (hereditary information) of an organism.

Germ cells* - The reproductive cells in multicellular organisms.

Germ layers◆ - The three germ layers are the endoderm, mesoderm and ectoderm and are the three precursory tissue layers of the early, primitive embryo (which form at approximately two weeks in the human) that give rise to all tissues of the body.

Graft-versus-host disease (GVHD)✚ - Manifestations of the reaction of engrafted donor cells against host tissue; clinical symptoms involve the skin, liver, and intestinal tract with potential for effect on additional organs. Acute GVHD occurs usually within the first 100 days post transplant and is initiated

by T lymphocytes of donor origin. Chronic GVHD is generally seen after the first 100 days and may also be caused by donor T cells, but cytokines (IFN-g, TNF, IL-1) may also play a role in the disease process.

Graft-versus-leukaemia (GVL) effect✚ - The immune mediated elimination of residual leukaemia by donor-derived cells infused with the stem cell graft. Similar effects in diseases other than leukaemia are termed **Graft-versus-Tumor** reactions.

Harvest✚ - The collection of HPC-M, HPC-A or other products for use in transplantation.

Hematopoietic✚ - Referring to the production of blood.

Hematopoietic stem cells (HSCs) ◆ - The precursors of mature blood cells that are defined by their ability to replace the bone marrow system following its obliteration (for example, by g-irradiation) and can continue to produce mature blood cells.

Hematopoietic cell transplantation◆ - The transplantation of hematopoietic stem cells with blood-forming potential. Hematopoietic stem cells provide rapid and sustained reconstitution of blood formation and are found in adult bone marrow, umbilical cord blood, peripheral blood and in foetal liver.

Histocompatible◆ - A tissue or organ from a donor (the person giving the organ or tissue) that will not be rejected by the recipient (the patient in whom the tissue or organ is transplanted). Rejection is caused because of the immune system of the recipient sees the transplanted organ or tissue as foreign and tries to destroy it. Tissues from most people are not histocompatible with other people. In siblings, the probability of histocompability is higher, while identical twins are almost always histocompatible.

Homologous◆ - Similar or uniform, often used in the context of genes and DNA sequences. In the context of stem cells, the term homologous recombination is a technique used to disable a gene in embryonic stem cells.

Human admixed embryo[‡]: a human admixed embryo is -

[‡] This definition is taken from the UK Human Fertilisation and Embryology Act (as amended 2008), available from: http://www.legislation.gov.uk/ukpga/2008/22/pdfs/ukpga_20080022_en.pdf acc. 19 June 2012.

(a) An embryo created by replacing the nucleus of an animal egg or of an animal cell, or two animal pronuclei, with- (i) two human pronuclei, (ii) one nucleus of a human gamete or of any other human cell, or (iii) one human gamete or other human cell,
(b) Any other embryo created by using- (i) human gametes and animal gametes, or (ii) one human pronucleus and one animal pronucleus,
(c) A human embryo that has been altered by the introduction of any sequence of nuclear or mitochrondrial DNA of an animal into one or more cells of the embryo,
(d) A human embryo that has been altered by the introduction of one or more animal cells, or
(e) Any embryo not falling within paragraphs (a) to (d) which contains both nuclear or mitochondrial DNA of a human and nuclear or mitochondrial DNA of an animal ("animal DNA") but in which the animal DNA is not predominant.

Human embryonic stem cell (hESC) ◆- A stem cell that is derived from the inner cell mass of a blastocysts and can differentiate into several tissue types in a dish. They are similar to embryonic stem cells from the mouse; however, in the mouse, it is possible to inject those cells into a blastocyst, to make a new mouse, while this is not, and should not, be possible in humans for ethical reasons. Human embryonic stem cells are harder to grow than mouse embryonic stem cells.

Human cells, tissues, or cellular or tissue-based products✚ - Articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.

Human tissue✚ - Any organ, organ sample or specimen obtained from a living or cadaveric human donor.

Inner cell mass◆ - A small group of cells attached to the wall of the blastocysts (the embryo at a very early stage of development that looks like a hollow ball). Embryonic stem cells are made by isolating and culturing the cells that make up the inner cell mass. In development, it is the inner cell mass that will eventually give rise to all the organs and tissues of the future embryo and foetus, but do not give rise to the extra-embryonic tissues, such as the placenta.

In vitro+ - Latin for "in glass", the term *in vitro* refers to experiments that are performed outside an organism's body, in laboratory glassware (or as is more often the case, plasticware) such as a test tube or a Petri dish.

In vitro fertilization (IVF) + - A procedure where an egg cell (the oocyte) and sperm cells are brought together in a laboratory dish (i.e. *in vitro*), so that a sperm cell can fertilize the egg. The resulting fertilized egg, called a zygote, will start dividing and after a several divisions, forms the embryo that can be implanted into the womb of a woman and give rise to pregnancy.

In vivo + - Latin for "within the living", the term *in vivo* refers to experiments conducted using a whole, living organism. *In vivo* experimentation is often necessary to confirm hypotheses that can not be thoroughly tested in the artificial environment of laboratory glassware. *In* vivo research, which can be conducted in animals or controlled human clinical trials, provide more complete information on the overall effects of a disease or its treatment.

Induced pluripotent stem cell (iPSC)✚ - Is a cell taken from any tissue from a child or adult that has been genetically modified to behave like an embryonic stem cell. As the name implies, these cells are pluripotent, which means that they have the ability to form all adult cell types.

Mesemchymal stem cells◆ - Also known as bone marrow stromal cells, mesenchymal stem cells are rare cells, mainly found in the bone marrow, that can give rise to a large number of tissue types such as bone, cartilage (the lining of joints), fat tissue, and connective tissue (tissue that is in between organs and structures in the body).

Morphology◆ - Study of the shape and visual appearance of cells, tissues and organs.

Multipotent stem cells◆ - Stem cells whose progeny are of multiple differentiated cell types, but all within a particular tissue, organ, or physiological system. For example, blood-forming (hematopoietic) stem cells are single multipotent cells that can produce all cell types that are normal components of the blood.

Neural stem cells◆ - A type of stem cells that resides in the brain, which can make new nerve cells (called neurons) and other cells that support nerve cells

(called glia). In the adult, neural stem cells can be found in very specific and very small areas of the brain where replacement of nerve cells is seen.

Nucleus◆ - A part of the cell, situated more or less in the middle of the cell, that is surrounded by a specialized membrane and contains the DNA of the cell. This DNA is packaged into structures called chromosomes, which is the genetic, inherited material of cells.

Oglipotent progenitor cells◆ - Progenitor cells that can produce more than one type of mature cell. An example is the myeloid progenitor cell which can give rise to mature blood cells, including blood granulocytes, monocytes, red blood cells, platelets, basophiles, eosinophiles and dentrict cells, but not T lymphocytes, B lymphocytes, or natural killer cells.

Parthenogenesis◆ - A form of reproduction where an egg develops without the fusion of sperm with the egg cell. Parthenogenesis occurs commonly among insects and other arthropods. Artificially inducing parthenogenesis with human eggs may be a means to isolate stem cells from an embryo, without fertilization.

Phenotype◆ - The description of the characteristics of a cell, a tissue or an animal; as black and white fur of a mouse are two phenotypes that can be found. The phenotype is determined by the genes (or the genotype) and by the environment. For example, short sature is a phenotype that can be genetically determined (and therefore inherited from the parents), but can also be caused by malnourishment during childhood (and therefore be caused by the environment).

Peripheral blood stem cell✚ - Hematopoietic cell with multilineage potential obtained from peripheral blood rather than bone marrow.

Placenta✚✚- A structure in the pregnant uterus that nourishes a viviparous (developing organism that will be live-born) foetus with the mother's blood supply. The placenta is formed from the uterine lining and embryonic membranes.

Plasticity◆ - A phenomenon used to describe a cell that is capable of becoming a specialized cell type of different tissue. For example, when the same stem cell can make both new blood cells and new muscle cells.

Pluripotent stem cells✚ - Pluripotent means many (pluri) potentials (potent). In other words, these cells have the potential of taking on many fates in the body, including all of the more than 200 different cell types. Embryonic stem cells are pluripotent, as are iPSCs that are reprogrammed from adult tissues. When scientist talk about pluripotent stem cells they mostly mean either embryonic or iPSCs.

Post-implantation embryo◆ - Implanted embryos in the early stages of development until the establishment of the body plant of a developed organism with identifiable tissues and organs.

Pre-implantation embryo◆ - Fertilized eggs (zygotes) and all of the developmental stages up to, but not beyond, the blastocysts stage.

Pre-implantation genetic diagnosis§ - Pre-implantation genetic diagnosis (PGD) is a technique that enables people with a specific inherited condition in their family to avoid passing it on to their children. It involves checking the genes of embryos created through IVF for this genetic condition.

Primitive streak** - Thickening in surface of embryos which results in the first clearly recognisable stage in embryo development.

Progenitor cell◆ - A progenitor cell, often confused with stem cell, is an early descendant of a stem cell that can only differentiate, but it cannot renew itself anymore. In contrast, a stem cell can renew itself (make more stem cells by cell division) or it can differentiate (divide and with each cell division evolve more and more into different types of cells). A progenitor cell is often more limited in the kinds of cells it can become than a stem cell. In scientific terms, it is said that progenitor cells are more differentiated than stem cells.

Regenerative medicine§ - It is an emerging interdisciplinary field of research and clinical applications focused on the repair, replacement or regeneration of cells, tissues or organs to restore impaired function resulting from any cause, including congenital defects, disease, trauma and aging. It uses a combination of several technological approaches that moves it beyond traditional transplantation and replacement therapies. These approaches may include, but are not limited to, the use of soluble molecules, gene therapy, stem cell

§ This definition is adopted from Mason C and Dunnill P, 'A Brief Definition of Regenerative Medicine', *Regenerative Medicine* 3 (1) (2008) 1-5.

transplantation, tissue engineering and the reprogramming of cell and tissue types.

Reproductive cloning◆ - The transfer into the uterus of an embryo derived by nuclear transfer with the intent to establish a pregnancy. Off-spring would be genetically identical to the donor of the transferred nucleus. A range of animals have been generated by reproductive cloning, notably Dolly the sheep.

Reprogramming* - Increase in potency. Occurs naturally in regenerative organism (dedifferentiation). Induced experimentally in mammalian cells by nuclear transfer, cell fusion, genetic manipulation or in vitro culture.

Safety✚ - Refers to relative freedom from harmful effects to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time.

Self-renewal* - The ability of a stem cell to divide and produce copies of itself for an indefinite period of time. This is the defining property of stem cells.

Somatic cells◆ - All the cells within the developing or developed organism with the exception of germline (egg and sperm) cells.

Spare or surplus IVF embryo [**] : embryos become surplus (or spare, supernumerary) "..." if they cannot be transferred to the woman´s uterus in IVF treatment, for reasons of embryo morphology (poor quality embryos), or because of medical or other considerations which are independent of the aims of human embryonic stem cell research.

Sperm** - The gamete (or mature male germ cell) produced by the male, usually through ejaculation. Millions of sperm are present in each ejaculate and roughly half of these will carry X chromosomes, the other half carrying Y chromosomes. A single sperm is called sperm is called a spermatozoon.

Stem cells (SCs) ◆ - Cells that have both the capacity to self-renew (make more stem cells by cell division) as well as to differentiate into mature, specialized cells.

[**] This statement of meaning is adopted from the one contained in Porz R et al, 'A Challenged Choice: Donating Spare Embryos to Stem Cell Research in Switzerland', *Swiss Medical Weekly* 138 (37-38) (2008) 551-56.

Stem cell science (SCS) [††] - It is an emerging field in the biomedical area of regenerative medicine which involves basic research of stem cells and its clinical translation into the application, commercialization and distribution of stem cell-based knowledge and therapies.

Stem cell tourism [‡‡] - The manifestation of people who travel from one jurisdiction to another across the globe in pursuing and engaging in unregulated and unproven stem cell-based therapies.

Therapeutic cloning◆ - The generation of embryonic stem cells from an embryo derived by nuclear transfer for therapeutic purposes. The resultant cell line would be genetically identical to the donor of the transferred nucleus. In humans, the therapeutic potential includes research using patient- or disease-specific human embryonic stem cells to study the basis of disease or advance towards tissue replacement.

Tissue-specific stem cell✚ - *(also referred to as somatic stem cells or adult stem cells)* Undifferentiated cells found in various tissues within the human body that have the ability to self-renew and give rise to specialised cell types and tissues needed by the body. Most tissue-specific cells are multipotent, meaning the cells have the capacity to change into more than one type of cell within the body but not cells of all three germ layers. Multipotent stem cells have less differentiation potential than pluripotent stem cells. Examples of tissue-specific stem cells include hematopoietic stem cells, mesechymal stem cells (bone marrow-derived meschymal stromal cells) and neural stem cells.

Totipotent stem cells◆ - Stem cells that can give rise to a cell types that are found in an embryo, foetus, or developed organism, including the embryonic components of the trophoblast and placenta required to support development and birth. The zygote and the cells at the very early stages following fertilization (i.e., the 2-cell stage) are considered totipotent.

Transdifferentation◆ - The ability of a particular cell of one tissue, organ or system, including stem cell or progenitor cells, to differentiate into a cell type

[††] Author's definition is drawn from the information in Gottweis H et al, *The Global Politics of Human Embryonic Stem Cell Science: Regenerative Medicine in Transition* (Palgrave Macmillan, 2009).
[‡‡] Author's definition is formulated from the investigation contained in Ryan KA et al, 'Tracking the Rise of Stem Cell Tourism', *Regenerative Medicine* 5 (1) (2010) 27-33.

characteristic of another tissue, organ, or system; e.g., blood stem cells changing to liver cells.

Umbilical cord blood (UCB) stem cells ◆- Hematopoietic stem cells are presented in the blood of the umbilical cord during and shortly after delivery. These stem cells are in the blood at the time of delivery, because they move from the liver, where blood-formation takes place during foetal life, to the bone marrow, where blood is made after birth. Umbilical cord stem cells are similar to stem cells that reside in bone marrow, and can be used for the treatment of leukaemia and other diseases of the blood. Efforts are now being undertaken to collect these cells and store them in freezers for later use. However, one problem is that there may not be enough umbilical cord stem cells in any one sample to transplant into an adult.

Zygote ◆- The cell that results from the union of sperm and egg during fertilization. Cell division begins after the zygote forms.

LIST OF ABBREVIATIONS AND ACRONYMS[§§]

ACHR	American Convention on Human Rights
ALS	Amyotrophic Lateral Sclerosis
ALSU	Amyotrophic Lateral Sclerosis Untangled Group
AMC	Academia Mexicana de Ciencias (*Mexican Academy of Sciences)*
APSA	Annual Meeting of the American Political Science Association
ART	Assisted Reproductive Technologies
ASC	Adult Stem Cell
BB	Biobanking
BI	Biotechnology Institute
BMW	Blood Marrow
CIRM	California Institute for Regenerative Medicine
CB	Colegio de Bioética (*College of Bioethics)*
CC	Catholic Church
CEC	Clinical Ethics Committees
CENATRA	Centro Nacional de Trasplantes *(National Centre for Transplants)*
CIBIOGEM	Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados *(Inter-Secretariat Commission on Biosecurity of Genetically Modified Organisms)*
CIDE	Centro de Investigación y Docencia Económicas (*Centre of Teaching and Research in the Social Sciences)*
CIESAS	Centro de Investigaciones y Estudios Superiores en Antropología Social *(Centre for Research and Advanced Studies in Social Anthropology)*
CINVESTAV	Centro de Investigación y Estudios Avanzados *(Centre for Research and Advanced Studies)*
CNDH	Comisión Nacional de los Derechos Humanos *(National Commission of Human Rights, Mexico*)
CNR	Cell Nuclear Replacement
CNTS	Centro Nacional de Transfusión Sanguínea *(National Centre for Blood Transfusion)*
COFEPRIS	Comisión Federal de Prevención Contra Riesgos Sanitarios (*Federal Commission for the Prevention against Sanitary Risks)*
COM	Partido Convergencia *(Convergence Party)*
CONACYT	Consejo Nacional de Ciencia y Tecnología *(National Council for Science and Technology)*
CONBIOÉTICA	Comisión Nacional de Bioética *(National Commission of Bioethics)*
COLBIO	Colegio de Bioética *(College of Bioethics)*
Coord	Coordinator
CPEUM	Constitución Política de los Estados Unidos Mexicanos *(Political Constitution of the Mexican United States)*
DNA	Recombinant Deoxyribonucleic Acid
EC	European Council
ECtHR	European Court of Human Rights
Ed	Editor

[§§] The acronyms listed are indistinctively from English and Spanish, albeit the meanings in English of Spanish acronyms used are stated in italics.

EMA	European Medicines Agency
EU	European Union
FACT	Foundation for the Accreditation of Cellular Therapies
FCCyT	Foro Consultivo de Ciencias y Tecnología *(Consultative Body on Science and Technology)*
FCE	Fondo de la Cultura Económica *(Economic Culture Fund)*
FDA	Food and Drug Administration
GDP	Gross Domestic Product
GHA	General Health Act
GHC	General Health Council
GIRE	Grupo de Información y Reproducción Elegida *(Information Group on Reproductive Choice)*
GMO	Genetically Modified Organism
GTAC	Gene Therapy Advisory Committee
GVHD	Graft-Versus-Host Disease
hESC	Human Embryonic Stem Cell
HFEA	Human Fertilisation and Embryology Authority
HT	Human Tissue
HTA	Human Tissue Authority
HSC	Hematopoietic Stem Cell
IACHR	Inter-American Commission of Human Rights
IACtHR	Inter-American Court of Human Rights
Ibid	The Same Place
ICH	International Conference on Harmonisation
ICMS	International Cellular Medicine Society
IFAI	Instituto Federal de Acceso a la Información (*Federal Institute for Transparency and Access to Information*)
IIJ-UNAM	Instituto de Investigaciones Jurídicas de la Universidad Nacional Autónoma de México *(The Institute for Legal Research at the National Autonomous University of Mexico)*
Inc	Company
IVF	In Vitro Fertilisation
INEGI	Instituto Nacional de Estadística y Geografía *(National Institute of Statistics and Geography)*
IMSS	Mexican Social Security Institute (Instituto Mexicano del Seguro Social)
INMEGEN	Instituto Nacional de Medicina Genómica (*National Institute for Genomic Medicine*)
IPN	Instituto Politécnico Nacional *(National Polytechnic Institute)*
iPSC	Induced Pluripotent Stem Cell
ISCT	International Society for Cellular Therapy
ISSCR	International Society for Stem Cell Research
ISSFAM	Instituto de Seguridad Social para las Fuerzas Armadas de México *(Institute for Social Security and the Mexican Army Forces)*
ISSSTE	Institute of Social Security and Services for Civil Servants (Instituto de Seguridad y Servicios Sociales para los Trabajadores del Estado).
LANGEBIO	Laboratorio Nacional de Genómica para la Diversidad *(National Laboratory of Genomics for Biodiversity)*
LBOGM	Ley de Bioseguridad de los Organismos Genéticamente Modificados (Biosafety Law on Genetically Modified Organism)
ME	Ministry of Economy

MHRA	Medicine and Healthcare Products Regulatory Authority
MoH	Ministry of Health
MS	Multiple Sclerosis
MSD	Merck Sharp & Dohme
NAFTA/TLCAN	North American Free Trade Agreement/Tratado de Libre Comercio de América del Norte
NHI	Institutos Nacionales de Salud *(National Health Institutes)*
NHS	National Health Services
Netcord	International Network of Public Cord Blood Banks
NOMs	Normas Oficiales Mexicanas *(Official Mexican Norms or Standards)*
NRES	National Research Ethics Service
OAS	Organisation of the American States
OECD	Organisation for Economic Co-Operation and Development
PAHO	Pan American Health Organisation
PAN	Partido Acción Nacional *(National Action Party)*
PRD	Partido de la Revolución Democratica *(Party of the Democratic Revolution)*
PRI	Partido Revolucionario Institucional *(Institutional Revolutionary Party)*
PT	Partido del Trabajo *(Worker's Party)*
PVEM	Partido Verde Ecologista de México *(Ecological Green Party)*
RATE	Regulatory Authority for Tissue and Embryos
R&D	Research & Development
REC	Research Ethics Committee
SC	Stem Cell
SCJN	Suprema Corte de Justicia de la Nación (*Mexican Supreme Court)*
SCNT	Somatic Cell Nuclear Transfer
SCS	Stem Cell Science
SEP	Secretaria de Educación Pública *(Ministry of Education)*
SNI	Sistema Nacional de Investigadores *(National System of Researchers)*
Suppl	Supplement
S&T	Science and Technology
STA	Science and Technology Act
Trans	Translator
UBB	Umbilical Blood Biobank
UCB	Umbilical Cord Blood
UAN	Universidad Autónoma de Nayarit *(Autonomous University of Nayarit)*
UN	United Nations
UNAM	Universidad Nacional Autónoma de México *(National Autonomous University of Mexico)*
UNESCO	United Nations Educational, Scientific and Cultural Organisation
UNRISD	The United Nations Research Institute for Social Development
UK	United Kingdom
US	United States of America
Vol	Volume
WHO	World Health Organisation
WMA	World Medical Association

LIST OF FIGURES AND TABLES

NOTE ON TRANSLATION

All Spanish names, regulatory provisions, interview material gathered during this investigation and all other Spanish material quoted throughout this thesis, including the titles of works cited, have been translated into English by the author, unless otherwise indicated. It is also important to note that the abbreviations and acronyms used in this thesis to denote regulations and institutions are the original Spanish ones, unless otherwise stated. Therefore, all errors and transliteration oddities are my own.

PART I: INTRODUCTION

CHAPTER 1

May the people and the government respect the rights of all. Between individuals, as between nations, peace means respect for the rights of others.[1]

1.1. POSING THE PROBLEM

This thesis focuses on the governance of a particular emerging biotechnology in the Mexican context, stem cell science[2] (SCS). Currently, there is an absence of a specific legislative framework to oversee stem cell (SC) research, the creation and use of human embryonic stem cells (hESC), or related activities such as assisted reproductive technologies (ART).[3] The purpose of this thesis is thus to investigate the key issues and underlying factors which act, and have acted, as barriers to the development of an effective legal framework for the regulation of this field.

This thesis takes Mexico as a case study[4] and seeks to identify and analyse the emerging discussions taking place in the country regarding the regulation of SCS.[5] In so doing, I have concentrated on local factors which might either obstruct or facilitate the creation of an ethical and legal platform for the emerging field of SCS as an innovative biotechnology.[6] The exploration of existing and emerging debates in this area has identified several challenging issues, such as the power wielded by the Catholic hierarchy in its constant lobbying of politicians to endorse prohibitive regulation of SCS.[7] In Mexico, as in many comparable countries, the core of the discussion lies in the protection of embryonic life.[8] It is apparent that the legislative inertia in the area is directly

[1] Benito Juárez García, Mexican President (1861-72), who declared Mexico a secular state by advancing the separation of the Catholic Church from State affairs.
[2] Definitions of technical terms are provided in the Glossary. Terms which appear there are underlined in the text on the first occasion they appear.
[3] ART in Mexico has been available for a couple of decades now. However, thus far, the fate or final destiny of embryos which are no longer needed for fertility purposes is unknown. See Mendoza Cárdenas HA, *La Reproducción Humana Asistida: Un Análisis desde la Perspectiva Biojurídica (Assisted Reproduction: An Analysys from a Bio-legal Approach)* (Mexico: Fontamara, 2011). There are many concerns related to the legislative vacuum for ART. However, while these issues are worthy of exploration, I do not propose to analyse them in any specific or critical depth, because they lie outside the scope and focus of my main research objective, although general points about areas which touch upon SCS will be made.
[4] A detailed account of the methodology and methods applied in the conduct of this doctoral investigation is presented in Section 1.2 of this chapter.
[5] See Chapter 5.
[6] Ibid.
[7] The social and legal backgrounds of this country case study are examined in Chapter 2.
[8] See Isasi RM et al, 'Legal and Ethical Approaches to Stem Cell and Cloning Research: A Comparative Analysis of Policies in Latin America, Asia, and Africa', *The Journal of Law, Medicine & Ethics* 32 (4)

related to the opposition of the Catholic Church and of conservative politicians to hESC research.[9] Given that embryonic SC research requires the use and destruction of embryos, this opposition is unsurprising.

With regard to the status of the embryo, a radical change occurred in Mexico City in 2007, when the local legislature legalised elective termination of pregnancy up to the twelfth week of gestation.[10] This reform was constitutionally contested before the Mexican Supreme Court,[11] which later upheld its legality.[12] The Mexican Supreme Court adopted a liberal approach to the contested issue of abortion.[13] This provoked a backlash from conservative groups and politicians, who sought to amend local and federal constitutions in order to protect life from the moment of conception.[14] These events sparked a nationwide debate about the beginning of life and the protection of the embryo.[15] On the one hand, pro-life and Catholic groups' defence of the rights of human embryos to life and human dignity[16] enjoyed the support of

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(2004) 626-40. A detailed consideration of the various regulatory approaches towards SCS adopted worlwide goes beyond the scope of this thesis. There is a growing body of literature exploring global approaches to SCS regulation, on this see Skene L, 'Legal Regulation of Human Stem Cell Technology', in Quigley M, Chan S and Harris J (Eds) *Stem Cells: New Frontiers in Science and Ethics* (Singapore: World Scientific, 2012) 85-106; Chalmers D, 'Stem Cell Technology: From Research Regulation to Clinical Applications', in Capps B and Campbell A (Eds) *Contested Cells: Global Perspectives on the Stem Cell Debate* (London: Imperial College Press, 2010) 63-93; Walters L, 'An Intercultural Perspective on Human Embryonic Stem Cell Research', in Østnor L (Ed) *Stem Cells, Human Embryos and Ethics: Interdisciplinary Perspectives* (Oslo, Norway: Springer, 2008) 91-110; Halliday S, 'A Comparative Approach to the Regulation of Human Embryonic Stem Cell Research in Europe', *Medical Law Review* 12 (1) (2004) 40-69; also see Caulfield T, Zarzeczny A, McCormick J, Bubela T, Critchley C, Einsiedel E et al, 'The Stem Cell Research Environment: A Patchwork of Patchworks', *Stem Cell Reviews and Reports* 5 (2) (2009) 82-8.

[9] Ibid.

[10] See Medina-Arellano MdJ, 'Commentary: The Need for Balancing the Reproductive Rights of Women and the Unborn in the Mexican Courtroom', *Medical Law Review* 18 (3) (2010) 427-33.

[11] In Spanish *Suprema Corte de Justicia de la Nación*; hereinafter, I refer to it as the Mexican Supreme Court. See www.scjn.com.mx acc. 5 June 2012.

[12] This position only applies to the local jurisdiction, although it has had widespread social impact across the Country. This point is further explored in Chapter 5, Section 5.3.1, it thus analyses the Mexican Supreme Court ruling concerning issues of the beginning of life and its constitutional protection under the Federal Constitution.

[13] Ibid.

[14] See Chapter 5, Section 5.3.2 for further elaboration of this point.

[15] Ibid.

[16] The principle of human dignity also appears in international and regional human rights documents. Most countries in Latin America are part of the regional Inter-American Human Rights System, which is composed of the Inter-American Commission on Human Rights (IACHR) and the Inter-American Court of Human Rights (IACtHR). Relevant to this context is the American Convention on Human Rights (ACHR) (1969), commonly known as 'Pact of San Jose, Costa Rica' adopted by the Organisation of American States (OAS). The ACHR establishes in Section 11.1 that: 'Everyone has the right to have his honour respected and his dignity recognized'. Although the respect for human dignity is fundamental for the construction of constitutional and human rights doctrine, particularly in civil law traditions, the Inter-American Court of Human Rights (IACtHR which is the counterpart in the American continent of the European Court of Human Rights ECtHR) has not developed jurisprudence to provide support for explicit interpretation of the concept of human dignity or for its possible application to early human embryos; see Chapter 2, section 2.3 on this point. Interestingly, most of the IACtHR rulings which invoke the respect for human dignity are in cases of torture, enforced disappearance and illegal deprivation of liberty, on which see Amezcua L, 'Algunos Puntos Relevantes sobre la Dignidad Humana en la Jurisprudencia de la Corte Interamericana de Derechos Humanos' *(Some Relevant Points on Human Dignity in the Jurisprudence of*

conservative politicians within Congress.[17] On the other hand, pro-choice, feminist and liberal groups advanced concepts of autonomy and rights to freedom of the development of science. The latter is a growing academic community favouring a knowledge-based economy, and proffering arguments in favour of it.[18]

In this work, I will argue for the adoption of a policy and regulatory structure that acknowledges advances in the innovative field of regenerative medicine,[19] particularly those related to SCS. In developing such a framework, legislators, public policymakers, scientists and the wider local community will need to balance the potential of SCS for positive impact on people's health against considerations of the moral values attributed to the early stages of embryonic development. I will argue that a political compromise should be embraced which allows and fosters the conduct of SC research, under an applicable and appropriately enforced licensing scheme, within rigorous parameters.

I put forward arguments to advance a principles-based approach to SCS regulation in Mexico. Accordingly, this investigation identifies the main features that should allow the development of a permissive approach to SCS governance.[20] It is possible to balance researchers' interests in promoting biotechnology against the risks and limits that need to be observed in pursuing its development in Mexico.[21]

An overall review of SCS governance in the United Kingdom (UK) is presented and it is proposed that this regulatory scheme should serve as a basis for developing a way forward for Mexico.[22] In furthering a principles-based approach to regulation and expert licensing, it is proposed that embryonic SC research on spare embryos, which could not be implanted in fertility treatments,

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the Inter-American Court of Human Rights), *Revista Iberoamericana de Derecho Procesal Constitucional* (8) (2007) 339-55. See Chapter 3 for a revision of religious foundations of the concept of human dignity. For an account of arguments related to the constitutional protection of human dignity in the Mexican context, see Chapter 5, Section 5.2.1 and for stakeholder's understandings of this notion see Chapter 6, Section 6.6.1.

[17] See Chapter 6.

[18] See Chapter 6, particularly Section 6.4, for arguments on this point.

[19] Mexico has been actively involved in the development of this area in Latin America. Illustrative of this is that it has initiated a number of research and development (R&D) activities, and thus become an important player in this area. See Greenwood HL et al, 'Regenerative Medicine and the Developing World', *PLoS Medicine* 3 (9) (2006) 1496-500 and 'Regenerative Medicine: New Opportunities for Developing Countries', *International Journal of Biotechnology* 8 (2006) 60-77.

[20] See Chapter 4 on the legal approach for arguments and proposals of good governance features for SCS in Mexico.

[21] Ibid.

[22] See Chapter 4, Section 4.3 for the exploration of the UK's system of governance for embryonic and SC research.

and on those which can be created through somatic cell nuclear transfer (SCNT), often referred to as therapeutic cloning,[23] should be permitted up to the fourteenth day of embryonic development. This is ethically defensible, based on the potential benefits arising from the invention of novel therapies that might help in the alleviation and treatment of incurable and chronic illnesses.[24]

It is recommended that ethical expert bodies be established and in conjunction with the existing regulatory authority for biomedical research should rigorously evaluate, authorise and license any basic and clinical SCS projects on a case-by-case basis.[25] Maintaining a principles-based approach to regulation, I will put forward arguments for consolidating SCS governance, drawing on established constitutional principles,[26] along with perceptions elucidated through key stakeholders participation.[27] The constitutional principles invoked are: the right to healthcare protection, the right to enjoy the benefits of scientific and economic progress (knowledge-based economy), plus freedom of research.[28]

So far, there have been no specific constitutional and legal norms directly addressing the status of the embryo in Mexico, nor any secondary regulation.[29] To a certain extent, the Federal Congress has been reluctant to regulate this area, thus avoiding the debate about the status of the embryo.[30] Due to this legislative inertia, the Mexican Supreme Court has become involved in this discussion through its rulings on seminal cases connected to the status of the embryo.[31] I suggest that the Mexican Supreme Court might draw up initial discussions in this area. This suggestion is made for two reasons: first, the aforementioned legislative inertia and secondly, the increasingly prominent role in Mexico of judicial rulings in the field of medical law.[32]

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[23] See Lanza RP, Cibelli JB and West MD, 'Human Therapeutic Cloning', *Nature Medicine* 5 (9) (1999) 975-7.
[24] See Chapter 3 for the ethical arguments put forward in this thesis as a justification for advancing more liberal policies and regulations for SCS.
[25] See Chapter 4, Section 4.4.3.
[26] Ibid.
[27] See Chapter 6 for stakeholders' perceptions of the development of SCS in this context.
[28] These fundamental and constitutional rights are established within Articles 3 and 4 of the Political Constitution of the Mexican United States (referred to as the Federal Constitution). See Chapter 2, Sections 2.6 and 2.7 for further examination of these provisions.
[29] Ibid, *supra* note 12.
[30] See Chapter 5, Section 5.3.2.
[31] Ibid.
[32] The Mexican Supreme Court has progressively ruled in cases related to the constitutionality of the introduction of the morning-after pill as part of the women's reproductive health services in public hospitals. On this see Cossío-Díaz JR, 'The "Morning after Pill": The Impact of the Supreme Court Ruling in the Medical Field' (English Abstract), *Gaceta Médica de México* 146 (4) (2010) 251-6.

Notwithstanding the prominence of the prevailing debate as to the status of the embryo, the discussion presented in this thesis is not limited to that debate, as a significant number of other issues must be addressed from ethical and legal perspectives. This thesis thus also seeks to examine and bring to light the risk of having an under-regulated field. This has enabled the emergence of the phenomenon of SC tourism in Mexico, and a proliferation of untested stem cell-based therapies offered by private healthcare facilities, in contravention of the health regulations in force in the country, which proscribe the commercial use of human tissues and cells.[33]

Therefore, this research attempts to portray, on the one hand, how the lack of targeted legislation in the area leaves patients exposed to financial burdens and risks when seeking unregulated SC-based therapies, which are widely available in the country.[34] On the other hand, the prevailing legal lacuna generates uncertainties for scientists working in universities and national healthcare research institutions as to whether SC research activities are permitted and to what extent.[35] It may be assumed that whether embryo research takes place or not, many other areas of SCS will continue to be developed in Mexico, given that research on somatic or adult stem cells (ASCs) has already commenced and has been carried out in public and private healthcare centres, research institutes and laboratories.[36] However, scientists will face obstacles in their efforts to move forward and conduct further research, as a lack of investment may result from the legal uncertainty regarding the ethical and regulatory status of the SCS field.

The arguments used here aim to contribute to an informed discussion of SCS in Mexico. In this context, a compromise must be embraced which allows progress in SCS while providing due respect for embryonic life according to its developmental stage. As Mary Warnock has written: "...the compromise would not seem right to everyone, and would, to some, seem exceedingly wrong. But matters of legislation must necessarily seek to find a balance between the individual and society; between the demands of public and private morality."[37] The purpose of any contribution is to cultivate the "...thought, and the will to

[33] See Chapter 7 for further exploration and critical appraisal of the SC tourism emerging activity in Mexico.
[34] See Table 7.2 in Chapter 7.
[35] See Chapter 7, Section 7.4 for an examination of the available biomedical regulations.
[36] For a panoramic vision of the current SC research activities being carried out in Mexico, see Mayani H and Lisker R, 'Mexico, Stem Cells and Cloning' (English Abstract), *Gaceta Médica de México* 123 (1) (2007) 1-4.
[37] Warnock M, 'Do Human Cells Have Rights?' in Chadwick R, Kuhse H, Landman W, Schüklenk U and Singer P (Eds) *The Bioethics Reader: Editor's Choice* (Oxford: Blackwell, 2007) 313-27 at 327.

establish a successful balance, wishing one good against another. Such thought takes time and effort, but it is the only foundation of good law."[38] Hitherto, myriad issues regarding emerging biotechnology innovations have been situated in a lawless terrain.

In the next section, I will now go on to describing the methods and methodology that I applied in the conduct of this study. In the final section, I will summarise the main findings of the chapters that form the basis of this doctoral thesis.

[38] Ibid.

1.2. METHODOLOGICAL APPROACH

As explained in the previous section, the main objective of this thesis is to examine emergent debates concerning biotechnologies, specifically those related to SCS, using Mexico as a country case study. Consequently, this research aims to contextualise prevailing ethical, legal, political and religious concerns regarding SCS. Examining the debates in these arenas, it seeks to elucidate the perceptions of key stakeholders who currently shape the debate and who may have significant influence on the framing of any future regulation in this scientific field, then critically appraise the divergences and convergences among them. It explores whether it is feasible to draw on the regulatory approach adopted by the UK, in order to illuminate the way forward for governing SCS and its clinical applications in Mexico. It also aims to evaluate the risks posed by the persistent lack of regulation in this scientific field, since Mexico appears to be a popular destination for SC tourism.

1.2.1. MAIN RESEARCH QUESTIONS

This thesis addresses the following specific questions connected to the main objectives and arguments already put forward:

1) Is Mexico achieving progress in emerging biotechnologies, in particular those applied to medicine and life sciences?
2) What are the main factors hampering the creation of an effective legal framework for SCS in Mexico?
3) How can a secular nation such as Mexico develop a progressive approach to, and investment in, SCS in the face of confrontations between the religious and academic communities?
4) Is it feasible to develop a liberal legislative regime for SCS in Mexico?
5) What lessons could Mexico learn from the model of governance of the UK to pursue the progress of SCS in this emerging economy?
6) Is it feasible for Mexico to follow the model of governance of the UK in this biomedical field?
7) What are the constitutional foundations and legal mechanisms upon which legislators, policymakers and the judiciary could base flexible regulation of SCS?

8) What are the key themes among stakeholders, policymakers and social actors which are shaping the ethical, legal, social and political discussions of SCS?

1.2.2. RESEARCH DESIGN AND SOURCES

A case study methodological design was selected to conduct this investigation in order to identify and obtain an in-depth understanding of the main issues at stake.[39] The main purpose was to gather sufficient data to analyse the central issues in the SCS controversy in Mexico, thus allowing me to assess the effectiveness of current governance of biomedical activities and to make a proposal for reform.[40] An empirical study was carried out, based on the design of some leading empirical bioethics research.[41] Therefore, this thesis makes use of a variety of methods and sources, including a doctrinal analysis of extant legislation, ethical, political and religious discourses, as well as an analysis of relevant legislative processes and judicial decision-making. In order to achieve the objectives I have set out, the following methodological steps have been carried out.

Doctrinal analysis of the law includes the appraisal of the existing regulation concerning scientific innovation and research on health and connected areas, which will serve as a legal-analytical foundation to the exploration of the case study. This methodological step also involves the analysis of relevant literature reporting ethical, cultural, philosophical, religious and scientific studies in the field of SCS,[42] in order to address the various issues arising out of SCS practices and more specifically within the context of those nations where Catholicism tends to inform regulatory and policy-making events.

I also make use of a comparative methodology to engage in a systematic analysis of current legislation dealing with SC research and its clinical applications in the UK. The UK system of governance in this area is chosen for

[39] See Yin RK, *Case Study Research: Design and Methods,* 4th Edition (London: SAGE, 2009). Also see Flyvbjerg B, 'Case study', in Denzin NK and Lincoln YS (Eds) *The Sage Handbook of Qualitative Research* (London: SAGE, 2011) 301-16.

[40] The adoption of a case study methodology is appropriate, as it allows focus on a single phenomenon, with the aim of better understanding the broader problem to be analysed. The utility of case studies can be further explored in Gerring J, 'What is a Case Study and What is it Good for?' *American Political Science Review* 98 (2) (2004) 341-54.

[41] An account of the increasingly common empirical approach to the analysis of bioethical concerns in this discipline can be found in Häyry M and Takala T, *Scratching the Surface of Bioethics* (Amsterdam: Rodopi, 2003).

[42] See Takala T et al, Cutting Through the Surface: Philosophical Approaches to Bioethics (New York, NY: Rodopi, 2009).

comparative purposes because it offers a paradigmatic example of how to regulate biotechnologies, particularly in a way that favours biotechnological innovation. This will allow me to analyse any similarities occurring within the policymaking process between the two countries, in addition to recommending future regulatory steps for Mexico.[43] My decision to embark on this qualitative research was informed by my prior research experience within the National Legal Research Institute at the National Autonomous University of Mexico, where I engaged in legal research on the ethical issues surrounding hotly debated emergent themes, such as human reproductive cloning, therapeutic cloning and SC therapies.[44]

1.2.3. DATA COLLECTION AND ANALYSIS

The empirical segment of this case study makes use of analytical procedures to elicit and interpret the perceptions of key stakeholders who agreed to participate in this study. It employed semi-structured interviews with key participants, i.e. prominent Mexican stakeholders in the emergent SCS debate.[45] The empirical work is designed to explore the major themes framing the SCS debates in this context.[46] This also serves to translate the emerging moral concerns and practices affecting the political, legal and social aspects of this field.[47] It serves as a useful methodological tool in addressing questions about the feasibility of embracing a facilitative approach to SCS regulation.

The range of professional backgrounds amongst the participants was varied; they included politicians, judges, legal scholars, bioethicists, clinicians and molecular biologists (see Table 6.1).[48] The selection of interviewees was

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[43] My decision to perform a legal comparison which seeks to learn from established regulatory frameworks was motivated by and comes close to that embarked on in Farrell A-M, *Contaminated Blood: A Comparative Study of Policy-Making Arising out of HIV Contamination of the Blood Supply in France, the United Kingdom and Ireland* (School of Political Sciences, University of Manchester: PhD Thesis) (2004) 269.

[44] See Medina-Arellano MdJ, 'Stem Cell Therapies: Legal Issues', conference paper prepared for the VIII National Congress of the 'DELFIN' Inter-Institutional Summer Fellowship Programme for the Promotion of Research and Postgraduate Studies in the Pacific, Memoirs of the Congress (Mexico: UAN, 2003) and 'Legal Approaches towards Human Cloning in Mexico', conference paper prepared for the VII National Congress of the 'DELFIN' Inter-Institutional Summer Fellowship Programme for the Promotion of Research and Postgraduate Studies in the Pacific, Memoirs of the Congress (Mexico: UAN, 2002). Farrell asserts the necessity to make clear how personal or professional biographies, gender, class, race or ethnicity have informed the assumptions made and the approaches taken by those engaging in qualitative research, ibid *supra* note 43.

[45] See Sankar P and Jones NL, 'Semi-Structured Interviews in Bioethics Research', in Jacoby L and Sminoff LA (Eds) *Empirical Methods for Bioethics: A Primer* (Vol 11: Emerald Group Publishing Limited, 2007) 117-36.

[46] See De Vries RG, The View from Here: Bioethics and the Social Sciences (Oxford: Blackwell, 2007).

[47] See Kon AA, 'The Role of Empirical Research in Bioethics', *The American Journal of Bioethics* 9 (6) (2009) 59-65.

[48] See Chapter 6, Section 6.3.

based on their influential roles in shaping the ethical, legal and political debates. As a consequence of their prominence, the information elicited was considered likely to give a useful picture of the themes pertinent to the development, or otherwise, of the governance of SCS in Mexico.

Following ethics committee approval in the School of Law, University of Manchester, each potential participant was sent a personal invitation by electronic mail.[49] Following recruitment of a suitable cohort, semi-structured interviews were conducted in Mexico City and in the State of Nayarit in Mexico, between the months of November 2009 and January 2010. The questions were presented in a manner which allowed for the emergence of themes. One aspect of this is that they were sent electronically, in advance, to the participants. Half of the interviewees stated that they had not prepared any responses, despite receiving the questionnaire in advance. Interviews lasted between 45 and 115 minutes. The semi-structured questionnaire was originally written and designed in English. However, all participants spoke Spanish; therefore invitations, informed consent forms and questionnaires were designed in both English and Spanish.[50] I personally conducted all interviews; there was thus no need to use interpreters, since my native tongue is Spanish. Participants signed informed consent forms and anonymity was promised. They were notified that they possessed the right of refusal and withdrawal of their consent at any time, thus safeguarding their safety and confidentiality.

All interviews were digitally recorded and the digital data obtained was secured and kept confidential, as suggested by the internal ethics committee guidelines.[51] The author is the only person who has accessed, transcribed and analysed the data collected. Follow-up electronic correspondence was conducted with the participants, in order to seek feedback and to agree on the transcribed content of the interviews. In a few cases, additional information and data which enriched the research was provided. Once interviews were transcribed, each line of the transcripts was coded and analysed to detect

[49] I sent invitations to ten key stakeholders, of whom seven agreed to participate. None of the ten who were invited declined to participate in this investigation, but three of them failed to acknowledge or reply to the invitation. I tried again several times to contact them by e-mail and in their offices, but never received a definitive response, either positive or negative. Two of these three stakeholders who failed to reply were members of the Catholic Church hierarchy and held high position within that religious institution; the third was the president of the most active and popular pro-life organisation in Mexico.

[50] See Appendix A: i), ii) iii) and iv).

[51] See Aldridge J, Medina J and Ralphs R, 'The Problem of Proliferation: Guidelines for Improving the Security of Qualitative Data in a Digital Age', *Research Ethics Review* 6 (1) (2010) 3-9.

emerging themes.[52] Codes were grouped together in nodes, in order to saturate all possible interpretations and to refine the analysis of the canvassed themes.[53]

In addition, in order to map the rise of SC-based treatments which are offered in offshore controlled clinical trials and which are available in public health centres, an Internet search was performed to gather the relevant information.[54] This methodological procedure was considered appropriate, since according to relevant literature, most of the off-licence SC therapies available worldwide are marketed online.[55] The data used in this research was retrieved between November 2010 and December 2011. The web search, which was followed by a detailed content analysis of the websites located, allowed me to trace the establishments offering unproven SC therapies across the country, including the characterisation of the claims made and the services advertised, and overall impressions of the type of patients whom they sought to recruit.

1.2.4. LIMITATIONS

Certain limitations to the empirical part of this investigation must be acknowledged. The limited number of interviews means that it is not possible to draw generalisations from the data obtained; indeed, it was not intended to do so from the outset of this investigation. However, the empirical evidence presented herein represents a sum of relevant qualitative data, which does provide some insight into the issues raised by the Mexican stem cell debate. Additionally, it is to be hoped that the evidence gathered will provide an impetus to the development of further discussion around the contested issues. Consequently, this investigative project constitutes a modest initial effort to understand the social, moral and legal context of biotechnology and innovation in Mexico.

[52] I used qualitative research methods as relevant to case studies data analysis, on this see Corbin JM and Strauss AL, *Basics of Qualitative Research: Techniques and Procedures for Developing Grounded Theory*, 3rd Edition (Thousand Oaks, Calif.: Sage Publications, 2008).
[53] All these procedures were carried out using NVivo 7 software, on this see Bazeley P, *Doing Qualitative Data Analysis with NVivo* (London: SAGE, 2007).
[54] See Chapter 7, Section 7.2.
[55] See Lau D, Ogbogu U, Taylor B, Stafinski T, Menon D and Caulfield T, 'Stem Cell Clinics Online: The Direct-to-Consumer Portrayal of Stem Cell Medicine', *Cell Stem Cell* 3 (6) (2008) 591-4.

1.3. SUMMARY OF FINDINGS

The findings of this thesis are presented in seven main chapters that are summarised in what follows. The first of these, Chapter 2, examines the social and legal background to this study, including the scientific, health and political structures in Mexico, as a fundamental step towards an understanding of how scientific development, ethical discussion and legislation are construed in this context. The progress of SCS and its therapeutic applications are dependent on the nature of its engagement at national and international levels with local key cultural values and beliefs concerning several ethical dilemmas that SCS represents in practice. The identification of the local features of the Mexican social and legal context contributes to the evaluation of how evolving religious convictions, existing legal institutions, regulatory mechanisms, political changes and scientific structures make feasible the favouring of facilitative regulatory approaches to SCS in Mexico. This chapter casts light on the historical roots and evolution of secularity in Mexico and on the concomitant decline in the influence of the most conservative elements of the Roman Catholic Church. It explores the relevance of the role of the Mexican Supreme Court in the legal system as a potential force for the future activation of judicial discussions concerning the legitimacy of the regulation of SCS in Mexico, grounded in the constitutional rights to access to healthcare and freedom of research. It also seeks to highlight the government's heavy investment in scientific innovation (e.g. in the case of genomic medicine), which may in turn result in the consolidation of the rising power of the biomedical knowledge economy.

The philosophical approach taken by the study is outlined in Chapter 3, which argues that SCS is morally defensible and can be ethically justified on grounds of social utility. The principal argument made is that it is morally defensible to use early embryos within a fourteen-day limit and to use surplus IVF and created embryos for the sole aim of researching therapies to treat debilitating and fatal illnesses. These activities (carried out under stringent control, and in accordance with clear goals and adequate surveillance) are morally worthy activities which may contribute to the development of treatments and therapies for as yet incurable diseases, alleviating the suffering of affected people. This chapter also sketches out the opposing conservative and progressive readings of the Catholic doctrine, contrasting the respective religious convictions regarding the use of early embryos in SCS activities. It also

suggests that given the more liberal or progressive Catholic voices emerging in the country, it would be plausible to anticipate their support for the use of certain embryos for socially useful aims. Finally, it concludes that some of the available justifications of SCS may provide a feasible way forward to the creation of comprehensive regulation of this area of scientific research in Mexico. However, this approach requires the adoption of a pragmatic compromise between competing and conflicting ethical positions.

Chapter 4 deals with the regulatory approach proposed for SCS in Mexico, advocating the adoption of a flexible mechanism to regulate this innovative area of biomedical research. The main theme covered is the proposal for Mexico to adopt some of the features of the UK's system of SCS governance. It is acknowledged that although it may not be feasible to adopt such a liberal system wholesale, some of its elements could be emulated, such as the enactment of a principles-based regulatory approach to SCS, learning lessons from the experience of the UK model about how to enforce it effectively.

Chapter 5 (paper 1[56]) serves as an outline and exposition of the national situation concerning the existing religious, legal and political debates on governing the beginning of life and its direct linkage to the emerging debates related to SCS regulation in Mexico. It makes a call for further public dialogue and deeper discussion of the development of comprehensive regulation in this area. In short, it does not address directly the ethical issues of SCS, but instead discusses the policy weaknesses in some areas of biomedical research, such as genomic research, as well as criticising the undue influence exerted by the Catholic Church. This chapter therefore offers an initial discussion of the legal, ethical and religious parameters of the challenges faced by policy-makers and legislators in governing SCS. It also evaluates whether the concept of human dignity established in the Federal Constitution can be interpreted as protecting early embryos or life from conception, as maintained by Catholic doctrine. The acceptability of that interpretation is controversial, given the stringent secular foundations of the Mexican state. It is worth emphasising again that in Mexico political activity of members of the clerical hierarchy is restricted. They cannot take part in public affairs and their participation in political activity is proscribed by the relevant secondary regulation.[57] Therefore, the overt lobbying of politicians in Mexico on these matters by members of the Catholic

[56] Medina-Arellano MdJ, 'Stem Cell Regulation in Mexico: Current Debates and Future Challenges', *Studies in Ethics, Law and Technology* 5 (1) (2011) Article 2.

[57] From Articles 24 and 130 of the Federal Constitution emanates the Act on Religious Associations and Public Worship (1992).

community jeopardises and conflicts with the secularity postulated by the constitutional system. Finally, this chapter explores the latest judicial rulings of the Mexican Supreme Court related to the protection of embryos, the reproductive rights of women and the constitutional notion of human dignity. It is shown that even though the judges have adopted a progressive approach in matters of women's autonomy over their bodies (e.g. by upholding secondary regulations decriminalising abortion), their discussion of the legal and moral status of the embryo, as well as the interpretation of constitutional rights (e.g. reproductive rights and protection of health) are still at a very early stage. The judges have not discussed these issues in great depth and have limited themselves to affirming the constitutionality of secondary legislation.

Chapter 6 (paper 2[58]) explores the factors influencing and hampering the consolidation of adequate regulation of SCS in Mexico. It analyses the perceptions of key stakeholders regarding emerging political and scientific debates that might influence future policy approaches adopted in this area. It is demonstrated that the constant lobbying by Catholic and conservative groups in the political arena is the main reason for the absence of comprehensive SCS legislation in this context. It is this factor that contributes to the prevalent legislative inertia. It is also argued that it is viable to adopt progressive regulation of SCS, grounded on constitutionally sanctioned rights. It is concluded that a gradualist approach towards embryo research can be embraced, informed by the views elicited.

Chapter 7 (paper 3[59]), the penultimate section of this thesis, explores the emerging phenomenon of SC tourism in Mexico, taking three purveyors of SC therapies as case studies in order to analyse and appraise the regulatory status of these practices. It concludes that it is now essential to make efforts to develop governance in order to prevent abusive practices by private SC clinics which are already operating in Mexico. Initially, this means legitimising moral values, while adopting the regulatory policies necessary to encourage the development of SCS and investment in it. If Mexico wishes to play a key role in the scientific, clinical and commercial development of this field, the adoption of a strategy to develop appropriate governance is urgently needed.

[58] Medina-Arellano MdJ, 'Contested Secularity: Stem Cell Governance in Mexico', *Science and Public Policy* 39 (3) (2012) 386-402.
[59] Submitted to the journal: Revista Red Latinoamericana y del Caribe de Bioética RedBioética/UNESCO.

CHAPTER 2

SOCIAL AND LEGAL BACKGROUND: SETTING THE SCENE

2.1. THE MEXICAN LANDSCAPE

Having presented the issues to be discussed, it is now necessary to examine the background to this case study in order to set out the features shaping the relevant debates in the local context. This section offers a broad portrait of the basic ethical, legal, political and scientific structures in Mexico. This overview is significant, since it will help to understand how scientific knowledge, bioethical discussions and legislation are produced in this country. This review will also allow an assessment of how the use of the standing constitutional norms, scientific structures and legal institutions could favour a facilitative approach to SCS governance. A succinct account of the Mexican Supreme Court's role in the constitutional system is carried out, in order to appraise whether it may, through its future judicial decision-making, be an important player in activating legal reflection concerning constitutional disputes over SCS which may lead to legislative action being taken to regulate this scientific field.

Despite the lack of specific regulation of the SCS field, there are a number of legal provisions which may be applicable, if indirectly, to certain SCS research activities and clinical applications.[1] A brief exploration of the legal system and its structure, as well as the political, legislative and judicial arrangements, may provide some insights into why a legal vacuum exists in this area[2] and how the law might be used to push forward SCS in a newly emerging economy with a growing religious diversity.[3] Furthermore, this analysis will enable us to assess whether the creation of a legal platform for SCS is politically viable. In this chapter, I propose to survey the situation concerning public policies, politics and investment involving science, biomedical research and biotechnological innovation, in order to identify whether Mexico is

[1] See Chapter 5, Section 5.4 for an overview of the existing biotechnology regulation; also see Chapter 6, Section 6.4 for an analysis of the available legislation on biomedical research which is relevant for SC scientific and clinical application.

[2] I recognise that a general overview of the political, legal and scientific organisation of Mexico is a complex task. Therefore, this section aims to succinctly describe it and narrow down its notable features for this thesis.

[3] A discussion of religious pluralism in Mexico is elaborated in the next section; also see Chapter 5 for further insights on this point.

progressing and becoming a rising power of the biomedicine knowledge economy.[4]

2.2. ¡*VIVA MÉXICO*![5] THE STRUGGLE FOR DOMINANCE BETWEEN CONSERVATIVE AND LIBERAL FORCES

The Federal Constitution (1917) established Mexico as a secular state and guarantees religious freedom at the same time.[6] With regard to religious freedom, article 24 stipulates:

> Every person is free to practice the religious beliefs of his choice and to practice all such ceremonies, devotions or acts of worship pertaining to his respective faith, provided they do not constitute a crime or an offence punishable by the Law.[7]

Furthermore, article 130 of the Federal Constitution sets forth the principle of separation between the state and Church, which also empowers the legislature to create specific regulation in order to guarantee freedom of religion in the country.[8] The analysis of the secular attributes of the Mexican government constitutes one important point to be considered, since the introduction of Catholic religious beliefs into the political and legislative arenas has obstructed any attempt to regulate SCS in the country.[9]

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[4] See Salter B and Faulkner A, 'State Strategies of Governance in Biomedical Innovation: Aligning Conceptual Approaches for Understanding 'Rising Powers' in the Global Context', *Globalization and Health* 7 (3) (2011) 14.

[5] This Spanish phrase literally means 'Long live Mexico' and it is an emblematic expression commonly known as *El Grito de Independencia or Dolores* – 'Scream of Independence or Dolores, Hidalgo' pronounced by the Mexican liberal Catholic priest Miguel Hidalgo y Costilla, who with many other national heroes began the Mexican struggle for independence from the colonial government of the Spanish Catholic crown; nowadays, this phrase is shouted every year at midnight on the 15th of September by the Mexican President in the National Governmental Palace (and by local governors in their own States and municipalities) to celebrate and commemorate the anniversary of the Mexican independence. On this see Earle R, 'Padres de la Patria' and the Ancestral Past: Commemorations of Independence in Nineteenth-Century Spanish America', *Journal of Latin American Studies* 34 (04) (2002) 775-805; also see Serrano Migallón F, *El Grito de Independencia: Historia de una Pasión Nacional (The Scream of Independence: History of a National Passion)* (Mexico: Porrúa, 1981).

[6] For an extensive account on secularity and lay regime in Mexico through its history and constitutions, see further Galeana P, 'Historia y Laicismo en México' *(History and Secularity in Mexico)*, *Este País* 228 (April) (2010) 14-16, and 'A 150 Años de la Creación del Estado Laico En México' *(150 Years since the Creation of the Mexican Secular State)*, *ArchipiéLAgo, Revista Cultural de Nuestra América* 17 (66) (2009) 18-20.

[7] Mexican Supreme Court of Justice (Ed), *Political Constitution of the United Mexican States*, translated by Rodríguez Narváez SA and Vela E, 2nd Edition (Mexico: Coordination on Compilation and Systematization of Theses of the Mexican Supreme Court, 2008).

[8] Ibid, from Articles 24 and 130 of the Federal Constitution emanates the Act on Religious Associations and Public Worship (1992), by which the lay and secular attributes of the State are ratified and endorsed; for an overview on the politics and regulation of religious freedom in Mexico, see Gill A, 'The Politics of Regulating Religion in Mexico: The 1992 Constitutional Reforms in Historical Context', *Journal of Church and State* 41 (4) (1999) 761-94, also see Saldaña J (Ed), *Diez Años de Vigencia de la Ley de Asociaciones Religiosas y Culto Público en México (1992-2002) (Ten Years After the Enactment of the Religious Associations and Public Worship Act in Mexico)* (Mexico: IIJ-UNAM, 2003).

[9] Although a great number of the population are Catholics, they put aside their trust in the church when it comes to public affairs, as the Mexican population possesses the strong belief in the constitutional

In this context, the bioethical discussions are also shaped and clearly nuanced by two sectors of the community, holding respectively conservative and liberal views of bioethics; these two stances are further explored in the following paragraphs. In 1992, Manuel Velasco Suaréz,[10] then Minister of Health, created the National Commission of Bioethics (CONBIOÉTICA).[11] However, it was not until 2005, when it was officially instituted by a presidential decree, that we saw the emergence of a consultative governmental body—financially dependent on the Ministry of Health (MoH)—in order to influence policy on bioethical issues, at least at the national level.[12] Broadly, the mandate of this commission includes the identification and promotion of ethical practices concerning life sciences, biomedical research and emerging biotechnologies.[13] The CONBIOÉTICA has operated as a governmental advisory figure, it has influenced the national bioethics debates, as was originally intended;[14] however, recently it has had little effect on the creation of ethics-driven policies in the area of biomedicine.

In Mexico, according to data from the Population and Housing Census 2010, carried out by the National Institute of Statistics and Geography (INEGI), 83.9% of the population is Catholic;[15] however, most of this population self-reported being non-practicing; that is to say that people do not strictly follow the principles and doctrines of Catholic teaching, but consider themselves Catholics. The data also showed that the Catholic population has gradually

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separation of the church and state. In fact, in October 2011, a poll carried out by Consulta Mitofsky found that 49% of the population bellieved that abortion was a woman's right and should therefore be allowed. *Available at* http://consulta.mx/web/index.php/estudios/mexico-opina/390-el-aborto-en-la-opinion-publica acc. 31 May 2012. See Chapter 5 for discussion of the peculiar historical struggle between church and State in Mexico, as well as its later influence on the law and policy-making in the SCS field.

[10] For a concise summary of the extensive scientific and bioethical labours of this prominent Mexican researcher, considered to be the father of Mexican Bioethics, see Ruff T, 'Manuel Velasco-Suarez', (Editorial) *BMJ* 324 (7348) (2002) 1280.

[11] *Comisión Nacional de Bioética* in Spanish, its website is available at: http://www.cnb-mexico.salud.gob.mx; the official decree of the creation of this bioethics commission is *available at*: http://cnb-mexico.salud.gob.mx/descargas/pdf/decreto_conbioetica.pdf acc. 10 June 2012.

[12] On the emergence and evolution of bioethical reflections and studies in Mexico, see Wikler D, 'Bioethics Commissions Abroad', *HEC Forum* 6 (5) (1994) 290-304; Figueroa PR and Fuenzalida H, 'Bioethics in Ibero-America and the Caribbean', *Journal of Medicine and Philosophy* 21 (6) (1996) 611-27; Hernandez-Arriaga J, De Olivares VN and Iserson KV, 'The Development of Bioethics in Mexico', *Cambridge Quarterly of Healthcare Ethics* 8 (03) (1999) 382-85; also see Porter J K and De la Escosura G, 'Overview of Bioethics in Mexico', in Connor SS and Fuenzalida-Puelma HL (Eds) *Bioethics: Issues and Perspectives* (Vol 527; Washington, DC: PAHO Scientific Publication, 1990) 168-74.

[13] For a deeper review of the creation and functions of this commission, see Luengas I, Feinholz D and Soberón G, 'National Bioethics Commission: Its Mandate and Approach', *Bioethical Debate* (2) (2007) 43.

[14] Jiménez-Sánchez G, Lara-Álvarez CF and Arellano-Méndez, 'A Survey of the Development of Mexican Bioethics: Genomic Medicine as One of Its Greatest Challenges', in Pessini L, De Paul de Barchifontaine C and Lolas F (Eds) *Ibero-American Bioethics* (Springer, 2010) 159-73.

[15] See National Institute of Statistics and Geography (INEGI), Panorama de las Religiones en Mexico 2010 (*Outlook of Religions in Mexico 2010*), *available at:* http://www.inegi.org.mx/prod_serv/contenidos/espanol/bvinegi/productos/censos/poblacion/2010/panora_religion/religiones_2010.pdf acc. 10 June 2012.

decreased in the last ten years from 88% to the current 83.9%. For some, this decline of catholic practitioners is determined by the growing religious diversity and cultural pluralism, added to the structural crisis and erosion of trust experienced by the Catholic Church as a result of the paedophilia scandals, at least very recently in Mexico, when child abuse involving clerics of the Catholic Church came to light in the media.[16]

Despite Mexico's constitutionally enshrined secularity, the hierarchy of the Catholic Church has to a great extent succeeded in lobbying the legislatures on the protection of life.[17] Bioethics associations, which endorse a conservative stance, have also effectively shaped and informed legislators outside Mexico City.[18] Currently, the debate about the protection of embryonic life is promoted by conservative groups and is manifested through the intervention of the Catholic hierarchy via the media and lobbying in the political arena.[19] Politicians also seem responsive, concerned as they are with winning the votes of the religiously devout.[20]Thus, Catholic religious values have also been introduced into the nascent SCS debate.[21] In pluralistic societies, religious views are tolerable and indeed considered desirable, in order to achieve democracy. However, this situation does raise concerns, as Catholicism is not the only religion in Mexico, which "is a country in expansion in religion terms".[22] Indeed,

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[16] See Barranco B, '¿El Censo Revela una Crisis Católica?' *(The Census Reveals a Catholic Crisis?)*, *La Jornada Opinión* (13 April 2011) http://www.jornada.unam.mx/2011/04/13/opinion/024a1pol acc. 10 June 2012. Interestingly, this is a growing trend throughout Latin America and has been noted by Luna and Salles, writing on the emerging SC debate in Argentina: Luna F and Salles A, 'On Moral Incoherence and Hidden Battles: Stem Cell Research in Argentina', *Developing World Bioethics* 10 (3) (2010) 120-8.

[17] See Chapter 5, in particular Sections 5.3.2 and 5.4.2.

[18] For example, after the latest judicial ruling upholding the interruption of pregnancy (see Chapter 5 on this ruling), academic organisations tied to the Catholic church have led a reactionary movement to reform local constitutions protecting life from the moment of conception; on this see Amuchástegui A, Cruz G, Aldaz E and Mejía MC, 'The Complexities of the Mexican Secular State and the Rights of Women', *Religion, Politics and Gender Equality* (Geneva, Switzerland: UNRISD, 2010).

[19] See Blancarte R, 'Religiones, Bioética y Estado Laico' *(Religions, Bioethics and Secular State), Milenio: Jalisco* (27 April 2010) http://impreso.milenio.com/node/8757593 acc. 10 June 2012; and Blancarte R, '¿Qué Significa Hoy la Laicidad?' *(What does Secularity Mean Today?), Este País* 228 (April) (2010) at 33. Also see Chapter 5 and 6 for further discussion of the influence of Catholicism in the political arena.

[20] Hence, it must be noted that political or electoral interests are always present in the policy-making arenas, where ethical compromises are often determined by voters' tendencies. For a more detailed analysis of the way political consensus and pragmatic solutions regulate morally disputed issues, e.g. research on health, animal testing and drug consumption, see Wolff J, *Ethics and Public Policy: A Philosophical Inquiry* (London: Routledge, 2011).

[21] This situation mainly prevails among countries where the Roman Catholic Church has strong support among the population and has tried to determine the underlying morality to be reflected in the law regarding SCS; for example, on the Irish SC debate, see Gough F, 'Human Embryonic Stem Cell Research in Ireland: Ethical and Legal Issues', *Medical Law International* 11 (2011) 262-83; also see Oakley J, 'Democracy, Embryonic Stem Cell Research, and the Roman Catholic Church', *Journal of Medical Ethics* 28 (4) (2002) 228.

[22] Meza Zapata M, 'Religious Diversity throughout Mexican History and Philosophy: An Introduction to Understand Mexico's Contemporary Religious Context', *SUSI Project: Religious Pluralism* (Santa Barbara, CA: University of California, 2009) http://www.religion.ucsb.edu/projects/summerinstitute/Reference%20files/religion%20in%20home%20countries/Mexico-Marcela.pdf acc. 9 June 2012; on the evolution of the Catholic church role during the democratisation of Mexico, see Blancarte R, 'The Changing Face of Religion in the Democratization of

it enjoys a rich plurality and diversity of religious beliefs.[23] Therefore, if legislators are ready to hear Catholic views and then reflect those in SCS policies and regulation, they should also be prepared to include and give a chance to many other religious organisations to have their voices heard in the debate.[24]

At the other end of the scale, liberal attitudes towards SCS in the country are embodied in various nationally renowned scientific and academic associations, including organisations with bioethical expertise.[25] These include the Presidency Sciences Council, the Consultative Body on Science and Technology (FCCyT),[26] the Mexican Academy of Sciences (AMC),[27] the College of Bioethics (COLBIO)[28] and the Research Seminar on Ethics and Bioethics of the National Autonomous University of Mexico (UNAM),[29] among many others.[30]

Mexico: The Case of Catholicism', in Hagopian F (Ed) *Religious Pluralism, Democracy, and the Catholic Church in Latin America*. (Notre Dame, Ind.: University of Notre Dame Press, 2009) 225-56.

[23] For a quantitative and qualitative account of the existing pre-Hispanic and modern religious diversity in the country, see Masferrer Kan E, *Pluralidad Religiosa en México. Cifras y Proyecciones (Religious Plurality in Mexico. Figures and Projections)* (Mexico: Libros de la Araucaria, 2011).

[24] This current religious plurality in the country has also been meticulously documented in the literature, drawing on empirical studies conducted by the specialised academic organisations; see De la Torre R and Gutiérrez Zúñiga C (Coords), *Atlas de la Diversidad Religiosa en México (Atlas of Religious Diversity in Mexico)* (Mexico: CIESAS, Secretaría de Gobernación & CONACYT, 2007). The Mexican Supreme Court has also ruled on religious plurality and freedom; for a commentary on its ruling, see Carbonell Sánchez M, 'La Libertad Religiosa ante la Suprema Corte. Comentario al Amparo en Revisión 1595/2006' *(Freedom of Religion in the Supreme Court. Comments on the Amparo under Revision 1595/2006)*, *Cuestiones Constitucionales: Revista Mexicana de Derecho Constitucional* (21) (2009) 405-11.

[25] See Chapter 6, Section 6.5 for an analysis of this aspect.

[26] For a review of the role that the FCCyT has played in promoting projects of innovation in the country as a national academic consulting body, see Tigau CN, 'Track 2 Innovation Agents in North America: The View from Mexico', *NorteAmérica* 3 (2) (2008) 43-66.

[27] The Mexican Academy of Sciences (AMC) is an independent, not-for-profit nongovernmental body that brings together national scientists from diverse areas of knowledge: humanities, social and life sciences, engineering, etc. It currently has more than 2119 Mexican research associates, who have international and national prestige. From its creation as a private initiative by national academic scholars the Academy has built a good reputation and prestige in talking about scientific production and research. The aims, mission, vision and statutes of the AMC can be consulted at: http://www.amc.unam.mx/ acc. 9 June 2012.

[28] The COLBIO's publications, seminars and ongoing work can be found on its website at: http://colegiodebioetica.org.mx acc. 9 June 2012. This bioethics group has organised seminars and its members are the most prolific scholars in the area, who have published many books adopting liberal approaches to bioethics. Examples include Alvaréz del Río A, *Eutanasia: Hacia Una Muerte Digna (Euthanasia: Towards a Dignified Death)* (Mexico: Colegio de Bioética and FCCyT, 2008); Kraus A, *Diccionario Incompleto de Bioética (Incomplete Dictionary of Bioethics)* (Mexico: Ediciones Taurus, 2007). Interestingly, this academic association has worked closely with a homologous group on Bioethics and Biolaw in the University of Barcelona, which has effectively informed national policies on bioethical issues, including hESC policies in Spain. On this, see Casado M, 'A Vueltas sobre las Relaciones entre la Bioética y el Derecho' *(Emphasing on the Relationships between Bioethics and Law)*, *Revista Bioética* (19) (2011) 15-28 and 'En Torno a Células Madre, Pre-Embriones y Pseudo-Embriones: El Impacto Normativo de los Documentos del Observatorio de Bioética y Derecho de la UB' *(About Stem Cells, Pre-Embryos and Pseudo-Embryos: The Normative Impact of the Documents of the Observatory of Bioethics and Law of the UB)*, *Revista Bioética y Derecho* (19) (2010).

[29] This investigative group organizes permanent academic discussions within the Philosophical Research Centre in the largest University in Mexico (UNAM). It has also coordinated and edited specialised books addressing bioethical issues from a local context; for example, see González Valenzuela J (Ed), *Dilemas de Bioética (Bioethical Dilemmas)* (Vol I; Mexico: FCE, UNAM & CNDH, 2007) and *Perspectivas de Bioética (Perspectives on Bioethics)* (Vol II; Mexico: FCE, UNAM & CNDH, 2008).

[30] Other important progressive voices promoting reproductive and scientific freedom in this context are that of the Information Group on Reproductive Choice (GIRE), whose website can be located at www.gire.org.mx, and the group of Catholics for a Free Choice, whose website is *available at:*

These academic organisations have jointly issued public statements, calling for responsibility and caution from politicians who are opposed to promoting certain SCS activities (e.g. hESC research).[31] These public calls are intended for politicians, to call for public dialogue and deliberations, deep reflection and careful scrutiny concerning the broader scientific, ethical and social implications of SC research before passing any legislation which is aimed at preventing it or constitutional reforms protecting life from the outset.[32] Furthermore, according to researchers, a legislative ban on SCS would obstruct scientific progress and more generally, an affront to public health, since it will prevent the development of therapies to ameliorate people's health. [33] In addition, they have called for a secular nationwide bioethical debate on these issues.[34]

To summarise, this background section has given a panoramic view of the diverse social standpoints concerning the governance of SCS in Mexico. If the current disconnect between science, religion and politics persists, the possibility of establishing a suitable legal framework seems deeply challenging.[35] In light of this background, this thesis will assess whether liberal

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www.catolicasmexico.org acc. 9 June 2012; both of these civil organisations have played a crucial role in pushing forward progressive approaches toward the enactment of effectives measures to protect the reproductive rights and health of vulnerable women, as well as to encourage of secular dialogues on many other bioethical issues, such as gay marriage and adoption.

[31] See AMC, Research Seminar on Ethics and Bioethics-UNAM, COLBIO, FCCyT et al, 'Llamado de Prudencia y Reponsabilidad al Congreso de la Unión y a la Opinión Pública en Cuestión a las Reformas Iniciadas por el Partido Acción Nacional Relacionadas con la Protección de la Vida Humana y Prohibición de Cualquier Forma de Clonación' *(Call to the Congress of the Union and Public Opinion to Proceed with Caution and Responsibility in Relation to the Reforms Initiated by the National Action Party Concerning the Protection of Human Life and the Prohibition of any Form of Cloning), Communication* (23 of January 2009) http://www.comunicacion.amc.edu.mx/comunicacion/docs/amc-rrg-230109-d-clonacion.pdf acc. 9 June 2012.

[32] See Flores J, 'Lamentables las Leyes Antiaborto: A. Madrigal' *(Regrettable Anti-Abortion Laws: A. Madrigal)*, *La Jornada en las Ciencias* (18 January 2010) http://ciencias.jornada.com.mx/noticias/lamentables-las-leyes-antiaborto-a-madrigal/?searchterm=c%C3%A9lulas%20madre acc. 9 June 2012.

[33] In 2009, one of the editorials of the scientific journal *Ciencia* issued by the AMC also called for a public and ordered dialogue before legislating on SCS issues. See AMC, 'Editorial: La AMC Defiende la Libertad para Investigar con Células Tróncales Embrionarias' *(Editorial: The AMC Defends the Freedom of Research on Embryonic Stem Cells)*, *Ciencia* 2 (87) (2009); Ruíz Gutiérrez R, 'Editorial' *Ciencia* 60 (2) (2009) 3; also see AMC, 'Piden Científicos Impulsar Investigaciones con Células Troncales Embrionarias' *(Scientists Urge to Promote Research on Embryonic Stem Cells)*, *Noticia AMC/08/07* (15 June 2007) http://www.comunicacion.amc.edu.mx/noticias/piden-cientificos-impulsar-investigaciones-con-celulas-troncales-embrionarias/ acc. 9 June 2012.

[34] See AMC, 'Analizaron Especialistas de México y España el Carácter Laico de la Bioética en el Contexto Actual' *(Mexican and Spanish Experts Analysed the Secularity of Bioethics in the Current Context)*, *Boletín AMC/053/10* (15 May 2010) http://www.comunicacion.amc.edu.mx/comunicados/analizaron-especialistas-de-mexico-y-espana-el-caracter-laico-de-la-bioetica-en-el-contexto-actual/ acc. 9 June 2012. The call for secular discussion in bioethical debates is further explored in Chapter 6, Section 6.5.1.

[35] See Ruíz Gutiérrez R, 'Los Problemas Éticos y el Papel de la Academia Mexicana de Ciencias en las Concepciones Erróneas, Abusos, Prohibiciones y Uso Apropiado de Células Troncales' *(The Ethical Issues and the Role of the Mexican Academy of Sciences in Relation to the Misconceptions, Outrages, Prohibitions and Appropriate Use of Stem Cells)*, presented in the 1st Latin-American Conference of Innovation and Invention on Health, Faculty of Medicine-UNAM, Mexico (23 March 2010) http://www.amc.unam.mx/FeriInnovaciInvencienSalud.pdf acc. 9 June 2012.

approaches to governing emerging technologies, like those established in developed countries such as the UK, might feasibly be adopted in Mexico.[36]

2.3. STATE ORGANISATION AND THE CONSTITUTIONAL PARADIGM

Before exploring the political and scientific endeavours, it is pertinent to briefly delineate how the legal system in Mexico operates, since it will demonstrate some important features of the current situation in the country regarding the legislative inertia in the area of SCS and innovations.[37] This is not an easy task, due to the complex legal configuration; therefore, this outline is not exhaustive but aims to provide a sufficiently detailed context for the subsequent analysis.

The United Mexican States [38] constitute a republic, having a representative, democratic and federal system of a government under the Political Constitution of the United Mexican States (Federal Constitution), enacted in 1917.[39] The federation comprises 31 states and one Federal District.[40] These are free to organise their own internal local constitutions, but within a national regulatory system, all coordinated as a federation.[41] Local constitutions and state regulations should be consistent and should comply with the Federal Constitution; if any inconsistencies or incompatibilities arise, federal constitutional provisions prevail.[42]

Arguably, the Mexican legal system is a combination of the French civil law tradition and a constitutional law paradigm. [43] The written Federal Constitution represents the supreme legal instrument and the primary source of

[36] See Chapter 4 for an analysis of the main features of the UK's SC governance which could be emulated to better regulate this field in Mexico.
[37] See Chapter 5.
[38] Throughout this thesis, the country is referred to as Mexico, since this is how it is commonly known.
[39] According to Article 40 of the above-named constitution (In Spanish *Constitución Política de los Estados Unidos Mexicanos [CPEUM],* hereinafter referred to as the 'Federal Constitution'*),* see Mexican Supreme Court, *supra* note 7.
[40] The Federal District is popularly known as Mexico City; throughout this thesis, I use both terms interchangeably.
[41] According to the Federal Constitution, people will establish a representative, democratic and federal republic. This is established within the second title, chapter I, entitled "National sovereignty and the form of government", within Articles 39 to 41, ibid, *supra* note 7 at 105-123.
[42] As stated above, the Federal Constitution is the main source of the law in the legal system. Thus, according to Article 133, all domestic regulation, this is to say, federal and local statutes, Acts, regulations and codes, shall be enacted in accordance with the constitutional provisions and international treaties celebrated and ratified by the Mexican government; federal judicial decisions, doctrine, local customs and general principles of the law are also legal sources of the system. On the hierarchy of the sources of the law, see further Vargas J A, 'Introduction to Mexico's Legal System', *Legal Studies Research Papers* (School of Law, University of San Diego, 2008).
[43] Albeit the Mexican legal system is commonly known as being rooted in the French codification, the current regime is a hybrid, containing features of the United States of America (US) constitutional system and a civil law tradition. See further Merryman J H and Pérez-Perdomo R, *The Civil Law Tradition: An Introduction to the Legal Systems of Europe and Latin America,* 3rd Edition (Stanford University Press, 2007).

law in the country.[44] It also sets out the form and system of government, which is divided for its operation into three branches or powers: executive (the President of the Mexican Republic), legislative (the Congress of the Union[45]) and judicial (Mexican Supreme Court, federal and local courts).[46] This tripartite division also applies to the exercise of state and municipal powers; a broad specification of the functions of these authorities is explored in the next paragraphs.

All general or federal Acts[47] in Mexico are rooted in the Federal Constitution. Therefore, particular areas, such as health, science, technology and biomedical research, are regulated by general Acts (e.g. the General Health Act), and secondary regulation emanating from them. General Acts and secondary regulations are enacted to deal with particular matters which are addressed generically within federal legislation but have been subject to further scrutiny and more specific regulation.

Likewise, administrative norms or Mexican Official Norms (NOMs) are, in broad terms, complementary and mandatory rules issued by administrative federal authorities, which regulate technical issues in specific areas.[48] It is pertinent to explore the particularities of administrative provisions or NOMs in detail, because of their determinant role in driving and regulating economic conduct, as well as ensuring the quality and safety of commercial activities and services.[49]

The Federal Metrology and Standardisation Act[50] (hereafter denoted as the Standardisation Act), governs the area of the normalisation of services and products.[51] The Standardisation Act is enforced by the Ministry of Economy

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[44] For a brief exploration of the origin and evolution of the Mexican Constitution, see Vargas JA, *Mexican Law for the American Lawyer* (Durham, N.C.: Carolina Academic Press, 2009).
[45] Hereinafter referred to as the Federal Congress.
[46] Constitutional Article 49, ibid, *supra* note 7; more details of the structure, functions and composition of the three government branches can be found in Hernández MdP, 'Division of Powers in the 1917 Mexican Constitution', *Mexican Law Review* (2) (July-December) (2004), http://info8.juridicas.unam.mx/cont/mlawr/2/arc/arc5.htm acc. 10 June 2012.
[47] Throughout this dissertation, I will refer to Laws and Acts interchangeably.
[48] 'NOMs' can also be utilised and understood as 'Standard', because, in the 1940s, Mexico was incorporated into the International Organization for Standardisation (ISO) and its membership of this international organisation has informed the consolidation of normalisation in the country. See further Signet WD, 'Official Mexican Norms and Mexican Normalization: The Ticket to Modernization in an Emerging Economy?' *The University of Miami Inter-American Law Review* 29 (1/2) (1997) 253-96.
[49] Ibid.
[50] In Spanish *Ley Federal sobre Metrología y Normalización* (1992), the Standardisation Act establishes all relevant procedures for weights, measures, certifications, accreditation and supervision of all merchandise entering the Mexican market, and specifies the quality and safety requirements that these products have to fulfil according to health standards. See further Padrón M and Yanar-Rios V, 'Federal Law of Metrology and Standardization', in Elías-Fernandez E (Ed) *Doing Business in Mexico*, 2nd Edition (Juris Publishing, Inc., 2008).
[51] The Standardisation Act defines NOMs within Article 3, section XI, as: "Obligatory technical regulations enacted by the competent departments, in accordance to what is provided by Article 40 which establishes

(ME), responsible for creating NOMs, through the National Standardisation Commission,[52] which hosts consultative committees to create norms, the members being stakeholders in the area to be regulated.[53] The NOMs outline the standards required of products and processes when these can potentially threaten the safety or health of human beings, animals, plants or the environment; they also include requirements for commercial, sanitary, quality, safety and hygiene information.[54] Likewise, these norms regulate the requirements of the general characteristics, conditions and quality of products and services.

A further relevant development in the Mexican legal context is that of June 2011, the Mexican bicameral Federal Congress endorsed a seminal constitutional reform concerning fundamental human rights.[55] This constitutional reform incorporated internationally recognised human rights into the section previously known as 'Fundamental Rights', which contained the so-called individual guarantees of citizens; it has now been modified to contain 'Human Rights and Guarantees'.[56] Accordingly, Article 1 of the federal constitution expressly recognises the application of fundamental human rights and requires authorities (e.g. local and federal judges) to comply with all international human rights treaties which have been signed and ratified by Mexico.[57]

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the rules, particularities, qualities, directrix, characteristics and recommendations applicable to products, processes, instalments, system, activities, services of methods of production and operation, as well as all those related to terminology, labelling, packaging, containers and any other concerning their enforcement". For a detailed exploration of NOMs, see Huerta Ochoa C, 'Las Normas Oficiales Mexicanas en el Ordenamiento Jurídico Mexicano' *(The Official Mexican Norms in the Mexican Legal Order)*, *Boletín Mexicano de Derecho Comparado IIJ* XXXI (92) (1998).

[52] As provided by the law, NOMs are national mandatory administrative rules enacted by federal authorities such as the Ministry of Health and Economy. A catalogue of all current Mexican NOMs currently in force can be consulted at: www.economia-norms.gob.mx acc. 9 June 2012.

[53] It is worth noting that the Standardisation Act implements a consultative scheme by which relevant stakeholders, including consumers, patients, healthcare providers, commercial representatives and academic institutions can also participate in creating NOMs.

[54] All relevant norms related to the area of health are summarised in Karam Toumeh D and Placencia Villanueva R (Eds), Compendio de Normas Oficiales Mexicanas Vinculadas con el Derecho a la Protección de la Salud (Compendium of Official Mexican Norms Related to the Right of the Protection of Health (Vols I and II; Mexico: CNDH & IMSS, 2010).

[55] Mexican Official Federal Gazzete, Decree which Modifies the Official Denomination of Chapter I of the First Title and Reforms Diverse Articles of the Constitution of the Mexican United States, available in Spanish at http://dof.gob.mx/nota_detalle.php?codigo=5194486&fecha=10/06/2011 acc. 10 June 2012.

[56] The constitutional section that was reformed resembles what is commonly known as the dogmatic part of the majority of civil law constitutions. In other words, it is the section that generally contains a catalogue of fundamental and inalienable human rights and grounding principles of the legal system. The dogmatic section of the constitution comprises 29 articles. The Federal Constitution, as amended (text in Spanish), *available at* http://info4.juridicas.unam.mx/ijure/fed/9/ acc. 10 June 2012.

[57] See Carpizo J, 'Los Derechos Humanos: Una Propuesta de Clasificación de los Derechos Civiles y Políticos' *(Human Rights: A Proposal to Classify Civil and Political Rigths), Revista de la Facultad de Derecho de México-UNAM* 61 (256) (2012) 31-67.

In brief, the most substantial modifications to this section of the constitution are those concerned with the obligations imposed on all authorities to promote, respect, guarantee and effectively enforce human rights in accordance with the principles of universality, interdependence, indivisibility and progressiveness.[58] This constitutional reform also fortified the National Commission on Human Rights (CNDH):[59] the state must prevent, investigate and punish violations of human rights committed by one individual against another.[60] The reform imposes the burden on state legislatures to modify their own local regulations in line with the new constitutional human rights provisions.[61] Under this strengthened constitutional paradigm, it is plausible that multicultural considerations and different views might be accommodated through the use of the constitutional law and human rights frameworks, which guarantee freedom of science and protection of health at the same time.[62]

As initially stated within the SC debate, the core of the controversy lies in the source of these cells.[63] The most controversial SCs are those categorised as embryonic SCs, since their procurement involves the destruction of early embryos. Therefore, the divergent moral, religious and cultural views as to the status of the embryo remain unresolved.[64] As Gottweis *et al* point out, in the global political arena, SC regulatory settings are largely based on what kind of legal rules are followed with regard to embryonic protection, abortion and the beginning of life, and this matters within national legal frameworks.[65] The next question is whether or not *in vivo* and *in vitro* embryos are protected under the human rights umbrella and entitled to the respect of human rights.[66] Following

[58] See Martínez Bullé-Goyri VM, 'Reforma Constitucional en Materia de Derechos Humanos' *(Constitutional Reform on Human Rights)*, *Boletín Mexicano de Derecho Comparado* XLIV (130) (2011) 405-25.
[59] Ibid.
[60] On this, see Valadés D, 'La Protección de los Derechos Fundamentales Frente a Particulares' (*The Protection of Fundamental Human Rights with Regard to Individuals), Anuario de Derechos Humanos* 12 (2011) 439-70.
[61] See García Ramírez S, 'Hacia una Nueva Regulación Constitucional sobre Derechos Humanos (2009-2011)' *(Towards a New Constitutional Regulation on Human Rights (2009-2011), Boletín Mexicano de Derecho Comparado* XLIV (131) (2011) 817-40.
[62] The constitutional rights of health and freedom of research as applied to the furthering of SCS in Mexico are discussed in Chapter 4, Section 4.3.
[63] See Chapter 1 for a statement of the main arguments to be addressed in this thesis.
[64] Due to the divergent positions regarding the moral status of embryos, policies adopted in some endeavours are often judged to be ethically unjustifiable. See, for example, Brock DW, 'Creating Embryos for Use in Stem Cell Research', *The Journal of Law, Medicine & Ethics* 38 (2) (2010) 229-37.
[65] See Gottweis H, Salter B and Waldby C, *The Global Politics of Human Embryonic Stem Cell Science: Regenerative Medicine in Transition* (Basingstoke; New York: Palgrave Macmillan, 2009).
[66] See Brownsword R (Ed), *Global Governance and the Quest for Justice: Human Rights* (Oxford: Hart Publishing, 2004).

this line of thought, the question also arises whether research on embryonic SC constitutes an affront to constitutional rights.[67]

The scope of the protection of the right to life within the Mexican constitutional framework is not stated as explicitly as it is in some domestic or national legal settings across the world.[68] Thus, in some jurisdictions, the extent of the right to life and whether it encompasses embryos have had to be interpreted by human rights courts which have denied that they benefit from a fundamental right to life. For instance, in Latin American[69] and European[70] human rights jurisdictions, judges have been reluctant to extend the same level of protection to embryonic life as that granted to human individuals.[71]

Many opponents of abortion and embryonic SC research assert that life begins to matter morally and legally from conception[72] and that it is from that point onwards that the embryo is in possession of full human rights and human dignity, [73] notwithstanding the numerous alternative positions on this question.[74] Nonetheless, there is neither an agreed interpretation nor an explicit definition of the principle of human dignity in the Federal Constitution.[75] Furthermore, a literal reading of the constitution identifies no reference to the protection of life from conception.[76] Therefore, it is difficult to infer the existence

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[67] For instance, in Ireland, the constitutional protection of the 'unborn' has been debated on a few occasions; coincidentally, the latest discussions also originated in the absence of legislation on some controversial medical practices, such as abortion and assisted reproduction. See further McGuiness S and Uí Chonnachtaigh S, 'Implications of Recent Developments in Ireland for the Status of the Embryo', *Cambridge Quarterly of Healthcare Ethics* 20 (03) (2011) 396-408.

[68] In the European context, see, for instance Plomer A, *The Law and Ethics of Medical Research: International Bioethics and Human Rights* (London: Cavendish, 2005).

[69] In 1981, the IACtHR upheld in the *'Baby Boy'* case that the US Supreme Court's recognition of the right to abortion does not contradict the obligation of member states to protect life. See IACtHR, *'Baby Boy' Abortion Case, Resolution 23/81, Case N° 2141(USA),* [March 6, 1981].

[70] The European Court of Human Rights (ECtHR) has twice ruled to that effect, making these judgments paradigmatic for embryo research. See European Court of human Rights, *Vo v France (App no. 53924/00)* [2004] and *Evans v United Kingdom (App no. 6339/05)* [2007].

[71] See Zampas C and Gher JM, 'Abortion as a Human Right - International and Regional Standards', *Human Rights Law Review* 8 (2) 2008 249-94 at 267-8. At the beginning of 2011, the IACHR brought a petition to the IACtHR, in order to review Costa Rica's ban on assisted reproductive technologies, alleging violations to the rights to a private life, to a family and to equality and non-discrimination; see Case No. 12.361, Gretel Artavia Murillo et al, *(In Vitro Fertilisation),* Costa Rica. This latest case has not been heard yet; see IACHR, 'N^0 91/11, IACHR Takes Case Involving Costa Rica to Inter-American Court (16 August 2011) *at* http://www.cidh.oas.org/Comunicados/English/2011/91-11eng.htm acc. 10 June 2012. Also see Silk JL, 'Inter-American Commission on Human Rights: In the Matter of Ana Victoria Sanchez Villalobos and Others (Costa Rica), Admissibility Report N° 25/04, Petition 12.361 - Brief of the Allard K. Lowenstein International Human Rights Clinic at Yale Law School as Amicus Curiae', (2011) *available at* http://www.law.yale.edu/documents/pdf/Intellectual_Life/In_Vitro_Fertilization_-_Costa_Rica_-_Amicus.pdf acc. 10 June 2012.

[72] This position is strongly maintained by the most conservative sector of the Catholic religion; see Chapter 3, Section 3.4 on this point.

[73] See Chapter 6, Section 6.6.1 on this discussion.

[74] Ibid.

[75] See also the debate in 2008 of the Mexican Supreme Court of Justice concerning the protection of life from conception, in Chapter 5, Section 5.4.1.

[76] Ibid.

of the alleged right to life and dignity of embryos, at least under constitutional norms.

While the Federal Constitution lacks any explicit reference to embryos, the General Health Act (GHA) (1982), [77] which further regulates the constitutional right to healthcare protection, provides definitions of what is to be understood by the terms 'embryo' and 'foetus'. Within chapter 14 of the GHA, entitled Donations, Transplants and End of Life,[78] Article 314 provides:

> VIII. An embryo is the ***product of conception*** from that point onwards to the end of the twelfth week of gestation;
>
> IX. A foetus is the ***product of conception*** from the thirteenth week of gestation until delivery from the mother's womb.[79]

The GHA contains a secondary provision which further regulates the abovementioned chapter 14 of the health regulations. The Regulation on the Sanitary Disposal of Human Organs, Tissues and Cadavers (1985), [80] referred to as the 'Tissue Regulation', is a derived regulation which provides general rules concerning the removal, utilisation and transplantation of organs and tissues.[81] Similar to what is stated in the GHA, the Tissue Regulation enunciates in article 6o what is to be understood by the terms 'embryo' and 'foetus':

> …XIII. An embryo is the product of conception up to the thirteenth week of gestation;
>
> XIV. A foetus is the product of conception from the thirteenth week of gestation until its delivery from the maternal womb.

However, further provisions dealing with the legal treatment of these defined entities are absent from both the GHA and the Tissue Regulation.[82] Many questions arise from this legislative ambiguity, including these: Why is there a difference between the regulations as to the time limit of the application of the term 'embryo'? What does 'conception' mean in lay and biological terms? How are embryos created? Do *in vitro* embryos fall within the scope of definition of

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[77] In Spanish *Ley General de Salud* (1982) (last modified 5 May 2012), *available at* http://www.diputados.gob.mx/LeyesBiblio/pdf/142.pdf acc. 7 June 2012.
[78] Ibid; also see Chapter 7, Section 7.4 for further scrutiny of the GHA in what relates to the legal status of the use and application of human tissues and cells.
[79] Ibid (emphasis added).
[80] In Spanish Reglamento de la Ley General de Salud en Materia de Control Sanitario de la Disposición de Órganos, Tejidos y Cadáveres de Seres Humanos (1985) (last amended 27 January 2012), *available at* http://www.normateca.gob.mx/Archivos/66_D_3023_02-03-2012.pdf acc. 10 June 2012.
[81] The Tissue Regulation and its applicability to the clinical side of SCS are further examined in Chapters 4 and 7 of this thesis.
[82] This ambiguity has also been pointed out by Muñoz de Alba Medrano M, 'El Status Jurídico del Uso de las Células Troncales en México' *(The Legal Status of the Use of Stem Cells in Mexico),* in Cano Valle F (Coord) *Clonación Humana (Human Cloning)* (Mexico: IIJ-UNAM, 2003) 95-120.

the GHA or the Tissue Regulation? These questions are further addressed throughout this thesis.[83]

Mexico has signed and ratified international treaties and covenants which recognise the protection of life as a fundamental human right. An example of this is the United Nations (UN) International Covenant on Civil and Political Rights (1966), which provides the protection of life and prohibits its deprivation.[84] Mexico has also signed the American Convention on Human Rights (1978), which establishes in Article 4 that "Life shall be protected by law, in general, from the moment of conception."[85]

However, while Mexico is bound by this convention, it is not bound by what is stipulated in the provision cited above, since the Mexican state declared a particular reservation on this provision, by putting in place an interpretative declaration[86] as follows:

> With respect to Article 4, paragraph 1, the Government of Mexico considers that the expression 'in general' does not constitute an obligation to adopt or keep in force legislation to protect life 'from the moment of conception', since this matter falls within the domain reserved to the States.[87]

Indeed, some local legislatures decided to legislate on this matter between 2009 and 2010, when local constitutions were reformed to protect life from conception.[88] As previously explored, the current legal vagueness regarding human dignity and the status of the embryo itself opens the door for their judicial interpretation in broader and often divergent terms, when the

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[83] See Chapters 5 and 6 for further analysis of these questions.

[84] Article 6 (1) stipulates, "Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life." *Available at* http://www2.ohchr.org/english/law/pdf/cescr.pdf acc. 10 June 2012.

[85] American Convention on Human Rights (ACHR), commonly known as the 'Pact of San Jose, Costa Rica', *available at* http://www.oas.org/juridico/english/treaties/b-32.html acc. 10 June 2012.

[86] In September 2011, the President of Mexico (Felipe Calderón, 2006-2012) asked the Senate to authorize the removal of the interpretative declaration concerning the exception of the protection of life from the outset established by the Mexican state in the Pact of San Jose. However, the presidential request was unsuccessful. On this see further Gómez P, 'El Gobierno Frente al Estado Laico' *(The Government Facing the Secular State)*, *Milenio online* (30 September 2011) *at* http://impreso.milenio.com/node/9035272 acc. 10 June 2012; also see Rodríguez García A, '… Y Calderón pide al Senado Retirar Restricción para Proteger la Vida desde la Concepción' *(… And Calderón Requests to the Senate the Removal of the Restriction to the Protection of Life from Conception)*, *Proceso.com.mx* (26 September 2011) *at* http://www.proceso.com.mx/?p=282530 acc. 10 June 2012.

[87] Ibid, *supra* note 84.

[88] See Chapter 5, Section 5.4.2 for an analysis of this political backlash. A substantial literature has amassed, evaluating whether embryos can be considered to be persons or human beings. See, for example, Carpizo J, 'La Interrupción del Embarazo antes de las Doce Semanas' *(The Termination of Pregnancy before the Twelfth Week)*, in Carpizo J and Valadés D (Eds) *Derechos Humanos, Aborto y Eutanasia (Human Rights, Abortion and Euthanasia)* (Mexico: IIJ -UNAM, 2009) 81-175; Mendoza Cárdenas HA, '¿Embrión O Persona Humana? El Caso de México' *(Embryo or Human Person? The Mexican Case)*, *Revista de Bioética y Derecho* (11) (2007) 3-10.

abovementioned constitutional mechanisms to protect fundamental human rights are set in motion.[89]

2.4. LEGISLATIVE AND POLITICAL ARENAS

The aim of this sub-section is to give a succinct functional account of the political configuration and legislative processes within the Mexican legal system.[90] The Mexican Federation is organised into three levels of government: federal, state and municipal. The President of the United Mexican States is the head of the federal executive. Importantly, the executive branch has an essential responsibility to administer the federal states and local governments, which are supported by centralised offices (ministries) and decentralised entities.[91] The exercise of power within the executive branches of the states also rests with elected governors.[92]

Federal legislative power is exercised by a bicameral Federal Congress (the Congress of the Union), comprising an upper and a lower house.[93] The Chamber of Senators is the upper house of the Federal Congress, while the Chamber of Deputies is the lower house.[94] The Federal Congress holds ordinary and extraordinary legislative sessions and has a permanent commission which acts during its recesses to create, discuss and pass federal laws.[95]

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[89] In 2008, the Mexican Supreme Court ruled that under international norms, such as the Pact of San Jose, it is not bound to protect life from the outset, due to the existing reservation of the Mexican state; this point is further examined in Chapter 5, Section 5.4.1.

[90] This is not an attempt to provide a full account of the legislative processes, political elections and executive functions, but just an overview, which portrays the complexities of regulating emerging technologies in a contested Mexican secular state. For a detailed account of the Mexican legal and political system, see Vargas JA, *op. cit. supra* note 44 at 3-54.

[91] The executive branch's responsibilities, attributions and faculties are established in Articles 80 to 90; see *op. cit. supra* note 7, Chapter Three 'The Federal Executive Branch' at 191-203.

[92] Similarly, federal and local heads of the executive branches are elected for a six-year period with no chance of re-election, in accordance with the provision of the Federal Constitution, *op. cit. supra* note 7, Chapter Five: 'The States of the Federation and the Federal District', Article 116, at 267.

[93] All federal and local legislators serve for three years, except the members of the upper chamber, who are elected for a period of six years; *op. cit. supra* note 7, Chapter Two: 'The Legislative Branch' at 131-180. The unique legitimate method to constitute and renew the federal and legislative branches is through direct election, applying the principles of universal suffrage and relative majority and the principles of minority and proportional representation; thus, the Federal Constitution establishes the mechanisms and institutions governing the conduct of elections and explicitly precludes any possibility of consecutive re-election. For an interesting account on the prohibition of consecutive re-election in Mexico, see Weldon JA, 'The Prohibition on Consecutive Reelection in the Mexican Congress', *Election Law Journal: Rules, Politics, and Policy,* 3 (3) (2004) 574-79.

[94] The Chamber of Deputies (*Cámara de Diputados)* of the Federal Congress has 500 members, 300 directly elected by electoral districts and the rest distributed according to proportional representation; the Chamber of Senators (*Cámara de Senadores)* is constituted of three Senators elected by each State and the remainder appointed according to the principles of majority, minority and proportional representation, being in total 128 members of the upper chamber; ibid, *supra* note 93.

[95] Articles 65 and 78 of the Federal Constitution; ibid, *supra* note 7.

The Senate has the exclusive power to ratify the appointment of the Attorney General[96] and to designate the justices of the Mexican Supreme Court, who are initially proposed by the Mexican President.[97] Thus, a relevant feature of the upper chamber is its essential role in conducting foreign affairs, since the Senate authorises the foreign policy conducted by the executive power, as well as approving international treaties agreed by the Mexican government and ratifying diplomatic appointments made by the executive.[98]

The Federal Congress has the exclusive right to legislate on federal norms, laws or Acts.[99] Unlike the Federal Congress, local legislatures or congresses are unicameral.[100] The executive and members of the legislatures can initiate legislative proposals.[101] Local legislatures exercise concurrent legislative powers in respect of issues that are not explicitly reserved to the Federal Congress,[102] matters of concurrent jurisdiction being biotechnology, education, health and the strengthening and development of scientific research and innovation.[103] Once federal Acts and regulations are enacted, these need to be enforced through official decrees promulgated by the President of Mexico and published in the official Federal Gazette;[104] the executive has the presidential right of veto.[105]

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[96] Procurador General de la República in Spanish.
[97] This point is examined in the next sub-section.
[98] As provided by constitutional Articles 76 and 133, ibid, *supra* note 7.
[99] According to Article 73, laws, acts and regulations enacted by the Federal Congress fall under the category of federal status, which can be divided into regulatory Acts and ordinary regulations. Regulatory Acts are those that enlarge, expand and describe in detail constitutional normative provisions, such as public health, environmental regulation and technology transfer, whereas ordinary or secondary regulations are not directly derived from constitutional norms; instead, they regulate in detail the organisation, powers and functions of governmental agencies and institutions. There are further regulations to set down specific provisions for the implementation of federal Acts or Laws; these are called *'reglamentos' (regulations),* as provided by Article 89, and can be issued by the Federal Congress or the Mexican President, in administrative matters; following the civil law tradition, the codified areas, at both federal and state levels, are civil, criminal and commercial law, along with their corresponding procedural codes. For a doctrinal review of Mexican codification, see Vargas JA, *op. cit supra* note 44 at 55-62.
[100] Notably, the legislative branch of the Federal District is commonly known as the Mexico City Legislative Assembly; its composition and particularities are established in the corresponding section of Article 122 of the Federal Constitution; ibid, *supra* note 7 at 295.
[101] Ibid, *supra* note 7, 'The Initiation and Enactment of Laws' at 148.
[102] The matters of exclusive and concurrent legislative powers are established in Articles 73 and 124 of the Federal Constitution, ibid, *supra* note 7. For an interesting analysis on the particularities and difficulties between concurrent and exclusive jurisdiction, see Carbonell Sánchez M, 'The Federal State of the Mexican Constitution: An Introduction to its Problematic', *Mexican Law Review* (3) (2005).
[103] The creation of public policies and regulation of health is an area of concurrent jurisdiction, in accordance with Article 4, paragraph 3 of the Federal Constitution, which sanctions the right to health protection and stipulates that "The law shall set forth the rules and conditions of access to health services and shall establish the concurrence of the Federation, the Federal District and the States in matters of general public health as provided in section XVI of Article 73 of this Constitution"; ibid, *supra* note 7 at 17. For a practical revision of the concurrent jurisdiction in the area of health, as well as the Mexican Supreme Court rulings in this respect, see Cossío-Díaz JR, 'The "Morning After Pill": The Impact of the Supreme Court Ruling in the Medical Field' (English Abstract), *Gaceta Médica de México* 146 (4) (2010) 251-6.
[104] In Spanish: *Diario Oficial de la Federación.* Its official website is at http://dof.gob.mx acc. 10 June 2012; it contains all executive decrees promulgated by the federal executive to date.
[105] According to constitutional Articles 71 and 72, ibid, *supra* note 7 at 148-153.

Of particular interest is that the Federal Constitution can be amended or reformed following a rigid and exhaustive legislative procedure.[106] Any legislative initiative to reform the Federal Constitution has to be debated and passed by two-thirds of members of the Union Congress who attend the session established for that purpose.[107] Later, it has to be voted in favour or against by the majority of the state congresses.[108] This is a relevant point, since there is a current legislative proposal to amend the Federal Constitution, seeking to protect life from the moment of conception, in the same terms as the reformed local constitutions.[109]

Currently, the political parties contesting the legislative and political arenas are these:[110] the centre-left Institutional Revolutionary Party (*Partido Revolucionario Institucional,* PRI), the right-wing or conservative National Action Party (*Partido Acción Nacional,* PAN), which currently runs the federal government, the left-wing Party of the Democratic Revolution[111] (*Partido de la Revolución Democrática,* PRD), the Ecological Green Party (*Partido Verde Ecologista de México,* PVEM), the leftist Worker's Party (*Partido del Trabajo,* PT), the New Alliance Party (*Partido Nueva Alianza,* PANAL) and the centre-left Convergence Party (*Convergencia* COM*)*.[112]

Throughout most of the 20th century, Mexican executives and legislatures were ruled by the PRI;[113] then, in 2000, the conservative political party PAN

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[106] On the rigid process to modify the Federal Constitution, see Carbonell Sánchez M, 'Notas Sobre la Reforma Constitucional en México' *(Notes on the Constitutional Reform in Mexico)*, *Revista de la Facultad de Derecho de México* (245) (2006) 229-54. Although the procedure for reforming the Federal Constitution is considered to be rigid, it has been reformed many times since its enactment in 1917.

[107] Article 135, Title Eight, 'Amendments to the Constitution', ibid, *supra* note 7 at 355.

[108] The participation of State legislatures in such reform is limited, since their only role is the pronouncement or vote in favour or against the reform; an interesting proposal to allow state congresses to participate actively in the constitutional reform process has been presented but not passed yet to the Federal Congress. See further Brito Melgarejo R, 'Strengthening the Participation of Local Congresses in the Mexican Constitutional Reform Process', *Perspectives on Federalism, available at* http://www.on-federalism.eu/attachments/020_download.pdf acc. 10 June 2012.

[109] This issue is further addressed in Chapter 5, Section 5.4.2.

[110] See Chapter 5, Section 5.2 and 5.3 for a revision of how much influence each of these political parties has on legislative processes in relation to the issues discussed throughout this thesis.

[111] Since its foundation, it has been considered to offer the strongest opposition to successive national governments. For a couple of years now, the PRD has been characterised by its key role in pushing forward a liberal or progressive legislative agenda, at least in the Mexico City Legislative Assembly, where it has a majority and this fact has proved to be crucial in issues of sexual, reproductive and health rights; for example, in that jurisdiction, the PRD has amended the Civil and Criminal Codes to decriminalise abortion and legalise same-sex marriage and adoption. On the abortion debate in Mexico City, see Lamas M and Bissell S, 'Abortion and Politics in Mexico: "Context is All"', *Reproductive Health Matters* 8 (16) (2000) 10.

[112] A detailed outline of the Mexican electoral system, as well as the official registry of political parties contending elections, can be found on the official website of the country's Federal Electoral Institute *at* http://www.ife.org.mx/portal/site/ifev2/The_Mexican_Electoral_System/ acc. 7 June 2012.

[113] Actually, political opposition to the PRI grew during the 1990s and Mexican local and federal legislatures experienced diversification in the seats occupied by competing political parties. For a detailed account and analysis of this political 'autocracy', democratic transition and the decline of the PRI's hegemony, see Klesner JL, 'Electoral Competition and the New Party System in Mexico', *Latin American Politics and Society* 47 (2) (2005) 103; also see Magaloni B, 'The Demise of Mexico's One-Party Dominant

won the presidential elections and has ruled until the present day.[114] Paradoxically, the political change not only brought further democratisation to the country, but also jeopardised the foundation of the secular Mexican state:[115] since the PAN came to power, its legislators and government officials have tried intensively to bring their private religious beliefs into the public sphere of government.[116]

None of the political parties aforementioned enjoys an absolute majority of legislative seats in the Federal Congress, mainly because of the proportional electoral regime.[117] Therefore, the political scene is characterised by ideological diversity and the overall number of conservative or liberal members of any political party is not sufficient to achieve an absolute majority in legislative processes.[118] In general terms, this diversity indicates how difficult negotiations will be on issues regarding newly emerging biotechnologies in a pluralistic political scenario, where the tension between conservative-religious groups and progressive tendencies is difficult to settle and it is impossible to implement radical laws and policies, whether pro-life or pro-choice.[119]

Regime: *Elite Choices and the Masses in the Establishment of Democracy*', in Hagopian F and Mainwaring SP (Eds) *The Third Wave of Democratization in Latin America: Advances and Setbacks* (Cambridge University Press, 2005) 121-48 and Magaloni B, *Voting for Autocracy: Hegemonic Party Survival and Its Demise in Mexico* (Cambridge Studies in Comparative Politics: Cambridge University Press, 2006).

[114] The PAN is considered to be the conservative right-wing party in Mexico, its internal doctrine being closely tied to that endorsed by the most conservative side of the Catholic Church in Mexico. It has openly opposed the liberalisation of abortion and many other policies related to reproductive health. For an interesting study of the influence of the Catholic church on abortion issues over legislators belonging to this political party, see Taracena R, 'Social Actors and Discourse on Abortion in the Mexican Press: The Paulina Case', *Reproductive Health Matters* 10 (19) (2002) 103-10.

[115] See Chapter 6 for this discussion.

[116] This religious interference with public policy matters is apparent in the recent national discussions concerning the incorporation of the emergency contraceptive pill into the public health system, as well as the liberalisation of abortion norms in Mexico City. For an interesting qualitative study exploring the political scenario in Mexico in relation to women's reproductive rights and the role of the Catholic church in these discussions, see Carrillo H, 'Imagining Modernity: Sexuality, Policy and Social Change in Mexico', *Sexuality Research and Social Policy* 4 (3) (2007) 74-91.

[117] The political parties listed had registered with the IFE up to the mid-term elections of 2009; this election represented a debilitating political event for the party currently running the country, at least in the Federal Congress. For an interesting examination of the change of politics and a preliminary analysis of the coming July 2012 Presidential and Federal Congress elections, see Klesner JL, 'The 2009 Mexican Midterm Congressional Elections', *Electoral Studies* 29 (3) (2010) 537-40.

[118] In November of 2011, a legislative initiative was introduced in the Senate, proposing a constitutional reform to allow the creation of coalition governments in Mexico, but it has not been discussed yet. On this see Milenio.com, 'Propuesta de Gobiernos de Coalición de Manlio Fabio Beltrones' *(Legislative Initiative to Propose Coalition Governments by Manlio Fabio Beltrones), Milenio online* (22 November 2011) *available at* http://www.milenio.com/cdb/doc/noticias2011/9ba077ad272132591cfa416dc19f24b2 acc. 10 June 2012; the analysis of the feasibility of implementing this system under the existing political regime is beyond the scope of this thesis.

[119] This political divergence and its impact on the regulation of SCS are further addressed in Chapter 5, Section 5.4.2 and Chapter 6, Section 6.5.1.

2.5. THE MEXICAN SUPREME COURT: IMPACT ON HUMAN RIGHTS AND MEDICAL LAW

The federal judicial branch, in which judicial power is vested, is the Mexican Supreme Court.[120] It has had a major impact on protecting human rights and interpreting constitutional norms, due to its paramount role as the guardian of the constitution.[121] The Mexican constitutional paradigm is characterised by the unique federal *sui generis* judicial proceedings designed to enforce, protect and guarantee the fundamental human rights of citizens; this procedural mechanism for citizens is outlined in the following paragraphs.

The historical and deep-rooted federal judicial means of defence or 'remedies', widely known as the writ of *Amparo,* is available for citizens to address any violation of their civil and fundamental rights perpetrated by the authorities.[122] Any citizen can file a writ of *Amparo* before the collegiate circuit and district courts, in relation to a violation of fundamental rights.[123] By this means, federal courts create *Jurisprudencia.*[124] The legal judgments contained therein are not considered to be a primary source of law, but still create binding judicial precedents for all lower courts in future and similar cases.[125]

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[120] According to Article 92 of the federal constitution, it is made up of 11 judges or ministers of justice—hereinafter Justices—who are proposed by the Mexican President and elected by the Senate to serve for fifteen years; States' judicial powers are vested in their respective Supreme Tribunals of Justice. On the organisation and structure of the judiciary, see Chapter Four 'The Judicial Branch', *op. cit. supra* note 7 at 201. On the process of selection of the members of the Supreme Court, see Astudillo C, 'El Nombramiento de los Ministros de la Suprema Corte de Justicia en México', in Von Bogdandy A, Ferrer MacGregor E and Morales Antoniazzi M (Eds) *La Justicia Constitucional y su Internacionalización ¿Hacia un IUS Constituionale Commune en América Latina?* (Vol I; Mexico: IIJ-UNAM, 2010) 345-86.

[121] See Magar E, Magaloni B and Sanchez A, 'No Self-Control: Decentralized Agenda Power and the Dimensional Structure of the Mexican Supreme Court', prepared for the *APSA Annual Meeting of the American Political Science Association* (Washington DC, 2010); also see Sánchez A, Magaloni B and Magar E, 'Legalist vs. Interpretativist: The Supreme Court and the Democratic Transition in Mexico', in Helmke G and Ríos Figueroa J (Eds) *Courts in Latin America* (New York: Cambridge University Press, 2011) 187-218.

[122] Articles 103 and 107 of the Federal Constitution underlie the *Amparo* Act (1936) (In Spanish *Ley de Amparo, Reglamentaria de los Artículos 103 y 107 de la Constitución Política de los Estados Unidos Mexicanos),* which establishes specific provisions and procedural rules to activate this means of defence.

[123] The rulings of the courts are applicable only to those who claim and win the *Amparo* from the federal justices. Although the reliefs apply only to petitioners, they may also be applicable to others, since the rulings in *Amparo* trials may serve as a reference for subsequence cases, but these cannot be considered as having equal force with precedents in common law systems. For a detailed exploration of the background, particularities and effects of the writ of *Amparo,* see Carmona Tinoco JU, 'Domestic and International Judicial Protection of Fundamental Rights: A Latin American Comparative Perspective', in Costa Oliveira J and Cardinal P (Eds) *One Country, Two Systems, Three Legal Orders—Perspectives of Evolution* (Springer, 2009) 339-57.

[124] It can be considered to be the equivalent of case law in Anglo-Saxon traditions, although it does not perform the same enforceability function as precedents do in the common law regime.

[125] Articles 94 and 107 of the Federal Constitution regulate the means and rules by which *jurisprudencia* can be created; in essence, Article 192 of the *Amparo* Act provides that "obligatory jurisprudencia is constituted by the resolutions dictated by the Supreme Court of Justice functioning in plenary or in chambers, provided that what is resolved there is based upon five consecutive and uninterrupted decisions that have been approved by at least eight Justices (Justice Ministers) when a jurisprudence is issued by the plenary Court, or by four Justices when a jurisprudence is produced by a chamber. In addition, jurisprudences are the resolutions that harmonize the contradictory decisions issued by the chambers or

In 1994, the Mexican Supreme Court was substantially modernised through constitutional reform, which restructured the functions of the judiciary to make it the ultimate interpreter of the federal constitution.[126] The judicial reform instituted two further procedures for judicial review, now known as 'actions of unconstitutionality' (*acciónes de inconstitucionalidad)* and 'constitutional controversies' (*controversias constitucionales),*[127] but the *Amparo* writ remains available.[128]

According to article 105 of the Federal Constitution, 'actions of unconstitutionality'[129] allow legislative minorities in the federal or local congresses, as well as the Attorney General, to contest before the Mexican Supreme Court any regulation, Act or law passed by the majority of legislators of the contested congress. On the other hand, the device of 'constitutional controversy' enables all branches—executive, legislative and judicial—and levels of government—federal, state and municipal—to challenge laws enacted

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by the plenary." For a critique of the system on the process of creation and publication of the *jurisprudence* in Mexico, see Magaloni AL, 'La Suprema Corte y el Obsoleto Sistema de Jurisprudencia Constitucional' *(The Supreme Court and the Obsolete System of Constitutional Jurisprudence)*, *Cuadernos de Trabajo del CIDE, División de Estudios Jurídicos* (December 2011), *available at* http://www.cide.edu/publicaciones/status/dts/DTEJ 57.pdf acc. 10 June 2012.

[126] The Court was not authorised to interpret constitutional provisions before the 1994 reform, on which see Julio Ríos-Figueroa, 'Fragmentation of Power and the Emergence of an Effective Judiciary in Mexico, 1994-2002', *Latin American Politics and Society* 49 (1) (2007) 31-57; also see Natarén Nandapaya CF and Castañeda Ponce D (Eds) *La Suprema Corte de Justicia de la Nación en la Reforma del Estado* (Mexico: IIJ-UNAM, 2007).

[127] Article 105 of the Federal Constitution sets forth these procedural mechanisms for the safeguarding of constitutional provisions. The law regulating both the actions of unconstitutionality and constitutional controversy procedures is the Regulation of Sections I and II of Article 105 of the Federal Constitution (1995) (in Spanish: *Ley Reglamentaria de las Fracciones I y II del Artículo 105 de la Constitución Política de los Estados Unidos Mexicanos*), *available at* http://www.diputados.gob.mx/LeyesBiblio/pdf/205.pdf acc. 10 June 2012.

[128] New judicial eras (*épocas* in Spanish) start when there is a major reform to the structure and functions of the federal judiciary, which contains all the judicial decisions issued by the Court that are binding on all lower courts. See Mexican Supreme Court, *¿Qué es una Época en el Semanario Judicial de la Federación?* (*What is an Era in the Official Journal of the Mexican Supreme Court*?), *available at*: http://www.scjn.gob.mx/CONOCE/QUEHACE/LAJURISPRUDENCIA/Paginas/queesepoca.aspx acc. 10 June 2012. The introduction of these legal tools, actions of unconstitutionality and constitutional controversies, marked the start of a new ninth era (*novena época)* of the court's rulings. In October 2011, as a result of the latest constitutional reform affecting *Amparo* proceedings, the Mexican Supreme Court officially decreed the initiation of its tenth era (*decima época)*. The official declaration by the Mexican Supreme Court of the beginning of the tenth era can be found *at* http://www.scjn.gob.mx/2010/pleno/Documents/Taquigraficas/2011/Octubre/pl20111004v2.pdf acc. 10 of June 2012. As a result of the latest constitutional reforms on human rights carried out in June of 2011, a new *Amparo* Act was enacted, but still need to be approved by the Senate, so up until now it has not been promulgated yet, on this see González MdL, 'Urge Nueva Ley de Amparo: SCJN' *(New Amparo Law Urgently Needed)*, *El Universal.mx* (10 January 2012) *available at* http://www.eluniversal.com.mx/nacion/192788.html acc. 10 June 2012. At time of writing there is no *Amparo* Act in force in the country, but this situation does not affect the major arguments advanced in this thesis. On this see Baltazar Robles GE, *El Nuevo Juicio de Amparo: La Reforma Constitucional (The New Amparo Trial: The Constitutional Reform)* (Mexico: Complejo Educativo de Desarrollo Integral COEDI, 2011).

[129] For more on this, see Fix-Fierro H, 'La Reforma Judicial de 1994 y las Acciones de Inconstitucionalidad' *(The Judicial Reform of 1994 and the Actions of Unconstitutionality)*, *Ars Iuris* (13) (1994). In addition, for an illuminating empirical study scrutinising and giving account of the results presented so far by the implementation of this constitutional tool, see López-Ayllón S and Valladares F, 'Unconstitutionality Actions in Mexican Constitution: The Empirical Balance of Twelve Years of Exercise', *Cuestiones Constitucionales: Revista Mexicana de Derecho Constitucional* (21) (2009) 175-211.

or acts perpetrated by another branch or at another level of government which might be considered to infringe its constitutional jurisdiction.[130] By the establishment of these mechanisms to protect constitutional norms, the highest court is empowered to completely strike down any secondary norm deemed to be unconstitutional. This has meant a remarkable change in the political context, as the impact of its judicial decisions is often reflected in how legislators react in favour of or against those judicial decisions, by reforming or providing new regulations, which were addressed by the Mexican Supreme Court.[131]

Lately, the Mexican Supreme Court has been especially involved in the development of medical law matters.[132] This has happened because of the failure of the legislative bodies to adopt adequate norms in line with established constitutional norms, in addition to their insufficient discussion of contested complex bioethical and human rights issues. The latest landmark judicial decisions are considered to be progressive with regard to the protection of human rights.[133] These decisions include the upholding of the legality of the decriminalisation of abortion in Mexico City,[134] the introduction of the emergency contraceptive pill as part of the catalogue of public health medicines,[135] the defence of the rights and status of members of the military infected with HIV and their protection against discrimination and, more recently, the legality of same-sex adoption and marriage.[136] An examination of the way the Mexican Supreme Court has dealt with issues relating to embryos,

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[130] For an historical account of constitutional controversies, as well as its particularities, see Martínez Ramírez F, 'Las Controversias Constitucionales como Medio de Control Constitucional' *(The Constitutional Controversies as a Mechanism for Constitutional Control)*, in Ferrer Mac-Gregor E and Zaldivar Lelo de la Rea A (Coords) *La Ciencia del Derecho Procesal Constitucional: Estudios en Homenaje a Héctor Fix-Zamudio en sus Cincuenta Años como Investigador del Derecho (The Science of Constitutional Procedural Law: Studies in Honour of Héctor Fix-Zamudio for his Fifty Years as a Legal Researcher)* (Vol VIII; Mexico: IIJ-UNAM, 2008) 567-602.

[131] See Chapter 5, Section 5.4.

[132] See Cossío-Díaz JR, 'El Impacto del Derecho en la Medicina' (*The Impact of Law on Medicine*), keynote speech presented in the seminar Implicaciones del Derecho en la Medicina: Análisis a través de Casos Prácticos (*Implications of Law on Medicine: Analysis through Case Studies*) organised by the Mexican Supreme Court and the National Academy of Medicine, Congress Unit of the Century XXI Medical Centre in Mexico (31 March 2011) *available at:* http://www.scjn.gob.mx/saladeprensa/Documents/Discursos%20de%20Ministros/Ministro%20Cossio%20Diaz/31MAR11.pdf acc. 10 June 2012; also see Cano Valle F and Jiménez Góngora A, *La Administración de Justicia en el Contexto de la Atención Médica (The administration of Justice in the Context of Healthcare)* (Mexico: IIJ-UNAM, 2003).

[133] See Cossío-Díaz JR, 'Constitutional Justice in Ibero-America: Social Influence and Human Rights', *Mexican Law Review* II (1) (2009) 153-61.

[134] See Chapter 5.

[135] See Cossío-Díaz JR, *op. cit. supra* note 103.

[136] On the military HIV case, see Amuchástegui A and Parrini R, 'Subject, Sexuality and Biopower: Legal Defence of Soldiers Living with HIV and Sexual Rights in Mexico', *Global Public Health: An International Journal for Research, Policy and Practice* 5 (3) (2010) 233-46. For a revision of the role of the supreme court, particularly, in the areas of sexual and reproductive rights, see Amuchástegui A and Parrini R, 'Sexuality, Identity, and Citizenship in Contemporary Mexico', *The Routledge Handbook of Sexuality, Health and Rights* (Routledge, 2010a) 370-8.

the right to life and health conducted in Chapter 5, provides some insights into the predominant discourses and positions held by the members of the court.[137]

The next section aims to explore, the implications of established scientific innovation and biomedical research systems for SC research issues, with particular regard to the constitutional rights of healthcare protection and freedom of research.[138] It will provide an overview of the way in which scientific development is pursued and of how financial investment is distributed and administered in the country. In addition, I will look at the regulatory models for science, technology (S&T) and innovation, while offering an insight into the investment injected by the federal government in order to expand biotechnology and biomedical science infrastructure. This will enable us to assess whether or not the creation of a legal platform of SCS as a part of biotechnology innovation, research and development (R&D) activities will be politically and structurally viable.

2.6. SCIENCE AND INNOVATION SYSTEM

Notwithstanding that the pursuit of science and freedom of research is a fundamental right sanctioned by the Federal Constitution, Mexico has historically expended one of the lowest percentages of its gross domestic product (GDP) on science (including all areas of S&T and R&D) of any country in the world.[139] This sub-optimal position still prevails today.[140] This situation impinges on constitutional rights, since the Mexican state has the obligation to pursue scientific and technological research, as well as to guarantee scientific freedom, as provided by Article 3, Sections V and VII:

> V…; it (the State) ***shall support scientific and technological research***, shall strengthen and promote the country's culture...
>
> VII. Universities and all other higher education institutions upon which the Law has conferred autonomy… shall carry out their purposes of educating, ***doing research and promoting culture in accordance with the principles (secularity)***

[137] This examination is found in Chapter 5, Section 5.4.1.
[138] Also see Chapter 6, Section 6.4.
[139] For a complete historical account of the emergence and development of science in Mexico and its interaction with the State, see Pérez Tamayo R, 'El Estado y la Ciencia en México: Pasado, Presente y Futuro' *(The State and Science in Mexico: Past, Present and Future)*, in Fix-Zamudio H and Valadés H (Coord) *Formación y Perspectivas del Estado en México* (Mexico: IIJ-UNAM & El Colegio Nacional, 2010) 319-49.
[140] In the literature it has also been reported that the advancing of Mexico's scientific and innovative endeavours requires the implementation of strategic and sustained policies to foster national systems of innovation and investment; on this see Dutrénit G, 'Premises and Instruments of Innovation Policy: A Reflection from the Mexican Case', in Martínez-Piva JM (Ed), *Knowledge Generation and Protection* (New York: Springer, 2010) 235-61.

> ***established in this Article, respecting freedom to teach and to do research and freedom to analyse and discuss ideas…***[141]

In other words, within this constitutional provision, it has set down an overarching legal framework in order to create policies for education, S&T, R&D and innovation. Furthermore, the Federal Congress has the authority to promote and legislate on foreign investment, technology transfer and technological knowledge, if required to pursue national progress.[142]

In general, the investment in S&T and R&D comes from public funding. In Mexico, public policy, design of S&T systems and funding are the responsibility of two federal governmental agencies: the Ministry of Education (SEP[143]) and the National Council for Science and Technology (CONACYT[144]), which operates under the oversight and coordination of the SEP. The relevant secondary regulation, which governs scientific and innovative technology, is the Science and Technology Act, originally created in 1970 but revised in 1999 and 2002. This act establishes CONACYT as the decentralised agency responsible for providing assistance to the federal government in the formulation, assessment and implementation of S&T policies. The programmes which CONACYT has so far implemented involve: the grant of scholarships; the implementation of incentives and national network programmes to consolidate national academia, including the national system of researchers (SNI); regional research centres, projects on scientific research, the identification and selection of emerging fields and overlooked areas; plus, importantly, the incorporation and repatriation of talented Mexican researchers who have been educated overseas and supported by CONACYT scholarships.[145]

In relation to biotechnology, the majority of emerging research—molecular biology, bioengineering and genetics[146]—is concentrated in public

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[141] Ibid, *supra* note 7 at 14-15 (emphasis added).
[142] The enactment of secondary legislation to regulate and establish policies in this area is reserved to the Federal Congress, whereas State legislatures have a concurrent jurisdiction to legislate in this matter. According to Article 73 of the Federal Constitution, the Federal Congress has full power to govern this area by the enactment of federal Statutes, Regulations or Acts. In relation to this matter, section XXIX-F establishes that the federal legislature has the power "To enact any laws aimed at promoting Mexican investment, regulating foreign investment, technology transfer and production, diffusion and application of scientific and technologic knowledge required for national development"; ibid, *supra* note 7 at 165.
[143] In Spanish *Secretaria de Educación Pública* (SEP), website at www.sep.gob.mx acc. 10 June 2012.
[144] *Consejo Nacional de Ciencia y Tecnología* (CONACYT) in Spanish, the programmes and structure of this council can be found on its website at: http://www.conacyt.mx/eng/home.html acc. 10 June 2012.
[145] See further, Dutrénit G and Vera-Cruz AO, 'Innovation Policy and Incentives Structure: Learning from the Mexican Case', in Drechsler W, Kattel R and Reinert ES (Eds) *Techno-Economic Paradigms. Essays in Honour of Carlota Perez* (London: Anthem Press, 2009) 105-24.
[146] For a wider review of the emergence and development of the field of genetics in Mexico, see Barahona A and Ayala FJ, 'The Emergence and Development of Genetics in Mexico', *Nature Review Genetics* 6 (11) (2005) 860-66.

universities and governmental research centres, yet this is regarded as being of a limited nature and of a low scientific calibre when compared to Mexico's closest neighbours and competitors, Brazil, Canada and the US.[147] Two of the main players in the area of biotechnology in Mexico are the Biotechnology Institute of the National Autonomous University of Mexico (UNAM)[148] and the National Laboratory of Genomics for Biodiversity (LANGEBIO), which is part of the Centre for Research and Advanced Studies (CINVESTAV) of the National Polytechnic Institute (IPN).[149]

In 2005, in a major advance in regulating emerging biotechnology, the Biosafety Act on Genetically Modified Organisms[150] (Biosafety Act hereinafter) was created in order to provide channels to counteract negative situations and promote ethical practices in biotechnology development. Likewise, the Inter-Sectoral Commission on Biosafety and Genetically Modified Organism (CIBIOGEM) was established as a public body which closely monitors and oversees the ingress and exportation of genetically modified crop (GMO) processes and products.[151]

Despite the fact that the state has not considered scientific development a priority and a factor in national and economic growth, as indicated by its limited funding, some successful cases in the biotechnology field are reported in the literature.[152] In fact, the government has shown great impetus in supporting private investment in certain areas of biomedical research and therapies in an attempt to stimulate the tourism industry (e.g. medical tourism),[153] rather than supporting science as an important element of national

[147] See Possani LD, 'The Past, Present, and Future of Biotechnology in Mexico', *Nature Biotechnology* 21 (5) (2003) 582-83.
[148] Here, it is worth noting that the UNAM is Mexico's largest public university. For a revision of the contributions of the Institute of Biotechnology to scientific development in Mexico, see Bolívar F et al, 'The Institute of Biotechnology at the National University of Mexico', *Process Biochemistry* 29 (3) (1994) 177-80.
[149] See Editorial, 'Biotech Round the World: Focus on Mexico', *Biotechnology Journal* 3 (9-10) (2008) 1131-34.
[150] In Spanish, *Ley de Bioseguridad de los Organismos Genéticamente Modificados.* An English version of the Biosafety Act can be found at: http://www.cibiogem.gob.mx/eng/Documents/Ing_LBOGM_P.pdf acc. 10 June 2012.
[151] For a broader revision of the policy-making process that concluded with the adoption of the Biosafety Act and the establishment of the Inter-Secretariat Commission, see Antal E and Tigau C, 'GMO PD for Biosafety in Mexico: Applications of a Hierarchical Model of Communication', *Place Branding and Public Diplomacy* 5 (1) (2009) 38-53. On the environmental impact and enforcement of the Biosafety Law, see Herrera Izaguirre JA et al, 'Mexico´s Environmental Law in the GMO Era', *New Series: Mexican Law Review* (1) (July-December) (2008) http://info8.juridicas.unam.mx/cont/mlawrns/1/cmm/cmm7.htm acc. 10 June 2012.
[152] For a more detailed account of the planning and successful cases reported in the emerging field of biotechnology in Mexico, see Bolívar F, 'Biotechnology in Mexico: Planning for the Future', *Nature Biotechnology* 15 (8) (1997) 742-43; Also see Bolívar F (Ed), *Fundamentos y Casos Exitosos de la Biotecnologia Moderna (Foundations and Successful Cases of Modern Biotechnology)* (Mexico: CONACYT, 2004).
[153] See Chapter 6 on this point.

development in itself.[154] What the current government has treated as a priority to foster national economic growth is the promotion of privately funded research and treatments in the area of biomedicine.[155]

In brief, it is worth pointing out that the Biosafety Act explicitly excludes from its legal jurisdiction, including CIBIOGEM, the oversight or monitoring of any activity related to the human genome and SC culturing, as stipulated by Article 6, section V:

> The following are excluded from the realm of application of this Law: …II. The utilization of *in vitro* fertilization techniques, conjugation, transduction, transformation or any other natural process, as well as polyploid induction, as long as no molecules of recombinant deoxyribonucleic acid (DNA), or genetically modified organisms are employed;… V. The human genome, human stem cell cultures, the modification of human stem cells and biosafety in hospitals, whose regulation corresponds to the General Law of Health and to the International Treatises in which the United Mexican States is a participant…[156]

Therefore, any unforeseen fortuity related to SC research, therapies or transplants falls outside the scope of action of these biosecurity authorities.[157] As others have observed, innovation in biotechnology in Mexico has a long way to go, as there is a missing link between academia, industry and government.[158] Thus, the only available source of public funding for biotechnology is provided by federal governmental agencies. This situation reduces the possibilities for technology transfer and for fostering national economic growth for the wider community. What is worse is that a science and technology base does not drive Mexican economic growth.[159] In 2010, the OECD science, technology and industry outlook reported that Mexico had the lowest R&D expenditure among its member countries.[160] Indeed, innovation outcomes were not prominent and a revision was recommended of Mexico's strategies to establish a better

[154] This point is further addressed and discussed in Chapter 7.
[155] Ibid.
[156] Ibid, *supra* note 150.
[157] See Chapter 7.
[158] See Wagner CK, 'Biotechnology in Mexico: Placing Science in the Service of Business', *Technology in Society* 20 (1) (1998) 61-73.
[159] See Helios Feria V and Hidalgo Nuchera A, 'Towards a National Innovation System in México Based on Knowledge', *The International Journal of Technology, Knowledge and Society* 4 (1) (2008) 225-33; also see Tigau CN, 'Track 2 Innovation Agents in North America: The View from Mexico', *NorteAmérica* 3 (2) (2008) 43-66.
[160] According to the OECD's report, R&D spending has fluctuated around 0.4% of GDP since 2000, which places the country in the lowest rank of performance on innovation, education and competitiveness. See Organisation for Economic Co-Operation and Development (OECD), 'Mexico', in *OECD Science, Technology and Industry Outlook 2010* (OECD Publishing, 2010) 202-03.

governance mechanism and implementation of renewed innovation policies at federal and state levels—added to the allocation of an adequate budget to support R&D.[161]

2.7. THE PURSUIT OF HEALTH: BIOMEDICAL AND LIFE SCIENCES[162] RESEARCH

The constitutionally sanctioned right to healthcare protection is established in Article 4, paragraph 3 of the Federal Constitution, which stipulates:

> Every person has the right to health protection. The Law shall set forth the rules and conditions to access health services and shall establish the concurrence of the Federation, the Federal District and the States in matters of general public health, as provided in section XVI of Article 73 of this Constitution.[163]

As stated before, the legislation that further regulates this constitutional right is the GHA, which is applied by the MoH; associated secondary regulations and administrative NOMs[164] also emanate from this act to specifically regulate certain areas of health, as broadly delineated in what follows.[165]

The Mexican healthcare system is highly complex; it accommodates three distinct modalities of autonomous health services: public, work-related and private.[166] In 2004 the healthcare system underwent major reforms.[167] Thus, in the public sphere, the social protection of health is administered by the MoH, while its financing comes from federal taxes and complementary contributions

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[161] Ibid.

[162] In the literature there seems to be no general definition of life sciences, which in general terms, throughout this thesis, is "…broadly defined to include all biological technologies and applications. This includes: biotechnology, pharmaceuticals, plant and animal technologies, medical devices, healthcare (e.g. translational research, clinical trials), biological related information technology (e.g. bioinformatics, telemedicine), as well as biological-related production and manufacturing". See Council on Competitiveness & Global Bioeconomy Consulting, 'Catalyzing Cross-Border Innovation: The Mexican Life Sciences Initiative', *Phase I Report* (December, 2005), *available at* http://www.compete.org/images/uploads/File/PDF%20Files/2-_Mexico_Life_Sciences_Initiative-Phase_I_Report_2005.pdf acc. 10 June 2012.

[163] Ibid, *supra* note 7 at 17.

[164] An ample and exhaustive compilation of all relevant Mexican Official Norms (NOMs) on health-related matters can be found in Karam Toumeh D and Placencia Villanueva R, *op. cit. supra* note 54.

[165] For a general review of some of the current regulatory Acts and secondary regulations related to health and genetics in Mexico, see Brena Sesma I and Romeo Casabona CM (Eds), 'Legislación Nacional México' *(National Legislation in Mexico),* in *Código de Leyes Sobre Genética (Code of Laws about Genetics)* (Vol I; Mexico: IIJ-UNAM, 2006) 747-838

[166] For an appraisal of the different healthcare schemes, see OECD, 'OECD Reviews of Health Systems: Mexico 2005', (OECD Publishing, 2005).

[167] For a review of the Mexican healthcare system and the major reforms performed at the beginning of the last decade, see Frenk J et al, 'Evidence-Based Health Policy: Three Generations of Reform in Mexico', *The Lancet* 362 (9396) (2003) 1667-71; Frenk J et al, 'Comprehensive Reform to Improve Health System Performance in Mexico', *The Lancet* 368 (9546) (2006) 1524-34; Frenk J, 'Global Lessons of the Mexican Health Reform: Empowerment through the Use of Evidence' (English Abstract), *Revista Peruana de Medicina Experimental y Salud Publica* 27 (3) (2010) 412-18 and Frenk J et al, 'Health Professionals for a New Century: Transforming Education to Strengthen Health Systems in an Interdependent World', *Lancet* 376 (2010) 1923-1958.

by state governments. Among the reforms enacted in 2004 was the incorporation of a Popular Health Insurance (*Seguro Popular)* scheme, which was incorporated as a public modality.[168] This subsidised insurance programme is offered to non-salaried people, the self-employed and rural workers and their families without health insurance. It requires users to pay an initial fee, depending on their socio-economic level.[169] The work-related health services are directed at people working for the government and private employers affiliated to this scheme. It is proportionally paid, whereby one third of the funds come from the employer, one third from the worker's salary and the rest from the government. The three main work-related healthcare providers are the Mexican Social Security Institute (IMSS[170]) for private-sector workers, the Institute of Social Security and Services for Civil Servants (ISSSTE[171]) for government employees and the Institute of Social Security for the Mexican Army Forces (ISSFAM[172]). The private healthcare sector is available for anyone who can pay; fees are established by market forces.[173] Notwithstanding the varied sources of healthcare protection and options to access it, the scale of morbidity in Mexico has increased in recent years.[174] This is one of the reasons to consider the conduct of valuable biomedical research on health in Mexico as a supreme goal to be pursued by any government that is serious about pursuing the welfare of its citizens.[175]

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[168] For a comprehensive and critical approach to the reforms carried out in the Mexican healthcare system, as well as an overview of its structure, see Laurell AC, 'Health System Reform in Mexico: A Critical Review', *International Journal of Health Services* 37 (3) (2007) 515.

[169] For an interesting analysis of the pros and cons of this new health insurance programme within the public administration in Mexico, see Lakin JM, 'The End of Insurance? Mexico's Seguro Popular, 2001–2007', *Journal of Health Politics Policy and Law* 35 (3) (2010) 313-52.

[170] In Spanish *Instituto Mexicano del Seguro Social* (IMSS)*;* as of 2005, this is the largest public healthcare provider, which covers more than 50 million people in Mexico. Ibid, *supra* note 166. The IMSS is governed by the Social Security Act (1995). An historical overview of the social security scheme in Mexico is provided by Díaz Limón J, 'La Seguridad Social en México un Enfoque Histórico', *Revista Jurídica de la Escuela Libre de Derecho de Puebla* 2 (2) (2000) 39-60.

[171] In Spanish *Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado* (ISSTE); the relevant regulation for the functioning of this public healthcare provider is the Act of Social Security and Services for Civil Servants (2007).

[172] In Spanish *Instituto de Seguridad Social para las Fuerzas Armadas de México* (ISSFAM); this army healthcare institution is governed by the Act of the Institute of Social Security for the Mexican Army Forces (2003).

[173] The relevant secondary regulation applicable to private insurance companies is the Act of Insurance Institutions and Mutual Companies (1935). For an interesting review of the current state of private and public insurance, see Coronado Alcántara MÁ, 'ISES, Instituciones de Seguros Especializadas en Salud: "Una Opción de Salud Privada, Asequible al Bolsillo y de Calidad"' *(ISES, Insurance Institutions Specialised on Health: "An Option of Private Health, Affordable Fees and Quality)*, *TEMAS de Ciencia y Tecnología* 11 (33) (2007) 29-46.

[174] Ortiz Hernández L and Perez Salgado D, 'Socio-Economic Stratification and Ill Health in Mexico', *Social Medicine* 6 (1) (2011) at 61.

[175] See Mercado-Martínez FJ et al, 'Qualitative Health Research. A Critical Review of Recent Work in Mexico', (English abstract) *Salud Pública de México* 53 (2011) 504-12.

The bulk of publicly funded biomedical and life science research has been carried out by the staff of physicians, nurses and medical students of the IMSS and ISSSTE, including the National Institutes of Health (NIH[176]), which is part of the public healthcare services provided by the MoH. The current thirteen NIHs have a very wide scope to conduct basic and clinical research in many areas of speciality.[177] The current relevant legal instrument governing biomedical investigations and research on humans is the Regulation on Biomedical Research (1987),[178] which establishes the requirements to be fulfilled in order to carry out biomedical research and therapeutic practices. However, this legislation is archaic and does not respond to the actual needs imposed by the rapid progress of biomedical developments.[179]

As previously mentioned, investment in S&T and R&D has not been a priority for the current federal government. However, there is a particular area of S&T that has been favoured: the field of genomic medicine.[180] The federal government and private investment firms continue to be heavily directed towards this biomedical innovation.[181] One of the most important achievements of biotechnology applied to medicine was the creation, in 2004, of the National Institute for Genomic Medicine (INMEGEN), [182] which aims to create

[176] The NIHs are specifically governed by the Act of the National Institutes of Health (2000).
[177] The NIHs are listed as follows: National Children's Hospital, National Institute of Cardiology, National Institute of Oncology, National Institute of Nutrition, National Institute of Lung Diseases, National Institute of Neurology, National Institute of Paediatrics, National Institute of Perinatology, National Institute of Psychiatry, National Institute of Public Health, National Institute of Rehabilitation, National Institute for Genomic Medicine and National Institute of Geriatrics. For a further revision of the NHIs in Mexico, see Sotelo J, 'La Revista de Investigación Clínica y los Institutos Nacionales de Salud' *(The Journal of Clinical Investigation and the National Institutes of Health), Revista de Investigación Clínica* 61 (4) (2009) 272-3.
[178] In Spanish *Reglamento de la Ley General de Salud en Materia de Investigación para la Salud*, *available at* http://info4.juridicas.unam.mx/ijure/nrm/1/387/default.htm?s=iste acc. 10 June 2012.
[179] Feinholz has pointed out that this legislation is outdated and does not comply with the current needs and reality of vulnerable communities; see Feinholz D, 'Las Investigaciones Biomédicas' *(Biomedical Research)*, in Brena Sesma I and Teboul G (Eds) *Hacia un Instrumento Regional Interamericano sobre la Bioética: Experiencias y Expectativas (Towards and Interamerican Regional Instrument on Bioethics)* (Mexico: IIJ-UNAM, 2009) 233-78. This point is further discussed in Chapter 7, Section 7.4.
[180] Genomic medicine is understood as "the use of information from genomes (from humans and other organisms) and their derivatives (RNA, proteins, and metabolites) to guide medical decision-making. The prospect of examining a person's entire genome (or at least a large fraction of it) to make individualised risk predictions and treatment…" See Ginsburg GS and Huntington WF, 'Genomic and Personalized Medicine: Foundations and Applications', *Translational Research* 154 (6) (2009) 277-87 at 278.
[181] See Séguin B et al, 'Genomics, Public Health and Developing Countries: The Case of the Mexican National Institute of Genomic Medicine (INMEGEN)', *Nature Review Genetics* 9 (Suppl 1) (2008) S5-9.
[182] This is the eleventh NIH. It is noteworthy that due to the prevailing fears of members of the Federal Congress regarding human cloning, the Institute was constituted under the condition that it should not carry out any activity related to human cloning, embryo or SC research, as provided within its internal regulations. Since 2000, the field of genomic medicine, including its adequate regulation, has received major attention, including when INMEGEN was first created as the National Council on the Human Genome. On this, see Muñoz de Alba Medrano M (Coord), 'Aspectos sobre la Regulación del Genoma Humano en México' *(Aspects on the Regulation of the Human Genome in Mexico)*, in *Reflexiones en Torno al Derecho Genómico (Reflexions about Genomic Law)* (Mexico: IIJ-UNAM, 2002) 191-209. This fears were also held in the international arena, for example, in the United Nations Declaration on Human Cloning (2005) it was not possible to reach a consensual decision after intense debate, so this international document has not been signed and ratified by all members countries. On this, see Isasi RM and Annas GJ, 'To Clone Alone: The United Nations Human Cloning Declaration', *Development* 49 (4)

personalised diagnoses and medicines for the Mexican population, based on genetic data.[183] The ambitious goal is to eliminate the dependence on foreign technology and innovations, by generating our own.[184] The increase in public and private vested interests on genomic medicine in Mexico was especially notable at the end of 2010, when a Mexican businessman, Carlos Slim, invested $65 million in this field. In conjunction with the INMEGEN, a new project was created, currently known as the Slim Initiative in Genomic Medicine.[185] The political processes undertaken by a group of scientists interested in conducting genomic medicine in the country, as well as its implications for SC regulation, are further explored later.[186] This heavy investment also aims to obtain independence from foreign biotechnology, as well as to position Mexico as a regional leader and serious global competitor in this scientific arena.[187] If the current government is seriously considering the development of cures for the chronic illnesses of the Mexican population, then it should consider all avenues of biomedical research, including the SCS field.

Although established clinics and university laboratories have made serious efforts to advance this field in the country, scientists must face the uncertainty of the legality of their practice.[188] Research on ASCs and haematopoietic SCs (HSCs) has been conducted in public and private healthcare centres for more than a decade now.[189] Despite the growing number of bone marrow (BMW) and umbilical cord blood (UCB) SC transplants carried

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(2006) 60-7; also see Andorno R, 'Global Bioethics at UNESCO: In Defence of the Universal Declaration on Bioethics and Human Rights', *Journal of Medical Ethics* 33 (3) (2007) 150-4 and 'The Invaluable Role of Soft Law in the Development of Universal Norms in Bioethics', *available at:* http://www.unesco.de/1507.html acc. 10 June 2012.

[183] See Jimenez-Sanchez et al, 'Genomic Medicine in Mexico: Initial Steps and the Road Ahead', *Genome Research* 18 (8) (2008) 1191-98.

[184] See Jiménez-Sánchez G, Silva-Zolezzi I, Hidalgo A and March S, 'Genomic Medicine in Mexico: Initial Steps and the Road Ahead', *Genome Research* 18 (8) (2008) 1191-8; also see Silva-Zolezzi I et al, 'Analysis of Genomic Diversity in Mexican Mestizo Populations to Develop Genomic Medicine in Mexico', *Proceedings of the National Academy of Sciences* 106 (21) (2009) 8611-16.

[185] This can be consulted at http://www.inmegen.mx/en/noticias/noticias-2010/slim-initiative-genomic-medicine/ and http://www.carlosslim.com/preg_resp_slim_genoma_ing.html acc. 10 June 2012.

[186] Analysis of the impact that the creation of INMEGEN has had in the field of SCS is explored in Chapter 5, Section 5.4 and Chapter 6, Section 6.5.2.

[187] See Bustamante CD et al, 'Genomics for the World', *Nature* 475 (7355) (2011) at 165.

[188] See Chapter 7 for a detailed discussion of the legal gaps and uncertainties that physicians, scientists and all healthcare providers may face as a result of the absence of specific regulation of the SCS field.

[189] See Ruíz-Delgado GJ, Hernández-Arizpe A, Macías-Gallardo J, Montes-Montiel M et al, 'El Programa de Transplantes de Células Hematopoyéticas de la Clínica Ruíz de Puebla (1993-2009)' *(The Programme of Hemotopoietic Stem Cell Transplantation in the Clinic Ruiz of Puebla)*, *Revista de Hematología de México* 9 (1) (2010) 15-20.

out in public hospitals,[190] funding is still limited and the lack of specific regulation means that research efforts are now widely scattered,[191] while private healthcare providers have also emerged all over the country.[192] A related trend is the increasing emergence of public and private biobanks which collect UCB and promise to cryopreserve it for the later procurement and use of embryonic SC for future therapeutic treatments.[193] In spite of the large number of public and private healthcare facilities carrying out SCS activities, legislative inertia prevails. This absence of regulation facilitates the spread of purveyors of dubious SC-based therapies, who freely operate across the country, risking physical and financial harm to terminally ill patients desperately seeking cures.[194]

Independently of the irreconcilable differences over the status of the embryo in this context, the Mexican government should urgently secure public trust and confidence in the current and future practices related to the transplantation and use of tissue and cells, as well as biologically derived products.[195] To date, the existing legal provisions for biomedical research are applicable, but may be insufficient to deal with the particularities, risks and challenges posed by the rapidly evolving area of SCS and its clinical applications.[196]

The strengthening of federal public funding and enactment of public policies and regulation to push forward SCS with adequate control can lead to

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[190] See Chapter 7, Table 7.1. In the public healthcare sector, most UCB SC transplants are carried out within the medical centres of the Mexican Social Security Institute IMSS. On this see Guerra-Marquez A et al, 'Cord Blood and Transplantation at the Mexican Institute of Social Security: The First 5 Years', *Transfusion* 51 (2) (2011) 328-32; also see Novelo-Garza B et al, 'Establishing a Cord Blood Banking and Transplantation Program in Mexico: A Single Institution Experience', *Transfusion* 48 (2) (2008) 228-36.

[191] See Academia Mexicana de Ciencias AMC, 'A Pesar de su Eficacia en Casos de Cáncer y Leucemia, México está Rezagado en Materia de Transplantes de Células Madre' *(Mexico is Lagging Behind on Stem Cell Transplantation, this Despite of its Effectiveness in Cancer and Leukaemia Cases)*, *Boletín AMC/029/10* (30 March 2010) http://www.comunicacion.amc.edu.mx/comunicados/a-pesar-de-su-eficacia-en-casos-de-cancer-y-leucemia-mexico-esta-rezagado-en-materia-de-transplantes-de-celulas-madre/ acc. 10 June 2012; also see Escobedo-Cousin MH and Madrigal JA, 'Las Células Madre y el Nicho' *(Stem Cells and the Niche)*, *Revista Hematología de México* 12 (2) (2011) 82-5.

[192] See Chapter 7 for a detailed scrutiny of the emergence of private SC therapy providers in Mexico; also see Table 7.2, which lists most of the existing SC clinics in the country.

[193] Note that despite the many private and public biobanks operating in the country, legislators have adopted no comprehensive legal instrument to govern these practices; however, the particular ethical and legal issues arising from the legislative vacuum in this area are beyond the remit of this thesis. On this legal lacuna, see Brena Sesma I, 'Biobanks, a Subject Pending upon Legislation' (English Abstract), *Boletín Mexicano de Derecho Comparado* XLIII (129) (2010) 1055-79.

[194] Ibid.

[195] See Cruz A, 'Células Madre, Rezago Jurídico' *(Stem Cells and Legal Backlog)*, *El Universal.mx* (21 July 2005), *available at:* http://www2.eluniversal.com.mx/pls/impreso/noticia.html?id_nota=127445&tabla=nacion acc. 10 June 2012.

[196] See Chapter 4 for a proposal for a better governance model as a way forward for Mexico to oversee SC research and clinical application. The issues concerning the inadequate and archaic legislation on biomedical research are explored, further analysed and discussed in Chapter 7.

the discovery of safe and effective treatments for saving lives. In sum, for an emerging economy such as Mexico, with enormous biotechnological potential to innovate, located in Latin America, where it is the third most important player after Argentina and Brazil, it is imperative to move towards a national economic policy which invests, promotes and develops the human capacity and infrastructure required to foster biomedical innovation.[197] It can be argued that the adverse scientific scenario and the lack of commitment of federal agencies to implement adequate public policies makes the investment of foreign capital into aspects of SCS feasible and attractive, for two main reasons: firstly, because of the national regulatory vacuum, researchers find few constraints in conducting experimental treatments; secondly, there is a growing body of scientific work and development of infrastructure in the private sector aimed at biotechnological innovation. Therefore, the current flexible economic policies and the lack of regulation in this area increase the potential for success for foreign, but not domestic, industries to carry out basic and translational SCS.[198]

In what follows, I move on to the analysis of the ethical and philosophical issues at the core of the SCS debate. Chapter 3, on the philosophical approach, advances arguments for the conduct of responsible research on embryos from a gradualist perspective (e.g. the use of spare IVF embryos, embryos created *in vitro* for research purposes and aborted foetuses). It is also argued that pursuing SCS for the development of treatment, in order to alleviate suffering, is a moral imperative.

[197] See Menchaca-Rocha A, 'Science and Technology in Mexico', *Nature Materials* 9 (10) (2010) 781-3.
[198] See Chapter 7, Section 7.3.

CHAPTER 3

PHILOSOPHICAL APPROACH: IN PURSUIT OF ETHICAL STEM CELL SCIENCE

> *We all benefit from living in a society, and, indeed, in a world in which serious scientific research is carried out and which utilises the benefits of past research. It is both of benefit to patients and research subjects and in their interests to be in a society which pursues and actively accepts the benefits of research and where research and its fruits are given a high priority. We all also benefit from the knowledge that research is on-going into diseases or conditions from which we do not currently suffer but to which we may succumb. It makes us feel more secure and gives us hope for the future, for our descendants, and ourselves and for others for whom we care.*[1]

3.1. THE CORE OF THE ETHICAL DISAGREEMENTS: 'CONTESTED CELLS'[2]

In a global context, for many, the progress of SCS represents the advance of scientific knowledge and promises the development of novel therapies, to the extent that it has been said to be a panacea in terms of regenerative medicine.[3] Others argue for caution; that before regulating this area, the potentiality possessed by SCS, in particular hESC research, must be meticulously appraised and discussed because of the moral and ethical concerns that it engenders.[4] On this point, Sorem Hølm argues that the potential of hESC research can be achieved while avoiding the unnecessary destruction of morally significant human embryos, because other types of cell (i.e. somatic cells) can be utilised.[5] In addition, it is important not only to pay attention to moral issues concerning ethically contested sources of SC, but also to ensure the adequate protection of human subjects who are recruited to participate in such biomedical investigations as both research volunteers and tissue providers.[6]

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[1] Harris J, 'Scientific Research is a Moral Duty', *Journal of Medical Ethics* 31 (4) (2005) 242-8 at 243.
[2] I am borrowing and applying this phrase in the same terms and sense as used by Capps B and Campbell A, in *Contested Cells: Global Perspectives on the Stem Cell Debate* (London: Imperial College Press, 2010).
[3] See Devolder K and Savulescu J, 'The Moral Imperative to Conduct Embryonic Stem Cell and Cloning Research', *Cambridge Quarterly of Healthcare Ethics* 15 (01) (2006) 7-21 at 10.
[4] See Cohen CB, 'Leaps and Boundaries: Expanding Oversight of Human Stem Cell Research', in Suzanne Holland S et al, (Eds) *The Human Embryonic Stem Cell Debate: Science, Ethics, and Public Policy* (Cambridge, MA; MIT Press, 2001) 209-22.
[5] See Holm S, 'The Ethical Case Against Stem Cell Research', *Cambridge Quarterly Healthcare Ethics* 12 (4) (2003) 372-83.
[6] See Master Z and Mendez I, 'Benefits, Risks and Ethical Considerations in Translation of Stem Cell Research to Clinical Applications in Parkinson's Disease', *Journal of Medical Ethics* 33 (3) (2007) 169-73; also see Cohen CB, 'Ethical Issues in Embryonic Stem Cell Research', *JAMA: The Journal of the American Medical Association* 285 (11) (2001a) 1439-40.

As argued throughout this thesis, the ethical and political opposition to SCS in Mexico, in common with other Latin American nations, has come from predictable actors, most notably the Catholic Church and other conservative elements.[7] These groups ground their arguments on human dignity and the sanctity of life of embryos, derived from conservative Catholic doctrine.[8] On the other hand, groups in favour of pursuing the development of SCS in Mexico are formed by scientists and members of the Mexican Academy of Sciences (AMC) and university institutions,[9] who have argued for more permissive or facilitative policies to regulate this innovative field of research effectively.[10] Key stakeholders in this latter group have maintained that with regard to the embryo, a moral gradualist position can be found through compromise;[11] that is to say, by conceding that embryonic life needs to be treated with due regard and not simply as a mere object in any SC research activity,[12] but maintaining that it can be used in research on the basis that it may be of benefit to the community. Whilst there may be some constraints on their use and safeguards for adequate respect provided in order to avoid the use of embryos as mere objects for the derivation of embryonic cell lines, their utilisation is justified by the amelioration of people's health that SCS represents.

This chapter summarises the moral discussions surrounding SCS and offers an ethical defence of this biomedical field. In so doing, it explains the philosophical approach adopted in this thesis to support furthering SC research in Mexico. In the first place, I consider that it is ethical to pursue the advancement of novel stem cell-based therapies in order to alleviate human suffering as well as life-threatening and debilitating diseases and injuries.[13]

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[7] See Chapters 2, 5 and 6 for the relevant religious debates in this context.

[8] It is important to highlight the fact that not all Catholics hold conservative views on bioethical issues. More unorthodox interpretations of the teachings of the faith also exist and inform the ongoing debates concerning the acceptability of SCS activities; for example, see Drane JF, *A liberal Catholic Bioethics* (Berlin, Germany: LIT Verlag Münster, 2010). In addition, a diversity of religious reflections on the morality of SC research can be interpreted and read from liberal angles; also see Peters T, Lebacqz K and Bennett G, *Sacred Cells?: Why Christians Should Support Stem Cell Research* (Lanham, Md: Rowman & Littlefield Publishers, 2008).

[9] See Chapter 2 and 6.

[10] See Chapter 6, section 6.5, on the need to promote scientific knowledge in Mexico, in particular that concerning SC research, which has been actively promoted by the renowned Mexican scientist Ricardo Tapia. His latest short publication on this topic can be found in 'La Ciencia es un Bien Público' *(Science is a Public Good)*, *Gaceta Electrónica INNOVACIÓN* (2011) http://www.foroconsultivo.org.mx/innovacion.gaceta/ acc. 11 June 2012.

[11] See Chapter 6, section 6.6 on this point.

[12] In Mexico, the adoption of a permissive legal framework for SCS based on a gradualist moral position has been intensively advanced by a prominent national researcher, Rubén Lisker; see 'Aspectos Bioéticos del Estudio y Uso de Células Troncales' (*Bioethical Aspects of the Use and Study of Stem Cells)*, in Pelayo R, Santa-Olalla J and Velasco I (Eds) *Células Troncales y Medicina Regenerativa (Stem Cells and Regenerative Medicine)* (Mexico: UNAM, 2011) 335-46.

[13] Here, it is important to acknowledge that so far there is no wide spread proof of the efficiency of SC therapies, and there is still a long way to go before we can see groundbreaking therapieutic benefits out of

Concerning the moral treatment of embryos, the approach that I uphold is that embryos are symbolic and special entities that should be treated with respect according to their stage of embryological development.[14] I do not claim that the moral stand adopted in this thesis is my own or that it provides new insights into liberal arguments.[15] Many bioethicists have dedicated entire volumes to advancing these moral arguments in favour of scientific progress, in particular SC research.[16] My aim here is to propose that some of the available justifications for furthering of ethically defensible SCS may provide a feasible way forward for the achievement of a pragmatic compromise between opposing stances in this context. This compromise is needed and if it is accomplished it will also allow for the creation of comprehensive and facilitative regulation of this area of scientific research in Mexico.[17] In what follows, these arguments are elaborated upon.

3.2. THE SCIENCE OF STEM CELLS: SOURCES AND DILEMMAS

This section attempts to elucidate, from a lay perspective, the biological and therapeutic aspects of SCS in order to identify the ethical concerns to which it gives rise. SCs are those biological units that are undifferentiated or unspecialised cells.[18] These have the potential to produce specialised cells which can form an organ, tissues or any part of the body.[19] The SC's potentiality for specialisation, or its plasticity, is determined according to its source of procurement.[20] Their differentiation potential is categorised as follows: totipotent stem cells are those that can originate a complete organism or human being;[21] they are found in the early development of the zygote, within 24-36 hours of the egg being fertilised, and also give rise to extraembryonic tissues, such as the placenta and UCB.[22] Pluripotent stem cells, which are found in early human embryos, may as cells in culture hypothetically be specialised into every

SCS activities. See Hyun I, 'The Bioethics of Stem Cell Research and Therapy', *The Journal of Clinical Investigation* 120 (1) (2010) 71-5.

[14] See Robertson JA, 'Symbolic Issues in Embryo Research', *The Hastings Center Report* 25 (1) (1995) 37-8.

[15] See Guenin LM, *The Morality of Embryo Use* (Cambridge: Cambridge University Press, 2008).

[16] For example, see Gruen L, Grabel L and Singer P (Eds), *Stem Cell Research: the Ethical Issues* (Oxford: Blackwell, 2007); Sagan A and Singer P, 'The Moral Status of Stem Cells', *Metaphilosophy* 38 (2-3) (2007) 264-84.

[17] See Chapter 4 on the regulatory model that is proposed to be adopted in Mexico as an exemplary model of governance for SCS.

[18] Turksen K, *Adult and Embryonic Stem Cells* (New York: Springer, 2012) at 11.

[19] See Barfoot J et al (Eds), *Stem Cells: Science and Ethics*, 3rd Edition (Edinburgh: Biotechnology and Biological Sciences Research Council, 2010).

[20] See Masters JRW, Palsson B and Thonson JA (Eds) *Embryonic Stem Cells* (Dordrecht: Springer, 2007).

[21] Ibid, at 3-4.

[22] Ibid.

type of human cell, but cannot form tissues to support foetal development.[23] These pluripotent cells can be isolated from the inner cell mass of the blastocyst 5-10 days after the fertilisation of the ovum and can form an embryo which, in an appropriate environment, may develop into a foetus.[24] Multipotent stem cells can give rise to specific differentiated cells or the tissues from which they originate.[25] These are also called somatic or adult SCs and can be harvested from cord blood, foetal tissues and a few adult tissues, e.g. BMW, teeth and adipose cells derived from tissues (cell type: adipocyte).[26] The origins, types and utilities of SCs often shape the core ethical controversies.[27] Scientists have succeeded in reprogramming somatic cells from skin into a pluripotential state.[28] These are now commonly termed induced pluripotent stem cells (iPSC);[29] in other words, iPSCs appear to have the self-renewal and therapeutic potentiality of embryonic SCs. Therefore, if a greater proliferation of iPSCs could be realised, the use of these cells has the potential to eliminate the need for embryonic SCs.[30] However, this has yet to be proved to be achievable.

To date, hESC research has tended to be favoured over ASC research, due to the allegedly superior therapeutic potential it possesses.[31] For instance,

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[23] See Ye K and Jin S, *Human Embryonic and Induced Pluripotent Stem Cells: Lineage-Specific Differentiation Protocols* (New York, N.Y.: Humana Press, 2011). However, it is worth highlighting the fact that many authors have stated that the potential benefits attributed to embryonic SCs have been overvalued. On this, see Capps B, 'Bioethics and Misrepresentation in the Stem Cell Debate', *Cardiff Centre for Ethics, Law and Society* (2005) http://www.ccels.cf.ac.uk/archives/publications/2005/capspaper.pdf acc. 11 June 2012.

[24] Ibid, *supra* note 18.

[25] See Bongo A and Lee EH (Eds), 'Stem Cells: Their Definition, Classification and Sources', in *Stem Cells: From Bench to Bedside* (Singapore: World Scientific Publishing, 2005) 1-13.

[26] See Phinney DG, *Adult Stem Cells: Biology and Methods of Analysis* (New York: Humana Press, 2011).

[27] See Baune Ø et al, 'The Moral Status of Human Embryos with Special Regard to Stem Cell Research and Therapy', in Østnor L (Ed) *Stem Cells, Human Embryos and Ethics* (Oslo, Norway: Springer, 2008) 1-20.

[28] Currently, differentiated cells, such as skin cells, can theoretically be induced into their pluripotent (akin to embryonic) state. These cells are known as induced pluripotent stem cells (iPSC). See Takahashi K et al, 'Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors', *Cell* 131 (5) (2007) 861-72; and Yu J et al, 'Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells', *Science* 318 (5858) (2007) 1917-20.

[29] Ibid.

[30] Although there are high risks in reprogramming specialized SCs to a pluripotent state, many scholars have affirmed that research on embryonic SCs needs to continue. See Lee H, Park J, Forget BG and Gaines P, 'Induced Pluripotent Stem Cells in Regenerative Medicine: An Argument for Continued Research on Human Embryonic Stem Cells', *Regenerative Medicine* 4 (5) (2009) 759-69. It has also been said that the use of iPSCs for SC research generates new ethical concerns; on this see Neri D, 'The Race Toward 'Ethically Universally Acceptable' Human Pluripotent (Embryonic-Like) Stem Cells: Only a Problem of Sources?' *Bioethics* 25 (5) (2011) 260-66.

[31] One of the alternative means proposed to generate non-controversial embryos is the use of animal eggs to create human admixed embryos. However, while there are also ethical issues that must be evaluated concerning the creation of human-animal hybrid embryos, or chimeras, for SC research, the purpose of this thesis is not to advance arguments in favour of the creation of this alternative source of embryonic SC, so these issues are not addressed. On these debates, see Holm S, "New Embryos' - New Challenges for the Ethics of Stem Cell Research', *Cells Tissues Organs* 187 (4) (2008) 257-62; Hammond-Browning N and Holm S, 'Hybrid Embryos - Ethics, Law and Rhetoric in the United Kingdom's Stem Cell Policy', in Capps B and Campbell A, *op. cit. supra* note 2 at 377-94; Hayden H and Davies M, 'The Science and Ethics of Human Admixed Embryos', *Obstetrics, Gynaecology & Reproductive Medicine* 19 (9) (2009) 235-

research into embryonic cells may contribute to the advance of basic SCS by obtaining knowledge of embryologic development, genomic illnesses and tissue-specific SC regeneration;[32] it may also help to alleviate chronic diseases, because embryonic SC differentiation is not limited to particular organs or functions.[33]

In broad terms, many of those who oppose hESC research, particularly those whose opposition stems from strong religious beliefs, attribute the same moral significance to embryos as to living human beings. The crux of the matter lies in the fact that hESC research involves the use and destruction of embryos, or nascent human life.[34] Therefore, according to those who accord high moral status to embryos, it is morally wrong to pursue hESC research.[35] In addition, objectors advance the slippery slope argument, which holds that this research could lead to other immoral acts such as human reproductive cloning and the commodification of human life.[36] Arguments expressed against hESC research are based on the ascription of particular moral features to the embryo, such as potentiality (having the potential to become a complete human being and therefore deserving the protection of its life),[37] the sanctity of embryonic life, and dignity (mainly advanced by religious doctrines).[38] Some of these arguments are addressed further below.

On the other hand, notwithstanding the limited plasticity of somatic SCs, these cells are successfully utilised in SC clinical translation and transplants; for example, the transplantation of ASCs harvested from BMW is an established and successful therapeutic procedure used in treating many blood disorders

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39; Hyun I, 'Ethical Standards for Human-to-Animal Chimera Experiments in Stem Cell Research', *Cell Stem Cell* 1 (2) (2007)159-63.

[32] See Taupin P, *Stem Cells and Regenerative Medicine: Embryonic and Adult Stem Cells* (Vol II; New York: Nova Science Publishers, 2008).

[33] See Funderud S, 'Stem Cells: Sources and Clinical Applications', in Østnor L (Ed) *op. cit. supra* note 27 at 21-30.

[34] See Gómez Lobo A, 'On the Ethical Evaluation of Stem Cell Research: Remarks on A Paper By N. Knoepffler', *Kennedy Institute of Ethics Journal* 14 (1) (2004) 75-80 and 'Does Respect for Embryos Entail Respect for Gametes?' *Theoretical Medicine and Bioethics* 25 (3) (2004) 199-208. For arguments against the claim that early embryos can be attributed the same moral considerations as living human beings, see DeGrazia D, 'Must we Have Full Moral Status Throughout our Existence? A Reply to Alfonso Gómez-Lobo', *Kennedy Institute of Ethics Journal* 17 (4) (2008) 297-310.

[35] See Mieth D, 'Stem Cells: The Ethical Problems of Using Embryos for Research', *The Journal of Contemporary Health Law and Policy* 22 (2005) 439-47.

[36] A critical appraisal of the classic slippery slope arguments formulated against human cloning and embryo research can be found in Macklin R, 'Splitting Embryos on the Slippery Slope: Ethics and Public Policy', *Kennedy Institute of Ethics Journal* 4 (3) (2009) 209-25.

[37] See Brown MT, 'The Potential of the Human Embryo', *Journal of Medicine and Philosophy* 32 (6) (2007) 585-618; also see Reichlin M, 'The Argument from Potential: A Reappraisal', *Bioethics* 11 (1) (1997) 1-23. Against the potentiality arguments in these debates, see Devolder K, 'Human Embryonic Stem Cell Research: Why the Discarded-Created-Distinction Cannot be Based on the Potentiality Argument', *Bioethics* 19 (2) (2005) 167-86.

[38] See President's Council on Bioethics, *Human Dignity and Bioethics: Essays Commissioned by the President's Council on Bioethics* edited by Pelegrino E (Notre Dame, Ind.; University of Notre Dame Press, 2008).

and in clinical trials for the treatment of spinal cord injuries.[39] While the use of ASCs avoids the ethical controversies inherent in the use of embryos for research, it nevertheless raises significant ethical issues. For example, the use of somatic cells also generates ethical considerations in relation to the adequate protection of human subjects participating in SC clinical research,[40] consent procedures,[41] avoiding adverse events, reactions and issues related to the safety,[42] cross-contamination, cryopreservation, collection and banking of cord blood SCs[43] and SC lines,[44] including the sharing of the benefits obtained from the research conducted on donated or stored tissues and cells.[45]

In addition, ethical boundaries need to be set in order to ensure that all clinical SC research is free of coercion and that ethical safeguards are in place.[46] For example, in the case of creation of *in vitro* embryos for research, it is imperative to prevent the exploitation of vulnerable people, such as the women who are used as oocyte suppliers,[47] as well as to consider issues regarding the ownership of tissues and cells used in research.[48] Therefore, there is an unquestionable need to create adequate regulation of ethically defensible research, in order to ensure the conduct of SCS activities in an ethical and responsible manner, as is discussed further in the chapter on the legal approach taken in this thesis.[49] In what follows, both secular and religious (namely

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[39] See Appasani K and Appasani RK, *Stem Cells & Regenerative Medicine: From Molecular Embryology to Tissue Engineering* (New York: Humana Press, 2011).

[40] See Hug K and Hermerén G (Eds), *Translational Stem Cell Research: Issues Beyond the Debate on the Moral Status of the Human Embryo* (New York: Humana Press, 2011).

[41] See Lo B et al, 'Informed Consent in Human Oocyte, Embryo, and Embryonic Stem Cell Research', *Fertility and Sterility* 82 (3) (2004) 559-63.

[42] On the relevance of the ethical surveillance of the procedural side and products of these activities in SC research, see Hyun I et al, 'New ISSCR Guidelines Underscore Major Principles for Responsible Translational Stem Cell Research', *Cell Stem Cell* 3 (6) (2008) 607-09; Knoppers BM et al, 'Stem Cell Charter', *Regenerative Medicine* 5 (1) (2010) 5-6; Dawson L et al, 'Safety Issues in Cell-Based Intervention Trials', *Fertility and Sterility* 80 (5) (2003) 1077-85; Trounson A, 'New Perspectives in Human Stem Cell Therapeutic Research', *BMC Medicine* 7 (1) (2009) 29.

[43] See Sullivan MJ, 'Banking on Cord Blood Stem Cells', *Nature Reviews Cancer* 8 (7) (2008) 555-63.

[44] See Knoppers BM and Isasi RM, 'Stem Cell Banking: Between Traceability and Identifiability', *Genome Medicine* 2 (10) (2010) 73.

[45] See Quigley M, 'Stem Cell Therapies & Benefiting from the Fruits of Banned Research', in Quigley M, Chan S and Harris J (Eds) *Stem Cells: New Frontiers in Science and Ethics* (Singapure: World Scientific, 2012) 163-86.

[46] This is in order to avoid ethical misconduct such as occurred in the Korean cloning fraud scandal, as briefly explained in Chapter 7, section 7.3. See also Aera H, 'The Ethical and Regulatory Problems in the Stem Cell Scandal', *Journal of International Biotechnology Law* 4 (2) (2007) 45-68.

[47] See Steinbrook R, 'Egg Donation and Human Embryonic Stem-Cell Research', *New England Journal of Medicine* 354 (4) (2006) 324-26; Magnus D and Cho MK, 'Issues in Oocyte Donation for Stem Cell Research', *Science* 308 (5729) (2005) 1747-48.

[48] I owe this observation to Sarah Devaney. For ongoing ethical and legal discussions concerning the patentability and property rights regarding SC lines derived from embryos, see Devaney S, 'Tissue Providers for Stem Cell Research: The Dispossessed', *Law, Innovation and Technology* 2 (2) (2010) 165-91; also see Plomer A and Torremans P, *Embryonic Stem Cell Patents: European Law and Ethics* (Oxford University Press, 2009); Andersson AM, 'Embryonic Stem Cells and Property Rights', *Journal of Medicine and Philosophy* 36 (3) (2011) 221-42.

[49] An indepth analysis of all the ethical issues identified above goes beyond the scope of this thesis. For the legal approach of this thesis, see Chapter 4.

Catholic) arguments are briefly scrutinised, before it is argued that SCS is morally justifiable.

3.3. GRADUALIST ETHICAL REFLECTIONS ON STEM CELL SCIENCE

In non-religious discussions of the permissibility of SCS, particularly concerning whether the use of early embryos is morally justifiable,[50] it is argued that this research is morally defensible because it will lead to the discovery of cures and therapies which may, in turn, save many lives and ameliorate people's suffering.[51] Therefore, it is a worthy goal. In secular debates, there are diverse views on the moral status of early embryos.[52] For some, an early embryo acquires moral worth after the fourteenth day following the fusion of sperm and ovum or later;[53] therefore, it is ethically acceptable to use it for SC research before that point. On this view, before that time, early embryos constitute a mere clump of cells, so there is no moral objection to carrying out research on them.[54] In this thesis, I am adopting the argument that it is morally defensible within a fourteen-day limit to use early embryos in research which may help to overcome debilitating and fatal illnesses. In this context, the utilisation for research and treatment purposes of *in vitro* fertilised or frozen embryos remaining after ART procedures is ethically defensible, because it is preferable to use them to treat and aid those who are seriously ill, rather than let them perish without due regard for their value.[55] Following the social utility argument, is also morally justifiable to allow the creation of embryos by SCNT techniques for research and therapeutic purposes, since these activities may help in developing therapies which are of benefit to those suffering from fatal diseases.[56]

In relation to the fourteen-day position on hESC research, it is held that embryological development is a process by which different events need to occur for an early-stage embryo to achieve individuality and therefore moral

[50] See Kenny A, 'The Beginning of Individual Human Life', *Daedelus* 137 (2008) 15–22, quoted in Baldwin T, 'Morality and Human Embryo Research', *EMBO Reports* 10 (4) (2009) 299-300 at 299.
[51] See Lanza RP et al, 'The Ethical Reasons for Stem Cell Research', *Science* 292 (5520) (2001) 1299.
[52] See Maienschein J, *Whose View of Life?: Embryos, Cloning, and Stem Cells* (Cambridge, Mass.: Harvard University Press, 2003).
[53] See Green RM, *The Human Embryo Research Debates: Bioethics in the Vortex of Controversy* (Oxford: Oxford University Press, 2001).
[54] See Cohen CB, *Renewing the Stuff of Life: Stem Cells, Ethics, and Public Policy* (Oxford: Oxford University Press, 2007).
[55] Ibid.
[56] See Liras A, 'Future Research and Therapeutic Applications of Human Stem Cells: General, Regulatory, and Bioethical Aspects', *Journal of Translational Medicine* 8 (1) (2010) 131.

significance.[57] Supporters of this position argue that it is not until day fourteen that twinning can be discounted and that individuality is thus assured.[58] It is also after this point that there is formed the first primitive streak of the embryo, from which the nervous system and organs of the body begin to grow.[59] In short, proponents of this ethical position advance the notion that we do owe a certain level of moral consideration to the early stage of embryonic development, but not the same level that is accorded to individual human beings.[60] Following this view, it is paramount to show due regard to early human embryos and not to treat them in a frivolous manner. In pursuing ethical hESC activities, a degree of reverence is needed in order to use embryonic SCs for legitimate scientific purposes and for the progress of knowledge.[61]

The use of donated cryopreserved embryos left over from IVF treatments and the creation of such embryos for both research and therapeutic purposes is ethically justifiable, because these can serve worthy regenerative medicine ends.[62] The use of spare IVF embryos has two aims. On one hand, creating *in vitro* embryos and using donated IVF embryos promises to aid SC research in the development of therapies to treat incurable diseases and to advance knowledge concerning embryology and birth abnormalities.[63] *In vitro* embryos, created by whatever means, are also morally significant because of their potential contribution to the alleviation of human suffering and restoration of health.[64] Advancing knowledge and discovering new therapies are morally relevant and laudable ends which, in turn, provide sound support for the use of early embryos (and supernumerary IVF embryos that would otherwise be

[57] See Steinbock B, *Life Before Birth: The Moral and Legal Status of Embryos and Fetuses*, 2nd Edition (Oxford: Oxford University Press, 2011).
[58] Ibid.
[59] Ibid. For a philosophical account criticizing the concession of special respect for early embryos, see Devolder K and Harris J, 'The Ambiguity of the Embryo: Ethical inconsistency in the Human Embryonic Stem Cell Debate', in Gruen L, Grabel L and Singer P (Eds), *op. cit, supra* note 16 at 16-31; Harris J, 'Stem Cells, Sex, and Procreation', *Cambridge Quarterly of Healthcare Ethics* 12 (4) (2003) 353-71.
[60] See Robertson JA, 'Human Embryonic Stem Cell Research: Ethical and Legal Issues', *Nature Review Genetics* 2 (1) (2001) 74-8.
[61] See Gibson S, 'Uses of Respect and Uses of the Human Embryo', *Bioethics* 21 (7) (2007) 370-8. For a more attentive approach to the special respect for embryos, see Meyer MJ, 'Respecting What we Destroy: Reflections on Human Embryo Research', *The Hastings Center Report* 31 (1) (2001) 16-23.
[62] Ethical issues in relation to informed choices and appropriate procedures to grant consent in the donation of IVF embryos are addressed in Cohen CB et al, 'The Use of Fresh Embryos in Stem Cell Research: Ethical and Policy Issues', *Cell Stem Cell* 2 (5) (2008) 416-21. Ethical arguments against the use and donation of spare IVF embryos and their creation solely for research aims are found in McLeod C and Baylis F, 'Donating Fresh Versus Frozen Embryos to Stem Cell Research: In Whose Interests?' *Bioethics* 21 (9) (2007) 465-77.
[63] See Cohen CB, 'Ethical and Policy Issues Surrounding the Donation of Cryopreserved and Fresh Embryos for Human Embryonic Stem Cell Research', *Stem Cell Reviews and Reports* 5 (2) (2009) 116-22; Sandel MJ, 'Embryo Ethics -The Moral Logic of Stem-Cell Research', *New England Journal of Medicine* 351 (3) (2004) 207-9.
[64] See Douglas T and Savulescu J, 'Destroying Unwanted Embryos in Research', *EMBO Reports* 10 (4) (2009) 307-12.

discarded).[65] Therefore, allowing the donation and use of surplus IVF embryos and the creation of *in vitro* embryos for research guarantees that these embryos are employed in a purposeful way.[66]

The creation of *in vitro* embryos solely for research purposes is regarded as ethical, because it can contribute to the advancement of basic SCS and its clinical applications, which may in turn help to eradicate devastating diseases.[67] In the context of regenerative research, the creation and use of embryos for SC research actualizes their moral significance, because their utilization is not arbitrary. For example, in the UK, if any research project is approved, it will be required to demonstrate that the research will serve to provide valuable knowledge.[68] In pursuing ethical research, it should be required in Mexico that the safety, transparency and alignment with purposeful objectives of the procedures be established, in order to ensure that the design of research projects conducted with SC lines derived from embryos that have been created solely for research has worthwhile ends that are equal to reproductive aspirations, such as the amelioration of human health.[69]

There is a wider range of ethical justifications for the use of embryos before the fourteen-day, SCNT and supernumerary embryos, which are supported by more sophisticated philosophical arguments.[70] However, further discussion of these views goes beyond the scope of the argument here; I can only touch on such an extensive ethical discourse. The following subsection

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[65] See Brock DW, 'Creating Embryos for Use in Stem Cell Research', *The Journal of Law, Medicine & Ethics* 38 (2) (2010) 229-37; Devolder K, 'Creating and Sacrificing Embryos for Stem Cells', *Journal of Medical Ethics* 31 (6) (2005) 366-70.

[66] See Wert GD and Mummery C, 'Human Embryonic Stem Cells: Research, Ethics And Policy', *Human Reproduction* 18 (4) (2003) 672-82.

[67] The creation of IVF embryos for the sole aim of research also generates ethical social risks in that it opens the door to the potential exploitation of vulnerable women as egg providers and to the enormous health risks that ovary hyperstimulation can bring to those women willing to donate. On this, see further Baylis F and McLeod C, 'The Stem Cell Debate Continues: The Buying and Selling of Eggs for Research', *Journal of Medical Ethics* 33 (12) (2007) 726-31. The creation of human-animal chimeras is presented as an alternative measure to reduce the use of women's eggs for SC research activities. However, the ethical status of the creation of inter-species embryos for research purposes is also contested. On this, see Hyun I, 'Ethical Standards for Human-to-Animal Chimera Experiments in Stem Cell Research', *Cell Stem Cell* 1 (2) (2007) 159-63; Behringer R, 'Human-Animal Chimeras in Biomedical Research', *Cell Stem Cell* 1 (3) (2007) 259-62; Karpowicz P et al, 'Developing Human-Nonhuman Chimeras in Human Stem Cell Research: Ethical Issues and Boundaries', *Kennedy Institute of Ethics Journal* 15 (2) (2005) 107-34; Baylis F, 'Animal Eggs for Stem Cell Research: A Path not Worth Taking', *American Journal of Bioethics* 8 (12) (2008) 18-32.

[68] See Curzer HJ, 'The Ethics of Embryonic Stem Cell Research', *Journal of Medicine and Philosophy* 29 (5) (2004) 533-62.

[69] See Mertes H and Pennings G, 'Ethical Concerns Eliminated: Safer Stimulation Protocols and Egg Banking', *The American Journal of Bioethics* 11 (9) (2011) 33-5 and 'Oocyte Donation for Stem Cell Research', *Human Reproduction* 22 (3) (2007) 629-34.

[70] Philosophical counter-arguments at the core of these discussions can be further reviewed in Marquis D, 'The Moral-Principle Objection to Human Embryonic Stem Cell Research', *Metaphilosophy* 38 (2-3) (2007) 190-206; President's Council on Bioethics, *Human Cloning and Human Dignity: The Report of The President's Council on Bioethics* (New York: Public Affairs Reports, 2002), in particular Leon Kass's contribution to this collection of essays.

briefly describes the ethical position held by the Roman Catholic Church, which is relevant in the Mexican political arena.

3.4. CATHOLIC STANCES ON STEM CELL SCIENCE

In a globalised and pluralistic world, there are a significant number of diverse religious views that are worth accounting for in an ethical review.[71] Here, I shall focus on Catholicism because of its arguable prevalence in Mexico.[72] In Latin American countries, including Mexico, the ethical standpoints of the Catholic doctrine concerning SCS and related areas have played a very influential and powerful role in the political arena.[73] In this context, a brief exploration of this specific religious stand on SCS is necessary.

The most conservative factions of the Catholic Church embrace the notion that the early embryo possesses exactly the same moral significance as a living human being, so it must be treated as a person from the moment of conception.[74] Furthermore, embryos are bearers of human dignity whose lives are sacred at all stages and deserve full moral consideration.[75] Therefore, to

[71] It is controversial in Roman Catholic traditions, but in many other religions, such as Judaism or Islam, the use and destruction of embryos for research is not as highly contested as in Catholicism. In Israel and certain Muslim countries, research on embryos is considered to improve human life and alleviate human suffering. Thus, more liberal approaches to regulation are accepted. Examples of these religious underpinnings are represented in the Iranian and Israeli cases. See Prainsack B, "Negotiating Life': The Regulation of Human Cloning and Embryonic Stem Cell Research in Israel', *Social Studies of Science* 36 (2) (2006) 173-205; Saniei M, 'Human Embryonic Stem Cell Research in Iran: The Role of the Islamic Context', *SCRIPTed: A Journal of Law, Technology & Society* 7 (2) (2010) 315-25, *available at* http://www.law.ed.ac.uk/ahrc/script-ed/vol7-2/saniei.pdf acc. 11 June 2012.

[72] For reasons of space and scope, not all of the existing religious stances on SCS are addressed in this work. However, the ethical views regarding SC research within diverse religious traditions from Islam to Judaism are considered in Cohen CB, 'Religion, Public Reason, and Embryonic Stem Cell Research', in Guinn DE (Ed) *Handbook of Bioethics and Religion* (Oxford University Press, 2006) 129-42.

[73] On the role played by the ethical standards of the Catholic Church in the existing debates concerning the permissibility or prohibition of SC research and connected areas in the Latin American context, see Diniz D, 'Embryonic Stem Cell Research: Ethical Challenges for Developing World Bioethics', *Developing World Bioethics* 8 (3) (2008) ii-iv; Luna N, 'Abortion and Embryonic Stem Cells in the Fraternity Campaign: Science and Ethics in the Teachings of the Catholic Church' (English Abstract), *Revista Brasileira de Ciencias Sociales* 25 (74) (2010) 91.

[74] It is said that in terms of the original teachings of Catholicism, the view of the beginning of life was different in the past. During the nineteenth and early twentieth centuries, within canon law, the official teaching dictated by Saint Augustine and also influenced by the intellectual work of the theologian St. Thomas Aquinas was that foetuses were formed and unformed and that the latter did not have the same moral status because they lacked human souls and the capacity for sentience. Aquinas believed that ensoulment occurred at the 40th and 90th day of male and female foetuses respectively. Therefore, formed foetuses were those that had acquired souls. See Hug K, 'Sources of Human Embryos for Stem Cell Research: Ethical Problems and Their Possible Solutions', *Medicina* 41 (12) (2005) 1002-10 at 110. For modern interpretations of Aquinas's theory concerning the beginning and protection of human life, particularly as applied to the embryonic SC debates, see Eberl JT, 'Issues at the Beginning of Human Life: Abortion, Embryonic Stem Cell Research, and Cloning', in *Thomistic Principles and Bioethics* (London; Routledge, 2006) 62-94.

[75] In 1987, the Vatican's Congregation of the Doctrine for the Faith issued an encyclical 'Instruction on Respect for Human Life in its Origin and on the Dignity of Procreation: Replies of Certain Questions of the Day', which explained how human life ought to be protected from conception; see *Donum Vitae Instruction*, *available at* http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19870222_respect-for-human-life_en.html acc. 11 June 2012. For a further scholarly revision of this instruction, which

destroy sanctified life in the course of embryonic SC research is an affront to the respect for human life and dignity, so this activity is morally wrong and sinful.[76] Roman Catholic teachings have vigorously defended respect for the sanctity and dignity of life,[77] in particular that of the early embryo, and have proffered fierce opposition to embryonic SC research that contravenes this sacred value of human life.[78] In 2008, the Congregation for the Catholic Faith published a new papal instruction, *Dignitas Personae,* which further elaborated the position of the Holy See on issues concerning embryos, SC research and other bioethical issues.[79] In essence, the Vatican reasserted its previously unwavering position that embryos are human beings enjoying human dignity and the right to life from conception and are therefore members of the human community.[80]

Following the latest encyclical Catholic mandate, the use of frozen oocytes or IVF cryopreserved embryos and the creation of embryos by SCNT to acquire hESCs for research are considered immoral and to amount to taking the lives of innocent human beings.[81] Embryos are regarded as equal to persons, being sacrosanct and enjoying full moral status and human dignity from the moment of conception.[82] In orthodox Catholic teaching, the notion of human

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analyses the canonical moral law and its normative implications for civil society, see Bauzon S, 'Catholic Reflections for an Updated Donum Vitae Instruction: A New Catholic Challenge in a Post-Christian Europe', *Christian Bioethics* 14 (1) (2008) 42-57.

[76] See Garcia L, 'Protecting Persons', in Tollefsen C (Ed) *John Paul II's Contribution to Catholic Bioethics* (Norwell, MA: Springer, 2004) 93-106.

[77] One of the main proponents of the dignity of embryonic life in secular discussions is Leon Kass; see his *Life, Liberty, and the Defense of Dignity: the Challenge for Bioethics* (San Francisco: Encounter Books, 2002). Kass's defence of human dignity has been severely criticised because in the view of some, Kass and others have failed to provide a comprehensive explanation of what is understood by this concept. Therefore, this notion is highly disputed. This lack of clarity has provoked some scholars, including Ruth Macklin, to conclude that this notion has no meaning in itself and merely signifies respect for autonomy and self-determination. For others, Steven Pinker among them, the use of this notion is irrational. On these discussions, see Macklin R, 'Dignity is a Useless Concept', *BMJ* 327 (7429) (2003) 1419-20; Pinker S, 'The Stupidity of Dignity', (updated May 28, 2008) http://www.tnr.com/article/the-stupidity-dignity acc. 9 June 2012; Harris J, 'Cloning and Human Dignity', *Cambridge Quarterly of Healthcare Ethics* 7 (02) (1998) 163-67; Schüklenk U, 'Defending the Indefensible', *Journal of Bioethical Inquiry* 7 (1) (2010) 83-8.

[78] See Doerflinger RM, 'The Ethics of Funding Embryonic Stem Cell Research: A Catholic Viewpoint', *Kennedy Institute of Ethics Journal* 9 (2) (1999) 137-50.

[79] See Congregation of the Doctrine of the Faith, *Dignitas Personae (on Certain Bioethical Questions)* (9 December 2008) *available at:* http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html acc. 11 June 2012.

[80] See Eilidh Campbell J and Blackler S, 'Religion and Dignity: Assent and Dissent', in Malpas J and Lickiss N (Eds) *Perspectives on Human Dignity: A Conversation* (Springer Netherlands, 2007) 127-34.

[81] According to *Dignitas Personae*, even the adoption of IVF surplus embryos to be given an alternative chance to be implanted in another woman's womb and brought to life is problematic. However, this position has been contested as unconvincing, because prohibiting frozen embryo adoption may also compromise the dignity of childless couples wishing to start a family. See Murphy TF, 'Dignity, Marriage and Embryo Adoption: a Look at Dignitas Personae', *Reproductive BioMedicine Online* 23 (7) (2011) 860-8; also see Berkman J and Carey KN, 'Ethical and Religious Directives for a Catholic Embryo Adoption Agency: A Thought Experiment', in Brakman SV and Weaver D (Eds) *The Ethics of Embryo Adoption and the Catholic Tradition: Moral Arguments, Economic Reality and Social Analysis* (New York: Springer, 2007) 251-74.

[82] For ontological views on the inner moral worth of embryos, their right to life and their dignity, see Robert G, 'Embryo Ethics: Justice and Nascent Human Life Bioethics with Liberty and Justice', in Tollefsen C (Ed)

dignity is incompatible with the pursuit of hESC research.[83] Arguably, the major issues addressed by the Vatican in *Dignitas Personae* are those concerning the diminishing of life by the unnecessary use of biotechnology, thus transgressing the early-stage embryo's inner human dignity.[84] Moreover, the encouragement of research on embryos may lead to the instrumentalisation of humanity and the desecration of human life, since these will subsequently be destroyed and treated as artefacts for unscrupulous research.[85]

The official Roman Catholic magisterium maintains that scientific research on somatic cells, placenta and UCB should proceed,[86] whereas hESC activities are morally wrong and therefore totally proscribed.[87] This position is supported by the argument that non-hESC sources of procurement of these cells are the only ethical ones, because they do not involve the harming of human beings. In addition, according to the Church, these cells offer almost the same therapeutic advantages as those sought through embryo-derived SC research.[88]

On the other hand, a more liberal ethical reading concerning SCS can be found within Catholicism.[89] Liberal Catholic views maintain a middle ground concerning the moral status of the embryo and support hESC research in some circumstances for humanitarian reasons.[90] Margaret Farley asserts that an early embryo is considered a potential human being until individuation occurs, that is to say, on the fourteenth day after the sperm and egg merge, so a distinction between conception and individualisation is crucial.[91] Farley points out:

> In its earliest stages (prior to the development of the primitive

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op. cit. supra note 73, 43-58; Doerflinger RM, 'Old and New Ethics in the Stem Cell Debate', *The Journal of Law, Medicine & Ethics* 38 (2) (2010) 212-19.

[83] See Delaney J, 'The Catholic Position on Germ Line Genetic Engineering', *The American Journal of Bioethics* 9 (11) (2009) 33-4.

[84] On this, see Zivotofsky AZ and Jotkowitz A, 'A Jewish Response to the Vatican's New Bioethical Guidelines', *The American Journal of Bioethics* 9 (11) (2009) 26-30. For secular approaches to the analysis of the unethical use of embryos as a means to an end and to the respect for human dignity as a moral constraint for certain types of experimental medical research, see Steinbock B, 'Moral Status, Moral Value, and Human Embryos: Implications for Stem Cell Research', in *The Oxford Handbook of Bioethics* (Oxford University Press, 2007) 416-41; Brownsword R, 'Bioethics Today, Bioethics Tomorrow: Stem Cell Research and the "Dignitarian Alliance", *Notre Dame Journal of Law Ethics Public Policy* 17 (1) (2003) 15-51; Van Der Graaf R and Van Delden J, 'Clarifying Appeals to Dignity in Medical Ethics From an Historical Perspective', *Bioethics* 23 (3) (2009) 151-60.

[85] See Surprises AF, 'Vatican Issues Authoritative Statement on Reproductive Science', *Biotechnology Law Report* 28 (1) (2009) 39-40.

[86] See Prieur MR et al, 'Stem Cell Research in a Catholic Institution: Yes or No?' *Kennedy Institute of Ethics Journal* 16 (1) (2006) 73-98.

[87] See Fisher A, 'Stem Cells, What's all the Fuss About?' in *Catholic Bioethics for a New Millennium* (Cambridge University Press, 2012) 131-51.

[88] Ibid.

[89] For liberal Catholic approaches to the field of bioethics see the work of Drane JF and Peters T et al, *op. cit. supra* note 8.

[90] See Farley MA, 'Roman Catholic Views on Research Involving Human Embryonic Stem Cells', in Holland S (Ed) *op. cit. supra* note 4.

[91] Cohen CB, *op. cit. supra* note 54 at 102.

> streak or to implantation) to constitute an individualized human entity with the settled inherent potential to become a human person. The moral status of the embryo is, therefore (in this view), not that of a person, and its use for certain kinds of research can be justified. (Because it is, however, a form of human life, it is due some respect—for example, it should not be bought or sold.) (Farley 2000, p. D- 4)[92]

This alternative Catholic position opens the door to considering as morally permissible the utilisation of embryos before the fourteenth day of development, discarded IVF embryos and aborted foetuses, because they are not persons or even potential human beings.[93] Following this line of thought within Catholicism, these early entities are not actual persons and their use in SC research may help to save many lives, which is desirable because it genuinely contributes to and serves human welfare and the common good.[94]

In sum, within the regional Latin American context, the most conservative sector of the Catholic Church has fiercely attempted to influence policies against SCS.[95] However, liberal Catholic voices can be heard and have begun to influence the Catholic community in Mexico.[96] These voices tend to support abortion, a broad array of contraceptive methods, same-sex marriage and other tolerant positions related to the beginning and end of life.[97] It is therefore plausible that liberal-ethical Catholic stances will influence current and future policies in the area of biotechnology, specifically in regard to regenerative medicine, in many countries in this region.[98]

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[92] As quoted by Outka GH, 'The Ethics of Human Stem Cell Research', *Kennedy Institute of Ethics Journal* 12 (2) (2002) 175-213 at 180.

[93] See Farley MA, 'Stem Cell Research: Religious Consideration', in Carlson BM (Ed) *Stem Cell Anthology* (Amsterdam: Academic, 2010) at 362-363.

[94] Ibid.

[95] This point is also addressed in Chapter 2, Section 2.2.This is exemplified by the ethical and religious arguments advanced in the Brazilian and Argentinean legislative and political debates on SCS. See Luna F and Salles A, 'On Moral Incoherence and Hidden Battles: Stem Cell Research in Argentina', *Developing World Bioethics* 10 (3) (2010) 120-8; Cesarino L and Luna N, 'The Embryo Research Debate in Brazil: From the National Congress to the Federal Supreme Court', *Social Studies of Science* XX (X) (2011) 1-24.

[96] See Catholics for Free Choice in Mexico (Católicas por el Derecho a Decidir), *available at:* http://www.catolicasmexico.org/ns/ acc. 11 June 2012. According to the national poll carried out by Catholics for Free Choice and the Population Council, 53% of those interviewed accepted abortion under certain circumstances. Thus, Mexican scholars estimate that the number of practising Catholics is decreasing every year. See Blancarte R, 'México. Un País Cada Vez Menos Católico' *(Mexico. A Less and Less Catholic Country), Redes Cristianas* (March 2011) http://www.redescristianas.net/2011/03/16/mexico-un-pais-cada-vez-menos-catolicoroberto-blancarte/ acc. 11 June 2012; also see Blancarte R, *Sexo, Religión, y Democracia (Sex, Religion and Democracy)* (Mexico: Planeta, 2008).

[97] See introductory Chapters 1 and 2; also see Carrillo H, 'Imagining Modernity: Sexuality, Policy and Social Change in Mexico', *Sexuality Research and Social Policy* 4 (3) (2007) 74-91. For an overview of the evolving role of the Catholic doctrine in the public sphere in the Latin American context, see Hagopian F, *Religious Pluralism, Democracy, and the Catholic Church in Latin America* (University of Notre Dame Press, 2009).

[98] It is worth pointing out that an in-depth exploration of this point goes beyond the remit of this thesis.

3.5. CONCLUDING REMARKS

Many who favour the advancement of SCS see this scientific activity as a moral imperative grounded on arguments of freedom of research and the alleviation of human suffering.[99] However, that is a more extreme position than the middle-ground approach which I attempt to argue for here.[100] A more cautious view of the advancement of embryonic SC research is found in the ethical justification of the use of embryos before the fourteenth day of development as representing an immense value in advancing regenerative medicine.[101] There are sound reasons to use such embryos in "promoting some good through obstructing debilitating diseases".[102]

Having sketched a few of the ethical issues prevailing in the SCS debates, it is important to reflect briefly on how ethical abstractions may be accommodated in efficient policies to avoid wrongdoing and protect all subjects involved in this science. Some bioethicists have asserted that a consensus on the sensitive issues of SC research cannot be achieved, because of the contrary and intractable moral stances of those who favour SCS and those who oppose it on any scale.[103] However, Master and Crozier have advanced arguments in favour of adopting a moral compromise policy to facilitate and encourage the progress of SCS, using the US context as a case study.[104] They propose that it may be plausible through a discussion of mutual concessions between rival parties to arrive at an agreement upon related points, whereby each party concedes certain elements of its expectations in order to reach a global consensus that is valid for all, considering SCS research as a morally laudable end, despite some of its means.[105] In this sense, the utilisation of some embryos (e.g. frozen ones and those created solely for research) and the procurement of oocytes for hESC research whenever there is no other means of deriving them can be justified on both liberal and conservative grounds. Within Catholicism, the most liberal

[99] See Devolder K and Savulescu J, *op. cit. supra* note 3.
[100] This position appears to be viable in the Mexican context, based on key stakeholders' perceptions presented in Chapter 6.
[101] See McLaren A, 'Ethical and Social Considerations of Stem Cell Research', *Nature* 414 (6859) (2001) 129-31.
[102] See Klostergaard L, 'Embryonic Stem Cell Research is not Dehumanising Us', *Journal of Medical Ethics* 35 (12) (2009) 774-77.
[103] See Solbakk JH and Holm S, 'The Ethics of Stem Cell Research: can the Disagreements be Resolved?' *Journal of Medical Ethics* 34 (12) (2008) 831-32; Brock DW, 'Is a Consensus Possible on Stem Cell Research? Moral and Political Obstacles', *Journal of Medical Ethics* 32 (1) (2006) 36-42. On the other hand, other scholars are more empathetic regarding the idea that progressive and facilitative ethical and legal oversight in this area can be gradually embraced. See Robertson JA, 'Embryo Stem Cell Research: Ten Years of Controversy', *The Journal of Law, Medicine & Ethics* 38 (2) (2010) 191-203.
[104] See Master Z and Crozier G, 'The Ethics of Moral Compromise for Stem Cell Research Policy', *Health Care Analysis* 20 (1) (2012) 50-65.
[105] Ibid.

voices converging in this arena have shown a strong presence in the Mexican context.[106] Therefore, scientists, citizens and relevant policymakers should engage in public deliberation by which different ethical standpoints can be heard and equally appreciated in order to achieve consensus and moral compromise. This policy consultation process must be pursued in order to adjust the ethical points agreed upon into any policy or legislation that attempts to oversee ethically and effectively the responsible progress of this area of biotechnology.

This chapter has sought to summarise the existing ethical arguments pertaining to the furthering of SCS in order to alleviate major diseases; the next suggests a regulatory framework which can accommodate the ethical approach proposed, and advances arguments in favour of the adoption of a principles-based approach to the regulation of SCS in Mexico.

[106] See Catholics for Free Choice in Mexico, *supra* note 96. It is noteworthy that the episcopal authority of the Catholic Church in Mexico follows the most restrictive reading of the teaching of the doctrine of the faith, so it is acknowledged that a moral compromise with this faction of the religious tradition in this area will be unacceptable. On the other hand, there are different voices that argue against the implementation of policies based on religious values. See Strong C, 'Why Public Policy on Embryo Research Should not be Based on Religion', *The American Journal of Bioethics* 11 (3) (2011) 33-5.

CHAPTER 4

LEGAL APPROACH: STEM CELL SCIENCE PRINCIPLES-BASED REGULATION

> *Principles-based regulation for emerging technologies… may help address the existing problem that rules-based regulation cannot keep up with the pace of new developments. Particularly if implemented as an interim approach while regulators develop more traditional rule-based approaches, principles-based regulation can serve in a flexible, adaptable, and dynamic gap-filling role.*[1]

4.1. THE QUEST FOR EFFECTIVE REGULATION

As noted in the introductory chapter of this thesis, Mexico has not embraced specific nationwide (i.e. federal) legislation to regulate SCS or any connected activity.[2] In many nations, the failure to develop legislation in this domain is caused, at least in part, by the seemingly insurmountable controversy that surrounds the use, creation and destruction of embryos for the procurement of SCs.[3] Similarly, there are diverse activities unconnected to the embryo controversies that are also in need of legal scrutiny.[4]

Despite the fact that activities involving the use of SCs for financial gain are carried out in the country, e.g. the commercialisation of unsubstantiated

[1] See Carter RB and Marchant GE, 'Principles-Based Regulation and Emerging Technology', in Marchant GE, Allenby BR and Herkert JR (Eds) *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight* (The International Library of Ethics, Law and Technology, Vol 7; Springer Netherlands, 2011) 157-66 at 165.

[2] Some recommendations for the regulation of the use of human tissues and cells in Mexico has been advanced by legal scholars; for example, see Rudomin Zevnovaty P, 'Recomendaciones para el Empleo en México de Células Provenientes de Tejidos Embrionarios Humanos para la Investigación' *(Recommendations for Mexico in Relation to the Use of Cells Procured from Human Tissues for Research)*, in Moctezuma Barragán G (Ed) Derecho y Cultura: El Genoma *(Law and Culture: The Genome)* (Vol 5; Mexico: IIJ-UNAM, 2001-2002) 21-41, *available at:* http://www.juridicas.unam.mx/publica/librev/rev/derycul/cont/5/ref/ref3.pdf acc. 8 June 2012.

[3] In some countries, despite the fact that a growing research on diverse SCS activities has been identified, no comprehensive or explicit legislation governing this field and connected activities of emerging technologies has been enacted so far. See Isasi RM and Knoppers BM, 'Mind the Gap: Policy Approaches to Embryonic Stem Cell and Cloning Research in 50 Countries', *European Journal of Health Law* 13 (2006) 9-25.

[4] See Chapter 7 for a legal scrutiny of diverse SCS activities in need of further analysis and targeted regulation. Also see Isasi RM and Knoppers BM, 'Beyond the Embryo: Transnational, Transdisciplinary and Translational Perspectives on Stem Cell Research', *SCRIPTed: A Journal of Law, Technology & Society* 7 (6) (2010) 529-33, http://www.law.ed.ac.uk/ahrc/script-ed/vol7-2/isasi.asp acc. 8 June 2012; Isasi RM and Knoppers BM, 'Beyond the Permissibility of Embryonic and Stem Cell Research: Substantive Requirements and Procedural Safeguards', *Human Reproduction* 21 (10) (2006) 2474-81.

ASC treatments[5] and conventional cellular therapies,[6] Mexican legislators have failed to enact adequate legislation for these emerging events.[7] However, to say that this area is completely unregulated would be misleading, as federal regulation broadly covering the area of health care and clinical translation of research may be applicable, albeit indirectly, to some activities involving the use of SCs. Thus, the area of SCS is marked by legal uncertainties about the types of SC research and clinical activities that are restricted or permitted.[8]

This chapter presents the regulatory framework and context pertinent to cutting-edge SCS governance in the UK as a paradigmatic example of regulation in this field, in particular that related to principles-based regulation to govern SC research which uses gametes and embryos. It identifies the relevant features and legal context in which this regulation has developed. Although applying the liberal regulatory regime of the UK to the Mexican context is not completely plausible, this thesis advocates the emulation of some of the successful key regulatory qualities of the UK to provide legal certainty and precise parameters for SCS development and progress in Mexico. I will demonstrate why it is prudent for Mexico to embrace a principles-based approach to SCS regulation as adopted in the UK, in order to enhance existing legal mechanisms to regulate this scientific field effectively, by allowing responsible scientific behaviour and biomedical innovation to be encouraged simultaneously.

4.2. EXPERT LICENSING AND GUIDING PRINCIPLES: THE UNITED KINGDOM'S STEM CELL SCIENCE GOVERNANCE

Among the priorities of the UK government for more than two decades has been the effective oversight of SC research and treatment involving embryos in order to advance and promote scientific knowledge and economic growth. This has led to it becoming a worldwide example of good governance in these aspects of SCS. Moreover, it is recognised as having a relatively permissive and liberal regulatory framework for this scientific activity.[9] Nevertheless, SCS and

[5] See Chapter 7 of this thesis for a detailed discussion on the marketing of untested SC therapies in Mexico.
[6] Chapter 7, Section 7.5 provides a general view of established hematopoietic SC therapies available and Table 7.1 also lists cellular therapies offered in healthcare centres across the country.
[7] See Chapter 5.
[8] See Chapter 7.
[9] This approach to regulation is considered one of the more liberal in the SCS field. However, the special licensing scheme and expert committee's authorisation procedures lead us to infer the opposite. Indeed, this legislation authorises the creation and use of embryos for the purpose of research, but under close

clinical applications are extensively controlled, as activities involving therapeutic and research use of embryos and gametes are reviewed, approved and closely monitored by a special government body, the Human Fertilisation and Embryology Authority (HFEA).[10] The following sub-sections outline a brief account of the background of the UK's current regulatory structure for SCS, covering aspects of the regulation of gametes and embryos for research and therapies.[11]

4.2.1. HUMAN FERTILISATION AND EMBRYOLOGY ACT AND AUTHORITY: REGULATION OF GAMETES AND EMBRYOS

In response to the successful birth in the UK of the first 'test tube baby', Louise Brown,[12] the UK parliament commissioned, in 1982, an independent special committee of inquiry into human fertilisation and embryology, which became known as the Warnock Committee.[13] This committee issued the Warnock Report (1984) that contained recommendations to pursue emerging biomedical activities under certain conditions and with rigorous ethical and legal oversight.[14] In 1990, the UK parliament enacted the first legislation regulating the subject, the Human Fertilisation and Embryology Act (HFE Act), which extensively incorporated the Warnock Report's recommendations.[15] The political compromise was to accord a certain degree of respect to embryos

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and rigorous supervision. See Lee RG and Morgan D, *Human Fertilisation and Embryology: Regulating the Reproductive Revolution* (London: Blackstone Press, 2001).

[10] Having a facilitative approach is not an indication of lack of respect for human life. Conversely, what these models seek is to ameliorate health and alleviate human suffering. See Holm S, 'Therapeutic Cloning and the Protection of Embryonic Life: Different Approaches, Different Levels of Protection- a View from the United Kingdom', in Gunning J, Holm S and Kenway I (Eds) *Ethics, Law, and Society* (Vol IV: Ashgate, 2009) 229-36.

[11] Although the initial steps to governing the field of SCS in the UK started out by discussing the regulation of matters concerning *in vitro* fertilisation and embryology, this outline focuses on the issues considered relevant in the regulation of SCS as a whole. For further discussions on the HFEA's role in regulating reproduction, see Horsey K and Biggs H, *Human Fertilisation and Embryology: Reproducing Regulation* (Biomedical Law and Ethics Library; London: Routledge-Cavendish, 2007).

[12] See Deech R and Smajdor A, *From IVF to Immortality: Controversy in the Era of Reproductive Technology* (Oxford: Oxford University Press, 2007) at 7-28.

[13] The committee was presided over by the English moral philosopher Mary Warnock, and composed of medical doctors, ethicists, lawyers and theologians, among other professionals, was instituted to provide advice to legislators on profound bioethical dilemmas concerning the regulation of newly emerging ART activities. See Wilson D, 'Creating the 'Ethics Industry': Mary Warnock, In Vitro Fertilization and the History of Bioethics in Britain', *BioSocieties* 6 (2) (2011) 121.

[14] Warnock M (chair), Committee of Inquiry into Human Fertilisation and Embryology, *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (London: 1984). This report became the cornerstone for subsequent UK parliamentary debates on the issue. See Warnock M, *A Question of Life: The Warnock Report on Human Fertilization and Embryology* (Oxford: Blackwell, 1985).

[15] See The Human Fertilisation and Embryology Act (HFE Act) (1990), *available at:* http://www.legislation.gov.uk/ukpga/1990/37/contents/enacted acc. 8 June 2012.

according to their developmental stage, that is to say a gradualist position which argued for respect for the embryo's special status.[16]

The HFE Act embodies a compromise between research on embryos and establishing a licensing scheme, including a 14-day time limit[17] on experiments on *in vitro* embryos and the fulfilment of certain requirements including written informed consent from couples who donate embryos for research.[18] Further public consultations to review and extend the scope of the 1990 HFE Act sought to accommodate advances in hESC research whilst incorporating societal concerns and scientific developments into the existing regulations.[19] In 2001, the HFE Act was modified,[20] endorsing the licensing scheme to generate embryos (including their creation by SCNT) for research purposes, apart from fertility treatments, which implies the gain of knowledge on embryo development and serious diseases, as well as the therapeutic application of the knowledge obtained from research to the treatment of degenerative and fatal illnesses.[21]

The HFEA[22] is the statutory authority established by virtue of Section 5 of the HFE Act.[23] The Authority is responsible for the ethical evaluation, monitoring and licensing of all fertility and SC research activities involving the

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[16] See Mulkay M, *The Embryo Research Debate: Science and the Politics of Human Reproduction* (Cambridge: Cambridge University Press, 1997).

[17] Research on embryos can only proceed before the appearance of the primitive streak, which is supposed to occur after the 14th day of embryo creation, as covered by section 4 (3) (b) of the HFE Act, *supra* note 15. This timeline also indicates that twinning—that is, individualisation—cannot occur, as afterwards the nervous system starts to develop. See further Warnock M and Braude P, 'Research Using Preimplantation Human Embryos', in Kuhse H and Singer P (Eds) *A Companion to Bioethics,* 2nd Edition (Malden, MA: Wiley, 2009) 487-94.

[18] See Jackson E, *Medical Law: Text, Cases, and Materials*, 2nd Edition (Oxford: Oxford University Press, 2010) at 636-53.

[19] Although the HFE Act initially regulated the complex issues of ART activities, newly emerging forms of embryo creation fell outside its scope, since they were not available at the time of its enactment; for example, embryos created by CNR and its use in diverse methods of reproduction (e.g. human cloning). See Plomer A, 'Beyond the HFE Act 1990: The Regulation of Stem Cell Research in the UK', *Medical Law Review* 10 (2) (2002) 132-64. Also see Brownsword R, 'Stem Cells, Superman, and the Report of the Select Committee', *Modern Law Review* 65 (4) (2002) 568-87.

[20] These revisions were conducted as a consequence of the birth in 1997 of the first cloned adult mammal, Dolly the sheep, which opened the door to the possibility of reproductive cloning, on this see Greene A, 'The World after Dolly: International Regulation of Human Cloning', *George Washington International Law Review* 33 (2001) 341-62. With regard to human cloning, an immediate reaction of the parliament in Britain was to introduce a separate statutory provision to prohibit reproductive cloning explicitly, see the Human Reproductive Cloning Act (2001). Conversely, taking advantage of the troubling circumstance and owing to the vagueness of the definition of the embryo in the 1990 HFE Act, pro-life groups contested this legislation in court, but they failed in the end, as modifications to the Act clarifying these issues were forthcoming. For ethical arguments advancing the legitimacy of reproduction by cloning, which claim their foundation on "procreative autonomy" and fundamental human rights and dignity, see Harris J, '"Goodbye Dolly?" The Ethics of Human Cloning', *Journal of Medical Ethics* 23 (6) (1997) 353-60.

[21] The Human Fertilisation and Embryology (Research Purposes) Regulations 2001 (SI 2001/188). On these regulatory amendments, also see Morgan R, 'A Tight Fit? Deficiencies in the Human Fertilisation and Embryology (Research Purposes) Regulations 2001', *Statute Law Review* 28 (3) (2007) 199-217.

[22] For more details on the statistics and detailed up-to-date data on the functioning, licensing procedures and monitoring of ART and SCS activities in the UK, see The HFEA's website at http://www.hfea.gov.uk/ acc. 8 June 2012.

[23] See HFE Act, *supra* note 15. Also see Lee RG and Morgan D, *Human Fertilisation & Embryology: Regulating the Reproductive Revolution* (London: Blackstone, 2001) at 102-133.

use of human gametes and/or embryos.[24] It is both a centralised governmental agency and an independent regulatory authority.[25] The HFEA is mainly composed of lay members, free from any political affiliation or other private interest.[26] It is charged with enforcing the HFE Act and having legal oversight, approval and licensing of all reproductive technologies and of embryological and SC research activities.[27] It also supervises and monitors the facilities where these therapeutic activities and investigations are conducted.[28]

In 2007, the HFE Act underwent significant revision to reflect the evolution of societal attitudes and to incorporate recent scientific advances.[29] This review aimed to update the legislation's ability to regulate in accordance with the UK's core principles for better regulation, such as proportionality, accountability, consistency, transparency and targeting.[30] These principles were adapted and incorporated into the HFEA's guiding principles within its own Code of Practice[31] to advance and maintain scientific competitiveness and innovation in this emerging technology domain, as well as to ensure compliance and ethical behaviour by regulators and regulatees.[32] The HFE Act (as revised in 2008) and the HFEA continue to delineate the main substantial and procedural rules governing ART and SC research activities involving gametes and embryos in the UK.[33]

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[24] The statutory definition of an embryo can be found in Section 1 (1) (a) of the HFE Act (2008). Also see HFEA, *Guidance to License Applications* at http://www.hfea.gov.uk/5435.html acc. 8 June 2012.

[25] In 2010, owing to the economic pressures and in an attempt to reduce administrative costs, the newly elected UK government, through the Department of Health, issued the report: *Liberating the NHS: Report of the Arm's-Length Bodies Review*. This review declares the intention of closing down the HFEA and HTA, and reallocating their functions to other bodies. Notwithstanding the changes announced by the UK government, the arguments on expert regulation, good practice and the principles-based approach to regulation may still apply equally to any regulatory body in this innovative scientific field.

[26] See Allyse M, 'Embryos, Ethics and Expertise: The Emerging Model of the Research Ethics Regulator', *Science and Public Policy* 37 (8) (2010) 597-609.

[27] For a critique on the role and responsibilities of the HFE Authority before the latest 2008 amendments to the regulatory regime, see Morgan R, 'A Lack of Foresight? Jurisdictional Uncertainties in the Regulatory Interface between the HFEA, the UK Stem Cell Bank and Beyond', *Legal Studies* 27 (3) (2007) 511-35.

[28] See HFE Authority, *Inspections,* at http://www.hfea.gov.uk/6672.html acc. 14 March 2012.

[29] See Fenton R, Heenan S and Rees J, 'Finally Fit for Purpose? The Human Fertilization and Embryology Act 2008', *Journal of Social Welfare and Family Law* 32 (3) (2010) 275-86.

[30] See Better Regulation Task Force, "Regulation – Less is More: Reducing Burdens Improving Outcomes, a BRTF Brief to the Prime Minister – ANNEX B 'The Five Principles of Good Regulation'", (March 2005), at http://www.bis.gov.uk/files/file22967.pdf acc. 8 June 2012.

[31] See HFEA, *Code of Practice,* 8th Edition (London, last reviewed October 2011), *available at* http://www.hfea.gov.uk/docs/8th_Code_of_Practice.pdf acc. 8 June 2012.

[32] See Callus T, 'Ensuring Operational Compliance and Ethical Responsibility in the Regulation of ART: The HFEA, Past, Present, and Future', *Law, Innovation and Technology* 3 (1) (2011) 85-111.

[33] The HFE Act was subjected to further revisions in September 2007. Major public consultations and discussions on new technologies appearing in SCS culminated in the incorporation of new provisions and modifications to the HFE Act (as amended 2008), *available at* http://www.legislation.gov.uk/ukpga/2008/22/pdfs/ukpga_20080022_en.pdf acc. 8 June 2012.

Importantly, the HFE Act encapsulates the principal purposes or criteria to be authorised and licensed when studying embryos.[34] It establishes that the utilisation of embryos for research will be allowed only if no alternative source is available and if it is likely to increase knowledge and facilitate the development of treatments for serious illnesses.[35]The HFE Act (as amended 2008) authorises the storage and use of supernumerary embryos from fertility treatments, which otherwise are destined to be discarded, conditional on the granting of informed consent by couples.[36] It also allows the creation of embryos *in vitro* and by cell nuclear replacement CNR[37] or SCNT for research purposes, including the creation of human admixed embryos solely for research ends, subject to these same criteria.[38]

Under the HFE Act, the legal oversight, licensing and monitoring of SCS activities in the UK are grounded on principles-based regulation.[39] The regulatory authority is required to maintain a set of guiding principles that they and regulated subjects must observe in carrying out activities governed by this legislation.[40] For example, anyone carrying out licensed research on embryos must treat them with due respect.[41] This approach seeks to provide flexibility to regulated subjects while encouraging responsible behaviour and compliance with legal requirements, communal goals and guiding principles.[42]

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[34] See the HFE Act (as amended 2008) Schedule 2 (3A) (1) (2).
[35] See the HFE Act (as amended 2008) Schedule 3.
[36] See Franklin S, 'Embryonic Economies: The Double Reproductive Value of Stem Cells', *BioSocieties,* 1 (1) (2006) 71-90 and 'Embryo Transfer: A View from the United Kingdom', *Women in Biotechnology* (2008) 123-42.
[37] The utilisation of the wording of cell nuclear replacement CNR (mainly referred to as SCNT) was utilised in the Quintavalle case, see *R (on the application of Quintavalle) v Secretary of State for Health* [2003] UKHL 13, also see Morgan D and Ford M, 'Cell Phoney: Human Cloning after Quintavalle', *Journal of Medical Ethics* 30 (6) (2004) 524-26 and Fox M, 'Pre-Persons, Commodities or Cyborgs: The Legal Construction and Representation of the Embryo', *Health Care Analysis* 8 (2) (2000) 171-88. An in-depth analysis of these issues goes beyond the remit of this thesis.
[38] Human admixed or human–animal hybrid embryos are defined in section 4A (6) of the HFE Act (as amended 2008). For an illustration of the analysis of the policy-making process as well as the ethical and legal aspects of the permissibility to create human–animal admixed or hybrid embryos in the UK, see Hammond-Browning N and Holm S, 'Hybrid Embryos - Ethics, Law and Rhetoric in the United Kingdom's Stem Cell Policy', in Capps B and Campbell A (Eds) *Contested Cells: Global Perspectives on the Stem Cell Debate* (London: Imperial College Press, 2010) 377-94. On the scientific, legal and ethical issues that prompted the permissibility of the use and creation of this type of embryo, see Bahadur G et al, 'Admixed Human Embryos and Stem Cells: Legislative, Ethical and Scientific Advances', *Reproductive BioMedicine Online* 17 (Suppl. 1) (2008) 25-32. The controversial ethical issues affecting this embryonic entity, as well as its creation and use for research, are explored further in the philosophical approach presented in Chapter 3.
[39] See Devaney S, 'Regulate to Innovate: Principles-Based Regulation of Stem Cell Research', *Medical Law International* 11 (2011) 53-68.
[40] Ibid.
[41] See The Human Fertilisation and Embryology Authority Code of Practice, 'Principles', *available at:* http://www.hfea.gov.uk/184.html acc. 9 June 2012.
[42] See Carter R B and Marchant G E, *op. cit. supra* note 1, at 157-59.

In sum, the incorporation of specific regulations based on appropriate principles (e.g. proportionality, accountability, consistency and transparency),[43] such as those included in the UK's body of regulation of ART and embryo research activities on the use, storage and transplantation of tissues and cells, as well as on the therapeutic application of SC-based therapies, constitutes a paradigmatic example of good governance from which the Mexican legal system could learn and benefit in its own social and cultural context. Thus, among the guiding principles of a UK regulatory authority, the HFE Authority, are these: avoiding discrimination against prospective patients by treating them fairly;[44] according due respect to the privacy, confidentiality, dignity and comfort of all participants[45] in the conduct of all licensed activities; securing proper respect for the status of the embryo;[46] providing participants with intelligible information and accurate scientific data on all licensed procedures;[47] ensuring due provision of consent before carrying out any activity;[48] and conducting "all licensed activities with proper skill and care and in an appropriate environment, in accordance with good clinical practice, to ensure optimum outcomes and minimum risks for patients".[49] Following this example by adopting guiding principles in the Mexican context, as accorded by the relevant regulatory bodies and stakeholders, would provide scope for determining whether scientific activities were being carried out in accordance with the spirit of the applicable legislation. In addition, if regulators embrace such guiding principles, this will facilitate inspections and adherence to these principles by regulatees (see Figure 4.1).

The compliance and enforcement policies applied by the HFEA seek to promote an effective observance of the legislation and to take the required

[43] The potential benefits of the adoption of a principles-based regulatory approach as applied to financial systems is explained in Black J, 'Making a Success of Principles-Based Regulation', *Law and Financial Markets Review* 1(3) (2007) 191-206. It is pertinent to acknowledge that this regulatory approach was in place in the UK when the recent financial global crisis occurred and that it remains in force. It has been shown that some of the pitfalls can be overcome and that principles and enforcement mechanisms can be improved; see Black J, 'The Rise, Fall and Fate of Principles Based Regulation', *London School of Economics and Political Science, Law Department, LSE Working Papers* 17 (2010) *available at* http://eprints.lse.ac.uk/32892/1/WPS2010-17_Black.pdf acc. 10 June 2012. All in all, this system of regulation has proved to be efficient in regulating cutting-edge biotechnology such as SCS; see Devaney S, *op. cit.* supra note 39.
[44] Ibid, *supra* note 41, 'Regulatory Principles', Principle 1.
[45] Ibid, Principle 2.
[46] Ibid, Principle 3.
[47] Ibid, Principle 5.
[48] Ibid, Principle 6.
[49] Ibid, Principle 7.

actions if infringements are detected.[50] These policies also aim to suggest improvements in the operation of research centres that can be identified during inspection processes.[51] The HFEA's guiding principles are intended to be a guiding set of standards rather than rigid rules, and they are regularly brought up to date. These principles are flexible provisions, rather than dense fixed rules, focused on communal goals and desired outcomes (e.g. ethics-driven research).[52] In this manner, the inherent elements of the state-of-the-art SCS field, such as uncertainty, risk and unanticipated innovations, can be managed rapidly and with more flexibility, in accordance with the spirit and purposes of the legislation.[53]

This approach, thoughtfully applied to the development of regulation in Mexico should secure public trust in SCS therapeutic and research activities, assuring the safety and health of the population whilst providing certainty to scientists and clinicians in their activities and eliminating the fraudulent commercial use of tissues and cells. Any treatment and research related to ART and *in vitro* embryos should be regulated separately and more rigorously than other activities involving human tissues and cells, because of the dangers implicit in non-compliance with good practice in these procedures.[54] Specific national regulation of ART and embryo research would specify the prohibitions and the list of principal purposes that can be licensed for the conduct of research activities. Examples of such purposes are to further knowledge of embryo development; to develop treatments for severe medical conditions; to promote and generate knowledge on infertility treatments, causes of miscarriage and better methods of contraception; and to advance the detection

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[50] See HFEA, *Compliance and Enforcement Policy*, (01 October 2011), *available at* http://www.hfea.gov.uk/docs/2011-10-01_Compliance_and_Enforcement_Policy_(2011).pdf acc. 9 June 2012.

[51] Ibid.

[52] See Black J, 'Regulation as Facilitation: Negotiating the Genetic Revolution', *The Modern Law Review* 61(5) (1998) 621-60 and 'Forms and Paradoxes of Principles-based Regulation', *Capital Markets Law Journal* 3 (4) (2008) 425-57.

[53] Devaney S, *op. cit. supra* note 39.

[54] It is worth noting that UK governance arrangements to regulate separately ART and the use of derived embryonic SCs lines for therapeutic activities have been criticised as engendering potential conflict regarding the seeking of consent for use of aborted foetuses and embryos from SC therapies, among many other issues. On this see Pfeffer N, 'Framing Women, Framing Fetuses: How Britain Regulates Arrangements for the Collection and Use of Aborted Fetuses in Stem Cell Research and Therapies', *BioSocieties* 2 (4) (2007) 429. At some point, the UK government intended to merge the HFEA and the HTA, including some of the functions of the MHRA, into a new body called the Regulatory Authority for Tissue and Embryos, but this proposal was abandoned following criticisms. See UK Parliament, *Human Tissue and Embryos (Draft) Bill, the Joint Committee on Human Tissue and Embryos* (Vol I: Report, 2006-07); also see O'Dowd A, 'Government Backs Down on Merger of Regulators but Gives Go-ahead to Inter-species Embryos', *BMJ* 335 (7623) (2007) 741. I am indebted to David Gurnham for drawing my attention to this relevant point.

of gene abnormalities in embryos before implantation.[55] These purposes should be identified in accordance with the pressing health needs of the Mexican population. Thus, public consultation is integral to the creation and enactment of policy and legislation in this field.

4.2.2. PATHWAYS FOR THE ETHICAL AND LEGAL OVERSIGHT OF HUMAN TISSUES, STEM CELLS AND THERAPIES

It is important to highlight that in 2002, the UK national stem cell bank was set up.[56] All SC lines derived from research projects are compulsorily stored in the bank, as the HFEA will only grant SC research licenses to researchers who agree to deposit each SC line there.[57] This centralised bank serves as a repository of ethically sourced and high-quality SC lines to facilitate the sharing of existing lines to any institution that demonstrates that it has adequate ethical and legal measures in place.[58] In 2005, the UK parliament established a national organisation, the UK Stem Cell Initiative, which aims to be consolidated as a worldwide leader in the hESC research arena, thus furthering the responsible scientific progress of SCS as a whole.[59] These are the actions taken by the British government to facilitate the advancement of the SC field while safeguarding the safety, security and interests of the public.

The regulation of human tissues other than embryos and gametes and SC lines for research and transplantation in the UK is vested in a different regulatory body, the Human Tissue Authority (HTA),[60] which was created by the Human Tissue Act 2004 (HT Act).[61] The HT Act governs the processes of removal, disposal, storage and transplantation of organs, tissues and cells, which is of paramount importance to the clear regulation of the granting of

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[55] Ibid, *supra* note 35 and 36.

[56] See the UK Stem Cell Bank's website at http://www.ukstemcellbank.org.uk/ acc. 8 June, 2012; also see Twine R, "From Warnock to the Stem Cell Bank': Evaluating the UK's Regulatory Measures for Stem Cell Research', *Journal of International Biotechnology Law* 2 (1) (2005) 1-14.

[57] See Stacey G and Hunt CJ, 'The UK Stem Cell Bank: A UK Government-Funded, International Resource Center for Stem Cell Research', *Regenerative medicine* 1 (1) (2005) 139-42; also see Healy L et al, 'The UK Stem Cell Bank: Its Role as a Public Research Resource Centre Providing Access to Well-Characterised Seed Stocks of Human Stem Cell Lines', *Advanced Drug Delivery Reviews* 57 (13) (2005) 1981-88.

[58] See UK Stem Cell Bank, *Code of Practice for the Use of Human Stem Cell Lines* (April 2010), *available at*:http://www.ukstemcellbank.org.uk/pdf/Code_of_Practice_for_the_Use_of_Human_Stem_Cell_Lines_(2010).pdf acc. 8 June 2012. Also see Stacey G, 'Establishment of the UK Stem Cell Bank and its Role in Stem Cell Science', in Bhattacharya N and Stubblefield P (Eds) *Frontiers of Cord Blood Science* (Springer London, 2009) 299-306.

[59] See the UK Stem Cell Initiative at http://www.dh.gov.uk/ab/UKSCI/index.htm acc. 8 June 2012.

[60] See the HTA's website at: http://www.hta.gov.uk/ acc. 8 June 2012.

[61] See 'The Human Tissue Act 2004' (last amended in 2008), *available at*: http://www.legislation.gov.uk/uksi/2008/3067/made acc. 8 June 2012. For a critical appraisal of the amended act, as well as an illustrating analysis of its scope, ethical and legal implications see Brazier M and Cave E (Eds), 'Chapter 17: Organ and Tissue Transplantation', in *Medicine, Patients and the Law,* 5th Edition (London: Penguin, 2011).

appropriate consent that must be sought from living donors and donations of post mortem body parts.[62] It also outlines a consistent legal framework to oversee the inspection, monitoring and approval of the transplantation of organs, tissues and cells for therapeutic and research purposes.[63]

The role of the HTA, which was established in 2005, is the legal oversight and licensing of the removal, storage and transplantation of human biological material, that is, organs, tissues and cells, from both living and deceased individuals,[64] including the use of derived SCs in therapeutic and research activities.[65] Thus, it regulates the utilisation of tissues and body parts for public display, education and training.[66] In 2009, this oversight body endorsed its Code of Practice which guides the practices of those conducting organ tissue transplantation and research.[67] A significant feature of the authorisation and licensing of tissue and cell research activities is that research must acquire ethical approval from a relevant Research Ethics Committee (REC) registered in the National Health Service (NHS).[68] NHS RECs are composed of lay people and experts with healthcare and science backgrounds. Their decisions are ethics-driven and undertaken on a confidential and private basis to avoid

[62] This strong focus on the consent process, although not the only one, was adopted by providers in response to the public outrage at the illegal retention of children's organs, body parts and foetal tissues without consent in the Alder Hey Children's Hospital, Liverpool and the Bristol Royal Infirmary. On this see Brazier M, 'Human Tissue Retention', *The Medico-Legal Journal* 72 (2) (2004) 39-52. For an interesting discussion concerning the ethical aspects of consent connected to these scandals and the regulations adopted, see the criticism of Harris J, 'Law and Regulation of Retained Organs: The Ethical Issues', *Legal Studies* 22 (4) (2002) 527-49 and the response by Brazier M, 'Retained Organs: Ethics and Humanity', *Legal Studies* 22 (4) (2002) 550-69.

[63] See Kent J and Meulen R, 'Public Trust and Public Bodies: The Regulation of the Use of Human Tissue for Research in the United Kingdom Biobanks and Tissue Research', in Lenk C et al, (Eds) *Biobanks and Tissue Research* (Vol. 8: Springer Netherlands, 2011) 17-35.

[64] Theoretical issues concerning the acknowledgment of ownership of human biological material, more specifically by the providers of SC lines and tissues for therapeutic and research purposes, are examined in depth in Devaney S, 'Tissue Providers for Stem Cell Research: The Dispossessed', *Law, Innovation and Technology* 2 (2) (2010) 165-91. I am indebted to Sarah Devaney for drawing my attention to this point, although the analysis of these concerns goes beyond the remit of this thesis.

[65] See Yuko E, McAuley A and Gordijn B, 'Ireland and the United Kingdom's Approaches to Regulation of Research Involving Human Tissue Biobanks and Tissue Research', in Lenk C et al, *op. cit. supra* note 54, 165-83, at 172.

[66] See HTA, 'Code of Practice 7: Public Display', *available at* http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code7publicdisplay.cfm acc. 9 June 2012.

[67] See HTA's Codes of Practice, *available at:* http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm acc. 12 June 2012. For an enlightened analysis of the policy issues and legal mapping of the UK's governance of organ and tissue donation for transplantation and research, see Price D, *Human Tissue in Transplantation and Research: A Model Legal and Ethical Donation Framework* (Cambridge University Press, 2009). For a further discussion of the ethical good practice issues arising out of the procurement and use of embryonic SC derived lines, see Murdoch A et al, 'The Procurement of Cells for the Derivation of Human Embryonic Stem Cell Lines for Therapeutic Use: Recommendations for Good Practice', *Stem Cell Reviews and Reports* (2011) 1-9.

[68] The guidelines and governance of REC at the NHS can be found at http://www.nres.npsa.nhs.uk/, also see *Governance Arrangements for NHS Research Ethics Committees*, *available at* http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4058609.pdf acc. 9 June 2012.

conflicts of interest and to guarantee the transparency, trust and reliability of their appraisals.[69]

The clinical translation of SCS and its derived biological products (before commercialisation or manufacture can be allowed) is so unique that rigorous regulations and compliance mechanisms are in place to govern this specific aspect of the field.[70] The UK has incorporated the European normativity in this matter through the Medicines and Healthcare Products Regulatory Authority (MHRA),[71] which is the competent authority managing the medical applications of tissues and cells (SC-based), ensuring that activities licensed by the HTA are conducted in accordance with the Code of Practice for Tissue Banks providing Tissues of Human Origin for Therapeutic Purposes.[72] The monitoring procedures for the observation of tissue- and cell-based medical applications are drawn from standards internationally recognised as good clinical practice[73] and good manufacturing practices.[74]

Here, it is relevant that somatic SC therapies, gene therapies and tissue-engineered products are considered and regulated as medicines (under the Regulation (EU) 1394/2007, Article 2).[75] In this way, at a domestic level, the MHRA recognises the delivery of advanced SC-based therapies, provided that they meet standards of quality, safety and efficacy.[76] Moreover, the granting of

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[69] For a detailed account of the ethics of good research practices and regulations of research enforced in the UK, see Biggs H, *Healthcare Research Ethics and Law: Regulation, Review and Responsibility* (London: Routledge-Cavendish, 2010).

[70] In the European context, the Regulation on Advanced Therapies (Regulation (EC) 1394/2007), which is enforced by the European Medicines Agency (EMA), governs the use of regenerative medicine and novel therapies arising from advances in SCS. It is worth noting that in the US, the Food and Drug Agency (FDA) regulates these activities by enforcing the Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products. See further Tiedemann G and Sethe S, 'Regulatory Frameworks for Cell and Tissue Based Therapies in Europe and the USA', in Steinhoff G (Ed) *Regenerative Medicine: From Protocol to Patient* (Dordrecht: Springer, 2011) 937-68. For a hard critique of the stringent role of the FDA in regulating autologous SC-based therapies in the US, see Garfield SM, 'FDA Oversight of Autologous Stem Cell Therapies: Legitimate Regulation of Drugs and Devices of Groundless Interference with the Practice of Medicine?' *Journal of Health & Biomedical Law* 7 (2) (2011) 233-72. For more on the regulatory aspects of the clinical translation of SC research, see Chapter 7, sections 7.3 and 7.4.

[71] See the MHRA's website on the regulation of advanced therapy medical products at http://www.mhra.gov.uk/Howweregulate/Advancedtherapymedicinalproducts/index.htm acc. 9 June 2012.

[72] See The Code of Practice for Tissue Banks, *available at* http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4034263.pdf acc. 10 June 2012.

[73] See The MHRA's Good Clinical Practices *at* http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/index.htm acc. 10 June 2012.

[74] See The MHRA's Good Manufacturing Practices, *available at* http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodManufacturingPractice/index.htm acc. 10 June 2012.

[75] Ibid, *supra* note 61.

[76] See The Medicines for Human Use (Clinical Trials) Regulation 2004, Part 2 (2) (c), *available at:* http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf acc. 10 June 2012. Clinical trials of investigational medical products in the UK are governed by The Medicines for Human Use (Clinical Trials) Regulation 2004 which incorporates the provisions established by the Eruopean Clinical Trials

the ethical appraisal of trial protocols and approval of the clinical trials of SC therapies is not under the control of RECs but is under a separate and independent ethics body, in this case, from June 2011 the National Research Ethics Service (NRES)[77] within the UK Department of Health, which is in charge of granting ethical oversight and approval.[78] Responsibility for the governance of research, laboratory processes and clinical trial oversight lies with the statutory bodies of the HFEA, the HTA and the MHRA, which are supported by the ethical evaluation provided by the RECs and NRES.[79]

The previous sub-sections have described how all authorities and regulated subjects are guided by good practice standards under a principles-based approach to regulation. In the following sub-sections, I will attempt to show how some of the essential features of the UK's SC regulatory practices, guiding principles and authoritative expert bodies might be incorporated into the current health regulation system in Mexico. The goal is the adoption of facilitative and flexible policies for the responsible advancement of SC research (meticulously monitored), with the expectation that it will advance future discoveries towards the development of safe and secure SC therapies to alleviate severe diseases. Another aim is to make recommendations on the furthering and achievement of scientific development and on encouraging responsible practices among researchers, physicians and clinical practitioners involved in this emerging field.

4.3. 'REGULATE TO INNOVATE':[80] ENCOURAGING RESPONSIBLE STEM CELL SCIENCE IN MEXICO

While biomedical legal provisions that broadly apply to some SCS activities exist in Mexico, these rules are not comprehensive and not designed to regulate the complex field of SCS.[81] There is an urgent need for a fundamental review of the current regulatory regime for biomedical research to identify potential

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Directive (EC2001/20). See Messenger MP and Tomlins PE, 'Regenerative Medicine: A Snapshot of the Current Regulatory Environment and Standards', *Advanced Materials* 23 (12) (2011) H10-H17 at H13.

[77] Before 1st of June 2011, the ethics body in charge of ethical revision was the Gene Therapy Advisory Committee (GTAC). In December 2008, the GTAC issued a public warning on unproven SC treatments that spread across the globe, *available at* http://www.dh.gov.uk/ab/GTAC/Stemcelltherapy/index.htm acc. 10 June 2012.

[78] For a complete overview of its role in the ethical oversight of clinical SC research and in specific cases of autologous SC transplantations, see Weber S, Wilson-Kovacs D and Hauskeller C, 'The Regulation of Autologous Stem Cells in Heart Repair: Comparing the UK and Germany', in Lenk C et al, *op. cit. supra* note 54, 159-68.

[79] Ibid, notes 59 and 67.

[80] I have borrowed this phrase from Sarah Devaney's proposal on flexible and facilitative governance for SCS and its applications; see Devaney S, *op. cit. supra* note 39.

[81] See Chapter 7, for a further review of the existing biomedical regulation in Mexico.

improvements in terms of scope, application and effective enforcement.[82] The absence of specific legislation for SCS clinical applications (and for this biomedical domain as a whole) may put the lives of patients at risk and may jeopardise the establishment of public trust and responsible scientific progress in the country.[83]

To claim that the liberal model of SC governance, as in the UK, could be straightforwardly transplanted to the Mexican legal system would be reckless, given the dissimilar social and political attitudes towards the embryo and SCS in general—and more importantly, the distinct legal traditions of the common and civil law.[84] Nonetheless, the emulation by existing Mexican institutions of some of the essential components of the UK's licensing scheme and principles would be of benefit to regulators and regulatees, and therefore to the protection of public health, since it would allow the establishment of a consistent system of governance which might lead to the development of well constructed basic and clinical SC research. The UK's regulatory insights, through the lens of good governance, allow me to advance a proposal for effective regulatory processes in the field of complex biotechnologies, where socio-cultural and religious values, scientific goals and the pursuit of commercial profit and political interests are in the balance.[85]

As liberal regulation of embryo research may be difficult for legislators to introduce in Mexico, it is important to review the UK's system of governance in order to identify those of its elements which are relevant to the Mexican context and can be adopted to deal with the growth of uncontrolled clinical applications of SCS. As reviewed in the previous section, the HFE Act, enacted in the UK for ART and SC activities, gives a special status to embryonic life by assuring that all licensed research will contribute to the increase in knowledge related to serious diseases and biological development, and that embryos will be treated with due respect.[86] Analysis of views elicited from key Mexican stakeholders in this debate[87] indicates the possibility (at least on the part of prominent scholars and scientists) of bringing forward liberal arguments in legislative debates that will allow the regulation of research on spare IVF

[82] Ibid.
[83] Ibid.
[84] See Chapter 2 for an overview of the legal tradition in Mexico, as well as the features relevant to understanding the production of legislation, scientific knowledge and biomedical innovation in this context.
[85] See Chapters 5, 6 and 7.
[86] Ibid, *supra* note 41.
[87] See Medina-Arellano MdJ, 'Contested Secularity: Governing Stem Cell Science in Mexico', *Science and Public Policy* 39 (3) (2012) 386-402.

embryos and those created by SCNT (establishing a cut-off point or a timeline, e.g. a 14-day rule).[88] In light of scientific facts as well as ethical and legal considerations, stakeholders perceive that they have a moral duty to provide support to the discovery of possible treatments and cures for the chronically and terminally ill.[89]

The following sub-sections discuss the viability of advancing regulation for some SCS activities, grounded on constitutionally sanctioned rights. They also assess the possibility of incorporating the guiding principles governing the UK's independent regulatory bodies into the existing health institutions, authorities and supervisory agencies in Mexico.

4.3.1. ENABLING REGULATION: CONSTITUTIONALITY OF STEM CELL SCIENCE

In the case of Mexico, there is a relevant connection between the permission to pursue basic and clinical SCS research and human rights framework.[90] The State has the obligation to guarantee constitutionally sanctioned rights to healthcare protection (Article 4, third paragraph) and the pursuit of scientific and technological research, as well as scientific freedom (Article 3, Sections V and VII)[91]—and indeed the related constitutional and fundamental rights to life (Article 1) and to self-determination (Article 2).[92]

The individual's constitutional right to health gives rise to corresponding duties of the state to pursue research into health and to provide safe and effective medical treatments and care through the MoH and all relevant public healthcare and academic institutions.[93] Therefore, the feasibility of achieving

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[88] See Chapter 6, section 6.6.2 on this point.

[89] Ibid. The ethical principles underpinning these arguments are further detailed in Chapter 3, which explains the philosophical approach adopted in this thesis.

[90] See Chapter 2, section 2.3, which gives an overall account of the Mexican constitutional system and the newly compulsory adoption of human rights as binding for all ordinary and federal courts and authorities in Mexico. As regards the connection between bioethical and human rights concerns in this context, see Martínez Bullé Goyri VM, 'Aspectos Bioéticos de los Derechos Humanos', (*Bioethical Aspects of Human Rights)* in Maqueda Abreu C and Martínez Bullé Goyri VM (Coords) *Derechos Humanos: Temas y Problemas (Human Rights: Themes and Problems)* (Mexico: IIJ-UNAM, 2010) 391-411.

[91] See Chapter 2, Sections 2.6 and 2.7 for an examination of the significance of these constitutional rights. Latin American scholars have also proposed permissive regulations for SC research in state legislation founded on the internationally established human right of freedom of research; see Bergel SD, 'Células Madre y Libertad de Investigación', (*Stem Cells and Freedom of Research) Revista Bioética* 17 (1) (2010) 13-28. Bergel also points out that individuals have the right to access to new scientific developments and knowledge, which is a bioethical issue to reflect on; see Bergel S D, 'El Acceso a los Logros de la Ciencia como Tema Bioético', (*The Access to Scientific Developments as a Bioethical Issue) Revista Bioética* 19 (1) (2011) 45-59.

[92] Also see Chapter 6, Section 6.4 on this argument.

[93] As outlined in Chapter 2, section 2.7. For more on the secondary Healthcare Services Provision Regulation, which specifies certain rules for human subjects in research and clinical practices, see *Reglamento en Materia de Prestación de Servicios de Atención Médica* (1986), *available at* http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MPSAM.pdf acc. 10 June 2012. In this area, a Mexican Official Norm (NOM-178-SSA1-1998) delineates the minimal requirements to be fulfilled by healthcare establishments.

legislation in the field, expanding a facilitative framework for health-related scientific innovation, can be framed from constitutional provisions.[94]

SCS holds the promise of eliminating suffering, improving people's health, reducing pain and saving many lives, as the positive realisation of all rights in many circumstances depends on the necessary (but not sufficient) condition of people being alive for them to claim and exercise other fundamental rights.[95] Thus, the states should promulgate regulations that prevent people from physical harm and promote the protection of each individual's health, integrity and safety. By guaranteeing that appropriate legal provisions are in place, the guiding principles and standards are enacted by which innovative treatments involving SCs are ethically reviewed, rigorously assessed, approved and licensed by relevant supervisory bodies.[96]

Despite the lack of nationwide agreement on the issue of the beginning of life, the adoption of adequate measures to regulate the creation and utilisation of *in vitro* created embryos for SCS research should be advanced. According to John Robertson, "If there is a right to create and discard embryos to achieve pregnancy, then *a fortiori* the right to create and destroy embryos to stay alive and reduce pain and disability should also be recognised".[97] The enactment of a comprehensive and specific regulation of both activities (embryonic SC research and ART) will guarantee due respect and special treatment for *in vitro* embryos and adequate protection of the health of individuals undertaking SC therapies, as well as legal certainty for clinicians, physicians and healthcare providers involved in SCS therapeutic and research activities.

Although the possibility of adopting a permissive approach to hESC research can be constitutionally grounded (based on the secularity of the State and due to the fact that embryonic life is not explicitly protected by the Federal Constitution[98]), its legitimacy is still unclear. Broader structural social changes have taken place in Mexico in modern times, as the population has become

[94] The plausibility of regulating the field of SC grounded on constitutional discourses has been advanced with greater clarity and profundity in Robertson JA, 'Embryo Culture and the 'Culture of Life': Constitutional Issues in the Embryonic Stem Cell Debate', *University of Chicago Legal Forum* (2006) 1-38.
[95] For an analysis of the human rights theory approach to the law and ethics of embryonic SC research, as well as medical research, see Plomer A, *The Law and Ethics of Medical Research: International Bioethics and Human Rights* (London: Cavendish, 2005).
[96] In the Inter-American Court of Human Rights, this argument for effective legal mechanisms to guarantee the right to health has been advanced on several occasions; see Keener SR and Vasquez J, 'A Life Worth Living: Enforcement of the Right to Health Through the Right to Life in the Inter-American Court of Human Rights', *Columbia Human Rights Review* 40 (2008-2009) 595-624.
[97] Robertson JA, *op. cit. supra* note 85, at 26.
[98] As explained in Chapter 5, Sections 5.2 and 5.3.1.

more secular; some local authorities have been able to formulate liberal policies which have later been accepted by the population, which has also led religious groups to attempt vigorously to influence politics.[99]

In July 2012, national elections are to be held to renew the members of the federal executive and legislature, so there are likely to be political changes, which may or may not lead to the consolidation of more liberal policies in the country.[100] Under the Mexican federal system, the national executive has no power to regulate this field at a legislative level (although it can enact administrative rules and guiding standards through its executive offices, e.g. the MoH), as the Federal Congress has the unique legislative power granted by the constitution to enact federal legislation.[101] The issue of the adoption of permissive legislation for hESC research and SC therapies may be a matter to be decided by the newly elected government and legislators in 2012. However, it is uncertain whether these actors will finally bridge the existing gap by introducing federal legislation, secondary regulations or administrative rules, either permissive or prohibitive, governing the use of embryos in basic and clinical SCS activities and connected practices.

Based on the secular foundations of the Mexican constitutional system, I suggest that the legitimacy of some SC research activities can be resolved through a political compromise.[102] Furthermore, according to the latest constitutional reform concerning the incorporation of human rights contained in all treaties signed and ratified by the Mexican government,[103] each state is obliged to pursue a progressive implementation and realisation of the human right to healthcare protection, as well as the enjoyment of the benefits of the advances of scientific knowledge.[104] Introducing legislative proposals with a stringent but facilitative approach combined with an expert licensing scheme

[99] See Chapter 5, section 5.3.2 for further details of the influence of Catholic groups in the legislative processes in Mexico. As pointed out by Caulfield, in the international scenario, regulations prohibiting embryo research are found in states where the presence of the Roman Catholic Church is more influential; see Caulfield T, 'The Regulation of Embryonic Stem Cell Research: A Few Observations on the International Scene', *Health Law Journal* (Special Issue) (2003) 87-95.

[100] See Chapter 6.

[101] See Chapter 2, Section 2.4.

[102] See Chapter 3 on the moral and political compromise that can be reached by relevant actors in the SCS debate.

[103] For an account of the human rights instruments available in the Latin American context, which are connected to bioethical issues, see Carmona Tinoco JU, 'Los Instrumentos Regionales en Materia de Derechos Humanos y la Bioética', (*Regional Instruments on Human Rights and Bioethical Matters)* in Brena Sesma I and Teboul G (Eds) *Hacia un Instrumento Regional Interamericano sobre la Bioética. Experiencias y Expectativas (Towards an Inter-American Regional Instrument on Bioethics. Experiences and Expectations)* (Mexico: IIJ-UNAM, 2009) 133-56.

[104] These human rights are established in the Universal Declaration of Human Rights (1948), in the International Covenant on Economic, Social, and Cultural Rights (1966) and other binding international documents signed and ratified by the Mexican Government.

that can ethically assess, review and approve all SC activities is feasible, resulting in the gradual fulfilment of the people's constitutional and human rights. Thus, the development of treatments (meticulously controlled) for many life-threatening and debilitating illnesses can be allowed. The following section proposes ways in which some of the essential features of the UK system can be incorporated into the existing regulatory structures in Mexico.

4.3.2. GOVERNING MECHANISMS: BETTER REGULATION PRINCIPLES AND INDEPENDENT OVERSIGHT BODIES

Governance for emerging biotechnologies, particularly in SCS, needs to be settled as a national legislative priority to ensure scientific quality, people's safety and sustainable growth. The establishment of appropriate institutions and instruments to oversee the creation and utilisation of embryos, derived SC lines and tissues for research and therapeutic applications is fundamental to the consolidation of efficient mechanisms of good governance in the field. By this means, the frivolous interests of the purveyors of fraudulent SC therapies can be thwarted.[105] To a great extent, the GHA and its secondary regulations, the Biomedical Research Regulation and Tissue Regulation, are inadequate,[106] as SCS and its clinical applications are different from all other scientific and therapeutic activities.[107] This distinction requires more specific regulations and their effective enforcement.

All clinical trials in Mexico must be free of charge, according to the current biomedical regulatory provisions.[108] Thus, if the purveyors of experimental SC treatments charge human subjects participating in these trials, they are clearly infringing the law.[109] Patients or research subjects should not be charged as if they were purchasing consumer merchandise. Their participation in experimental medical interventions, whose risks and benefits are uncertain, should be voluntary and free of any charge as provided by the biomedical regulation in force.[110] However, in Mexico, the problem with SC therapeutic and research activities is not only a lack of rules but also poor enforcement, which

[105] See Chapter 7 for a portrayal of the emergent business of untested SC therapies marketed in Mexico.
[106] See Chapter 7, section 7.4 for a further review of the inadequacy of existing biomedical rules dealing with therapies and research on health.
[107] As explored in Chapter 7, to date, there is no specific regulation for the use, storage, transplantation and medical application of many activities involving SCs.
[108] See Chapter 7.
[109] Ibid.
[110] Ibid.

has been negligible to date.[111] The existing rules are inadequate, as when they are enacted, the legislators do not treat the current scientific developments in our society as matters of priority.[112] Thus, legislation is out-dated and its enforcement becomes dysfunctional.[113]

Generating a nationwide regulatory regime for ART and embryo research is urgently necessary in Mexico. At the same time, specific Mexican Official Norms (NOMs) to resolve uncertainty and manage risk in the developmental area of SC clinical applications should be enacted.[114] The MoH has statutory powers to call for public consultation and invite relevant stakeholders to elaborate the required guidelines translated into specific NOMs for the utilisation, storage and transplantation of tissues and cells (including derived SC lines) for therapeutic or research purposes. These NOMs should be based on better regulation principles to establish good practice for medical applications using tissues and cells (see Figure 4.1). By adopting appropriate regulations, the uncertainty and biological risks inherent in the development of novel SC medical interventions can be efficiently addressed. Thus, specific and flexible supervision would facilitate the advancement of this innovative biomedical field while effectively dealing with the risks.[115]

Currently, the use and transplantation of organs, tissues and hematopoietic SCs are supervised by the National Centre for Transplantation (CENATRA) and permitted on a non-profit basis. According to the GHA, the commercial use of tissues and cells is illegal. Despite this rule, many private enterprises throughout the country have profited from the application of autologous SC transplantation, exploiting patients' biological raw material and exponentially harming them physically and financially.[116] In all cases, the therapeutic and research uses of tissues and cells (derived SCs) are unregulated, because there are no guidelines, normative provisions or principles to be followed when carrying out the storage, use or transplantation of this biological material.

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[111] Ibid.
[112] See Chapter 2, Section 2.6.
[113] For a general overview of the provisions on biomedical research in Mexico and Latin America, as well as a critique of the inadequacy and archaic state of the clinical research regulatory framework in Mexico, see Feinholz D, 'Las Investigaciones Biomédicas', (*Biomedical Research)* in Brena Sesma I and Teboul G, *op. cit. supra* note 103, 233-78.
[114] This is further reviewed and explored in Chapter 7.
[115] It is necesarity to embrace effective legal oversight for emerging technologies which engender more risks and uncertainties than clear positive outcomes, see further Graeme L, Harmon SHE and Arzuaga F, 'Foresighting Futures: Law, New Technologies, and the Challenges of Regulating for Uncertianty', *Law, Innovation & Technology* 4 (1) (2012) 1-33.
[116] See Tables 8.1 and 8.2 in Chapter 7.

All of the relevant authorities urgently require the creation of specific guidelines that incorporate the proposed regulatory principles as suggested in this chapter.[117] A special body within CENATRA should be created to license the use, storage and transplantation of tissues and cells, giving assurance that tissue and cell providers grant appropriate consent and that research and therapeutic activities are undertaken in accordance with good clinical practice guidelines.[118] These regulatory bodies should work closely with the oversight body that monitors clinical trials in Mexico,[119] which, through a separate ethics committee body, should ethically appraise trial protocols and then license and effectively monitor them to see that these protocols are conducted in accordance with the principles adopted.

4.4. Concluding Remarks

In Mexico, it is estimated that there are at least 150,000 spare cryopreserved embryos in ART clinics.[120] Although thousands of *in vitro*-created embryos are kept frozen for an undetermined time and without knowing their ultimate fate, these activities remain unregulated.[121] Thus, a great number of desperate patients are willing to undertake any kind of treatment derived from SC which offers a chance to alleviate their suffering, regardless of the high costs and risks, and even the fatal or adverse effects it may have on their medical conditions.[122] In a constitutional system such as that established in Mexico, these sensitive issues should be discussed in a democratic arena. Public dialogue and deliberation may drive legislators to consolidate an appropriate legal framework for these activities, according to societal attitudes. Although officials of the present government are openly opposed to SCS in general,[123] there is a pressing need to create guidelines and standards to be applied by the authorities in order to protect those already undertaking unsubstantiated SC-based therapies and to provide guarantees to scientists and clinicians willing to pursue responsible practices.

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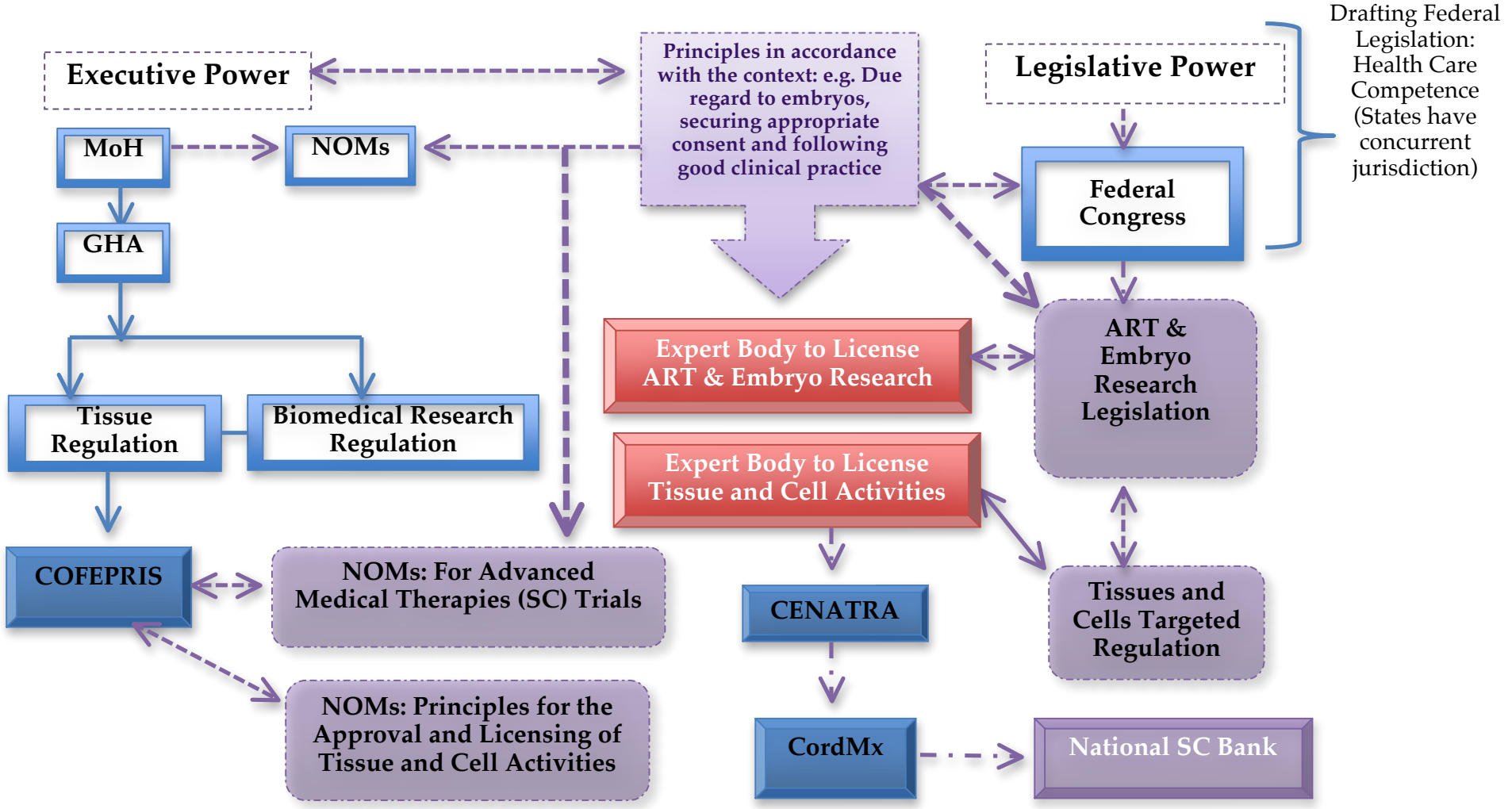
[117] See the previous sub-sections 4.2.1 and 4.2.2 of this chapter.
[118] See International Conference on Harmonization ICH/World Health Organisation WHO, *Guideline for Good Clinical Practice E6 (R1), Harmonised Tripartite Guideline* (10 June 1996) http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf acc. 10 June 2012.
[119] The oversight body for clinical trials in Mexico is the Federal Comission for the Protection against Sanitary Risk (COFEPRIS), this commision is critically examined in Chapter 7.
[120] See Ramos Curi JM, 'Los Defectos de la Fertilización Asistida' *(The Defects of Assisted Fertilisation),* Center for Advanced Social Research (CISAV) (31 January 2012) available online in Spanish at http://cisav.mx/los-defectos-de-la-fertilizacion-asistida/ acc. 11 June 2012.
[121] Ibid.
[122] See Chapter 8 for further details and critical analysis of this point.
[123] See Chapters 5 and Chapter 6.

Performing an in-depth revision of the available legal norms is also required to identify the areas to be enhanced and the improvements to be made in terms of scope and adoption of adequate guiding principles and methods of compliance.[124] The budget of the relevant regulatory agency should be increased to strengthen its financial capacity and provide clear principles to be enforced by the new regulatory bodies, in conjunction with existing authorities (CENATRA and COFEPRIS), which secure the adherence to the guiding principles of SC providers, clinicians and scientists.[125] All the authorities working together will strengthen the work of COFEPRIS, enabling it to assess and allow all therapeutic and research activities.[126] This can only be done if it has the capacity to incorporate well-trained and skilled personnel to perform the inspection and monitoring of all licensed activities.[127]

It is to be hoped that the successful adoption, enforcement and application of principles and legislation governing SCS research and therapy will provide valuable help to tackle the problem of the commercial exploitation by private enterprises and SC charlatans of desperate and vulnerable patients who also provide the biological raw material for the costly, unsafe and ineffective therapies they pay for. A principles-based regulation of this emerging technology in Mexico would effectively address the problems posed by the growth of fraudulent practices involving unsubstantiated SC therapies, as well as the current inadequacies of the existing rules-based regulation, whose scope is insufficient to maintain updated regulations that deal with the rapid pace of progress in the SCS field.

[124] See Devaney S, *supra* note 39.
[125] See Chapter 7, Section 7.6.
[126] Ibid.
[127] Ibid.

Figure 4.1. Proposal for Regulation of SCS and Derived Therapeutic Activities in Mexico



Proposals: Regulation and Organisation; Expert bodies for licensing; Current Authorities.

PART II: THE SUBMITTED ARTICLES

This thesis consists essentially of three original articles and four introductory chapters. The first introductory chapter presented the problem addressed in this thesis, as well as explains the methodology, research questions and the methods followed in producing this doctoral thesis. The other three introductory chapters, which precede this section, offered an account of the ethical and legal background to the issues tackled and of the philosophical and regulatory approaches embraced in addressing the problem. Chapters 5, 6 and 7, which follow, reproduce adaptations of the three original publications, abstracts of which are presented in this section. The thesis closes with Chapter 8, which outlines the results of this investigation and draws overall conclusions.

PAPER 1: STEM CELL REGULATION IN MEXICO: CURRENT DEBATES AND FUTURE CHALLENGES

Abstract. *The closely related debates concerning abortion, the protection of the embryo and stem cell science have been features of the legislative agenda in Mexico in recent years. This paper examines some contemporary debates related to stem cell science and the legal and political action that has followed in the wake of the latest Mexican Supreme Court judgment on abortion, which debates are directly linked to the degree of protection of the embryo stipulated in the Mexican Constitution. While some Mexican states have opted to take no further action, others, where conservative political forces are in the majority, have been very active in seeking to ensure that their constitutions are amended to protect human life from conception onwards. This intense legislative activity has not, however, been repeated at the federal level, where there is currently no overarching national regulatory framework governing stem cell research. Although major efforts have been made by the conservative bloc within the Senate to bring forward legislative proposals for the prohibition of human embryonic stem cell research, and despite the public expression by the federal government of its commitment to encourage inward investment and innovation in the area of biotechnology, stem cell science has so far remained unregulated. The legislative challenge is to resist such pressure from religious leaders and to act in accordance with the values and principles adopted by the community in the Mexican Constitution. In the final analysis, Mexico faces particular difficulties in accommodating conservative political forces on one hand, while recognising on the other its need, as an emerging economy, to promote a progressive approach to innovation in biotechnology.*

PAPER 2: CONTESTED SECULARITY: GOVERNING STEM CELL SCIENCE IN MEXICO

Abstract. *This paper explores the factors both influencing and hampering the consolidation of a legal framework for stem cell science in Mexico. Based on interview data from seven key stakeholders who have the potential to influence future policy or legislation concerning emerging technologies in the country, it identifies pivotal topics that are presently shaping the political, regulatory, religious and bioethical debates on the issue. It is acknowledged that there is a manifest need for a broader and lengthier public discussion of the ethical and legal concerns involved in stem cell science. However, given the enduring conflict between scientifically-minded, religious and political stakeholders, it remains uncertain whether such clarity and robust debate will be forthcoming, making it unlikely that a national regulatory framework for stem cell research will be adopted in the short to medium term.*

PAPER 3: THE RISE OF STEM CELL THERAPIES IN MEXICO: INADEQUATE REGULATION OR UNSUCCESSFUL OVERSIGHT?

Abstract. *The rapid pace of progress made in stem cell science poses significant challenges, particularly in countries where such novel biomedical activity is ethically controversial. Mexico has emerged as one of the favoured places for medical tourists to obtain unsubstantiated stem cell therapies, which are commonly untested and hazardous, yet easily available. This paper explores the regulatory landscape under which these therapies have emerged, which has led to a flourishing stem cell tourism phenomenon in the country. It also illustrates that even though there are relevant regulatory provisions and a governmental agency to oversee biomedical research, so far the ineffective enforcement of these legal mechanisms has allowed the spread of unauthorised stem cell therapies, which lack adequate evidence of quality, safety and efficacy. Three stem cell treatment providers are scrutinised as case studies in order to illustrate the main ethical and regulatory challenges represented by their operation. It is suggested that the ineffective enforcement of available legal provisions broadly applicable to stem cell therapies may jeopardise the establishment of public trust in this emerging field. It is crucial to strengthen the regulatory regime and agencies to effectively oversee the clinical application of stem cell science in order to protect those pursuing untested therapies.*

In what follows, the three articles are adapted from the form they were published, submitted or accepted for publication; there are some significant typographical changes in punctuation and grammar, as well as in the reference system and minor modifications in the structure and content of the papers.

CHAPTER 5

PAPER 1: STEM CELL REGULATION IN MEXICO: CURRENT DEBATES AND FUTURE CHALLENGES[1]

To be against science is as much antiscientific as to be uncritically pro science.[2]

5.1. INTRODUCTION

The successful isolation of hESC from human blastocysts announced by the research teams of Thompson[3] and Gearhart[4] in 1998 dramatically revolutionised the field of biomedical science. The discovery of hESCs as a potential resource for treating chronic diseases caused great excitement among the scientific community, the general public and the press.[5] A number of hypothetical benefits have emerged from the potential use of hESC to treat a variety of health disorders and regenerate tissues and cells.[6] However, scientists have stressed that the development of treatments and their translation to clinical use is still a long way off.[7] In subsequent years, this research has impacted not only on biotechnology, but also on the fields of social science and the humanities, given the legal, ethical and philosophical implications of this activity *per se*.[8] Meanwhile, others are concerned about the creation and use of embryos for hESC research, and this has been an intensely debated issue in bioethical and medical law discussions for more than a decade.[9]

In Latin American nations such as Mexico, Argentina and Brazil, the discussion regarding the regulation of SCS is also interlinked to debates on many other activities, such as abortion and ART, whose acceptability depends on what the moral status of the embryo is deemed to be.[10] In this context, these

[1] Adapted from Medina-Arellano MdJ, 'Stem Cell Regulation in Mexico: Current Debates and Future Challenges', *Studies in Ethics, Law and Technology* 5 (1) (2011) Article 2.
[2] Santosuosso A et al, 'What Constitutional Protection for Freedom of Scientific Research?' *Journal of Medical Ethics* 33 (6) (2007) 342-4.
[3] See Thompson JA et al, 'Embryonic Stem Cell Lines Derived from Human Blastocysts', *Science* 282 (1998) 1145-7.
[4] See Gearhart J, 'New Potential For Human Embryonic Cells', *Science* 282 (1998) 1161-2.
[5] See McKay R, 'Stem Cells - Hype and Hope', *Nature* 406 (406) (2000) 361-4.
[6] See Shi Y and Clegg DO, *Stem Cell Research and Therapeutics* (Vol 1: Advances in Biomedical Research; Springer, 2008).
[7] See, for example, Majlinda L, Alan T and Susan D, 'Law, Ethics, Religion, and Clinical Translation in the 21st Century - A Discussion with Pete Coffey', *Stem Cells* 28 (4) (2010) 636-8.
[8] See Chapter 3 on these discussions.
[9] Ibid.
[10] This interlinking feature is shared by developing countries in Latin America, where discussions about abortion, ART and hESC research are conducted in parallel. On this, see further Diniz D and Avelino D,

discussions are sometimes conducted in terms of 'When does life begin?' or, more specifically, 'When does life begin to matter morally?' At other times, the moral and legal status of the embryo is discussed in terms of the applicability of the human rights of embryos.[11] In Mexico, the debate is often about whether the concept of human dignity applies to the subjects of research, for example, embryos and the women who are the donors of eggs for SC research.[12] In this context, the main dilemmas are the questions of the moral and legal status of the embryo.[13] The political discussions to regulate this emerging activity are complex and featured by the battles of antagonists' groups: pro-life and pro-science assemblies.

Notwithstanding the injection of significant federal government funding for some areas of biomedicine (e.g. genomic medicine) in the country, no legal framework in relation to SCS has yet been established. By discussing the interlinking of the abortion and SCS debates, which are closely intertwined in Mexico, it is shown that any regulation adopted will still depend upon the position taken regarding the protection of life.[14] Given the synergistic nature of the relations between hESC research, abortion and ART disputes, the legal position that Mexico adopts in relation to abortion and embryo research, through its relevant institutions, will be crucial in determining the viability of the development of a legal platform for SCS activities. Nevertheless, this field of research and its clinical applications continue to pose countless ethical and legal problems that are not related to embryo research, for example, SC tourism.[15]

For almost a decade, the academic community in Mexico has publicly argued for the adoption of a systematic and comprehensive set of ethical and

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'International Perspective on Embryonic Stem Cell Research' (English Abstract), *Revista de Saúde Pública* 43 (2009) 541-7.

[11] See Habermas J, *The Future of Human Nature,* 2nd Edition (Cambridge: Polity Press, 2003).

[12] See Chapter 3 on these points.

[13] Isasi RM, Knoppers BM, Singer P and Daar AS, 'Legal and Ethical Approaches to Stem Cell and Cloning Research: A Comparative Analysis of Policies in Latin America, Asia, and Africa', *The Journal of Law, Medicine & Ethics* 32 (4) (2004) 626-40.

[14] In Latin America, constitutional courts play a determinant role in interpreting constitutional provisions, and therefore legitimising interests and rights. For example, in the case of Brazil, hESC research was allowed through a Supreme Court of Justice ruling; on this see Cesarino L and Luna N, 'The Embryo Research Debate in Brazil: From the National Congress to the Federal Supreme Court', *Social Studies of Science* XX (X) (2011) 1-24.

[15] In Mexico, there is a growing market of unsubstantiatied SC therapies which are being commercialised within the context of SC tourism. SC tourism is identified as a subcategory of so-called health or medical tourism, defined as activities involving patients in travelling from one country to another to seek SC therapies. Mexico, among other Latin American countries, has been identified as a target destination for patients/consumers who seek reproductive and regenerative medical services. On this see Smith E, Behrmann J and Williams-Jones B, 'Reproductive Tourism in Argentina: Clinic Accreditation and its Implications for Consumers, Health Professionals and Policy Makers', *Developing World Bioethics* 10 (2) (2010) 59-69. Also see Chapter 7 for a scrutiny of the problems arising from this emergent phenomenon of medical migration, particularly SC tourism.

legal norms for basic and applied SCS.[16] The challenges that legislators face are not simple. In establishing a set of norms for SCS, they need to accommodate the informed views of the wider community. Clerical leaders have strongly influenced the current debates by lobbying the federal legislature.[17] On the one hand, Mexican Senators who are members of the conservative political party formulated, at the federal level, legislative initiatives seeking to protect life from the moment of conception and to ban human reproductive cloning, with the addition of restrictive provisions for certain areas of SCS.[18] To counteract this interference of clerical lobbying, certain legislative actions have been taken by some political leaders with more liberal views on the issue, in order to reject the incorporation of religious beliefs into the law-making process. Legislators, whose aim it is to achieve purposive legislation free of any particular religious orientation, thus face pressure applied by members of the Catholic church.

Against this background, the aim of this chapter is to analyse the legal, political and religious difficulties in regulating SCS in a secular country such as Mexico. It is first sketched out the constitutional norms which provide the basis for the Mexican secular state. Then, in order to analyse the conflicting issues surrounding SCS regulation, it explores the initial steps taken by some members of the scientific community and politicians to discuss SCS, and the preliminary legislative proposals initiated as a result.[19] Subsequently, it examines seminal rulings by the Mexican Supreme Court on abortion issues which are related to the constitutional protection of life. In light of the important role of the Mexican Supreme Court in deciding on legal parameters when there is political inertia or an absence of political agreement, it will be assessed whether these rulings might help to stimulate a broader discussion of

[16] See Brena Sesma I, 'Hacia una Regulación Jurídica en México sobre la Investigación en Células Troncales' *(Towards Stem Cell Research Regulation in Mexico)*, in Brena Sesma I (Ed) *Células Troncales. Aspectos Científicos-Filosóficos y Jurídicos (Stem Cells. Scientific-Philosophical and Legal Aspects)* (Mexico: IIJ-UNAM, 2005) 181-194.

[17] In this local context, this intercession in the SCS debate by leaders of the Catholic Church is also noted by Blancarte R, '¿Qué Significa hoy la Laicidad?' *(What Does Secularity Mean Nowadays?) Este País* 228 (April) (2010) 30-3 at 33.

[18] Here, it is important to note that the concept of conception emerged from within the doctrine of the Catholic Church, as discussed in Chapter 3 of this thesis; thus, in the political and public debate regarding abortion and embryo research in Mexico, this concept has been used and understood within that context.

[19] In 2006, the Commission of Science and Technology within the Chamber of Deputies, in conjunction with the Consultative Body on Science and Technology (FCCyT), organised a workshop that brought together members of the legislature, scientific community and medical lawyers to analyse and discuss issues concerning the regulation of human cloning and SCS. As a result of this enlightened seminar, a final report was issued, without any major legislative action. See Foro Consultivo Científico y Tecnológico FCCyT (Ed) *Seminario de Clonación y Células Troncales: Memorias (Seminar of Cloning and Stem Cells: Memoirs)* (Mexico: FCCyT, 2006). Arguments in favour of SCS in Mexico are based on its therapeutic potential in regenerative medicine. See, for example: Lisker R, 'Ethical and Legal Issues in Therapeutic Cloning and the Study of Stem Cells', *Archives of Medical Research* 34 (6) (2003) 607-11.

the regulation of SCS in Mexico, or whether they will serve only as valuable examples for future discussions in this scientific sphere. In the final section, it is argued that the lack of a regulatory framework reflects the complexity of the conflicting political interests and understandings concerning the status of the embryo and the legitimacy of biotechnology research into aspects of SCS.

5.2. A SECULAR CONSTITUTIONAL STATE

The Mexican state was separated from the Catholic Church more than a hundred years ago, when it was declared that religious values should be put aside when deciding secular state and legal matters.[20] All of the constitutionally sanctioned rights detailed below confirm the secular character of the Mexican state. As it is argued for in Chapter 4, any regulation to be adopted shall follow the secular principles established in the Federal Constitution,[21] in accordance with the following constitutional provisions. Article 3, Sections I and II stipulates that:

> I. The education provided by the State shall be ***secular and, therefore, shall be maintained entirely apart from any religious doctrine***, in accordance with the right of freedom of beliefs set forth under Article 24 herein;
>
> II. The guiding principles for education provided by the State ***shall be grounded on the results of scientific progress***; such education shall also strive against ignorance and its effects, servitude, fanaticism and prejudices…;

Article 24:

> Every person is ***free to practice the religious beliefs*** of his choice…;

Article 40:

> It is the will of the Mexican people to constitute a representative, democratic and federal Republic composed by States, free and sovereign in all matters concerning their

[20] Mexico fought major wars in order to achieve independence and the separation of church and state. In brief, during the Presidency of Benito Juárez García were incorporated the so-called '*leyes de reforma'* by which freedom of worship and the designation of Mexico as a secular state were established. However, it was not until the new Constitution of 1917 (still in force) that the separation of church and state and the expansion of anti-clerical laws were first established. This led to a civil war commonly known as the 'Cristero religious war' led by Catholics and clerics fighting in the name of Christ against secularism in Mexico. Two years later, they were defeated by the Mexican government of the time. For an in-depth exploration of this topic, see Mabry DJ, 'Mexican Anticlerics, Bishops, Cristeros, and the Devout During the 1920s: A Scholarly Debate', *Journal of Church and State* 20 (1) (1978) 81-92; also see Chapter 2, Section 2.2 for an analysis of the secular foundation of Mexico.

[21] It is worth noting that Mexico operates under a federal legal system. Each member state has its own local constitution, but the Federal Constitution plays a major role. It overrides all of the lower sources of law at all times, and these should always be in accordance with its provisions. See Chapter 2, Section 2.3.

> internal affairs; but united in a federation established ***according to the principles (secularity)*** of this fundamental law; and

Article 130:

> The historic ***principle of separation between State and Church is a directive*** underlying the provisions set forth in this Article.[22]

In regulating SCS the diverse views prevailing must be included, heard and discussed in public deliberations, as was demonstrated by the public hearings held by the Mexican Supreme Court when ruling on abortion (this point is further addressed below), while resisting the pressure of lobbying, applied mainly by religious leaders. The Roman Catholic Church has a resilient presence in most Latin American regions, and its utmost conservative sector has tried to determine the underlying morality to be reflected in the law regarding SCS, although without much success.[23] Accordingly, when talking about the liberalisation of abortion or the permissibility of hESC research, the protection of the embryo remains a fundamental feature of societies that are presupposed to be subject to strong pressure from the more conservative contingent of the Catholic Church.[24]

Among plural societies, diversity of views is tolerable and also desirable in order to achieve a democracy. What is expected in a plural society with a secular form of government is that the regulations that are to be brought into force must be isolated as much as possible from any particular religious influence. Nevertheless, what is not acceptable is that any particular religious doctrine (e.g. Catholicism) be reflected in the law, thereby undermining the constitutional foundations of a secular nation.

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[22] Emphasis added. Articles 24 and 130 of the Federal Constitution bring forth a secondary regulation, the Religious Associations and Public Worship Act (1992), by which the designation of Mexico as a secular country is ratified and endorsed. See further Vázquez R, 'Laicidad y Razón Pública' *(Secularity and Public Reason)*, *Este País* 228 (April) (2010) 40-7.

[23] The presence and predominance of the Roman Catholic Church in some Latin American developing nations does not imply that there is homogeneity among the views and beliefs held by the members of this religion. Nevertheless, Catholicism is the predominant religion in Mexico and opposition to abortion and embryo research is dominated by the more conservative teachings of this faith. In homologous contexts, such as that of Argentina, these important features and nuances of the conservative Catholic intervention are meticulously explored by Luna F and Salles A, 'On Moral Incoherence and Hidden Battles: Stem Cell Research in Argentina', *Developing World Bioethics* 10 (3) (2010) 120-8.

[24] See Prainsack B and Gmeiner R, 'Clean Soil and Common Ground: The Biopolitics of Human Embryonic Stem Cell Research in Austria', *Science as Culture* 17 (4) (2008) 377-95.

5.3. POLITICAL AND LEGAL STRUGGLES: PLACING ISSUES IN CONTEXT

Abortion politics and the associated debate in Mexico are just the beginning of the long process of regulating SCS and are a facet of the divergence between religious and social values. The moral position regarding abortion is one of the issues to take into account before moving forward in SCS regulation.[25] Thus, regulation of hESC research constitutes an enormous legislative challenge, since the core of the controversy, lies in whether life from the outset is something that deserves the protection of the legal system and in what degree of protection should be accorded to the embryo. These controversial aspects of SCS have been disputed and are points of tension and conflict among politicians and religious leaders, with significant impact on the legislative actions of federal and local congresses with reference to the beginning and end of life.

The influence of the more conservative Catholic leaders on the political and legal agenda has been noticeable for more than a decade, during which members of the PAN political party have headed the federal government.[26] In contrast, the municipal legislature of Mexico City is composed mainly of members of the PRD[27] who have rejected any attempt to incorporate religious beliefs into the law-making process.[28] To date, in Mexico there is no legal framework with respect to SCS or any other activity involving the use of human embryos, such as ART practices.[29] Although the legislative debate about regulating SCS in the country was initiated in 2003 by PAN-members of

[25] See Holm S, 'Going to the Roots of the Stem Cell Controversy', *Bioethics* 16 (2002) 493-507.

[26] To set the political scene, it is relevant to point out that the federal government is currently headed by the PAN, which is considered to have a more conservative ideology, at least regarding the beginning and end of life. The PAN has historic links to the Catholic Church, which can be inferred from its extensive literature and its professed doctrine, defending life from the moment of conception in the terms of the catholic doctrine. For a more detailed exploration of the political and religious changes in Mexico since the coming to power at the federal level of the PAN, with its links to the Catholic Church, see further: Ard MJ, 'The Great Party Struggle and the Catholic Response to Revolution', in *An Eternal Struggle: How the National Action Party Transformed Mexican Politics* (Westport, Conn.: Praeger, 2003) 21-56. See also Chapter 2, Section 2.4 and Chapter 6, Section 6.5.1 for further exploration of the role that political parties have played in SCS discussions.

[27] This political party in Mexico is considered to hold a liberal ideology regarding the beginning and end of life. The fact that PRD enjoys a majority within the local Mexico City legislature allows the implementation of its own legal agenda, which is considered to be the most progressive and liberal in the country. This local legislature is characterised by its more liberal or progressive agenda, legalising abortion on demand in 2007 and same sex marriage in 2006, implementing the regulation of advance directives in 2008 and more recently, in December 2009, granting couples of the same sex the right to adopt a child. See also Chapter 2, Section 2.4 and Chapter 6, Section 6.5.1.

[28] See De la Dehesa R, 'Part III. Pathways, Chapter Five 'Life at the Margins: Coalition Building and Sexual Diversity in the Mexican Legislature', in *Queering the Public Sphere in Mexico and Brazil: Sexual Rights Movements in Emerging Democracies* (London: Duke University Press, 2010) 146-77.

[29] Here, I shall not discuss the issue of ART in Mexico, which is currently practiced by private and public clinics. Albeit they involve the use and destruction of human embryos for the sake of assisted reproduction, a legal lacuna is also visible in this area. Therefore, a special analysis of this current state of affairs requires a connected but separate discussion in future work.

the lower house in the Federal Congress, they failed to agree on a legal framework,[30] mainly because the religious values of the Catholic Church and its position on the status of the embryo which have been introduced into the debate; these points are explored further on.[31]

5.3.1. HUMAN DIGNITY IN THE MEXICAN CONSTITUTION

In 1917, the principle of human dignity was established in the Federal Constitution, making it one of the first constitutions to adopt this principle.[32] Article 1 of the Federal Constitution establishes the following:

> …Discrimination based on ethnic or national origin, as well as discrimination based on gender, age, disability or any kind of social status, health condition… or any other reason which attacks human dignity and which is intended to deny or restrict the individual's privileges and immunities shall be prohibited.

Nonetheless, while the concept is invoked in the Federal Constitution, it contains neither an agreed interpretation nor an explicit definition of the principle of human dignity.[33] However, in Mexico, conservative political leaders endorse the protection of early embryos based on the argument that they are bearers of human dignity.[34] Various religious and secular interpretations can be made, so that dignity can be seen to be linked to humans as rational beings, as sentient beings, as created beings or as beings with genetic constitutions typical of the members of the human species. Consequently, it is by no means clear that a straightforward assertion can be made from a literal reading of the Federal Constitution that human dignity is extended to, or possessed by, embryos.[35] What is clear is that respect for

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[30] See Brena Sesma I, 'Panorama sobre la Legislación en Materia de Genoma Humano en México' (*Panorama of the Legislation on the Human Genome in Mexico*), in Saada A and Valadés D (Eds) Panorama sobre la Legislación en Materia de Genoma Humano en América Latina y el Caribe (*Panorama of the Legislation on the Human Genome in Latin America and the Caribbean*) (Mexico: IIJ-UNAM/Red Latinoamericana y del Caribe de Bioética RedBioética-UNESCO, 2006) 289-342.

[31] See Chapter 3, Section 3.4 on the Catholic stances on SCS.

[32] See Häyry M, 'Another Look at Dignity', *Cambridge Quarterly of Healthcare Ethics* 13 (01) (2004) 7-14 at 7. The question of the role that human dignity plays in the Mexican legal system is a matter for another investigation; however, general observations are made on the use of this notion in emerging SCS legal and political debates in Mexico.

[33] The principle of human dignity is contained within the dogmatic section of the constitution, which sanctions fundamental human rights, yet it has been pointed out that the legal scope of this notion in the Mexican legal system is still in the process of formulation. See Valadés D, 'Eutanasia. Régimen Jurídico de la Autonomía Vital' *(Euthanasia. Legal Regime of the Vital Autonomy)*, in Carpizo J and Valadés D (Eds) *Derechos Humanos, Aborto y Eutanasia (Human Rights, Abortion and Euthanasia)* (Mexico: IIJ-UNAM, 2009) at 129-122.

[34] See further Chapter 3, Section 3.4 and Chapter 6, Section 6.6.1.

[35] See Medina-Arellano MdJ, 'Commentary: The Need for Balancing the Reproductive Rights of Women and the Unborn in the Mexican Courtroom', *Medical Law Review* 18 (3) (2010) 427-33.

human dignity is guaranteed to Mexican citizens as one of their fundamental rights established under the Federal Constitution.

5.3.2. LEGISLATION AND THE INFLUENCE OF THE ROMAN CATHOLIC DOCTRINE

In 2003, legislators in the lower chamber began an intensive campaign to discuss SCS and many others linked to it, such as the human genome, genomic medicine and SC research.[36] As stated earlier, the first attempt to discuss and regulate SCS in Mexico also occurred in 2003, when a legislative initiative to amend the GHA to prohibit human cloning and hESC research was put before the Chamber of Deputies by PAN-members legislators.[37]

To that end, the Chamber of Deputies took the initiative of inviting the Consultative Body on Science and Technology (FCCyT) to jointly organise a seminar where experts debated and expressed their scientific and ethical views regarding these scientific activities.[38] This seminar cannot be said to have borne legal fruit, given the failure of legislators to adopt a comprehensive legal framework to regulate reproductive cloning, hESC research and SCS as a whole. The one valuable outcome of the seminar was the publication of a final report, which conveyed to legislators the scientific side of SC research.[39] Although this was the first step in an attempt to regulate SCS in Mexico, it was not until the latest rulings by the Mexican Supreme Court in relation to abortion that local legislatures and political leaders decided to undertake legislative action to protect embryonic life from conception; these rulings are analysed later on in this chapter.

In spite of the great efforts of conservative forces to transplant religious values into the law, the legislative battle appears to have just begun. In the lower Chamber of Deputies, members of the PRD put forward a legislative proposal to reform the Federal Constitution in order to block any constitutional and legal changes based on religious values.[40] This reform embodies the amendment of Article 40 of the Federal Constitution to endorse unequivocally in the constitution the status of Mexico as a secular state, adding that by no

[36] Brena Sesma I, *op. cit. supra* note 16 at 313-14.
[37] Ibid.
[38] Foro Consultivo Científico y Tecnológico, *op. cit. supra* note 19.
[39] Ibid.
[40] It can be consulted in Spanish at http://www.diputados.gob.mx/cedia/sia/dir/DIR-ISS-05-10.pdf acc. 18 June 2012. I am indebted to Vivette Garcia Deisder, who drew my attention to this constitutional reform.

means shall any norms reflect religious interests or values.[41] This legislative proposal was then passed to the upper chamber, the Senate, where it was approved in March 2012;[42] it now goes before the local legislatures, requiring a vote in favour of it, from 17 state legislatures, to be finally passed.[43]

This legislative action is an attempt by liberal PRD-members of the Federal Congress to make explicit in the Federal Constitution the notion of 'secularity' as a form of government.[44] It also seeks to reinforce the 'separation of church and state', in other words, the separation of religious interests from the law in a plural democracy, in reaction to the recent lobbying by the Catholic Church among other political actors, thus making clear the necessity to establish the *de facto* separation of religion from state affairs.

Due to the constant and forceful actions against abortion on the part of pro-life and Catholic-religious groups, the brief history of attempts to regulate the SCS field has been marked by defeats and partial victories amongst congressmen, judges and the vast majority of civil society.[45] The result is that these attempts to legislate in this area have thus far been frustrated and legislation has never been approved. Before examining the seminal rulings and proposals dealing with the protection of the embryo and their political repercussions across the nation, it is appropriate to describe some of the relevant legal provisions regarding biotechnology applied to medicine in the country, as well as to examine the investment recently made by governmental and private investors in certain areas of biomedicine.[46]

5.4. Overview of the Regulation of Certain Areas of Biotechnology

To offer a current and up-to-date overview of biotechnology research in Mexico and its regulation is not an easy task.[47] Indeed, it seems more complicated if one considers biotechnology investment in aspects of SCS, which is at its initial stage of development in this country. It is at this stage that investment in this field will face political, cultural and potentially constitutional questions as to whether life should be protected from the outset, and whether embryo research

[41] For a closer examination of the motives that prompted this constitutional reform, see García Ramírez S, 'Estado Laico, Libertad y Democracia' *(Secular State, Liberty and Democracy)*, *Este País* 228 (April) (2010) 23-8.
[42] See Notimex, 'Aprueba Senado Reforma al 40 Constitucional: Se Consolida Estado Laico' *(Senate Approves the Reform of Article 40 Constitutional: The Secular State is Strengthened)*, *La Crónica de Hoy* (28 March 2012) *at* http://www.cronica.com.mx/nota.php?id_nota=649188 acc. 18 June 2012.
[43] Ibid.
[44] Ibid.
[45] Brena Sesma I, *op. cit. supra* note 16.
[46] Also see Chapter 2, Section 2.6 and 2.7 for an examination of policies on science and health in Mexico.
[47] Ibid.

in general and SCS in particular should proceed. With regard to a legal definition of an embryo and its protection, the Federal Constitution is silent. The document makes no reference to it, yet its secondary legislation establishes a definition as to what is to be understood by the term 'embryo'.[48]

It is relevant that the promotion of science, biotechnology and innovation are exclusively regulated by federal legislation, while local states have concurrent jurisdiction in this matter.[49] As initially stated, the GHA provides general rules for the regulation of health and certain aspects of biotechnology applied to medicine.[50] It sets forth secondary regulations, such as the Biomedical Research Regulation (1987) and Regulation on the Sanitary Disposal of Human Organs, Tissues and Cadavers (1985). The latter offers a description of what is to be understood by organs, cells and tissues.[51] Although these definitions are relevant to the SCS debate, this regulation fails to provide specific guidance or rules to be followed by researchers in the clinical utilisation and application of SC research.[52] The Biomedical Regulation makes brief reference to the issue of ART practices, which is also not widely regulated, and simply establishes that research is permissible only when there is no other means to solve infertility problems and when this activity is performed in line with the moral, cultural and social perceptions of the couples who are seeking for these treatments.[53]

Members of the PAN, however, have presented most of the legislative proposals and policies created in favour of biotechnology.[54] The federal government has publicly expressed its commitment to encouraging inward investment and innovation in the area of biotechnology, although it has not

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[48] See Chapter 2, Section 2.3 for further examination of this point.

[49] See Chapter 2, section 2.4 on the concurrent jurisdiction areas relevant to this discussion. In accordance with Article 3 of the Federal Constitution, one of the goals that the federal government must pursue is the development and strengthening of scientific and biotechnological research. Furthermore, Article 2 of the Science and Technology Act establishes that it is federal state policy to increase the scientific and technological capabilities and the training of researchers in order to solve essential national problems, which in turn will contribute to the advance and growth of community wellbeing.

[50] See Chapter 2, Section 2.7, Chapter 3, Section 3.4 and Chapter 7, Section 7.4 for all the regulatory provisions derived from the GHA that are relevant to this discussion.

[51] See Chapter 7, Section 7.4 for further examination of the Biomedical and Tissue regulations in this context.

[52] See Muñoz de Alba Medrano M, 'The Legal Status of the Utilization of Stem Cells in Mexico', *Mexican Law Review* (5) (2006) *at* http://info8.juridicas.unam.mx/cont/mlawr/5/arc/arc5.htm - II acc. 18 June 2012.

[53] The Biomedical Regulation in Article 40, Section XI stipulates that "assisted reproduction is that related to artificial insemination (homologous or heterologous), including *in vitro* fertilisation", yet no further specific provisions to regulate ART activities can be found. At the time of writing, further legislative developments are expected in the Federal Congress regarding the regulation of assisted reproduction in the country, which as previously mentioned also remains unregulated. Legislative proposals are being discussed in the Federal Congress, but no legislation has yet been passed.

[54] See, for example, Boardman ES, 'Mexico at the Vanguard: A New Era in Medicines of Biotechnological Origin', *Journal of Generic Medicines: The Business Journal for the Generic Medicines Sector* 7 (1) (2010) 4-7.

explicitly addressed the advancement of SCS. It has also invested in the development of a platform for genomic medicine as a key area in which to foster healthcare innovation.[55] An example of investment in biomedical innovation is the creation of the INMEGEN, which is one of the thirteen NIHs and directly subordinate to the MoH.[56] The main goal of this research centre is the promotion, regulation, development and utilisation of the research and medical applications derived from knowledge of the Mexican human genome.[57] This institute was created on the premise that building a legal and research platform for genomic medicine was justified on the grounds that it promised the amelioration of health problems through personalised medicine.[58]

The INMEGEN was founded as an NIH authorised to conduct genomic medicine research.[59] In order to be established, the GHA and its secondary regulation that governs the functioning of the NIH in Mexico were modified.[60] The NIH Act provides in Article 7 bis that:

> The National Institute for Genomic Medicine has the following functions: I. To carry out experimental studies and clinical research, studies of epidemiology, technological development and basic research in its areas of speciality to contribute to the comprehension, prevention, diagnosis and treatment of illnesses, the rehabilitation of patients and the promotion of preventive health; … IV. The furthering of links with national institutions to facilitate the creation of a research network and the development of genomic medicine and connected areas with the participation of international institutions…; V. To foster the development of projects involving specialised technology in order to obtain protocols of technological innovation which lead to the elaboration of methods of diagnosis, pharma-genomics and genetic therapy; and VI. To be the National Reference Centre for issues related to studies on genomic medicine and its applications.[61]

This development in biomedical research regulation has been recognised as an excellent result of lobbying by the director of the INMEGEN, who organised

[55] See Jiménez-Sánchez G, Frenk J and Soberón G, 'El Poder Transformador de la Genómica en la Economía Global' *(The Transforming Power of Genomic in the Global Economy)*, (18 August 2011), *available at:* http://estepais.com/site/?p=34614 acc. 18 June 2012.
[56] See Chapter 2, Section 2.7 on the structure of the health system in Mexico and for a scrutiny of the existing public healthcare institutes and research centres, including INMEGEN.
[57] See Schwartz-Marín E and Silva-Zolezzi I, '"The Map of the Mexican's Genome": Overlapping National Identity, and Population Genomics', *Identity in the Information Society* 3 (3) (2010) 489-514.
[58] See Jiménez-Sánchez G, 'Developing a Platform for Genomic Medicine in Mexico', *Science* 300 (5617) (2003) 295-6.
[59] Ibid.
[60] See National Institutes of Health Act, (in Spanish *Ley de los Institutos Nacionales de Salud*) *available at:* http://www.diputados.gob.mx/LeyesBiblio/pdf/51.pdf acc. 18 June 2012.
[61] Ibid.

several workshops and seminars in the Federal Congress in order to convince legislators and the federal authorities to invest in this innovative scientific field.[62]

With the creation of the INMEGEN, new provisions dealing with other aspects of biotechnology were also introduced into the GHA, beginning with a section entitled 'Biotechnology Products'. [63] Article 281 bis defines biotechnological products as:

> … those nutrients, ingredients, additives, raw materials, health supplies, pesticides, toxic or dangerous substances and waste materials in which living organisms or parts of them are involved in their processes or modified by a traditional technique or by genetic engineering.

This wording suffers from a lack of clarity with respect to modification by traditional techniques, suggesting that the modification of living beings by means of non-traditional techniques is allowed. In spite of the vagueness of this provision, however, these legislative actions can be considered as steps forward to regulate some aspects of biotechnology.

On the other hand, interestingly and not surprisingly, there is a clear dichotomy as to the current federal government's view of biotechnological development. While the federal government is investing considerable financial resources into genomic medicine, it has prevented the INMEGEN from conducting certain SC research activities. Thus, Article 3, section I of the INMEGEN's internal regulations stipulates that "...no research of any kind will be carried out on human stem cells derived from living embryos, or those procured by nuclear cell replacement…".[64] It is documented that there were many determining factors behind the decision of the federal government and legislators to create the INMEGEN, related to the fear that it would be possible to conduct reproductive cloning and hESC research activities.[65] Although the internal regulations of the INMEGEN clearly prohibit the conduct of hESC

[62] See Séguin B et al, 'Genomics, Public Health and Developing Countries: The Case of the Mexican National Institute of Genomic Medicine (INMEGEN)', *Nature Reviews Genetics* 9 (Suppl 1) (2008) S5-9.
[63] Since then, new provisions relating to the regulation of biotechnological goods and medicines have been incorporated into the GHA, the latest being one concerning biosimilar or biogeneric drugs. On this see further López Silva C, 'Mexico Recovers Leadership on Regulation of Biosimilar Biotech Drugs' (English Abstract), *Gaceta Medica de México* 148 (1) (2012) 83-90.
[64] Organic Statute of the National Institute of Genomic Medicine (2007), *available at* http://www.inmegen.gob.mx/tema/cms_page_media/642/INMEGEN%20ESTATUTO%20ORGANICO%202011_1.pdf acc. 31 March 2012.
[65] See Schwartz Marín E, *Protecting Genomic Sovereignty: Insights from Ethnography and Political Philosophy*, research paper prepared for the XV International Congress of Philosophy 'Philosophy for the New Genetic' organised by the Mexican Association of Philosophy (Mexico city: 25-29 January 2010) *available at* http://www.filosoficas.unam.mx/~afmbib/mayteAFM/Simposios/30.html acc. 18 June 2012.

research, other important ways of procuring embryonic SCs and many other types of SCs are not contemplated, nor is the possible use of diverse cells. In addition, this prohibition applies only to the INMEGEN, not to any of the other public and private research bodies in the country capable of developing biotechnology, especially with respect to SCS.

The financial investment on biomedicine is manifest in the creation of an infrastructure and legal platforms for genomic medicine under the pretext of the achievement of economic and social development.[66] The federal government is eager to advance certain emerging biotechnologies on one hand, while on the other hand maintaining restrictive policies in relation to SCS, as suggested by the existence of a prohibition in the internal INMEGEN regulations, notwithstanding that genomic medicine activities are not directly related to SCS investigations.

It is important to note that the government is not the only player to have injected financial resources into biotechnology and life science research.[67] Lately, Mexico has seen increasing interest from private foreign companies in nurturing biotech industries, creating international transnational alliances between countries and research institutes.[68] The influence of private forces, such as biotech and pharmaceutical companies, transcends the borders that conservative groups have attempted to draw in biotechnological policies. To date, at least one major private alliance with foreign investment has been formed: the Life Sciences Gateway Initiative represents some key regions in Mexico that have an emerging potential to develop biotechnology, including in the scientific field of SC research.[69] This alliance is enhanced further by links with the University of California-San Diego and Merck, Sharp & Dohme Mexico in promoting life science research within so-called Mexican clinical bio-clusters.[70] The Mexican states involved in this alliance are Morelos, Guanajuato, Guadalajara and Monterrey. These clusters have different strengths and

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[66] See Chapter 2, Section 2.7.
[67] Ibid.
[68] According to a study entitled "Catalyzing Cross-Border Innovation: The Mexican Life Sciences Initiative", carried out in 2005 by the Council on Competitiveness and Global Bioeconomy Consulting, ***life science*** is to be understood as "…broadly defined to include all biological technologies and applications. This includes: biotechnology, pharmaceuticals, plant and animal technologies, medical devices, healthcare (e.g. translational research, clinical trials), biological related information technology (e.g. bioinformatics, telemedicine), as well as biological-related production and manufacturing." See San Diego Crossborder Group Inc and Merck Sharp & Dohme (MSD), *San Diego Dialogue: Borderless Biotech & Mexico's Emerging Life Sciences Industry* (May 2007) *available at:* http://www.sandiegodialogue.org/pdfs/Borderless_Biotech.pdf acc. 18 June 2012.
[69] Ibid.
[70] See Editorial, 'Biotech Round the World: Focus on Mexico', *Biotechnology Journal* 3 (9-10) (2008) 1131-34.

activities. While the Morelos Institute specialises in research, Guanajuato has the largest agro-biotech cluster. Guadalajara, known as the Silicon Valley of Mexico, already conducts research using SCs procured from UCB and spare IVF embryos from fertility treatments.[71] In Monterrey, technology and clinical research centres are undertaking the same work.[72] The main goal of the alliance is to link health and life science national research with foreign enterprises based in Southern California.

One of the researchers involved in the life science alliance has pointed out that Mexico has the infrastructure and maintains the quality and standards of the USA or Europe, with the added advantage of having more patients for research and more room for clinical trials, highlighting the fact that many clinical research locations in the United States are overbooked.[73] In addition, he notes that the migratory policies in Mexico are more flexible and that a lack of regulation fosters freedom, yet the infrastructure is still primitive and there are not enough researchers.[74] This last point accentuates the urgent need for adequate regulation to facilitate the controlled development of SCS and to provide desirable conditions for all stakeholders, politicians, scientists and physicians involved in these projects.[75]

As a reaction to the prevailing legal lacunae in this area, in 2009 members of the national scientific community issued an open letter calling on the national legislators to be cautious in adopting regulations that would lead to the prohibition of all types of SCS practices.[76] This position among scientists and national researchers reiterates their ethical affirmation and the relevant constitutional right to freedom of research and the furthering of scientific knowledge as a public good within a democratic state, as expressed in one of the editorial of issues of the Mexican Academy of Sciences (AMC) journal.[77] The

[71] San Diego Crossborder Group Inc and Merck Sharp & Dohme (MSD), *supra* note 68.
[72] See Meade C, 'Regional Alliance Forms to Promote Life Sciences in Mexico', *The Daily Transcript (*June 20, 2008) http://www.sandiegodialogue.org/pdfs/MLSA_BIO_SDDT_article.pdf acc. 18 June 2012.
[73] Ibid.
[74] Ibid.
[75] Key stakeholders in Mexico have expressed concerns about having a domain such as SCS remain unregulated, since it represents an innovative area of scientific research which also involves many uncertainties, due to its rapid pace of progress. See Chapter 6 for a detailed discussion related to key stakeholders' attitudes towards SCS in Mexico.
[76] See AMC, Research Seminar on Ethics and Bioethics-UNAM, COLBIO, FCCyT et al, 'Llamado de Prudencia y Responsabilidad al Congreso de la Unión y a la Opinión Pública en Cuestión a las Reformas Iniciadas por el Partido Acción Nacional Relacionadas con la Protección de la Vida Humana y Prohibición de Cualquier Forma de Clonación' *(Call to the Congress of the Union and Public Opinion to Proceed with Caution and Responsibility in Relation to the Reforms Initiated by the National Action Party Concerning the Protection of Human Life and the Prohibition of any Form of Cloning)*, *Communication* (23 January 2009) http://www.comunicacion.amc.edu.mx/comunicacion/docs/amc-rrg-230109-d-clonacion.pdf acc. 18 June 2012.
[77] See Ruíz Gutiérrez R, 'Editorial', *Ciencia* 60 (2) (2009) 3.

AMC, which plays a crucial role in developing scientific research in the country,[78] enjoys the most prestigious and honourable public status, bringing together the whole scientific community working in public and private research centres.[79] Therefore, research projects and interests are at the heart of this organisation.[80] However, its claim is based on a line of thinking followed by a minority of the population, largely restricted to the academic sector.

5.4.1. THE CONSTITUTIONAL RIGHT TO LIFE IN THE MEXICAN SUPREME COURT

The Mexican Supreme Court has played an important role in interpreting the Federal Constitution.[81] Hence, it is relevant to analyse its judicial interpretations regarding the legal status of the embryo that were issued as a result of abortion reforms[82] approved by the local legislature of Mexico City.[83] Mexico City's legislature is mainly composed of members of the PRD who advocate liberal policies free from religious influence.[84] This last point suggests that the political context and the lack of a predominant religious influence may be the deciding factors in liberalising the regulation of certain activities such as abortion and SC research. Consequently, it is plausible that this liberal trend may in the near future extend to the regulation of SCS.

Thus far, the Mexican Supreme Court has failed to provide an accurate interpretation of the protection to be accorded to the embryo, if any, derived

[78] As pointed out in Chapter 2, Section 2.2.
[79] Ibid.
[80] On November 2011, the President of the AMC issued relevant proposals for the furthering and development of scientific knowledge in Mexico, highlighting the need to improve the quality of education, the training of high level human resources, the consideration of S&T as a national priority and the extent of investment in this area. These recommendations were fundamentally addressed to the future President of Mexico. See Menchaca Rocha A, *El Único Camino Hacia el Desarrollo de México Pasa por el Conocimiento: Recomendaciones para el Futuro Presidente de México (The Only Path Towards Mexico's Development is through Knowledge: Recommendations for the Next President of Mexico)* (Mexico: AMC, 2011) 19.
[81] As discussed in Chapter 2, Section 2.5, the Mexican Supreme Court is the highest judicial authority. One of its functions is to exercise constitutional control, when unconstitutionality is claimed, which is no more than the Court´s power to strike down any Act, law, regulation or secondary body of norms that may contradict or contest any provision of the Federal constitution, or otherwise to pronounce the legality of the provisions or norms challenged. Rulings issued by this Court are called *jurisprudence* or *judicial precedent* and can be considered similar to *case law* in common law systems. In order to create jurisprudence or judicial precedent, as a formal requirement, eight members of the Court must agree on the main points of any judgment. The Mexican Supreme Court's judicial precedents are binding on all lower courts, due to its hierarchical supremacy as a constitutional court over all the Courts within the judicial system.
[82] Presently, abortion in cases of rape can be carried out in all 32 states. In 29 states, when pregnancy ends by miscarriage, women are exempted from penalty, in contrast to other states, where it is not considered an exemption from punishment; in 28 states abortion is legal when the woman's life is at risk; in 11 states in cases of foetal impairment; in six states when there is insemination by a donor without the consent of the woman; and in one state for socio-economic reasons (for women with three or more children).
[83] For a detailed analysis of both rulings on abortion, see Pou Jiménez F, 'El Aborto en México: El Debate en la Suprema Corte Sobre la Normativa del Distrito Federal' *(Abortion in Mexico: The Debate in the Supreme Court about Mexico City's Regulation), Anuario de Derechos Humanos* (5) (2009) 137-52.
[84] See Chapter 2, Section 2.4.

from constitutional principles and fundamental rights. Although, it is acknowledged that the Mexican Supreme Court has played a prominent role as a broker between the federal government, legislators and society with respect to outstanding issues. The key role of the Mexican Supreme Court in the legal system may help, in the future, in addressing legal disputes on controversial topics where politicians, legislators and many other stakeholders in this field can neither accommodate nor conciliate.[85]

The reforms to the Mexico City Criminal Code passed by the local legislature in 2000 extended exemption from penalty to cases of abortion where the mother's life was at risk and to those where severe congenital conditions affected the foetus.[86] Legal scholars in Mexico point out that this reform seemed to constitute a significant achievement in incorporating a new language into public discourse, using terms such as sexual and reproductive rights.[87] However, the reform was contested immediately after its approval by a minority within the local legislature, PAN-members legislators.[88] They challenged the constitutionality of the reforms, arguing that the exemptions added to the criminal code in order to allow abortion where there were genetic or congenital malformations of the foetus violated the constitutional right to life of any such foetus.[89] Here, it is pertinent to highlight that both the claimants and the Mexican Supreme Court judges in their respective discussions alluded to the protection of the product of the conception, the embryo, foetus and unborn child, without establishing any distinction among them.[90]

Subsequently, in January 2002, the Mexican Supreme Court upheld the first judicial ruling regarding abortion norms and the protection of the unborn.[91] In doing so, it attempted to interpret the constitutional provisions and civil norms related to the protection of the product of conception.[92] The judges

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[85] On the role of the Mexican Supreme Court, see Chapter 2, Section 2.5.

[86] On this, see Billings DL et al, 'Constructing Access to Legal Abortion Services in Mexico City', *Reproductive Health Matters* 10 (19) (2002) 86-94.

[87] See further Madrazo A, 'The Evolution of Mexico City's Abortion Laws: From Public Morality To Women's Autonomy', *International Journal of Gynecology & Obstetrics* 106 (3) (2009) 266-9.

[88] See Action of Unconstitutionality 10/2000. Claimant: Legislators Members of the Mexico City's Legislature, *IUS No. 16974, IX Ninth Era,* (March 2002) *available at* http://200.38.163.161/UnaEj.asp?nEjecutoria=16974&Tpo=2 acc. 18 June 2012.

[89] Ibid.

[90] See Lobo T, 'Criterio Reciente de la Suprema Corte de Justicia de la Nación en Materia de Aborto' *(Recent Ruling of the Mexican Supreme Court on Abortion)*, *Revista de Derecho Privado* (3) (2002) 163-229; the original text of this ruling which can be consulted *at:* http://www.equidad.scjn.gob.mx/IMG/pdf/AI_10-2000.pdf acc. 18 June 2012.

[91] Ibid.

[92] An analysis of the interpretation of these normative provision made by the Supreme Court can be reviewed in Ordóñez J, 'El Reconocimiento Constitucional del Derecho a la Vida. Un Caso Paradigmático en la Suprema Corte de Justicia en México' *(The Constitutional Recognision of the Right to Life. A Paradigmatic Case in the Mexican Supreme Court)*, in Carbonell M (Coord) *Derechos Fundamentales y el*

asserted that federal civil norms provide that the unborn has the potential to invoke inheritance and donation rights, so it must be considered a bearer of rights and therefore must be protected from the moment of conception.[93] In this ruling, the then Mexican Supreme Court judges endorsed the constitutionality of the reforms based on the argument that the crime of abortion remained intact and that the exemptions were incorporated for socially accepted reasons.[94] In addition, the Mexican Supreme Court held that the reforms did not authorise the interruption of the life of the product of conception;[95] they merely conceded the possibility of exempting a woman from punishment when an abortion was performed under the exceptional circumstances newly incorporated into the criminal code. Thus, the constitutional right to life of the product of conception remained intact. It thus interpreted constitutional Articles 14 and 22 of the Federal Constitution as providing the following, respectively: "...no one shall be deprived of his or her life…" and the "...death penalty is forbidden…".[96] Accordingly, the constitution "protects any manifestation of human life, regardless of the current stage of biological development"[97]. The Court noted that Article 123 provides the protection of working rights for pregnant women by allowing maternity leave for them, interpreting this constitutional provision as showing that the aim of the constitution is to protect life from the outset.[98]

In addition, the Mexican Supreme Court recognised in its 2002 ruling that all human beings have the right to life under the Federal Constitution and that the product of conception is an early manifestation of life.[99] In the view of the judges, the constitution's aim, therefore, is to protect life from conception onwards.[100] Nonetheless, the judges were not consistent in ruling in this way, since they did not explain in lay terms what conception means or how one can determine when conception occurs. Finally, the judges decided that the product

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Estado, Memoria del VII Congreso Iberoamericano de Derecho Constitucional (Human Rights and the State, Memoir of the VII Iberoamerican Congress of Constitutional Law) (Mexico: IIJ-UNAM, 2002) 859-74.

[93] Legal protection of certain rights for the *nasciturus* or the unborn is found in Civil Codes in Mexico in relation to succession law. For example, according to the Federal Civil Code, the 'posthumously conceived' child has inheritance rights. On this see Márquez González JA, 'Part IV, Chapter 1 Intestate Succession', in *Family Law in Mexico* (The Netherlands: Kluwer Law International, 2011) 164-6. Although this point raises concerns with respect to inheritance rights of children procreated by unconventional techniques, such as IVF, the discussion of this issue goes beyond the scope of this thesis.

[94] Thesis: P/J. 14/2002 (Jurisprudence), Derecho a la Vida del Producto de la Concepción. Su Protección Deriva de la Constitución Política de los Estados Unidos Mexicanos, de los Tratados Internacionales y de las Leyes Federales y Locales (The Right to Life of the Product of the Conception, its Protection is Derived from the Mexican Constitution, International Treaties, Federal and Local Regulations), IUS 187817 (IX Ninth Era) (February 2002), *at* http://200.38.163.161/leg/InfoTesis.asp?nIus=187817 acc. 18 June 2012.

[95] Ibid.

[96] Ibid, note 88 at 87.

[97] Ibid.

[98] Ibid, note 88 at 100-103.

[99] Ibid.

[100] Ibid.

of conception is protected not only under national civil norms but also by international treaties signed and ratified by the Mexican government, such as the UN Convention on the Rights of the Child (1990) and the American Convention of Human Rights (Pact of San Jose, Costa Rica) (ACHR) (1978). The former establishes the protection of children before and after birth, while the latter provides the fundamental right to life. At that time, the Court did not make it clear that the federal government had issued an interpretative declaration on the ACHR regarding the protection of life from conception onwards.[101]

To a certain extent, the 2002 ruling was significant in acknowledging the constitutional right to life,[102] in that the Mexican Supreme Court recognized the right to life of the product of conception. It did not, however, provide a clear account of the consequences of that safeguard. In other words, it merely analysed the constitutionality of the norms contested, without providing a clear pragmatic explanation of why and how life from conception onwards is deemed to be protected. While granting high constitutional protection to the product of conception, the Court failed to establish an accurate account of its implications, not only in the case of abortion exemptions, but in broader terms when talking about relevant areas involving the creation and utilisation of spare IVF embryos in assisted reproduction treatments, which were and are widely practiced in the country. In addition, the judgment is obscure, since there is a lack of legal reasoning to explain how and why the judges have arrived to the conclusion that that life should be protected from the outset; the ruling is mainly supported by arguments related to the potential of the unborn to become a bearer of succession rights. The judges provided no further reasoning in support of the conclusion that constitutionally sanctioned human rights, such a woman's reproductive autonomy and her right to decide over her body,[103] should somehow be put aside to protect life from conception, in order to secure the succession rights of a 'posthumously conceived' child. Such rights

[101] See Chapter 2, Section 2.3 for a detailed examination of the interpretative declaration issued by the Mexican government that exempts Mexico from the provision in the Pact of San Jose which protects life from conception.

[102] For a discussion of this, see Ordóñez J, 'El Reconocimiento Constitucional del Derecho a la Vida. Un Caso Paradigmático en la Suprema Corte de Justicia en México' *(The Constitutional Recognision of the Right to Life. A Paradigmatic Case in the Mexican Supreme Court)*, in Carbonell M (Coord) *Derechos Fundamentales y el Estado, Memoria del VII Congreso Iberoamericano de Derecho Constitucional (Human Rights and the State, Memoir of the VII Iberoamerican Congress of Constitutional Law)* (Mexico: IIJ-UNAM, 2002) 859-74.

[103] This is not to say that we have an argument in favour of abortion on demand as a result of unprotected sex. The point was merely that judges needed to be clearer when balancing conflicting basic rights, such as those concerned with the right to life and the ability to decide about our own offspring.

have a lower status in the legal system, since constitutional rights override secondary provisions within the constitutional paradigm.[104]

In 2007, when further reforms to Mexico City's Criminal Code were judicially contested, the Court radically changed its 2002 ruling. This time, the highest judicial authority provided a more detailed explanation of the level of protection accorded to the embryo. In April 2007, the local legislature of Mexico City again amended its Criminal Code and local Health Act.[105] The Criminal Code reform decriminalised abortion before the end of the twelfth week of pregnancy;[106] in other words, it legalised the elective termination of pregnancy up to twelve weeks of gestation. Two provisions were added to the local Health Act, stipulating that the Mexico City Department of Health, through healthcare providers (i.e. in public hospitals and clinics), must ensure access to first-trimester abortion services at no cost to local inhabitants and for a moderate fee to women from outside the city.[107]

Difficulties arose immediately upon the approval of the above stated reforms when the President of the National Commission on Human Rights (CNDH) and the federal Attorney General initiated actions of unconstitutionality against the amendments to the Criminal Code and local Health Act.[108] The central arguments adduced by the petitioners were based on the premise that life is constitutionally protected from the outset.[109] They also claimed that the decriminalisation of abortion in Mexico City infringed the basic right to life of the embryo and the unborn; thus, the reforms were said to transgress the human dignity possessed by embryos, since life begins to matter

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[104] For further analysis of the Mexican constitutional paradigm, see Chapter 2, Section 2.3.

[105] Official Gazzete of the Federal District (Mexico City) published on 26 of April 2007, reforms and amendments of Mexico City's Criminal Code (2002) and Health Act (1987) *available at* http://www.gire.org.mx/publica2/GacetaGDF_Aborto260407.pdf acc. 18 June 2012.

[106] Mexico City's Criminal Code (2002), as amended Articles 144, 145, 146 and 147.

[107] Mexico City's Health Act (1987), as amended Articles 16bis 6 and 16bis 8.

[108] Writ of Action of Unconstitutionality presented by the President of the CNDH against the reforms to Mexico City's Criminal Code and Health Law *available at* http://www.cndh.org.mx/node/545 acc. 18 June 2012.

[109] It should be pointed out that the President of the CNDH acted on his own authority and initiative, without the approval of the majority of the collegiate advisory council within the commission and despite the fact that half of the members of the council expressed their disapproval of any action of unconstitutionality being taken against the Mexico City reform. See further: Serrano-Migallón F, 'Intervención de Fernando Serrano Migallón en Relación a la Acción de Inconstitucionalidad Presentada ante la Suprema Corte de Justicia por el C. Presidente de la Comisión Nacional de los Derechos Humanos' *(Participation by Mr Fernando Serrano Migallón, President of the National Commission for Human Rights, in Relation to the Action of Unconstitutionality Discussed before the Mexican Supreme Court of Justice)*, *La Jornada en Ciencias: Foros* (2008) http://ciencias.jornada.com.mx/ciencias/foros/despenalizacion-del- aborto/controversia-en-la-cndh/intervencion-de-fernando-serrano-migallon acc. 18 of June 2012. Another relevant point is that both of the authorities who contested those reforms were appointed by the President of the Mexico and in the case of the Attorney General, he takes direct orders from the President. Additionally, as previously indicated, the Mexican President was brought to power by the conservative political party PAN.

morally and legally from the outset.[110] The petitioners further asserted that it is from conception onwards that the embryo is in possession of full human rights and human dignity, the numerous alternative positions on this question notwithstanding.[111] In addition, the allegation was also grounded in many international treaties and covenants that Mexico had signed and ratified. Consequently, the Mexican Supreme Court was again called upon to decide the constitutionality of those reforms; in response, it issued another landmark ruling in this area.

On 25 August 2008, in a plenary session, the Mexican Supreme Court issued a ground-breaking judgment on abortion law, upholding the constitutionality of abortion on demand in Mexico City.[112] Its new judgment contrasted with its previous seminal ruling of 2002.[113] This time, its discussions and the ruling predominantly concerned women's reproductive rights. Secondarily, but in more detail than in its previous judgment, it also reflected on the extent of protection of the constitutional right to life, excluding the discussion of the rights of the 'posthumously conceived' child.[114]

In order to reach a final judgment, the Mexican Supreme Court called for public hearings and deliberations in which all interested parties were to be able to express their opinions in relation to the contested issues contained within the actions of unconstitutionality presented by the President of CNDH and the Attorney General.[115] Subsequently, the Mexican Supreme Court held six of these

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[110] Ibid, *supra* note 108.

[111] Here, it is pertinent to note that the doctrine of the PAN states that: "Human beings possess an inner dignity and have material and spiritual ends to fulfil; therefore the community and its organs shall guarantee the freedom and the means to accomplish that destiny with dignity". See Asemblea Constituyente del PAN, 'Principios de Doctrina del Partido Acción Nacional' *(Principles of Doctrine of the National Action Party)*, (14 & 15 September 1939), *available at:* http://www.pan.org.mx/XStatic/pan/docs/espanol/p_doctrina1939%5B1%5D.pdf acc. 18 June 2012. We can infer cautiously that the actions of unconstitutionality were not grounded in constitutional norms, but rather were based on the doctrine of a conservative political party. For an interesting critique on the failed strategies applied by members of the PAN to strike down the reformed abortion provisions in Mexico city, see Hernández Vicencio T, 'The Partido Accion Nacional (PAN) in the Fight to not Decriminalize Abortion in the Distrito Federal, Mexico' (English Abstract), *Andamios* 8 (2011) 367-96.

[112] A detailed chronicle of the Mexican Supreme Court discussion carried out in the plenary session (in Spanish) is *available at* http://www2.scjn.gob.mx/cronicas/PDF/cr_desp_aborto.pdf acc. 18 June 2012.

[113] The Court is authorised to vary its judicial reasoning and judgments from time to time, in accordance with the current social circumstances and based on sound arguments. See further Sodero E, 'Sobre el Cambio de los Precedentes' *(On the Change of Precedents)*, *Isonomía* 21 (2004) 217-50.

[114] Action of Unconstitutionality 146/2007 and its appended 147/2007. National Commission on Human Rights and the Attorney General of the Republic, IUS 21469 (IX Ninth Era) (March 2009) at http://200.38.163.161/UnaEj.asp?nEjecutoria=21469&Tpo=2 acc. 18 June 2012.

[115] The Court issued special guidelines containing the formal requirements to be followed by the participants in the public hearings, as well as the procedural rules to be observed. See Mexican Supreme Court, *General Agreement 2/2008, of the Plenary of the Supreme Court of Justice of the Nation by which are Established the Guidelines to be Followed in Order to Celebrate Public Hearings Concerning Relevant Issues of National Legal Interest and Relevance* and *Reglas Operativas para el Desahogo de las Audicencias Públicas en Relación con las Acciones de Inconstitucionalidad 146/2007 y su Acumulada (Procedural Rules for the Celebration of the Public Hearings in Relation to the Action of Unconstitutionality 146/2007 and its appended)*, (10 March 2008).

public hearings, a remarkable and unusual mechanism, in order to take into account the views of all interested parties, given the national relevance and legal impact of the issue. At the six hearings, which took place in courtrooms and were broadcast internationally through the Court's special website, more than forty speakers from diverse sectors of the population, from the most secular to the most conservative, presented arguments for and against decriminalisation.[116] Amongst the strongest arguments made in favour of the legalisation of abortion were those who held that a woman's freedom over her physical and mental health should prevail over other concerns.[117] Such contributors also contended that religious values concerning the protection of the embryo could and should be put aside when determining secular legal matters.[118] Conversely, the conservative position was that each embryo is a sentient being with a genetic constitution typical of the human species, making the embryo part of humanity and consequently deserving of the protection of its human dignity and life.[119] During the final hearing, in a groundbreaking judgment, eight of the eleven judges orally and publicly upheld the constitutionality of the decriminalisation of abortion in Mexico City.[120]

In sum, clause eight of the final judgment refers to "the right to life, its nature and existence".[121] In addressing the allegation put forward by the claimants, the Court established that "life is a necessary condition for the actual existence of fundamental rights; however, this does not imply that the right to life should prevail over other fundamental rights, given that fundamental rights are not absolutes and that when they conflict, the appraisal of rights is necessary."[122] The Court asserted that "from a literal reading of the Federal Constitution there is no explicit text which grounds the argument that a foetus

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[116] In order to provide transparency, as well as to inform society as to the process of arriving at the final ruling, the Court created a micro-website where people could access all the particulars of the public hearings, the documents presented by the speakers and recordings of the speeches made before the Court, as well as the final ruling and the dissenting (concurrent) comments made by judges. This website was available online until February 2010, more than a year after the final ruling of the Court. This information was sourced from http://informa.scjn.gob.mx/ last acc. 7 February 2010.

[117] See Ubaldi Garcete N, *Constitutionality of the Abortion Law in Mexico City*, translated by Benton E and Villar R (Mexico: GIRE, 2010), *available at:* http://www.gire.org.mx/publica2/ConstitutionalityAbortionLawMexicoCity_TD8.pdf acc. 18 June 2012.

[118] Ibid.

[119] See, for example, Fernández del Castillo Sánchez C, '¿Interrupción Legal del Embarazo o Asesinato con Autorización de la Ley? *(Legal Interruption of Pregnancy or Authorised Legal Murder?)*', *Ginecología y Obstetricia de México* 9 (76) (2008).

[120] The Mexican Supreme Court also had the power to completely overrule the amendments made to the Penal Code and the Health Law if they had been found contrary to the provisions of the Constitution. It is noteworthy here that any ruling passed by a majority of eight of the 11 judges sitting *en banc* creates *jurisprudence*, which is binding on all Federal and lower courts in Mexico, in accordance with Article 43 of the Amparo Act; for more on the precedence system of the Mexican legal regimen, see Chapter 2, Section 2.5.

[121] Ibid, *supra* note 114.

[122] Ibid.

has a right to life; moreover, there is no constitutional obligation to defend life from conception, in particular through the criminal law."[123] Once more, the Court failed to clarify the use of the terms 'embryo', 'foetus', 'unborn' and 'product of conception', so this ambiguity persists in this ruling, but it did conclusively state that life is not protected from conception onward under constitutional norms.[124]

The Mexican Supreme Court judges affirmed that laws regarding the protection of life were derived from international covenants and treaties, but that the majority of these legal documents do not establish when life begins or from what moment it should be protected.[125] It also ruled that although Article 4 of the Pact of San Jose (ACHR) establishes when life is considered to begin, Mexico should not be bound by that specific stipulation, because of the reservation agreed by the Mexican government when ratifying the ACHR.[126] This reservation acknowledges that legislation concerning whether or not to protect life 'in general' from the time of conception is to be reserved to the jurisdiction of each of the member states of Mexico.[127] Therefore, the Mexican Supreme Court held that under international norms it was not constrained to protect life from the outset, nor from any particular point.[128] This time, the judges of the Mexican Supreme Court successfully provided a clear explanation of the binding status of the Pact of San Jose (ACHR), which they have previously failed to invoke (2002 ruling on abortion). The Mexican Supreme Court does, ultimately, have an interest in promoting and protecting life, for instance by means of the constitutionally sanctioned right to healthcare protection stated in Article 4 of the Federal Constitution. [129]

Furthermore, the Mexican Supreme Court held that the reforms enacted by the local legislature of Mexico City were important for the protection of women's health. It recognised that in enacting those reforms, Mexico City legislation was fulfilling what Article 4 of the Federal Constitution establishes regarding women's responsibility for and freedom over their own bodies, their physical and mental health and their life. The Mexican Supreme Court affirmed that even if there were an aspiration to protect the foetus, the complete

[123] Ibid.
[124] Ibid.
[125] Ibid.
[126] Ibid.
[127] Ibid.
[128] Ibid.
[129] Article 4, paragraph 2 (concerning the right to procreate) of the Federal Constitution establishes that "Every individual has the right to decide in a free, responsible and informed manner the number of children desired and the timing between each of them".

criminalisation of abortion would not ensure a healthy pregnancy, given the social context of poor, marginalised and rural women who cannot achieve the ideal conditions for their pregnancy.[130] Further, if abortion remained a crime, it would only serve to perpetuate discrimination against women, by depriving them of the right to decide over their bodies.[131]

It is relevant here that it does not follow that by allowing the interruption of pregnancy before the twelfth week, the Mexican Supreme Court or the states renounced any interest in protecting embryonic and foetal life.[132] However, the issue of the treatment of the embryo before that period of development remained unaddressed.[133] Thus, the judges failed to consider whether embryos created *in vitro* should enjoy the same level of protection as those which are not procreated as a result of IVF treatment. It is plausible that the Mexican Supreme Court's declaration of the constitutionality of provisions allowing abortion before a certain stage of embryonic development will serve as an enduring endorsement of a permissive legal framework for hESC research, since the Mexican Supreme Court's ruling can be seen to have indirectly initiated the acceptance of a gradualist view of the protection of embryonic development.

A valuable feature of this ruling is that the public proceedings held by the Mexican Supreme Court constitute an important example of how prevailing social values and opinions should be taken into account and considered in the construction of the law. The Mexican Supreme Court's decision to assess these values before issuing its ruling is exemplary for legislators and policy-makers; by encouraging the expression of stakeholders' views in public hearings regarding the status of the embryo and women's reproductive rights, the Court participated in and encouraged a democratic exercise. These practices show the need for the law to accommodate the diverse views which exist in a plural community by means of public engagement and deliberation before legislating on complex issues such as abortion and SCS.

The actions of the Mexican Supreme Court lead me to suggest that the Court may well establish the legality of SCS development and its due regulation by interpreting constitutional norms, yet this is feasible only if the

[130] Ibid, *supra* note 114.
[131] Ibid.
[132] For a discussion concerning the exceptions that the State can establish to allow abortion in certain circumstances without giving up its interest in protection life, see McGuinness S, 'Abortion: Prohibitions and Exceptions', *The American Journal of Bioethics* 9 (8) (2009) 70-2.
[133] See Medina-Arellano MdJ, *supra* note 35.

Court is called on to rule on the legality or constitutionality of SCS practices.[134] Given the prevailing legislative inertia, the suggested scenario is desirable and will mirror similar experiences of homologous legal, religious and political contexts. For instance, it was the Supreme Court of Justice of Brazil which finally decided the legality of SC research in that country, holding this scientific activity not to contravene any of its constitutionally sanctioned rights.[135]

However, in the case of the Supreme Court of Mexico, the discussion of the legal status of the embryo is extremely unrefined. Nonetheless, the positive features of its legal ruling on abortion and its potentially crucial role as a mediator of political, legal and religious forces are significant. The judges of the Mexican Supreme Court did not articulate the extent of protection between the initial stages of embryo development (such as zygotes and blastocysts) and the foetus. Its lack of certainty and limited arguments regarding the degree of protection accorded to the embryo opened the door for this debate to migrate to the political and legislative arena, as it provoked political and legal responses across the country, creating legislative repercussions for abortion and SCS.

5.4.2. POLITICAL IMPLICATIONS FOR STEM CELL SCIENCE REGULATION

The Federal Constitution, as interpreted by the Mexican Supreme Court in 2008, lacks a specific provision that protects life from the outset.[136] In response to this constitutional interpretation, some local legislatures amended their constitutions to protect life from the outset, whereas in the Senate, legislative proposals were introduced by PAN-legislators to amend the Federal Constitution and the GHA in the same terms as the local constitutions reforms; this later point is examined later on in this section.

Local constitutional reforms were immediately noticeable and had a widespread impact, amendments being made to the constitutions of seventeen states: ***Baja California***,[137] Campeche, Colima, Durango, Guanajuato, Jalisco, Nayarit, Oaxaca, Puebla, Querétaro, Quintana Roo, ***San Luis Potosí***, Sonora, Tamaulipas and Yucatán.[138] While there were variations in the reforms among the states, they all established that "life shall be protected ***from the moment of***

[134] This by means of any of the constitutional resources or legal tools available to guarantee the due protection of constitutional and fundamental human rights. On this, see Chapter 2, Section 2.3.
[135] See Cesarino L and Luna N, *op. cit. supra* note 14.
[136] Ibid, *supra* note 114.
[137] Emphasis added to denote those states whose constitutional reforms have been challenged before the Mexican Supreme Court.
[138] See Vela E, 'Current Abortion Regulation in Mexico', *Working Papers of the CIDE, Legal Studies Division* (50) (December 2010) *at* http://www.cide.edu/publicaciones/status/dts/DTEJ%2050.pdf acc. 18 June 2012.

conception until the natural end of life".[139] A reading of the amended text indicates the direct transplantation of Catholic doctrine into the local constitutions. Comparing the reformed provisions with documents issued by the Vatican reveals a close similarity in the wording used by the Church and local legislators. For instance, the Catholic Instruction *Dignitas Personae 'On Certain Bioethical Questions'* establishes that: "1. The dignity of a person must be recognized in every human being ***from conception to natural death***" and that "12. ...new medical techniques must respect three fundamental goods: a) the right to life and to physical integrity of every human being from conception to natural death..."[140]. This is evidence of the direct influence still exercised by the hierarchy of the Catholic Church over many political groups, demonstrating that there is far from being a *de facto* separation of law and religious belief in many states.[141] Some members of the federal Chambers of Deputies have denounced these reforms, promoted by members of the PAN, as linked to religious beliefs.[142] For example, the deputy Jaime Cardenas said in a speech that "the Church has promoted reforms and laws in several States…".[143] It is of great importance here, as mentioned before, that these reforms seem to be pre-emptive measures to prevent Mexican legislators from liberalising the rules on abortion and to halt any further development, such as embryo research. The question of the legal status of the embryo continues to be disputed.

In January 2009, the Attorney of the local commission on human rights of Baja California State initiated an action of unconstitutionality against the reform to its local constitution which protected life from conception;[144] it was alleged that this reform infringed fundamental rights and was incompatible with the Federal Constitution, since this does not protect life from the outset.[145] Likewise,

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[139] See Information Group on Reproductive Choice (GIRE), Table of Comparison of the Reforms Passed by Local Legislatures which Protect Life From Conception/Fertilisation 2008-2011 (14 September 2011), available at http://www.gire.org.mx/publica2/ReformasAbortoConstitucion_Marzo14_2011.pdf acc. 18 June 2012.

[140] See Congregation of the Doctrine of the Faith, *Dignitas Personae (on Certain Bioethical Questions)* (9 December 2008) *available at:* http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html acc. 18 June 2012.

[141] This point is stressed in Tapia R, 'La Religión y las Constituciones Estatales' *(Religion and State's Constitutions)*, *La Crónica de Hoy: Opinión* (11 November 2009) *available at:* http://www.cronica.com.mx/nota.php?id_nota=468190 acc. 18 June 2012.

[142] Faesler J, 'Nuestra Renovada República Laica' *(Our Renewed Secular Republic)*, *Este País* 228 (April) (2010) 52-5 at 53.

[143] Ibid.

[144] See Conesa Labastida L, 'Making the Best of it: A Conceptual Reconstruction of Abortion Jurisprudence in the United States and Mexico', *Mexican Law Review* II (2) (2010) 31-64.

[145] For a revision of the action of unconstitutionality presented by the Human Rights Attorney of Baja California, see Cook RJ and Erdman J (Coord), *Comentarios: Accion de Inconstitucionalidad 11/2009, Reforma al Artículo 7 de la Constitución Política del Estado Libre y Soberano de Baja California del 26 de Diciembre de 2008' (Commentaries: Action of Unconstitutionality 11/2009, Reforms to the Article 7 of the*

in October 2009, twelve legislators of the local Congress of San Luis Potosí State challenged their local constitutional reforms, alleging that these were not in line with federal constitutional provisions.[146] The Mexican Supreme Court was again convened to hear and rule on the constitutionality of the reforms challenged.[147] In September 2011, the Mexican Supreme Court dismissed the actions of unconstitutionality against the reforms of the Baja California[148] and San Luis Potosí[149] state constitutions, in which life is protected from the moment of conception.[150] Note that seven of the eleven judges who voted against the constitutionality of these reforms asserted in their concurring comments that matters concerning the constitutional protection of human rights (e.g. the right to life and women's reproductive rights) are reserved for the federation and not for local legislatures.[151] The Mexican Supreme Court needed a majority of eight judges to strike down the contested local constitutional reforms.

Arguably, the Mexican Supreme Court has shown an aspiration to advance liberties in the area of sexual and reproductive rights,[152] yet in these cases the constitutional court missed a clear opportunity to consolidate a sophisticated discussion by interpreting constitutional norms and elaborating a substantial body of judicial precedents directly relevant to the legal treatment of *in vivo* and *in vitro* created embryos, the protection of health, self-determination, freedom of research and related issues. The abortion and embryo debate is still alive in the Mexican courtroom and promises to be invoked in legal

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Constitution of Baja California on 26 December 2008), International Reproductive and Sexual Health Law Programme (Toronto, CA: 13 April 2012) *available at:* http://www.law.utoronto.ca/documents/reprohealth/BriefMexicoBajaSpanish2009.pdf acc. 18 June 2012.

[146] See González de la Vega J, 'Caso Aborto Constituciones Locales. Crónica de la Discussión IV/IV' (Abortion in the Local Constitutions Case. Chronicle of the Discussion IV/IV), Nexos en línea: El Juego de la Suprema Corte (30 September 2011), available at http://eljuegodelacorte.nexos.com.mx/?p=1479 acc. 18 June 2012.

[147] An official chronicle of the discussions held by the Mexican Supreme Court on these actions of unconstitutionality can be found in Spanish *at* http://www.scjn.gob.mx/Cronicas/Cronicas%20del%20pleno%20y%20salas/cr-290911-BCySLPvida.pdf acc. 18 June 2012.

[148] Action of Unconstitutionality 11/2009. Claimant: Attorney of the Comission on Human Rights in Baja California. The Invalidity of the Reform of Article 7 of the Political Constitution of Baja California is Dismissed Due to a Lack of Majority Vote, IUS No. 23348, (X Tenth Era) (January 2012) *at*: http://200.38.163.161/UnaEj.asp?nEjecutoria=23348&Tpo=2 acc. 18 June 2012.

[149] Action of Unconstitutionality 62/2009. Claimant: Deputies members of the LIX Legislature of the Congress of San Luis Potosi. The Invalidity of the Reform of Article 16, First Paragraph of the Political Constitution of San Luis Potosi is Dismissed Due to a Lack of a Majority Votes, IUS No. 23349, (X Tenth Era) (January 2012) *at*: http://200.38.163.161/UnaEj.asp?nEjecutoria=23349&Tpo=2 acc. 18 June 2012.

[150] See BBC News: Latin America and the Caribbean, 'Mexico Court Upholds Baja California Abortion Stance', (29 September 2011) *available at* http://www.bbc.co.uk/news/world-latin-america-15104022; also see Jurist, *'Abortion Case has Deeper Implications for Mexican Democracy'* (23 October 2011), *available at:* http://jurist.org/sidebar/2011/10/carlos-cisneros-mexican-abortion.php acc. 18 June 2012.

[151] Owing to space constraints, the concurrent comments assented by the seven judges are not analysed here.

[152] See Madrazo A and Vela E, 'The Mexican Supreme Court's (Sexual) Revolution?', *Texas Law Review* 89 (7) (2011) 1863-94.

deliberations at any time. If new actions of unconstitutionality reach the Mexican Supreme Court, such as infringements or restrictions of the freedom of research or effective protection of access to safe, high quality SC treatments, then the court could possibly interpret and extend progressively the scope of constitutional rights.[153]

In relation to the wave of reforms to local constitutions, a *de facto* political coalition is worth noting here. In most of the legislatures which have modified their local constitutions, members of the PAN do not hold a majority of seats. Rather, the PAN has been supported by PRI-legislators,[154] without whose support the reforms of the local constitutions would never have been possible.[155] These reforms were based on the same arguments put forward by the institutions that contested the reforms of Mexico City's criminal code.[156] Consequently, the political rejection of the Court's decision, which was anticipated, is a clear movement organised by the hidden coalition of the PAN and PRI in Mexico, at least on this issue.[157] The local reforms are expressions of the powerful influence of religious beliefs among the leaders of these political parties, especially given the historical links between the Catholic Church and the PAN, which has acquired new political allies to strengthen its cause.[158]

Arguably, this political alliance is motivated by the political parties' desire to attract votes in future elections from the Catholic population,[159] as well as to seek further national legislative reforms by calling for an amendment to the Federal Constitution.[160] As noted earlier, in a plural community established

[153] On the role of constitutional courts as arbiters in embryonic SC research controversies, as well as in interpreting sanctioned rights of health and freedom of research to allow SC therapeutic and research activities, see Robertson JA, 'Embryo Stem Cell Research: Ten Years of Controversy', *The Journal of Law, Medicine & Ethics* 38 (2) (2010) 191-203.

[154] Members of this political party are also presumed to hold more liberal views, since its founders were those who sought the separation of the Church from the State. For a deeper insight into the political ideologies, developments and agendas pursued by the three main political parties (PAN, PRD & PRI) in Mexico, see Wuhs ST, *Savage Democracy: Institutional Change and Party Development in Mexico* (Pennsylvania State University Press, 2008).

[155] See Amuchástegui A et al, 'Politics, Religion and Gender Equality in Contemporary Mexico: Women's Sexuality and Reproductive Rights in a Contested Secular State', *Third World Quarterly* 31 (6) (2010a) 989-1005. Recently, the PRI has allied itself with the PAN with regard to this mission. Without its support, the proposals of the PAN to amend local constitutions would not have been approved by local congresses. Only in the few states where the PRD controls the legislature have these amendments failed, in favour of more progressive regulations like those passed by Mexico City's Legislative Assembly.

[156] Ibid.

[157] Ibid.

[158] Ibid.

[159] See further: Tapia R, 'La Ciencia, el Vaticano y las Leyes' *(Science, the Vatican and Legislation)*, *La Crónica de Hoy*: *Opinión* (01 January 2009a).

[160] This is in accordance with Article 135, which literally provides that "This constitution can be amended or reformed by two thirds of the attending members of the Federal Congress at the respective session. Such amendments and reforms shall be valid when ratified by the majority of the State Legislatures. Either the Congress or the Permanent Commission during congressional recesses shall compute the State Legislature's votes and declare the approval of the respective amendments and reforms".

constitutionally on secular principles, any attempt to inject religious values into the law is considered a clear affront to the basic principles of the Federal Constitution. Controversially, by legislating in this way, members of the local legislatures are contravening the foundations of the secular state.

After the 2008 ruling of the Mexican Supreme Court of Justice on abortion and the local legislative amendments regarding the protection of life from the outset, discussions about human cloning, SC research and the status of the embryo reappeared on the federal legislative agenda. In the Senate, members of the conservative wing introduced legislative initiatives to modify the Federal Constitution and the GHA. The first legislative initiative sought to amend the Federal Constitution that, in general terms, proposed to modify Article 1 in the same terms as the local constitutions reforms.[161] The substance of this amendment is as follows:

> In the Mexican United States all individuals shall be entitled, ***from the moment of conception***, to the privileges and guarantees granted by this Constitution… .[162]

This proposal met divergent reactions in the Senate and has not yet even been deliberated. Thus, it is very unlikely that the Federal Congress will pass this proposal, since, as previously noted, legislators who support more liberal policies are currently pushing forward legislative initiatives to prevent religious doctrine from being translated into legislation.

On the other hand, the legislative initiative aiming to modify the GHA contains new provisions to be added to that legislation, placing a total ban on hESC research, as well as very tight restrictions on the use of ASC (particularly those procured from BMW) in clinical and research applications.[163] In short, the proposal consists of four clauses to be added to the GHA which would, in essence, prohibit research, manipulation or any intervention in order to carry out reproductive cloning. It also establishes what is to be understood by human reproductive cloning and prohibits the creation of embryos by SCNT, as well as the combination of any human cell with any other species, that is to

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[161] See Leal Angulo AC, *Por la Preservación de la Vida Humana* (*For the Preservation of Human Life*), 2nd Edition (Mexican Senate, LX Legislature: Legislative Initiative Presented by a Member of the PAN, 2009).
[162] Ibid, (emphasis added).
[163] Ortuño Gurza MT, *Legislative Initiative to Add Articles 100-Bis and 100-Ter and Reform Article 465 of the General Health Act*, (Mexican Senate, LX Legislature: Legislative Initiative Presented by a Member of the PAN, 25 November 2008) *available at:* http://sil.gobernacion.gob.mx/Archivos/Documentos/2008/11/asun_2507156_20081125_1227636713.pdf acc. 18 June 2012.

say the creation of animal-human chimeras.[164] It further proposes a criminal sanction for those who carry out human cloning and hESC research, amounting to the permanent cancellation of the licence to practise the medical profession in the case of healthcare providers and a range of one to eight years' imprisonment. It should be noted here that the legislative proposal contains no further provision to address the creation and use of IVF embryos which are currently cryopreserved in public and private clinics across Mexico. This last point raises several questions as to what is currently occurring in the unregulated field of ART. Mexican physicians are allegedly using SCs to treat the illnesses of Mexican and foreign patients, as well as establishing UCB biobanks, activities which are not covered by the law.[165]

These legislative initiatives are motivated and supported by the most conservative Catholic teaching on the beginning of life and the moral status of the embryo. Furthermore, renowned scientists in Mexico have called for a public dialogue in order to promote more liberal regulations and investment in the field of hESC research and SCS in general, arguing for medical progress with responsibility.[166] They stress the need for investment in this area and the enactment of adequate legislation to promote scientific knowledge and progress.[167] Mexican scientists have proposed that research on embryos should be allowed before the fourteen-day of embryonic development, because only after that point does the primitive streak develop and life become morally relevant.[168] Therefore, the use of early embryos for research is reasonable and desirable if there is an interest in furthering the creation of knowledge and the discovery of new ways to develop therapies to alleviate illness.[169]

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[164] The text of the legislative proposal does not make particular reference to a scientific definition of animal-human chimeras. It is also restricted to stating that any combination of genes different from those of the human species to create embryos is prohibited. The legislator is ambiguous when talking about this kind of embryo. However, the reference made corresponds to the prohibition of creating admixed embryos. It is also relevant that this legislative initiative is identical to the one previously presented in the lower house of the Federal Congress in 2003; also see Brena Sesma I, *op. cit. supra* note 30.

[165] See Dhar D and Hsi-en Ho J, 'Stem Cell Issue: Stem Cell Research Policies Around the World', *The Yale Journal of Biology and Medicine* 82 (3) (2009) 113-15.

[166] See AMC, *op. cit. supra* note 76.

[167] See Tapia R, 'Urgen Apoyos a la Investigación con Células Troncales en México' *(Urgent Need to Fund Stem Cell Research in Mexico)*, *Gaceta Electrónica INNOVACIÓN* 5 (5) (2008).

[168] See Tapia R, 'La Ética de la Investigación Científica y los Límites de la Ciencia' *(The Ethics of Science and the Limits of Science)*, in Alvaréz del Río A and Rivero Weber P (Eds) *El Desafío de la Bioética (The Challenge of Bioethics)* (Vol II; Mexico: FCE, 2009) 29-58; also see Chapter 6, Section 6.6.2 for more on gradualist stances towards embryo research in this context.

[169] See Lisker R and Tapia R, 'Clonación y Células Troncales' (*Cloning and Stem Cells)*, *Nexos* XXVIII (343) (2006) 29-33.

5.5. CONCLUDING REMARKS

For almost a decade, there has been considerable yet limited public discussion of SCS among legislators and between the scientific and legal communities. Much of the legislative effort has focused on prohibiting hESC research, yet no law has been enacted, creating a legal lacuna in this area.[170] SCS remains unregulated, leaving scientists and private clinics uncertain about what is permitted or prohibited in this area of biomedicine.[171] The brief and unsuccessful debates involving the regulation of SCS that have taken place in the Federal Congress and the associated discussions regarding the constitutional protection of life are just the beginning of the long process of regulating the emerging biotechnologies and are part of the interaction between religious and public moralities.

This chapter has discussed the initial political and legal battles surrounding the development of SCS in Mexico, along with the closely linked theme of the protection of life from the outset, which has prompted numerous political, legal and religious disputes. It has also explored the divergent views that were brought into the public sphere when the constitutionality of abortion laws in Mexico City was challenged. The Mexican Supreme Court was required to interpret the Federal Constitution in order to decide whether or not life is protected from the outset under constitutional provisions. However, the question of the protection of embryonic life is still disputed and remains unsolved in this context. The available discourses are highly emotional and imbued with religious doctrine, although opposing views tend to predominate. The continued lack of a specific regulatory framework is explained by the prevailing divergence of political interests and of ideological positions on the beginning of life and the legitimacy of biotechnological research into aspects of SCS.

The analysis of the seminal rulings of the Mexican Supreme Court evidences the difficulty of regulating activities related to the protection of life and to the intertwined debate regarding hESC research. It also reveals that the Mexican Supreme Court has gained relevant social and legal significance in

[170] See LeRoy W, 'An Intercultural Perspective on Human Embryonic Stem Cell Research', in Østnor L (Ed) *Stem Cells, Human Embryos and Ethics* (Oslo, Norway: Springer, 2008) 91-110.
[171] See González Martín N, 'Las Células Madre o Tróncales: Su Itinerario Jurídico en México' *(Stem Cells: Its Legal Agenda in Mexico)*, in Cienfuegos Salgado D and Macias Vazquéz MC (Eds) *Estudios en Homenaje a Marcia Muñoz de Alba Medrano: Bioderecho, Tecnología, Salud y Derecho Genómico (Studies in honour of Marcia Muñoz de Alba Medrano: Biolaw, Technology, Health and Genomic Law)* (Mexico: IIJ -UNAM, 2006) 247-60.

interpreting constitutional provisions. It has played a determinant role in ending legal disputes concerning the unconstitutionality of legal norms when legislators have failed to enact norms in accordance with constitutional provisions. Given the social regard in which the Mexican Supreme Court's decisions are held, it may be plausible for it to decide ultimately whether or not hESC research and SCS activities can proceed lawfully in accordance with constitutional norms. It may be time to discuss the issue from a different perspective, in social contexts where religious values still prevail.[172] In order to take a new standpoint on emerging biotechnologies (e.g. those related to SCS and its applications), legislators and policy-makers should call an ordered dialogue and public deliberations such as those organized by the Mexican Supreme Court. Such a programme of public deliberation might promote dialogue among stakeholders, legislators, religious groups and lay people, thus facilitating the achievement of agreement and political compromise over the regulation of SCS.

The current regulation in this area appears to be determined by the effectiveness of the Catholic Church's lobbying of policy-makers and legislators. The debate is profoundly dichotomous and sources of dissent have been suppressed and labelled as religious and archaic. On one hand, the federal government has clearly acted to encourage biotechnology applied to medicine (e.g. genomic medicine) in the country, while on the other, there is an approach to maintain restrictive policies towards particular biotechnology innovations, such as those applied to SCS.

Biomedical research and some activities involving the use of SCs are rapidly emerging in Mexico, driven by alliances of private investors and their interests, as well as those of foreign biotech industries. This will continue to develop further in the absence of any ethical or legal provisions. A crucial point here is that the enormous biotechnological potential and existing infrastructure for the conduct of biomedical research, combined with the lack of regulation of SCS and connected matters, make it feasible and favourable for foreign alliances, along with private clinics and research centres in Mexico, to conduct these activities without any legal or ethical surveillance.[173] It is to be hoped that legislators will take steps in the near future towards the creation of a legal framework in the SCS field.

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[172] See Diniz D, 'Embryonic Stem Cell Research: Ethical Challenges for Developing World Bioethics', *Developing World Bioethics* 8 (3) (2008) ii-iv.
[173] See Chapter 7 on this point.

CHAPTER 6

PAPER 2: CONTESTED SECULARITY: GOVERNING STEM CELL SCIENCE IN MEXICO[1]

> *… We live in a time when knowledgeable citizens are more than ever demanding meaningful control over the technological changes that affect their welfare and prosperity. Many therefore see this epoch as a proving ground for new political orders whose success will depend, in part, on our learning to live wisely with our growing capacity to manipulate living things and our equally growing uncertainty about the consequences of doing so.*[2]

6.1. INTRODUCTION

In the global economy, the governance of novel technologies could substantially influence the scientific, legal and economic growth of any nation.[3] Mexico, among other Latin American countries, is undergoing varied socio-cultural, religious and political confrontations pertaining to emerging biotechnologies, such as SCS.[4] In this case, the emergent debate on the ethics and regulation of SCS is clearly divided between conservative and more liberal stances.[5] This discussion has paralleled the disputes about the decriminalisation of abortion.[6] The central concern is the degree of protection deemed to be appropriate for the embryo with regard to its use and destruction, in order to obtain SCs for research.

Given the plurality of voices competing in the same space, this chapter aims to portray the emerging struggles that have promoted a legal inertia and a lack of political compromise to urge public dialogue, which will allow the

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[1] Adapted from Medina-Arellano MdJ, 'Contested Secularity: Stem Cell Governance in Mexico', *Science and Public Policy* 39 (3) (2012) 386-402.
[2] Jasanoff S, *Designs on Nature: Science and Democracy in Europe and the United States*, 4th Edition (Princeton, N.J.: Princeton University Press, 2007) at 14.
[3] Gottweis H, Salter B and Waldby C, *The Global Politics of Human Embryonic Stem Cell Science: Regenerative Medicine in Transition* (Basingstoke; New York: Palgrave Macmillan, 2009) at 20.
[4] For example, in August, 2011, Costa Rica's government was sued before the IACtHR, see No. 91/11, IACHR takes case involving Costa Rica to Inter-American Court, *available at:* www.cidh.oas.org/Comunicados/English/2011/91-11eng.htm acc. 17 June 2012; Costa Rica maintains a continued ban on ART, this prohibition has extensively based on religious arguments advanced by the Catholic Church and other religious groups in the country which maintain that ART constitutes a violation of the embryo's right to life, on this see Morven S and Vanderpoel S, 'Comment: Right to Life vs Right to Found a Family: The Case of Costa Rica', *BioNews* 625 (19 September 2011) *at:* http://www.bionews.org.uk/page_106023.asp acc. 17 June 2012. It is certainly the case that whatever decision is adopted by the IACtHR over this conflict will influence the regulation of the ART and SCS fields in the region.
[5] See Chapter 5, Section 5.2.
[6] Ibid.

establishment of governance for innovative biotechnologies, particularly SCS.[7] Thus, after describing some background data and the methodology utilised for this study, I seek to gain an insight into the core themes framing the debate, with regard to the ethics and regulation of SCS in Mexico. This analysis is drawn from the information elicited from seven semi-structured interviews with key Mexican stakeholders participating in the emerging SCS debate. In this account of stakeholders' perceptions, it is intended to present, as closely as the qualitative data allows, the main issues featured and the challenging questions of this domain. In so doing, this chapter provides a brief examination of the regulatory milieu. It then explores the current cultural diversity, as well as the religious and political activism prevailing in this context, which have nuanced the emergent discussion on SCS. It is suggested that a clearer understanding of the science and issues arising out of SCS needs to be disseminated, clarified and further inspected by expert bodies and policymakers if regulation in this area is ever to be achieved.

It is also argued that a flexible approach towards SC regulation is feasible, based on constitutional provisions, such as the right to healthcare protection and to pursue scientific and technological progress, as well as the obligation to guarantee freedom of research, which will be discussed in more detail below.[8] Notwithstanding that the Mexican legal system is theoretically permissive for SCS,[9] it is acknowledged, given the enduring conflicts between science, religion and political interests, it is unlikely that a national legal framework will be adopted unless there is a genuine institutional and political compromise

[7] In analogous socio-cultural plural endeavours, based on qualitative studies, the remarkable constraints within the scientific, social and cultural configuration toward achieving regulation for emerging biotechnologies have been shown; thus, proposals have been made to establish public dialogue and engagement in seeking to achieve facilitative regulation in a context where science is a goal to be pursued, as it is in the Argentinean case. On this, see Harmon SHE, 'Peering from the Shadows: Stem Cell Research and the Quest for Regulation in Argentina', *Stem Cell Reviews and Reports* (2011) and 'Ambition and Ambivalence: Encouraging a "Sci-Tech Culture" in Argentina through Engagement and Regulatory Reform', *Studies in Ethics, Law, and Technology* 5 (1) (2011a) Article 1, http://www.bepress.com/selt/vol5/iss1/art1/ acc. 17 June 2012.

[8] See Brena Sesma I, 'Hacia una Regulación Jurídica en México sobre la Investigación en Células Troncales' *(Towards Stem Cell Research Regulation in Mexico)*, in Brena Sesma I (Ed) *Células Troncales. Aspectos Científicos-Filosóficos y Jurídicos (Stem Cells. Scientific-Philosophical and Legal Aspects)* (Mexico: IIJ-UNAM, 2005) 181-194. For a concise introduction to the promising research on SCs being conducted in Latin America, see Borbolla-Escoboza JR, 'Stem Cells and Development in Latin America', *Stem Cells and Development* 19 (3) (2010) 283-4. On an international scale, it has also been reported that, despite the absence of legislation for SCS in Mexico, it actually has a 'flourishing stem cell industry'. See Dhar D and Hsi-en Ho J, 'Stem Cell Issue: Stem Cell Research Policies Around the World', *The Yale Journal of Biology and Medicine* 82 (3) (2009) 113-15 at 115.

[9] See Morales Aché PI, 'Un Enfoque Jurídico sobre la Clonación y Utilización de las Células Troncales Embrionarias' *(A legal Approach on Cloning and the Use of Embryonic Stem Cells)*, in Foro Consultivo Científico y Tecnológico FCCyT (Ed) *Seminario de Clonación y Células Troncales: Memorias (Seminar on Cloning and Stem Cells: Memoirs)* (Mexico: FCCyT, 2006) 77-87.

oriented towards achieving sustainable economic growth parallel to the wellbeing of the community.

While the existing antagonistic views regarding the embryo represent the main difficulty in consolidating regulation in the area, to date, there has been substantial basic and clinical research on ASCs in the country, but no evidence of research conducted on hESCs thus far.[10] Most of interviewees articulated that they hold a gradualist approach to the protection of embryos. In view of this, it is feasible to advocate for a legal framework for SCS which allows the use of spare embryos from ART clinics, since otherwise, they will be discarded. Up to now, the final destiny of the now thousands of existing frozen embryos is not clear due to the legal vacuum in this area.[11]

Finally, it is stressed that this legal lacunae in this terrain should not remain simply because researchers and clinicians are uncertain about the ethics and regulation that they are expected to follow. Furthermore, this unregulated scenario prevents researchers from engaging in sophisticated basic and applied SC research, which may potentially assist myriad patients hoping to benefit from advances in regenerative medicine.[12]

6.2. LEGISLATIVE INERTIA: PLURALISM AND RADICAL VOICES

It is pertinent to examine the background to the latest developments shaping the SCS controversy in Mexico. As highlighted before, this mirrors the complexities that some countries face where there is great Catholic influence and cultural pluralism when legislative initiatives to regulate emerging technologies are proposed.[13] Notably, debates on embryonic protection and SCS began as a result of religious politicisation encompassing the liberalisation of

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[10] See Mayani H, 'Células Troncales y Medicina Regenerativa en México', (*Stem Cells and Regenerative Medicine in Mexico)*, in Pelayo R, Santa-Olalla J and Velasco I (Eds) *Células Troncales y Medicina Regenerativa (Stem Cells and Regenerative Medicine)* (Mexico: UNAM, 2011) 347-60.

[11] ART technologies have now been available in Mexico for more than three decades, without ethical and legal oversight. Up until now, uncontrolled creation and vitrification of embryos for ART purposes is a common practice in the country; for example, see González-Santos SP, 'Space, Structure and Social Dynamics within the Clinical Setting: Two Case Studies of Assisted Reproduction in Mexico City', *Health & Place* 17(1) (2011) 166-74. In May 2011, an attempt to regulate ART in the country was made in the Federal Congress. However, this legislative initiative was not passed and has not yet actually been discussed. See Damián F and Valadez B, 'Frenan en San Lázaro Proyecto de Reproducción Asistida' (*In San Lazaro the Legislative Initiative to Regulate Assisted Reproduction was Set Back)*, *Milenio online* (8 November, 2011) http://prestage.milenio.com/cdb/doc/noticias2011/97186011b1e2c6897862b4e1b270534c?quicktabs_1=1 acc. 17 June 2012. For the purposes of scope and space, this legislative initiative is not analysed in detail here, however, major points of connected issues are laid out.

[12] The absence of targeted regulation also actualizes the potential harms to patients currently undertaking uncontrolled SC therapies offered across the country. This issue deserves fuller analysis which is presented in Chapter 7 of this thesis.

[13] See Chapter 5, Section 5.4.

abortion, similar to those that have occurred in comparable contexts.[14] Similarly, in Mexico there have been two episodes where SC research was discussed in parliament[15] -just after legislative reforms on abortion laws in Mexico City[16] and the related judicial decisions.[17] The aforementioned reforms were contested before the Mexican Supreme Court, which later upheld their constitutionality.[18] However, the Supreme Court cautiously neglected to enter a profound interpretation with regard to the scope of legal protection ascribable to *ex utero* or *in utero* embryos.[19]

On the other side of the spectrum, as a result of the judicial confirmation of the legality of the decriminalisation of abortion in Mexico City, a conservative campaign from religious (mainly Catholic) and right-wing political groups against these reforms and judicial decision was widely dispersed all across the country.[20] The concerns maintained by conservative groups regarding further liberalisation of abortion in other jurisdictions and progressive horizons for embryo and SCS regulation, led them to put forward constitutional amendments in states legislatures.[21] Therefore, the local constitutions of some states were reformed to incorporate:

> …the protection of life from the moment of 'conception' until its natural end.[22]

This is manifestly in line with the wording used in Catholic doctrine.[23] To a great extent, these constitutional reforms are troublesome, inasmuch as the conquest of secularity in Mexico was complicated and was achieved with many

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[14] See, for example, the US debates in Wertz D, 'Embryo and Stem Cell Research in the United States: History and Politics', *Gene Therapy* 9 (2002) 674-8.

[15] It should be noted that these legislative attempts to regulate the area were expected to be inclined to liberalise SCS policies in the country; however, that has not occurred. See Isasi RM & Knoppers BM, 'Mind the Gap: Policy Approaches to Embryonic Stem Cell and Cloning Research in 50 Countries', *European Journal of Health Law* 13 (2006a) 9-25 at 20.

[16] It is worth noting that the legislators who passed these reforms in Mexico City were considered to maintain leftist and progressive idelogogies on these matters. See Carrillo H, 'Imagining Modernity: Sexuality, Policy and Social Change in Mexico', *Sexuality Research and Social Policy* 4 (3) (2007) 74-91 .

[17] See Chapter 5, Section 5.4.1 for the latest Mexican Supreme Court's rulings on abortion.

[18] Ibid.

[19] Since the issue at stake was not the legal status of human embryos but rather the reproductive rights of women, it is understandable to a limited extent that the moderate discussion undertaken by the Mexican Supreme Court did not extensively include human embryo matters. During the writing of this thesis, in September 2011, the Mexican Supreme Court uphold the constitutionality of Baja California and San Luis Potosi's State constitutions that protect life from the outset, this ruling has only minnor impact on the general arguments stated herein.

[20] See Amuchástegui A et al, 'Politics, Religion and Gender Equality in Contemporary Mexico: Women's Sexuality and Reproductive Rights in a Contested Secular State', *Third World Quarterly* 31 (6) (2010a) 989-1005.

[21] See Chapter 5, Section 5.4.2.

[22] Ibid.

[23] See Tapia R, 'Aspectos Genómicos y Neurobiológicos de la Formación de la Persona Durante el Desarrollo Intrauterino' *(Genomic and Neurobiological Aspects of the Formation of the Person during the Intrauterine Development)*, GIRE (October 2009a), *available at:* http://www.gire.org.mx/publica2/AspectosGenomicos_oct09.pdf acc. 17 June 2012.

difficulties: it has cost many lives, as history recalls.[24] Furthermore, religious influence over state affairs is a hazardous reality for a pluralistic nation, since it jeopardises and undermines the secular foundations of the country. Therefore, it is imperative to establish a comprehensive public dialogue in which stakeholders, politicians and religious actors can embrace the necessary legislative actions, in order to accommodate diverse lay views and cultural and religious plurality at the same time.

6.3. METHODOLOGY

A qualitative methodology is adopted with the aim of capturing the lived experiences of the interviewed stakeholders, which also allows for the generation of contextual and critical ethical analysis.[25] Following qualitative methods, as applied to empirical bioethical inquiries, seven in-depth semi-structured interviews with an open-ended questionnaire were administered, in order to encourage participants to converse about their individual perceptions and attitudes towards SCS.[26]

In keeping with the methods adopted, the selection of participants was as follows: all the respondents are from Mexico and are prominent stakeholders who can potentially shape and influence the policy-making process and governance for emerging biotechnologies.[27] The criteria for the inclusion of the key stakeholders included a wide range of backgrounds. Whenever direct quotations are included, they are as follows: S1 (Physiologist), S2 (Judge), S3 (Medical Lawyer), S4 (Medical Lawyer), S5 (Physician), S6 (Senator) and S7 (Chemist). All of these stakeholders have contributed to the emergent SCS discussions, plus they hold top positions in academic and government institutions participating in the discussion (see Table 6.1).[28] The quotations

[24] For an historical account of the struggles between the Catholic Church and the Mexican State, which at one point erupted in a lamentable battle widely known as the "Cristero War", see Wilkie JW, 'The Meaning of the Cristero Religious War against the Mexican Revolution', *Journal of Church and State* 8 (2) (1966) 214.

[25] See Holm S and Jonas MF, Engaging the World: The Use of Empirical Research in Bioethics and the Regulation of Biotechnology (Oxford: IOS Press, 2004).

[26] Socio-bioethical inquiries pertaining to the study of contested issues surrounding basic and translational SCS are valuable methodological instruments to identify emergent themes gaining relevance in this field, including the identification of areas of understanding or disagreement; an example of an empirical investigation conducted to reflect on the ethical issues relating to SC clinical settings can be found in Williams C and Wainwright S, 'Sociological Reflection on Ethics, Embryonic Stem Cells and Translational Research', in Capps B and Campbell A (Eds) *Contested Cells: Global Perspectives on the Stem Cell Debate* (London: Imperial College Press, 2010) 157-188.

[27] See Sankar P and Jones NL, 'Semi-Structured Interviews in Bioethics Research', in Jacoby L and Sminoff LA (Eds) *Empirical Methods for Bioethics: A Primer* (Vol 11: Emerald Group Publishing Limited, 2007) 117-36.

[28] In some cases, when explicitly asked I was fully authorised to use the names of interviewees, but although permission has been obtained, it was decided to use the above-listed anonyms for the sake of

employed in the body of this chapter were carefully chosen to be representative of the opinions elicited from the available sample. The direct citations inserted are used to support the specific points and arguments introduced, as well as the particular claims sustained by stakeholders. With the permission of the participants, the interviews were digitally recorded and transcribed.[29] Transcripts were examined using qualitative content and thematic analysis, which also permitted the revision of every line of the transcription that was coded accordingly. This task was repeated and refined to assure accuracy and to incorporate emergent themes and information.[30] Follow-up electronic correspondence was continued with the participants, in order to seek feedback and agreement on the content transcribed from the interviews. In a few cases, additional data for the enrichment of the research was provided. The participants signed a consent form and were promised anonymity. They were notified that they possessed the right to refuse to participate and to withdraw their consent at any time, in order to safeguard their safety and confidentiality.

Some necessary limitations to this inquiry are acknowledged. Due to the small size of the sample that was used, wider community views cannot be claimed from the empirically generated representativeness, and the extent to which SCS is acceptable be determined from this data. Nevertheless, the main issues being disputed can be identified. Notwithstanding the above-stated empirical constraints, the study aims to provide a point of reference and contribute to tracking the roots of the emergent discussion of SCS regulation.

6.4. A Regulatory Framework for Stem Cell Science

The growing field of regenerative medicine across Mexico must incentivise government efforts to put adequate legal controls in place, especially when this field extends to commercial and therapeutic applications.[31] As stated in Chapter 5, Section 5.3.1 of this thesis, the Mexican constitution is silent regarding the legal treatment of the embryo. Although there are some secondary provisions

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the neutrality of the research being conducted. However, professions and institutional affiliations are provided in Table 6.1, in order to shed light on the backgrounds shaping the context and discussion. It is worth mentioning that two Catholic priests and the president of the most active pro-life organisation in Mexico were invited to participate in this inquiry; however, neither a negative nor a positive response was obtained from either of them.

[29] Interviewees were recruited by personal invitation mailed electronically following the approval of the internal ethics committee of the School of Law, University of Manchester. The interviews lasted between 45 and 115 minutes. The author personally conducted the interviews in Spanish between November 2009 and January 2010. All paritcipant's quotations used in this investigation are my own translations unless otherwise indicated; therefore all transliteration oddness remain as my own errors.

[30] See Forman J and Damschroder L, 'Qualitative Content Analysis', in Jacoby L and Sminoff LA (Eds) *Empirical Methods for Bioethics: A Primer* (Vol 11: Emerald Group Publishing Limited, 2007) 39-62.

[31] As explored in Chapter 7 of this thesis.

that mention this subject, they fall short of confronting the issues at stake.[32] In what follows, the existing constitutional provisions are succinctly examined. Thus, as was also suggested by the stakeholders, diverse legal routes should be explored in attempting to consolidate a facilitative and flexible legal framework for SCS.

In June 2011, legislators of the Federal Congress passed a seminal constitutional reform concerning fundamental human rights. [33] This constitutional reform incorporated the observance of internationally sanctioned human rights into the section previously known as 'fundamental rights', which contained the so-called individual guarantees of citizen; it has now been modified to contain 'human rights and guarantees'.[34] Accordingly, Article 1 expressly recognises the application of fundamental human rights and requires authorities to adhere to and comply with the international human rights treaties signed and ratified by Mexico.[35] Furthermore, Article 3, Sections V and VI, enshrine the obligation on the state to respect the freedom of research and to pursue the development of scientific and technological research.[36] Article 4, third paragraph, sets health protection as a constitutional right, it stipulates that: "...Every person has the right to ***healthcare protection***...".[37] Accordingly and grounded on those constitutional provisions, the use of a human rights approach to advance SCS and its regulation appears to be feasible.[38]

As stated, according to Article 3 of the constitution, there is a burden on the state's government to promote freedom of research and investigation in science and technology.[39] Furthermore, this freedom of research, as well as the right to enjoy the benefits of scientific progress and its application have also been endorsed as fundamental rights in international legal documents.[40] For instance, these rights are established, respectively, in Article 12 of UNESCO's

[32] See Chapter 2, Section 2.7.
[33] For a further revision of this constitutional reform, see Chapter 2, Section 2.3.
[34] See the Official Decree published in the Mexican Official Federal Gazzete, http://www.dof.gob.mx/nota_to_imagen_fs.php?codnota=5194486&fecha=10/06/2011&cod_diario=237901 acc. 17 June 2012.
[35] Ibid.
[36] The constitutional right to promote science and technology research is further regulated by its secondary regulation, the Science and Technology Act.
[37] See Chapter 2, Section 2.7.
[38] The idea of connecting a human rights approach to regulation of certain health areas in Latin America has previously been advanced, in particular, as a tool for tobacco control; see Cabrera OA and Madrazo A, 'Human Rights as a Tool For Tobacco Control in Latin America', *Salud Pública de México* 52 (2010) S288-S97.
[39] See Chapter 2, Section 2.6.
[40] See Ruffert M, *The Global Administrative Law of Science* (New York: Springer, 2011) 29-53.

Universal Declaration on the Human Genome and Human Rights (1997),[41] in Article 2 of the Universal Declaration on Bioethics and Human Rights (2005)[42] and Article 15, first paragraph of the UN International Covenant on Civil and Political Rights (1966),[43] all of which Mexico has agreed to. However, public policies have not yet addressed the issue of basic and clinical SCS, this in fulfilment of the constitutional norm, as must be if the fundamental right of freedom to pursue scientific research is to be realised. Some steps have been taken in order to draw legislative attention to this topic: for instance, seminars have been organised by legislators to bring together well-established investigators from different areas, who have participated actively in the bioethical arena.[44] Regarding the political complexity to achieve regulation, one of the stakeholders (S3) stated:

> ... here in the area of Health and Law, we have organised public debates, we have invited researchers ... we had a public event about stem cells in 2004, where they came …the publication is of 2005 and they came in 2004, … experts came from everywhere in the world, from the United States, Europe, … and they talked about the topic … I believe that it is very important to disseminate the knowledge [of SCS]; as long as there is no knowledge it is not possible to have an informed debate… unfortunately, at the moment all topics are seen by the political parties as points to be compromised. In other words, you cede this to me and I concede to you another piece, like a pawn within a political game, and in reality they are not realising how important these topics are for the population, and not only for the wider population but for individuals, since these are topics that also concern the privacy of the person.

On the other side of the spectrum, a crucial point was raised by the stakeholders: the necessity to establish clear aims in developing a platform for SCS, in addition to the transparency of the research process and products, if the research projects are deemed to be based on the potential health benefit that they represent for the community.[45] The stakeholders felt that the failure to

[41] See Harmon SHE, 'The Significance of UNESCO's Universal Declaration on the Human Genome & Human Rights', *SCRIPTed: A Journal of Law, Technology & Society* 2 (1) (2005) 20-46.
[42] See Ten Have H and Jean MS (Eds), The UNESCO Universal Declaration on Bioethics and Human Rights: Background, Principles and Application (Paris: UNESCO, 2009)
[43] See Chapman AR, 'Towards an Understanding of the Right to Enjoy the Benefits of Scientific Progress and its Applications', *Journal of Human Rights* 8(1) (2009) 1-36.
[44] See Foro Consultivo Científico y Tecnológico FCCyT (Ed), Seminario de Clonación y Células Troncales: Memorias (Seminar on Cloning and Stem Cells: Memoirs) (Mexico: FCCyT, 2006).
[45] This argument, which is based on the potential contribution of SCS and its clinical applications to alleviate health suffering, 'the social utility aim', has been used to generate the production of SC biovalue

achieve a legal framework for this research activity and the lack of success in the creation of a legal framework are due to legislative inconclusiveness, as well as a lack of clarity of the objectives and goals to be pursued by researchers.[46] Stakeholder 3 affirmed:

> I think that the problem should not be centered only on the embryo, but the problem or part of the problem must be focused on the aim, and I believe that it is very important, the aim of the research on stem cells, if we take into account that research on stem cells is going to permit the advance of science, but also to a certain extent we cannot totally believe in what scientists are saying, that they are going to discover cures for all illnesses, so I believe that we have to be cautious, but to take into account: What is the aim? What is the cost? What are we going to clarify? What are we going to get out of this research? And I believe that this point of view of what is the aim that is sought [in SC research] is not present in the discussion.

On that same point, Stakeholder 6 stated:

> I believe that this has to be done [SCS] through very clearly established projects which are related to the combat of illness, very well defined in … not only in our country but everywhere in the world, that is to say, the manipulation or work on stem cells must always be linked to a project that aims to attack the most serious illnesses in the country.

Stakeholders suggested that the regulation of SCS must be the result of a comprehensive public, plural and secular debate, given the diverse religious and cultural voices prevailing in this context. Moreover, any policy and regulation adopted regarding biosciences, specifically SCS, must look at the local context and the specific points that it is attempting to regulate. In doing so, a democratic deliberation regarding science, technology and innovation is more likely, which needs to be in line with the most recent advances in science, and

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to advance this field; see Waldby C, 'Stem Cells, Tissue Cultures and the Production of Biovalue', *Health* 6 (3) (2002) 305-23.

[46] The importance of achieving transparency and clarity on the objectives pursued when conducting SC research has been highlighted as a necessary step in order to gain the necessary accountability and trust to effectively develop and regulate this field while at the same time, it guarantees the integrity of scientists and encourages the sharing of the scientific knowledge. See Devaney S, *The Regulation of Innovation: Legal and Ethical Issues in Stem Cell Research* (School of Law, University of Manchester: PhD Thesis) (2010) 260; also see Knoppers BM, Isasi RM and Willemse L, 'Stem Cell Charter', *Regenerative Medicine* 5 (1) (2010) 5-6.

which is to make best use of available resources.[47] Currently, not all voices were included in the limited discussion:

> The stem cell debates and regulation are being conducted without taking into account the researchers' voices. (S1)
>
> I am in favour of human embryonic stem cell research, but due to political pressures in my work, I cannot assume an open posture. (S4)
>
> I am in favour of a more progressive and permissive approach. (S6)

As a point of reference, the stakeholders indicated that the successful regulatory reforms of other countries must be followed, and permissive approaches were favoured.[48] Most of stakeholders agreed with the establishment of an expert body, which would review and license any research on a case-by-case basis, as is the case in the UK.[49] Stakeholders indicated that the implementation of an expert ethical regulatory bodies meticulously deciding, case-by-case, on the SC treatments and experiments to be conducted in the country is desirable.[50] The expertise of ethics oversight bodies, as similar to the HFEA in the UK, would provide an example of how to regulate emerging technologies like hESC research, while providing protection and a certain level of respect for embryos.[51] For instance, they indicated that, in order to be in accordance with this expertise and licensing model:

> … in principle… we need to state that it [SC research] must be considered case by case, and it must be legislated accurately. This will allow us to determine what is valid or not. (S4)

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[47] In democratic societies all voices need to be heard in looking an agreement or middle point about contended issues such as SCS, particularly when it involves the use of early embryos or its creation solely for research purposes. See Cohen CB, *Renewing the Stuff of Life: Stem Cells, Ethics, and Public Policy* (Oxford: Oxford University Press, 2007).

[48] It is acknowledged that an effective regulatory solution for the challenges actualised by SCS is difficult to achieve. However, it is possible to improve the norms in any regime that is adopted. See Brownsword R, *Rights, Regulation and the Technological Revolution* (Oxford: Oxford University Press, 2008).

[49] See Chapter 4 for an examination of the UK system of SCS governance, as well as the possibility of emulating certain regulatory features in the Mexican legal regime. As indicated by Sarah Franklin, the British legislative experience may allow fruitful regulatory lessons to create a preferable legal setting, rather than no legislation at all, see Jacob MA and B Prainsack B, 'Embryonic Hopes: Controversy, Alliance, and Reproductive Entities in Law and the Social Sciences', *Social & Legal Studies* 19 (4) (2010) 497-517.

[50] See Allyse M, 'Embryos, Ethics and Expertise: The Emerging Model of the Research Ethics Regulator', *Science and Public Policy* 37 (8) (2010) 597-609.

[51] See Holm S, 'Therapeutic Cloning and the Protection Of Embryonic Life: Different Approaches, Different Levels of Protection- A View from the United Kingdom', in Gunning J, Holm S and Kenway I (Eds) *Ethics, Law, and Society* (Vol IV; Aldershot: Ashgate, 2009) 229-36.

> The research should be permitted upon approval of a specific committee that could guarantee the transparency, responsibility and efficiency of the researchers. (S3)

Nevertheless, a few stakeholders acknowledged that SCS and its regulation in Mexico is not a priority in the legal, economic and political agendas. For example:

> Look, in accordance with the General Health Act, in terms of new technologies which impact health and its need for legislation, I find that there are 10 things more important to legislate on than human stem cells [research]. (S7)

In opposition to the secondary importance attributed by a few of the stakeholders to SCS regulation in Mexico, the majority of stakeholders expressed the view that organised ethical debates are needed before sophisticated SCS activities are undertaken. An open dialogue, which includes scientists and the wider community, is also called for, in order to evaluate the types of SC research and the benefits and potential harms this science represents. Nevertheless, as analysed from the elicited perceptions, due to the enduring divergence and battles between conservative, religious and secular positions, at the present, it is not clear whether the creation of any legal framework for SCS will be adopted. The enduring religious and political disputes over the regulation of certain scientific activities lead legislators to enact prohibitive provisions that in the longer term obstruct the global scientific development and delays biotechnology innovation.[52] Notwithstanding that it is the state's duty to guarantee the freedom of scientific research and its progress,[53] the federal legislature has failed to generate an ordered debate that might culminate in an appropriate legal framework.

6.5. CONTROVERSIAL CELLS IN CONTEXT

The overt opposition towards biomedical activities is characterised by the antagonistic discourses articulated by pro-life (conservative) groups and leaders of the Catholic Church.[54] On the other hand, the growth of opposing liberal stances represented by pro-choice (predominantly secularist) groups creates

[52] See Marchant GE and Pope L, 'The Problems with Forbidding Science', *Science and Engineering Ethics* 15(3) (2009) 375-94.
[53] See Donders Y, 'The Right to Enjoy the Benefits of Scientific Progress: In Search of State Obligations in Relation to Health', *Medicine, Health Care and Philosophy* 14(4) (2011) 371-81.
[54] See Tapia R, 'La Ética de la Investigación Científica y los Límites de la Ciencia' *(The Ethics of Science and the Limits of Science)*, in Alvaréz del Río A and Rivero Weber P (Eds) *El Desafío de la Bioética (The Challenge of Bioethics)* (Vol II; Mexico: FCE, 2009a) 29-58.

parallel endeavours. This situation makes it difficult to legislate on controversial bioethical issues, thus it has given rise to legal vacuums not only for SC research but also for ART and health-related legislation.[55] Based on the empirical data collected, this section outlines, in broader terms, the factors obstructing the establishment of a deliberative body, which would lead to the creation of concrete minimum legal standards for the advancement of SCS. It also provides a general overview of the policies promoted, so far, on innovation in biotechnology. The interview data suggests that the scientific and political course of events to regulate SCS activities are not very promising, at least for the moment. This unpromising scenario is marked by a lack of political interest to promote emerging biomedical technologies and innovation. The legislative inertia also reflects a reluctance to engage in an interdisciplinary and meaningful conversation over the status of embryos, even in the face of clear evidence that the fate of surplus embryos left over from fertility treatment is unknown.[56]

6.5.1. The Political and Bioethical Struggle: Catholicism versus Secularism

The PAN political party, currently in power in Mexico,[57] has shown a conservative stance towards certain biomedical technologies, in specific SCS.[58] This is mostly based on arguments extracted from Catholic doctrine.[59] Furthermore, this political party has shown a particular reluctance to encourage the advancement of SCS or any closely related activity.[60] However, the presence of legislators with Catholic views is not limited to the PAN: on the contrary, it is also present in other political parties that are supposed to uphold more secular views.[61] For example, other prominent PRI-members have joined conservative sectors to promote a prohibitive agenda on bioethical dilemmas, in order to obtain the sympathy and votes of the Catholic constituency.[62] Following this

[55] See Tapia R, 'La Religión y las Leyes sobre Salud' *(Religion and Health Laws)*, *La Crónica de Hoy: Opinión* (22 June 2011) http://www.cronica.com.mx/nota.php?id_nota=587145 acc. 18 of June 2012.
[56] Ibid, *supra* note 11.
[57] At the time of writing of this thesis.
[58] See Chapter 5.
[59] See Blancarte R, '¿Qué Significa hoy la Laicidad?' *(What Does Secularity Mean Nowadays?) Este País* 228 (April) 2010) 30-3.
[60] See 'Religiones, Bioética y Estado Laico' *(Religions, Bioethics and Secular State)*, *Milenio: Jalisco* (27 April 2010a) http://impreso.milenio.com/node/8757593 acc. 18 June 2012.
[61] Similarly, in the case of Germany and the USA, where policies regarding hESC research are informed not only by minority religious articulations but also by a broader secular population that inserted into the SC discourses voices of scepticism and notes of caution regarding emergent technologies. See Jasanoff S, *op. cit. supra* note 2.
[62] See Chapter 5, Sections 5.3 and 5.4.2 for further examination of this political alliance.

conservative agenda, members of the federal and local legislatures (particularly those affiliated with the PAN and PRI) have pursued a dignitarian agenda on medico-legal issues.[63] Despite the strong hegemony of the Catholic Church and pro-life groups, the stakeholders stressed that their influence has not been translated into the enactment of any regulation on SCS, giving rise to the legal vacuum in this terrain (S1, S3-6).

In contrast to conservative stances, the PRD-members (left-wing politicians) in the political arena are actively promoting more liberal stances towards the regulation of biomedical, sexual and reproductive themes.[64] For instance, they have put forward legislative initiatives that proposed the liberalisation of abortion, plus same-sex marriage and adoption in Mexico City.[65] Additionally, within the Federal Congress, there is also a diversity of ideological and ethical backgrounds, including the left-wing, liberals, socialists and ecologists.[66] This ideological heterogeneity in the political arena explains the complexity of achieving a legislative compromise to govern innovations in health, science and biotechnology. Consequently, notwithstanding the considerable presence of Catholic beliefs among the legislators, a majority is not reached and obtaining majority approval to implement either radical conservative or progressive agendas is complicated, at least in the Federal Congress.[67]

On the other hand, the initial academic discussion on bioethical issues has been mainly concentrated on the emergence of genomic medicine in the country.[68] In the same manner as in the political arena, the bioethical academic discourses in Mexico feature a clash of antagonistic ideologies, divided between liberal-secular (embodied by pro-choice and pro-science groups) and

[63] Here, I am referring to a dignitarian agenda in terms of an *ethos* derived from the most conservative doctrine of Catholic teaching which promotes respect for human dignity as a sacred value inherent to all human beings, see further Campbell A, 'Ethos and Economics: Examining the Rationale Underlying Stem Cell and Cloning Research Policies in the United States, Germany, and Japan', *American Journal of Law and Medicine* 31 (2005) 47-86; the dignitarian agenda pursued by MPs in the Federal Congress also differs from that advanced by the "dignitarian alliance", which promotes respect for human dignity as a paramount foundation of human rights, on this perspectives on dignity see Beyleveld D and Brownsword R, *Human Dignity in Bioethics and Biolaw* (Oxford: Oxford University Press, 2001); also see Brownsword R, 'Bioethics Today, Bioethics Tomorrow: Stem Cell Research and the "Dignitarian Alliance"', *Notre Dame Journal of Law Ethics Public Policy* 17 (1) (2003) 15-51.

[64] See Chapter 5, Section 5.3.

[65] See Unzelman AC, 'Latin America Update: The Development of Same-Sex Marriage and Adoption Laws in Mexico and Latin America', *Law and Business Review of the Americas* 17 (135) (2011).

[66] See Chapter 2, Section 2.4 for a review of the proportional system of representation in the legislature in Mexico, including an overview and examination of the composition and seats occupied by the members of the existing political parties in the Federal Congress up to the federal elections of 2009.

[67] Ibid.

[68] See Jiménez-Sánchez G, Lara-Álvarez CF and Arellano-Méndez A, 'A Survey of the Development of Mexican Bioethics: Genomic Medicine as One of its Greatest Challenges', in Pessini L, De Paul de Barchifontaine C and Lolas F (Eds) *Ibero-American Bioethics* (Springer, 2010) 159-73.

conservative (pro-life with a Catholic foundation) postures.[69] Blancarte points out that, in Latin America, the historical Catholic tradition has dominated the sphere that all religions could occupy in bioethical discussions, through monopolising and not recognising the plurality of stances among religions.[70]

In brief, all stakeholders indicated that much of the initial SCS debate was dominated by Catholic members alongside those with conservative views within the government and legislatures. In addition, all expressed their disagreement with the interventions by religious groups and criticised the fact that the views on embryo research, ART and abortion, which are held by politicians and local governments and which are guided by members of the PAN and PRI, are fuelled by the most conservative views of Catholic doctrine, which are later transplanted into the policy-making arena. All stakeholders' claim that there is undue interference by Catholic leaders, since the Catholic Church, along with conservative groups, has successfully persuaded the political party currently in power, as well as a few legislators in the Federal Congress, to maintain an outright ban on SCS. The Catholic lobbying over legislators seeking to forbid SCS activities has been common in many countries where this religion enjoys certain empathy from the population.[71]

It is worth noting that the aforementioned situation is constantly evolving and that political control of the pro-life and religious alliances has somewhat lessened, due to the growth of divergent voices that have also gained ground in the debate. A gradual shift from the conservative debate to a secular discussion on bioethics has also arisen, which includes liberal reflections on the emerging biotechnologies and innovations.[72] Therefore, the academic discussion recently formulated by those scholars and civil society groups (i.e. pro-science) has favoured the advancement of science and biotechnology, particularly SCS, focusing on the achievement of a progressive legal framework, which facilitates the conduct of responsible scientific research.[73]

The stakeholders' opinions emphasised the importance of secularity within the bioethical discourse, while keeping a balanced account of the state of biotechnology and its ethical ramifications (S1, S4-7). Through explaining

[69] See Blancarte R, 'Laicidad y Bioética' *(Secularity and Bioethics)*, in Soberón G and Feinholz D (Eds) *Aspectos Sociales de la Bioética: Memoria (Social Aspects of Bioethics: Memoir)* (Vol 3; Mexico: CONBIOÉTICA, 2009a).
[70] Ibid.
[71] On this, see Oakley J, 'Democracy, Embryonic Stem Cell Research, and the Roman Catholic Church', *Journal of Medical Ethics* 28 (4) (2002) 228.
[72] See Chapter 2, Section 2.2 for more discussion on this evolving scenario.
[73] See Tapia R, *op. cit. supra* note 54.

secularity, they argued in favour of a neutral common point, allowing the expression of varied voices and respect for the different ideas and beliefs which converge in a democratic state. Given the current ambivalence in the national bioethical discourse, embracing any legislation on the contested issues will be a complex task, unless an inclusive and ordered public dialogue can be established which includes the wider community, including civil society groups, academic associations, stakeholders and experts in bioethics.[74]

6.5.2. TAKING A GLANCE AT BIOTECHNOLOGY AND INNOVATION

In 2003, well-established researchers at the AMC urged the government to implement public policies that could facilitate innovation, for example, in biotechnology applied to health.[75] The main recommendation was to inject more financial resources to create human resources with the capability of transforming this field in Mexico.[76] It was also proposed that investments be increased in the existing public institutions that already had the infrastructure to develop biotechnology. The priority that was initially identified was the necessity to efficiently administer and expand the current resources. Likewise, the creation of laws, regulations and appropriate rules, which could provide efficient supervision, was also recommended.[77] For this, all stakeholders stressed the need to strengthen the existing links between private and public research institutes and the governmental agencies, as a way of achieving better outcomes for R&D and its adequate regulation.

One important step in the advancement of biotechnology was registered in 2005 when, as a result of an ordered and inclusive dialogue, the Biosafety Act on Genetically Modified Organisms was passed in the Federal Congress.[78] This regulation establishes clear rules for key stakeholders in this area, as well as guaranteeing a certain protection for consumers and the welfare of the community.[79] This experience showed that links between the stakeholders,

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[74] See Gottweis H, Salter B and Waldby C, *op. cit. supra* note 3.
[75] See Bolívar F (Ed), *Recomendaciones para el Desarrollo y Consolidación de la Biotecnología en México* (Mexico: CONACYT-AMC, 2003); also see Chapter 2, Sections 2.6 and 2.7 which outlines the status of investment in and policies on science, biotechnology innovation and biomedicine research in the country.
[76] Ibid.
[77] Ibid.
[78] In Spanish, *Ley de Bioseguridad de los Organismos Genéticamente Modificados.* An English version of the Biosafety Act can be found at: http://www.cibiogem.gob.mx/eng/Documents/Ing_LBOGM_P.pdf acc. 18 June 2012.
[79] As a measure to closely observe and support actions on activities related to GMO and the implementation of the Biosafety Act on GMO and its regulation, the government created CIBIOGEM, the Inter-Sectorial Commission on the Biosafety of Genetically Modified Organisms. See Falkner R and Gupta A, 'The Limits of Regulatory Convergence: Globalization and GMO Politics in the South', *International Environmental Agreements: Politics, Law and Economics* 9 (2) (2009) 113-33.

scientific community, and policy-making sectors are crucial, in order to create public trust and construct adequate regulatory frameworks that would cover safety issues and measure the risks associated with the new technologies.[80] Interestingly, unconnected with the main issue being discussed and through extrapolating the worries of Mexican politicians over novel scientific activities, this regulation explicitly put aside the oversight of specific areas of biotechnology applied to medicine, such as SCS and ART practices.[81]

Nonetheless, the fragmented investment in biomedical sciences was found to be a common concern shared by most of the stakeholders (S1, S3-7). This worry lies in the urgent necessity to create efficient communication links between the academic sector, policymakers and the scientific community.[82] This need for links, as explained by the stakeholders, was also highlighted during the last national discussion concerning the regulation of biotechnology industries – namely GMOs in Mexico (S1, S3-5, S7).[83] Moreover, as argued by the stakeholders, it is expected that a similar scenario to that which occurred in 2005 would have to occur in order to generate the necessary legal provisions for any activity involving embryos, SCS research and ART practices. However, it appears that the ordered dialogue desired by stakeholders is not an easy task, since the status of the embryo continues to be a contentious topic about which legislators and policy-makers avoid serious discussion.

The stakeholders have also drawn attention to the need to involve the private sector in the generation of scientific innovation. Therefore, adequate legislation is urged, particularly when taking on new therapies developed from SCS.[84] So far, private investment in biotechnology and interest by private industries in continuing to foster this activity are seen in the creation of research clusters in different regions of Mexico.[85] Recently, private funds were allocated

[80] Ibid.
[81] Article 6 provides: "The following are excluded from the realm of application of this Law: …II. The utilization of *in vitro* fertilization techniques, conjugation, transduction, transformation or any other natural process, as well as polyploid induction, as long as neither molecules of recombinant deoxyribonucleic acid (DNA) nor genetically modified organisms are employed;… V. The human genome, human stem cell cultures, modification of human stem cells and biosafety in hospitals, whose regulation corresponds to the General Law of Health, and to the International Treatises in which the United Mexican States is a participant…", *supra* note 78.
[82] See Tapia R, *op. cit. supra* note 54.
[83] See Aerni P and Bernauer T, 'Stakeholder Attitudes Toward GMOs in the Philippines, Mexico, and South Africa: The Issue of Public Trust', *World Development* 34 (3) (2006) 557-75.
[84] See Chapter 7 on this discussion.
[85] See Chapter 2, Section 2.6. Also see Editorial, 'Biotech Round the World: Focus on Mexico', *Biotechnology Journal* 3 (9-10) (2008) 1131-34.

to biomedical research seeking to expand biotechnological incubators, particularly in molecular and genetic research.[86]

In the biomedical field, in the last decade the Mexican government has invested in genomic medicine as a way to achieve health and welfare development and build up personalised medicine for the Mexican population.[87] It was acknowledged by all stakeholders that the creation of the INMEGEN was a positive step towards motivating further investment in many other areas of biotechnology. One of the main arguments that effectively worked towards the creation of this research centre was the shift from a society dependent on foreign economies and health developments to one capable of creating its own knowledge-based health economy.[88]

Equal to what was encountered with the regulation of GMOs, one of the main concerns raised by Mexican politicians, before the foundation of INMEGEN, was related to the possibility that members of this health research centre might conduct hESC research and human cloning by members of the scientific community in the newly created biomedical research centres.[89] So, in order to allay the fears held by certain politicians, the INMEGEN was created subject to the condition that any studies related to reproductive human cloning or embryo research were banned (S3).[90] Unsurprisingly, this prohibition only confirms the reluctance of legislators to tackle the contested issue of regulating embryo and SCS. Furthermore, genomic medicine is not closely related to human reproductive cloning. Stakeholders perceived the prohibition imposed on INMEGEN as an action to ease the fears of the hierarchy of the Catholic Church and conservative members of the Federal Congress (S1, S3-7).[91]

As a result of the investment in genomic medicine, there are huge expectations that this field could be a tool for economic growth in Mexico.[92] Meanwhile, the stakeholders' concerns were focused on the transparency

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[86] See Vargas-Parada L, 'Funds Go Toward Biomedical Business Incubators in Mexico', *Nature Medicine* 17 (1) (2011) 7.
[87] See Jiménez-Sánchez G, Frenk J and Soberón G, 'El Poder Transformador de la Genómica en la Economía Global' *(The Tranforming Power of Genomics in the Global Economy)*, (18 August 2011) http://estepais.com/site/?p=34614 acc. 18 June 2012.
[88] Ibid.
[89] See Chapter 5, Section 5.4.
[90] This is also documented in Schwartz Marín E, 'Protegiendo el "Mextizaje": El INMEGEN y la Construcción de la Soberanía Genómica' *(Protecting the 'Mextizaje': The INMEGEN and the Construction of the Genomic Sovereignty)*, in López Beltrán C (Ed) *Genes (&) Mestizos: Genómica y Raza en la Biomedicina Mexicana (Genes (&) Mestizos: Genomic and Race in the Mexican Biomedicine)* (Mexico: Ficticia, 2011) 155-84.
[91] See Jiménez-Sánchez G, 'Developing a Platform for Genomic Medicine in Mexico', *Science* 300 (5617) (2003) 295-6.
[92] Ibid, *supra* note 87.

needed from all research centres, in order to generate more public trust.[93] Thus, research projects and the knowledge gained from these must be disseminated to the wider population. As a consequence, as argued by stakeholders, there has been a lot of noise doubting the legitimacy and reliability of the research conducted in research centres (S3, S5, S6). This fact is not optimal for the advancement of new projects in biotechnology. According to the participants, there is a compelling fear that, in the future, private research centres might conduct SCS, since there is no monitoring and legal oversight in the area.[94] First and foremost, the claim made by the interviewees, in relation to the consolidation of scientific projects, which must be characterised by transparency in the process of creation and communication of knowledge, is an important element in advancing SCS.

Notwithstanding the aforementioned governmental support to GMO and genomic medicine research, public investment in many other areas of science, technology and innovation has not increased during the last two periods of federal government, as was affirmed by the stakeholders (S1, S3-5).[95] The disconnection between the advances of science and technology and the public policies pursued by the federal government is visible. According to the stakeholders, at present Mexican science and technology lack adequate support and public funding in many areas of knowledge. Additionally, it has been pointed out that institutionalised politics, which obstruct the creation of science within research centres and institutes in Mexico, might stop the flow of developments in biotechnology.[96] For instance, in 2010, the OECD reported that Mexico has the lowest R&D among OECD members.[97] It was recommended that a revision of Mexico's strategies to establish effective governance and implementation of transformed innovation policies at federal and state levels be added to the aim of adequate funds to support R&D.[98] Thus, in the area of SCS, public calls by academic and scientific organisations have been made to urge investment in this field, in order to prevent obstructions to biomedical

[93] The necessity to generate public awareness and engagement in scientific endeavours seeking to foster trust between SCS and the wider community has been elaboraed in Bates SR, Faulkner W, Parry S and Cunningham-Burley S, 'How Do We Know It's not Been Done Yet?! Trust, Trust Building and Regulation in Stem Cell Research', *Science and Public Policy* 37 (9) (2010) 703.
[94] See Chapter 7 on the emergent SC therapies enterprises in Mexico.
[95] See Chapter 2, Section 2.6.
[96] See Menchaca Rocha A, El Único Camino Hacia el Desarrollo de México Pasa por el Conocimiento: Recomendaciones para el Futuro Presidente de México (The Only Path Towards Mexico's Development is through Knowledge: Recommendations for the Next President of Mexico) (Mexico: AMC, 2011) 19 http://www.amc.mx/recomendaciones_2012.pdf acc. 18 June 2012.
[97] See OECD, 'Mexico', in *OECD Science, Technology and Industry Outlook 2010* (OECD Publishing, 2010) 202-3.
[98] Ibid.

innovation.[99] Certainly, to date, there has been a growing research potential for SCS, as well as public and private interest in this field.[100]

6.6. HUMAN EMBRYONIC STEM CELLS – THE STATUS OF THE EMBRYO

A set of stakeholders' perceptions concerning the status of the embryo is highlighted in this section. The following sub-themes emerged and shaped this section:

- Whether or not *ex utero* and *in utero* embryos are viewed as sacrosanct, bearing life, or special entities that must be treated with dignity
- Claims about a gradualist approach to protecting the embryo
- Whether or not spare embryos from IVF clinics are regarded as viable for research since, to date, there have been no crystal clear details about their final destiny
- Whether or not embryonic and adult SC research constitutes a legitimate means to improve and alleviate people's suffering

Interestingly, most of the stakeholders considered embryos to be special entities which should be treated with due respect in accordance with their stage of development (S1, S2-4, S7).[101] A minority of the respondents maintained that early embryos must be seen as just a bunch of cells useful for scientific purposes (S5-6).[102]

6.6.1. SANCTITY OF LIFE AND HUMAN DIGNITY

The opposition to hESC research, in this context, finds its rationale in the protection of early embryonic life. On the basis of this position, embryonic creation and destruction should be prohibited.[103] In that case, the fundamental question concerns when life begins and from what point it is significant, morally and legally speaking. The Catholic Church has issued encyclical letters establishing that human life begins at and is worthy of protection from the

[99] See Tapia R, 'Urgen Apoyos a la Investigación con Células Troncales en México' *(Urgent Need to Fund Stem Cell Research in Mexico)*, *Gaceta Electrónica INNOVACIÓN* 5 (5) (2008).
[100] Ibid.
[101] See Chapter 3, for an ethical defense for the development of SCS.
[102] This moral position is close to the argument that early embryos are simply clusters of cells no different from any other human cells, including those of skin or hair. See Harris J, *On Cloning* (London: Routledge, 2004); also see Harris J, *The Value of Life* (London: Routledge, 1985).
[103] For a concise review of the divergent postures towards SCS and human cloning, see Salles ALF, 'La Clonación y el Debate sobre Células Troncales' *(Human Cloning and the Debate about Stem Cells)*, in Luna F and Salles ALF (Eds) *Bioética: Nuevas Reflexiones sobre Debates Clásicos (Bioethics: New Reflexions about Classic Debates)* (Argentina: FCE, 2008) 303-338.

moment of conception.[104] Therefore, embryos are human beings to be afforded protection of life and dignity, as is indicated in the instruction *Dignitas Personae: On Certain Bioethical Questions* issued by the Congregation for the Doctrine of the Faith.[105] Often, this stance is transplanted into the legal and political spheres, where politicians holding this view defend the protection of embryos as bearers of human rights and dignity: thus, their use and destruction is not acceptable.[106] In the Mexican scenario, conservative members of the PAN have followed this religious belief, inasmuch as it is also indicated within the statutes of the ruling political party, which promotes the sanctity of life and dignity of humankind from conception.[107]

Most of the stakeholders agreed that human dignity is an inalienable principle granted in the constitution, but limited to individuals and citizens, and open to diverse interpretations.[108] Therefore, the concept of 'personal dignity' emerged in the interviews (S1-4, S6, S7). According to the Federal Constitution, human dignity is one of the paramount principles within the catalogue of fundamental rights adopted therein.[109] Notwithstanding this, the principle is centred on the protection of an individual understood as a 'person'. The meaning and significance of the notion of human dignity has been largely explored in different areas and contexts, for instance, in the role it plays within the bioethical, human rights and healthcare arenas.[110] Attention has also been drawn to the significance of this notion in the policy-making debates on SCS across the globe.[111] In Mexico, legal scholars and philosophers have affirmed that human dignity is a valuable principle in bioethical debates.[112] However, as

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[104] For a review of the Catholic stances on SCS, see Chapter 3, Section 3.4.

[105] In this document the Roman Catholic Church doctrine expressed its total opposition to hESC research and placed very narrow restriction or recommendations on the conduct of ASC research, see *Dignitas Personae (on Certain Bioethical Questions)* (December 2008), *available at:* http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html acc. 18 of June 2012.

[106] See, for example, President's Council on Bioethics, *Human Dignity and Bioethics* edited by Pellegrino E (Notre Dame, Ind.: University of Notre Dame Press, 2008).

[107] See Chapter 5, Section 5.3.

[108] The notion of personal dignity has been categorised as one of the many denotations attributed to this abstraction; for example, paradigmatic empirical studies have provided useful understandings of this concept in the area of healthcare. See further Jacobson N, 'A Taxonomy of Dignity: A Grounded Theory Study', *BMC International Health and Human Rights* 9 (3) (2009).

[109] See Chapter 5, Section 5.3.1 on the role that the notion of human dignity plays within the Mexican constitutional paradigm.

[110] See Andorno R, 'Human Dignity and Human Rights as a Common Ground for a Global Bioethics', *Journal of Medicine and Philosophy* 34 (3) (2009) 223-40. In the European context, the notion of human dignity has also served as a barrier to the consolidation of domestic policies concerning hESC research. See Farrell A-M, 'The Body Politics: Ethical Concerns, Regulatory Dilemmas and Human Embryonic Stem Cell Research in the European Union', *Zeitschrift für Rechtssoziologie* 28 (2) (2007) 215-27.

[111] See Caulfield T and Brownsword R, 'Human Dignity: A Guide to Policy Making in the Biotechnology Era?' *Nature Reviews Genetics* 7 (1) (2006) 72-6.

[112] See González Valenzuela J, Genoma Humano y Dignidad Humana (Human Genome and Human Dignity) (Mexico: Anthropos, 2005).

was pointed out by stakeholders, this constitutional principle of human dignity in a secular state cannot be read as a religious concept (S1, S3-7).[113] Instead, it should be understood as a legal notion that needs to be filled with meaningful content agreed by the community.[114] It is precisely the vagueness of this notion that allows its interpretation as either a facilitative or restrictive conceptual tool, for or against emerging technologies in biomedicine.[115]

Although it was affirmed in the interviews that human dignity is of paramount value in the Mexican constitutional system, it was also recognised that human dignity is seen as a barrier to the discussion of SCS. For example:

> It should not be incorporated into the stem cell debate... It's a concept for a citizen that implies pride, honour and respect ... Social and religious prejudices cannot be allowed to guide our legal system anymore. (S6)

In this context, it seems that human dignity is deemed to be a unique value attached to individuals and citizens but not to other entities, for example, early embryos. However, the notion of human dignity will continue to be an abstract notion within the legal system that is not encountered in biological terms,[116] as expressed by the respondents:

> Human dignity does not have any relation to biology at all. (S1)

> It is a cultural concept; at the end of the day it signifies the possibility for human beings to make their own decisions … the importance of this notion in legal systems is increasing every day. (S2)

According to the stakeholders, it might be risky to include this principle in any secondary regulation dealing with embryo research, if some guidance about its interpretation has not been previously provided. This guidance must serve as a

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[113] The religious use and interpretation of the notion of human dignity, as well as its utility in bioethical and policy-making debates, has also been hotly debated and criticised from diverse philosophical standpoints. On this, see, for example, Schüklenk U and Pacholczyk A, 'Editorial: Dignity's Wooly Uplift', *Bioethics* 24 (2) (2010) ii.

[114] This understanding of human dignity within the Mexican legal system is also pointed out in Valadés D, 'Eutanasia. Régimen Jurídico de la Autonomía Vital' *(Euthanasia. Legal Regime of the Vital Autonomy)*, in Carpizo J and Valadés D (Eds) *Derechos Humanos, Aborto y Eutanasia (Human Rights, Abortion and Euthanasia)* (Mexico: IIJ-UNAM, 2009) at 135-150.

[115] Brownsword R, 'So What Does the World Need Now? Reflections on Regulating Technologies', in Brownsword R and Yeung K (Eds) *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes* (Oxford: Hart, 2008b) at 30.

[116] This abstract understanding of dignity is closely related to what has been described as the mystery of its meaning, which may keep it from being unravelled. On this account of the notion of dignity see further Gurnham D, 'The Mysteries of Human Dignity and the Brave New World of Human Cloning', *Social & Legal Studies* 14 (2) (2005) 197-214.

pathway, which could provide enough flexibility for the use of this principle in the process of authorising research.[117] Without a doubt, this principle is an abstract legal term that grounds fundamental rights which cannot be taken away, and the notion should remain and be interpreted in secular terms. As the respondents argued:

> It is important but separated from any kind of religious interpretation... It must signify respect for each other as individuals. (S3)

> It is a subjective principle, it is important in our legal system, and if you consider that an embryo is a human being, then human dignity should be protected. (S5)

Ultimately, it appears to be crucial in this context to take into consideration the plurality of views converging in the arena. However, the incorporation of divergent voices is not an easy task but will greatly strengthen the regulatory legitimacy.[118] Following this, a clearer understanding, or broader interpretation, of human dignity needs to be delineated, either by the court or legislators, [119] if this notion is to be deemed useful in any future regulation addressing embryonic and all SC research, as long as it is clearly determined who are the recipients of this notion.[120] This might provide a balance among the wider religious views and secular community, given that Catholicism is not the only religion in the country and, up until now, the claims for respecting human dignity of the embryo are mainly based on religious grounds.

6.6.2. GRADUALIST STANCES

For some supporters of hESC research, embryos are deemed to be special entities worthy of respect and having a commensurate moral status, depending on the stage of biological embryonic development.[121] Many of the stakeholders supported this middle position by which legal protection and respect for

[117] A further proposal for the adoption of a principles-based approach to regulate SCS in Mexico is presented in Chapter 4 of this thesis.
[118] See Brownsword R, 'Ethical Pluralism and the Regulation of Modern Biotechnology', in Francioni F (Ed) *Biotechnologies and International Human Rights* (Portland, Or.: Hart Publishing, 2007) 45-70.
[119] The Mexican Supreme Court has denoted dignity as foundational for human rights stating that it is the 'basis and condition of all others: the right to always be acknowledged as a human person. Thus, from human dignity all other rights stem, insofar as they are necessary for man to integrally develop his personality' (sic), text quoted in Madrazo A and Vela E, 'The Mexican Supreme Court's (Sexual) Revolution?' *Texas Law Review* 89 (7) (2011) 1863-94.
[120] See Schroeder D, 'Dignity: One, Two, Three, Four, Five, Still Counting', *Cambridge Quarterly of Healthcare Ethics* 19 (01) (2010) 118-125.
[121] These arguments were expressed during the UK policy-making processes in this field; on this see Mulkay M, *The Embryo Research Debate: Science and the Politics of Human Reproduction* (Cambridge: Cambridge University Press, 1997).

embryos increased in proportion to the stage of embryonic growth (S1-5, S7).[122] When the participants commented on this point, for example, they said:

> It has special status, but it is not as a human being. It is deemed to be protected, but not in the same category as human beings and persons. (S3)

> I opted for a gradualist protection of the embryo, in accordance with the social interpretation. (S4)

These asserted ethical positions reveal that embryonic research might be morally justifiable by stakeholders in this context. The embryo is seen as a potential human being, which is entitled to some degree of legal protection but not equal to that possessed by individuals.[123] From a biological point of view, a renowned researcher who has actively advocated for SCS in the country, Ruben Lisker, has also advanced two arguments supporting this position.[124] First, he argues that the impact of the loss of a family member is different depending on the stage of development of human life, which is why it is not the same thing to have a miscarriage. [125] He continues by focusing on the misfortune of the death of a newborn, or tragically losing a five-year-old child.[126] Lisker also asserts that an embryo, which is created for the sole purpose of harvesting SC, lacks the potential to become a human being, since it was not created for that purpose.[127] Finally, he proposes that within the Mexican context, life should be counted as morally and legally relevant from birth onwards.[128] This position is maintained overall by interviewees, as is shown by the following elicited response:

> The creation of embryos to procure stem cells should proceed. I am in favour of a more permissive approach... I cannot see the limits, since embryos are created for research purposes but not for reproductive cloning... It is byzantine to think that an embryo before the twelfth week of gestation is a human being; protection should be adapted accordingly to modern times. (S5)

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[122] For an analysis of the legal construction of embryos, see Fox M, 'Pre-persons, Commodities or Cyborgs: The Legal Construction and Representation of The Embryo', *Health Care Analysis* 8 (2) (2000) 171-188.
[123] See Bortolotti L and Harris J, 'Stem Cell Research, Personhood and Sentience', *Reproductive BioMedicine Online* 10 (2005) 68-75. Also see McLachlan HV, 'Persons and Their Bodies: How we Should Think About Human Embryos', *Health Care Analysis* 10 (2) (2002) 155-64.
[124] See Lisker R, 'Ethical and Legal Issues in Therapeutic Cloning and the Study of Stem Cells', *Archives of Medical Research* 34 (6) (2003) 607-611.
[125] Ibid, at 609.
[126] Ibid.
[127] Ibid.
[128] Ibid.

For the minority of stakeholders, an early embryo, e.g. a zygote, is not a human being but possesses the potential to become viable and create human life.[129] This position is assumed as follows:

> It [the early embryo] is not human life, but viability is an important point of reference. (S2)

Notwithstanding the above view, the stakeholders indicated that the procurement of SCs from early embryos is not translated as undue respect for the embryo. On the contrary, the establishment of a timeline indicates that there is a limit and respect for the early manifestation of life.[130] It is inferred that the generation of an informed and open debate is essential, in order to engage the public in a dialogue to establish the limits on the use of early embryos.[131] Within the public dialogue, cultural and local circumstances are crucial to establish proper and monitored use of early embryos, since the moral and pragmatic problems, which the use of hESCs implied, are difficult to compromise on.[132] On the above points, stakeholders considered that:

> An informed debated is needed to draw a limit or period for the protection of embryos… Early embryonic development cannot be considered human life. (S3)

> The embryo could be protected after the cellular division, that is to say, after the 14th day of development … the embryo is a special form of life. (S1)

> The timeframe should be determined in accordance with cultural conditions. (S4)

The participants also maintained that the use of early embryos is not seen as a lack of respect for human life, as long as there is a justified limitation and safe conditions for the use and procurement of embryos for research, since the action could ameliorate human life and health.[133] In addition, the participants agreed that the establishment of a timeline for conducting research on embryos is feasible and will draw the boundaries for hESC research:

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[129] See Sorem H, 'The Ethical Case Against Stem Cell Research', *Cambridge Quarterly Healthcare Ethics* 12 (4) (2003) 372-83.

[130] Even in countries with permissive SCS legal frameworks, the time line to be drawn for the use of early embryos in research remains contested; for more on this, see Greely HT, 'Moving Human Embryonic Stem Cells from Legislature to Lab: Remaining Legal and Ethical Questions', *PLoS Medicine* 3 (5) (2006) 0571-575.

[131] See, for example, the public deliberations as a policy-making process established in Singapore when regulating SCS, in Ho C, Capps B and Voo T, 'Stem Cell Science and its Public: The Case of Singapore', *East Asian Science, Technology and Society: An International Journal* 4 (2010) 7-29.

[132] See Chapter 3 for a discussion of this.

[133] See McGee G and Caplan A, 'The Ethics and Politics of Small Sacrifices in Stem Cell Research', *Kennedy Institute of Ethics Journal* 9 (2) (1999) 151-8.

> We cannot talk about life, but better we can talk about a form of life of cell... once this cell is obtained, then the spare material is discarded, but on the seventh day of [embryonic] development… then again the argument is that these cells are discarded biological material. (S5)

> My personal opinion is that we cannot consider them [the early stages of embryonic development] as human life … It is a process of development. (S4)

In the view of some of the stakeholders, it seems feasible that research can be allowed within the first 14 days of embryonic development, since it is at this point that the primitive streak of the embryo is formed.[134]

> … they are a bunch of cells until the nervous system is developed right after the fourteenth day of development [embryonic]… This is my point of view … there are a lot of references where this claim can be validated. (S5)

> I think that the creation of clear projects to conduct stem cell research must be established, seeking to combat chronic and severe illness... Through well-defined projects it can be possible to eliminate the suffering of ill people not only in this country but in many other regions around the world... We need to pursue research on embryonic SCs to develop treatments and alleviate the most worrisome illnesses in the country. (S7)

On this basis – as was also agreed by the stakeholders— since embryos are not analogous to human beings, a higher moral commitment is due to those patients who are suffering from chronic diseases and who base their hopes on the development of treatments and cures from hESC research, and SCS applications in general.[135]

6.6.3. SPARE EMBRYOS FROM *IN VITRO* FERTILISATION

As highlighted earlier, despite the fact that ART procedures have been available in Mexico for many years, no specific law has yet been enacted.[136] The area is

[134] This argument has been advanced in most countries where there is a liberal and facilitative approach to SCS, see Chalmers D, 'Stem Cell Technology: From Research Regulation to Clinical Applications', in Capps B and Campbell A (Eds) *Contested Cells: Global Perspectives on the Stem Cell Debate* (London: Imperial College Press, 2010) 63-93.
[135] See Devolder K and Savulescu J, 'The Moral Imperative to Conduct Embryonic Stem Cell and Cloning Research', *Cambridge Quarterly of Healthcare Ethics* 15 (01) (2006) 7-21.
[136] See Mendoza Cárdenas HA, La Reproducción Humana Asistida: Un Análisis desde la Perspectiva Biojurídica (Assisted Reproduction: An Analysys from a BioLegal Approach) (Mexico: Fontamara, 2011).

only vaguely addressed in general secondary provisions.[137] Thus, the treatment of the embryo, the number that should be created and implanted, as well as the rate of successful final fertilisation are not closely controlled and overseen: their fate and final destiny in Mexico is unknown.[138] Moreover, ethical and legal guidelines for research on gametes and embryos discarded from IVF clinics have yet been issued.[139] So far, very little is known about the mechanisms and requirements of gamete and embryo donation, as was pointed out in the interviews:

> The point is that mechanisms should be established: From where do we procure the germ cells? Authorisation must be granted to create a number of IVF embryos… If they are spare embryos from *in vitro* fertilisation: Where are they? Are they destroyed? … As an option, informed consent and authorisation from the parents can be obtained to use IVF spare embryos for research. (S4)

On the point of allowing research on frozen IVF embryos:

> … it is not justifiable to prohibit research on embryonic stem cells on spare embryos from assisted reproduction … It must be a very important part of the rules because, on one hand, there are thousands of supernumerary embryos frozen in IVF clinics; we already have a lot of spare embryos but we do not know their final destination. (S1)

It is worth noting that, under this unregulated context, research on supernumerary IVF embryos to procure SCs for therapeutic purposes in Mexico is already being conducted.[140] IVF and certain SCs practices are carried out without any specific regulation or guidelines to be followed. Here, most of the interviewees agreed that the procurement of embryonic SC from discarded IVF embryos, if available, should proceed instead of leaving the embryos to perish:[141]

> In relation to assisted reproduction techniques, … for this kind of embryo [supernumerary], the only final destination is

[137] Ibid.
[138] See Moctezuma Barragán G, 'La Reproducción Asistida en México. Un Enfoque Multidisciplinario' *(Human Assisted Reproduction in Mexico. A Multidisciplinary Approach)*, in Martínez Bullé Goyri VM (Coord) *Cuadernos del Núcleo de Estudios Interdisciplinarios en Salud y Derechos Humanos (Notebooks of the Group of Interdisciplinary Studies on Health and Human Rights)* (Mexico: IIJ-UNAM, 1998).
[139] Ibid.
[140] See Cuneo S et al, 'Stem Cells from Umbilical Cord Blood as a Source for Future Genetic and Therapeutic Uses in Patients from IVF Donation Programs', *International Congress Series* 1271 (2004) 167-170.
[141] See Franklin S, 'Embryonic Economies: The Double Reproductive Value of Stem Cells', *BioSocieties* 1 (01) (2006) 71-90.

> destruction, otherwise it could be used for research; or perhaps because of the long time that it was stored, it may not be viable to be used for any purpose anymore … In this case, my way of thinking is that it is better to use them [spare embryos] for research if they can help in developing therapies… Instead of putting them in boiling water, as it has been done, I would prefer that they [spare embryos] are used for research; I prefer they are used for research. (S3)

All of the stakeholders agreed that ART and SC research activities are equally valid medical mechanisms to alleviate health disorders;[142] these therapies are directed towards accomplishing the fundamental rights established within the Federal Constitution, as provided within the fundamental rights catalogue under Article 4, which sanctions the 'right to access to health and to reproduce'.[143] As was pointed out by the stakeholders, these are both treatments and it is contradictory to prohibit one and not the other: if that is so, the justification for permission or banning must be explicit:

> It is completely contradictory [prohibition of research on spare embryos] … since embryos are already created for therapies [ART procedures]… and since there is no specific legislation on assisted reproduction and the generation of *in vitro* embryos, in a strict sense there must be a legislation that establishes what it is legal or illegal to do with those embryos; for instance, if they can be sold or not, or issues about ownership of tissues; if IVF embryos can be destroyed or not, and if so, then it would be better to permit their utilisation to procure stem cells and conduct any kind of research, provided that there are specific rules and limits to be observed, etc... like in civilised countries! (S4)

Most stakeholders (S1, S3-7) perceived the use of surplus embryos as not morally contested but as a complex activity to be monitored and regulated. Additionally, they suggested that transparent rules be provided, from which society can benefit and by which it can participate in this debate. Issues about consent from the couples whose gametes were used to create embryos have not been considered in the public health agenda.[144] Notwithstanding the ethical controversy and moral divergence on hESC research, it has been pointed out

[142] See Devolder K, 'Creating and Sacrificing Embryos for Stem Cells', *Journal of Medical Ethics* 31 (6) (2005a) 366-70.
[143] See Mexican Supreme Court of Justice (Ed), *Political Constitution of the United Mexican States*, translated by Rodríguez Narváez SA and Vela E, 2nd Edition (Mexico: Coordination on Compilation and Systematization of Theses of the Mexican Supreme Court, 2008).
[144] See Svendsen MN and Koch L, 'Unpacking the 'Spare Embryo': Facilitating Stem Cell Research in a Moral Landscape', *Social Studies of Science* 38 (1) (2008) 93-110.

that the creation of adequate legal norms, by which risk and safety issues are comprehensively established and must be rigorously observed when conducting research on these spare embryos and cells.[145] However, the stakeholders recognised that the wider community is not yet well-informed or aware about the social, health and ethical implications of the conducting SC research. Nevertheless, it is essential to begin the discussion concerning ART practices and a growing unregulated market, such as SC-based therapies.[146]

6.7. CONCLUDING REMARKS

Drawing on empirical data, this chapter has explored the crucial conflicts that seem to be deciding factors in developing any governance of emerging biotechnologies, particularly SCS. I have outlined that the political party currently heading the Mexican Federal Government maintains a strongly conservative stance. Furthermore, the lobbying of politicians and policy-makers by the hierarchy of the Catholic Church, to implement its own views and ethical beliefs on the issue hampers the consolidation of any legal setting. Drawing on stakeholders' opinions, it is expected that a change in the political context would open the door to the adoption of a permissive legal framework. This change in the political arena must allow the inclusion of diverse voices in an inclusive, public and ordered policy-making process. A wider examination of the ethical and legal issues involving SCS is necessary, and it has been shown that it is the disconnection between the scientific community, policy-makers and bioethics experts, which overshadows the future of SCS in Mexico.

The recent antagonistic discussions and the absence of any consensus regarding the protection accorded to the embryo, if any, represent a major complexity translated into legal vacuum in this area. On the other hand, the current normative provisions fall short of providing guidelines to follow regarding emerging biotechnologies and innovations on health. However, it is feasible to adopt a flexible legislation grounded on constitutional norms, such as the right to have access to healthcare, freedom of research, and pursuit of scientific development. On the other hand, the aim of any legislation regarding emerging biotechnologies must be to promote responsible, fair and

[145] See Cohen CB et al, 'The Use of Fresh Embryos in Stem Cell Research: Ethical and Policy Issues', *Cell Stem Cell* 2 (5) (2008) 416-21.
[146] Mexico has been identified as one of the places in Latin America where untested SC-based therapies are being marketed; see Ryan KA et al, 'Tracking the Rise of Stem Cell Tourism', *Regenerative Medicine* 5 (1) (2010) 27-33. The ethical and legal implications of the marketing of these therapies is further explored in Chapter 7.

humanitarian research. The legislative inertia cannot remain, since there is a high potential to contribute to the growth of the economy by encouraging biotechnology research, particularly given the EU ban on patenting SC therapies, which Mexico could take advantage of.[147] As the stakeholders have suggested, one step towards adopting any regulation is by learning from the experiences of countries where the policy-making process has been successfully established, like the UK.[148]

Finally, it should be kept in mind that, in order to construct an accurate legal setting in accordance with the local context, a truly deliberative process, which includes the various social players interested in developing bioethical and legal governance over this issue, must be established.[149] A minimum basic ethical reference point for the discussion of SCS should be prepared, while making possible the inclusion of diverse ethical stands. Even countries with a strong Catholic influence have adopted a regulatory regime for SCS: Why not Mexico?[150]

Table 6.1: General Description of Interview Subjects

Stakeholder	Professional Background	Academic Centre or Institution	Duration of Interview (minutes)
S1	Psychologist (PhD in bioethics)	Department of Psychology, Psychiatry and Mental Health, Faculty of Medicine - UNAM	61
S2	Judge (PhD in law)	Mexican Supreme Court	46
S3	Medical lawyer (PhD in bioethics)	Institute for Legal Research (IIJ-UNAM)	70
S4	Medical lawyer (LLM bioethics)	National Institute of Genomic Medicine, INMEGEN	86
S5	Physician (PhD in biochemistry)	Institute of Cellular Physiology - UNAM	120
S6	Senator (PhD in economics)	Mexican Senate (Federal Congress)	68
S7	Chemist (PhD in biomedical research)	National Institute of Genomic Medicine, INMEGEN	32

[147] See Callaway E, 'European Court Bans Patents Based on Embryonic Stem Cells', *Nature News* (18 October 2011) http://www.nature.com/news/2011/111018/full/news.2011.597.html acc. 18 June 2012.
[148] See Chapter 4 for a review of the UK's SCS model of governance.
[149] See, for example, Salter B and Salter C, 'Governing Innovation in the Biomedicine Knowledge Economy: Stem Cell Science in the USA', *Science and Public Policy* 37 (2) (2010) 87-100.
[150] I am indebted to David Gurnham for having initially formulated this question for me.

CHAPTER 7

PAPER 3: THE RISE OF STEM CELL THERAPIES IN MEXICO: INADEQUATE REGULATION OR UNSUCCESSFUL OVERSIGHT?[1]

2011, year of tourism in Mexico[2]

7.1. INTRODUCTION

The continuous progress of the clinical side of SCS has become difficult both to ignore and to govern. Indeed, its novelty has surpassed the capacity of governments across the globe to create effective legal control over novel SC therapies.[3] Equally, many of those therapies being offered are made available without scientific evidence to support their safety and efficacy.[4] In addition, as a result of the globalisation of healthcare, a relatively new industry has appeared in the international arena: medical tourism.[5] 'Medical tourism' and 'health tourism' are terms used to denote the movement of citizens across national borders in order to seek and acquire healthcare services; it is an activity that is considered to be an expression of an increasingly private medical trade.[6] Travel across jurisdictions by people seeking unregulated SC therapies is a subcategory of medical tourism, generally denoted 'SC tourism'[7]; this last subcategory has rapidly expanded all across Mexico, its ethical and legal implications in this context are explored in this chapter.

Tourism is one of the main inputs to Mexico's economic development.[8] Medical tourism is a profitable facet of this tourism, with the result that the

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[1] Adapted from Medina-Arellano MdJ, 'The Rise of Stem Therapies in Mexico: Inadequate Regulation or Unsuccessful Oversight? *Submitted to the Revista Red Latinoamericana y del Caribe de Bioética RedBioética/UNESCO*.

[2] Motto decreed by the current President of Mexico; during 2011, public policies focused on promoting all areas of tourism in the country.

[3] See Kiatpongsan S and Sipp D, 'Offshore Stem Cell Treatments', *Nature Reports Stem Cells* (3 December 2009) *available at:* http://www.nature.com/stemcells/2008/0812/081203/full/stemcells.2008.151.html acc. 12 June 2012.

[4] See Regenberg AC et al, 'Medicine on the Fringe: Stem Cell-Based Interventions in Advance of Evidence', *Stem Cells* 27 (9) (2009) 2312-19.

[5] See Reisman D, *Health Tourism: Social Welfare through International Trade* (Northampton, MA: Edward Elgar Publishing, 2010).

[6] Hopkins L et al, 'Medical Tourism Today: What is the State of Existing Knowledge', *Journal of Public Health Policy* 31 (2) (2010) 185-98; also see Kawachi IO and Wamala SP, *Globalization and Health* (New York: Oxford University Press, 2007).

[7] Zarzeczny A and Caulfield T, 'Stem Cell Tourism and Doctors' Duties to Minors-a View from Canada', *American Journal of Bioethics* 20 (5) (2010) 3-15.

[8] See Mexico's National Institute of Statistics and Geography INEGI, *Mexico at Glance 2008, available at* http://www.inegi.gob.mx/prod_serv/contenidos/espanol/bvinegi/productos/integracion/pais/mexvista/2008/Mexatg08.pdf acc. 12 June 2012.

country has become a popular destination for medical amenities.[9] For a number of years, the medical community has forged links with private tourism brokers and governmental agencies.[10] Medical tourism has become a priority area of investment in current policies on tourism in order to consolidate Mexico as an established destination for prospective patients.[11] It is positioned with China, Costa Rica, India and Thailand as a country with a flourishing SC tourism industry.[12]

In Mexico, most experimental SC therapies are offered by the private sector operating under a profit-seeking business model, as national policies are flexible enough to favour such endeavours.[13] The growth of the SC tourism industry has been fuelled by the ever-increasing demand from desperate patients, who will engage in any type of therapy available in the SC marketplace.[14] This phenomenon is also encouraged by media hyperbole, which exaggerates claims about the actual or known therapeutic value of SCs, thus taking advantage of the naive optimism of patients suffering from debilitating and degenerative diseases.[15]

This chapter explores the existing biomedical regulatory regime that may be broadly applicable to the clinical application of experimental SCS in Mexico. It also aims to shed light on the efficacy of the relevant governmental agency in registering, monitoring and surveying the emergence of SC therapies

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[9] See Bookman MZ and Bookman KR, *Medical Tourism in Developing Countries* (New York: Palgrave Macmillan, 2007).

[10] See, for instance, Medical Tourism Magazine, 'Mexico: A Medical Tourism Mecca Across the Border', (8 January 2008), *available at:* http://www.medicaltourismmag.com/article/mexico-a-medical-tourism-mecca-across-the-border.html acc. 12 June 2012.

[11] Following these economic-tourism driven policies, last year the Ministry of Tourism (MoT) hosted the international 'Medical Tourism Congress' in conjunction with Canadian and United States medical associations and economic organisations, *available at* http://www.congresodeturismomedico.com/portal/ acc. 12 June 2012.

[12] See Kiatpongsan S and Sipp D, 'Monitoring and Regulating Offshore Stem Cell Clinics', *Science* 323 (5921) (2009) 1564-5; also see Lau D et al, 'Stem Cell Clinics Online: The Direct-to-Consumer Portrayal of Stem Cell Medicine', *Cell Stem Cell* 3 (6) (2008) 591-4 (discussing how unproven SC therapies are widely marketed on the web to recruit prospective patients worldwide).

[13] See OECD, 'Mexico', in *OECD Tourism Trends and Policies 2010* (OECD publishing, 2010) 210-16; also see Ministry of Tourism (MoT) in Mexico, 'Impulsa el Gobierno Federal Política Pública para Turismo Médico' (*The Federal Government Fosters Public Policy for Medical Tourism) Press Release* (17 February 2011), *available at:* http://www.sectur.gob.mx/es/sectur/sect_Boletin_013_Impulsa_Gobierno_Federal_Politica acc. 12 June 2012.

[14] See Levine AD, 'Stem Cell Tourism: Assessing the State of Knowledge', *SCRIPTed: A Journal of Law, Technology & Society* 7 (2) (2010) 274-82 http://www.law.ed.ac.uk/ahrc/script-ed/vol7-2/levine.pdf acc. 12 June 2012. For example, the engagement of patients in many untested SC therapies in an attempt to ameliorate their suffering, notwithstanding the lack of clinical or scientific evidence of the efficacy of those therapies, is explored from an anthropological approach in Song P, 'Biotech Pilgrims and the Transnational Quest for Stem Cell Cures', *Medical Anthropology* 29 (4) (2010) 384-402; for an in-depth analysis of the discourse of hope surrounding SC therapies Murdoch CE and Scott CT, 'Stem Cell Tourism and the Power of Hope', *American Journal of Bioethics* 10 (5) (2010) 16-23.

[15] See Zarzeczny A et al, 'Stem Cell Clinics in the News', *Nature Biotechnology* 28 (12) (2009) 1243-6; also see Qiu J, 'Trading on Hope', *Nature Biotechnology* 27 (9) (2009) 790-2.

in the country. It is organised as follows: first, a general overview of the global rise of the SC tourism phenomenon is presented. This is followed by an outline of the current regulatory regime and the national authority responsible for overseeing biomedical research in Mexico. This leads on to arguments concerning the inadequacy of this regulatory system in providing a suitable scheme to oversee SC therapies and in guaranteeing the wellbeing and safety of SC tourists.[16] It also demonstrates that the existing legal provisions are not rigorously applied by the relevant public agency. Three SC therapy providers are scrutinised as case studies in order to elucidate the legal and ethical challenges that governmental authorities face in effectively overseeing and monitoring the emergence of these therapies. Evidence is also provided of a need to identify improvements that can be made in terms of extending the scope of the current regulatory provisions to provide comprehensive rules to regulate the area, and to fortify the available compliance mechanisms.

In the final section, I suggest that the absence of targeted regulation and ineffective law enforcement relating to SCS and clinical applications may jeopardise the establishment in Mexico of public trust and responsible medical progress in this emerging field. If the current government wants Mexico to be considered a legitimate provider of medical tourism services, it is crucial to extend the scope of existing norms and to strengthen the enforcement capability of relevant agencies, along with the adoption of specific standards or guidelines to regulate clinical applications of SCS. Adequate regulation and effective law enforcement will ensure the safety and wellbeing of those seeking SC treatments, while also facilitating innovative biomedical research and promoting responsible medical practices.[17]

7.2. METHODS

The empirical enquiry to collect the data used in this chapter was undertaken during the period 2010-2011. This investigation involved the following phases: first, I performed a detailed Internet search using the Google® search engine in order to identify SC treatments and providers advertising these services on the web. This open web search that I carried out sought to identify the relevant information and procedures self-reported by the providers scrutinised in our

[16] The terms “stem cell tourists” and “stem cell patients” are used throughout the paper without distinction.
[17] The normative proposal that is advanced in this thesis to regulate the SCS field in Mexico is found in Chapter 4.

selected case studies.[18] Secondly, data used in this paper was also retrieved from www.clincialtrials.gov in order to gather information on registered SC clinical trials being carried out in Mexico.[19] A systematic search for academic literature relevant to SC tourism and the clinical application of SCS was conducted to determine the current global state of scientific knowledge in this domain.[20] Official notes and data to support and corroborate the information retrieved from the online search were also obtained through an online public request submitted to the Mexican government's portal for transparency and access to information.[21]

7.3. THE BOOM IN STEM CELL TOURISM: CAUSE FOR CONCERN

Across the world, patients are crossing national borders seeking unregulated SC treatments;[22] in a few cases, these are presented and marketed in conjunction with complementary and alternative medicine (e.g. holistic medicine, homeopathy, acupuncture).[23] The lax regulatory regime existing in many countries worldwide, as is the case in Mexico, may compromise not only patients' safety but also progress and trust in SCS.[24] If this situation is not comprehensively monitored and regulated by national jurisdictions, cases of scientific misconduct could possibly materialise, such as the scandal featuring the Korean researcher Hwang Woo-Suk, who was found to have falsified research concerning the derivation of embryonic SC lines from SCNT (therapeutic cloning).[25] Therefore, adequate regulatory regimes are needed in

[18] See Yin RK, *Case Study Research: Design and Methods*, 4th Edition (London: SAGE, 2009).
[19] This US online database provides general information about clinical trials conducted in many parts of the world and is one of the most reliable public sources of information concerning clinical trials worldwide. For an interesting introductory study to clinical trial seettings, see Speid L, *Clinical Trials: What Patients and Healthy Volunteers Need to Know* (Oxford University Press, 2010).
[20] To identify and characterize the relevant literature systematically and perform the web search, the following English and Spanish key words were used: 'medical tourism', 'stem cell biobanking', 'stem cell tourism', 'stem cell therapy Mexico', 'stem cell tourism Mexico', 'terapia células madre México', 'cell therapy Mexico', 'células troncales México', 'terapia celular México'.
[21] See *Instituto Federal de Acceso a la Información* (IFAI), www.infomex.org.mx acc. 12 June 2012.
[22] See Sipp D, 'The Unregulated Commercialization of Stem Cell Treatments: A Global Perspective', *Frontiers of Medicine* 5 (2011) 1-8.
[23] See Sipp D, 'Stem Cell Stratagems in Alternative Medicine', *Regenerative Medicine* 6 (3) (2011) 1-8.
[24] See, for example, Cohen CB, 'International Stem Cell Tourism and the Need for Effective Regulation. Part II: Developing Sound Oversight Measures and Effective Patient Support', *Kennedy Institute of Ethics Journal* 20 (1) (2010) 27-49 and 'International Stem Cell Tourism and the Need for Effective Regulation, Part I: Stem Cell Tourism in Russia and India: Clinical Research, Innovative Treatment, or Unproven Hype?' *Kennedy Institute of Ethics Journal* 20 (3) (2010a) 207-30.
[25] In 2006, the experimental results announced by Hwang in *Science* were fabricated, since somatic cell nuclear transfer procedures were not used to procure embryonic stem cell lines; only two embryonic SC lines existed, not the eleven he reported, and these were obtained from *in vitro* fertilised eggs. This scandal prompted academy and policy discussions placing the trust and veracity of this field under risk. See further Parry J, 'Korean Cloning Studies Were Fakes', *British Medical Journal* 332 (7533) (2006) 67; also see Aera H, 'The Ethical and Regulatory Problems in the Stem Cell Scandal', *Journal of International Biotechnology Law* 4 (2) (2007) 45-68. Furthermore, Hwang's scientific fraud brought to light major ethical

order to guarantee sufficient protection of patients and research subjects enrolled in SCS activities and clinical applications.

International scientific organisations have expressed concerns about the expansion of unproven SC treatments, which are largely marketed through the Internet.[26] For example, the International Society for Stem Cell Research (ISSCR) has published *Guidelines for the Conduct of Human Embryonic Stem Cell Research* (2006) and *Guidelines for the Clinical Transplantation of Stem Cells* (2008); it has also produced a *Patients Handbook on Stem Cell Therapies* (2008).[27] In response to the rise of offshore and dubious SC clinics worldwide and the need for their further scrutiny, the ISSCR launched a website to provide accessible information to the lay public seeking to learn more about clinical applications of SCS and those willing to undertake SC treatments.[28]

Furthermore, academics have urged caution and expressed concerns about the absence of an international moral consensus or agreed guidelines on whether it is acceptable or not for private clinics to offer officially unauthorised SC therapies.[29] In the years to come, SC tourism will continue to expand and will be poorly regulated on an international scale.[30] The regulatory issues become more complex when medical groups have vested interests in ensuring that for-profit SC medical applications proceed with minimal government surveillance.[31] Such a group is the International Cellular Medicine Society (ICMS), a private medical organisation in the USA,[32] where the federal Food and Drug Administration (FDA) has judicially challenged Regenerative

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concerns regarding the abuse and exploitation of women, since it unveiled the unscrupulous behaviour towards his research assistants, from whom he obtained eggs in a coercive manner for his research projects. See Gottweis H, 'South Korean Policy Failure and the Hwang Debacle', *Nature Biotechnology 24 (*2) (2006) 141; Kakuk P, 'The Legacy of the Hwang Case: Research Misconduct in Biosciences', *Science and Engineering Ethics* 15 (4) (2009) 545-62.

[26] See Taylor PL et al, 'Patients Beware: Commercialized Stem Cell Treatments on the Web', *Cell Stem Cell* 7 (1) (2010) 43-9.

[27] These guidelines and their appendices can be consulted on the ISSCR's website at: www.isscr.org acc. 12 June 2012; also see Daley GQ et al, 'The ISSCR Guidelines for Human Embryonic Stem Cell Research', *Science* 315 (5812) (2007) 603-4; Hyun I et al, 'New ISSCR Guidelines Underscore Major Principles for Responsible Translational Stem Cell Research', *Cell Stem Cell* 3 (6) (2008) 607-09.

[28] The ISSCR issued recommendations online, such as the 'Top 10 stem cell treatment facts' as part of the advice provided to people thinking of travelling for SC-based therapies; see website: www.closerlookatstemcell.org acc. 12 June 2012.

[29] See Gunter KC et al, 'Cell Therapy Medical Tourism: Time for Action', *Cytotherapy* 12 (8) (2010) 965-68.

[30] See DeRenzo LN, 'Stem Cell Tourism: The Challenge and Promise of International Regulation of Embryonic Stem Cell-Based Therapies', *Case Western Reserve Journal of International Law* 43 (3) (2011) 877-918.

[31] See Lysaght T and Campbell AV, 'Regulating Autologous Adult Stem Cells: The FDA Steps Up', *Cell Stem Cell* 9 (5) (2011) 393-6.

[32] The ICMS, a private, non-governmental organisation composed of physicians, has launched an SC accreditation programme that seeks to certify stem cell clinics and treatments mainly located and marketed outside the US in order to encourage prospective patients (stem cell tourists) to acquire treatments abroad, since these are still not approved or authorised in their home countries; see website: http://www.cellmedicinesociety.org/physicians/accreditation acc. 12 June 2012.

Sciences, one of the commercial clinics certified by the ICMS.[33] The FDA has filed an injunction and requested judicial action to prevent Regenerative Sciences from performing untested autologous SC-based therapies.[34] In the USA, under federal regulations, autologous adult stem cell[35] therapies are considered to be highly manipulated biological medical products and are therefore categorised as medicines, which require FDA approval before being marketed.[36] It is reasonable to concede that the FDA and homologous regulatory authorities worldwide should oversee any experimental SC treatment or derived products,[37] since positive evidence of quality and safety is required before these treatments can reasonably be administered to patients.[38]

Since very few SC clinical trials have taken place thus far, there is no conclusive scientific evidence of the effectiveness and safety of SC treatments.[39] For instance, authorisation to conduct the first hESC[40] clinical trial in the UK occurred only recently.[41] In the USA, clinical trials using iPSC[42] have also commenced.[43] The US-based Geron company recently began conducting a phase I clinical trial in which hESCs were used to treat spinal cord injuries. However,

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[33] See Cyranoski D, 'FDA Challenges Stem-Cell Clinic', *Nature News* 466 (909) (2010) http://www.nature.com/news/2010/100817/full/466909a.html acc.12 June 2012.

[34] See *FDA vs Regenerative Sciences, LLC et al, US District Court for the District of Columbia 'Complaint'* (August 6, 2010) http://www.fdalawblog.net/files/regenerative-sciences---injunction-complaint.pdf acc. 12 June 2012.

[35] See Phinney DG, *Adult Stem Cells: Biology and Methods of Analysis* (New York: Humana Press, 2011).

[36] See Dolgin E, 'Survey Details Stem Cell Clinics Ahead of Regulatory Approval', *Nature Medicine* 16 (5) (2010) 495.

[37] See Robertson JA, 'Embryo Culture and the 'Culture of Life': Constitutional Issues in the Embryonic Stem Cell Debate', *University of Chicago Legal Forum* (2006) 1-38 at 18.

[38] See Fink DW, 'FDA Regulation of Stem Cell-Based Products', *Science* 324 (5935) (2009) 1662-63. Here, it is worth noting that at the time of writing, the US Federal Bureau of Investigation had arrested three persons who offered unapproved autologous SC treatments and claimed to cure amyotrophic lateral sclerosis (ALS), a degenerative, so far untreatable and fatal disease; see http://www.fbi.gov/sanantonio/press-releases/2011/federal-indictments-lead-to-arrests-in-stem-cell-case acc. 12 June 2012.

[39] See Steinhoff G, Regenerative Medicine: From Protocol to Patient (Dordrecht: Springer, 2011); also see Taupin P, Stem Cells and Regenerative Medicine: Patents and Clinical Trials (New York: Nova Science Publishers, 2010).

[40] As noted in Chapter 3, Section 3.2, hESCs are undifferentiated pluripotent cells which possess great plasticity and which under appropriate circumstances are able to specialise as almost any type of cell and tissue of the human body; see Ludwig TE and Thomson JA, 'Defined Culture Media for Human Embryonic Stem Cells', in Masters JRW, Palsson B and Thomson JA (Eds) *Embryonic Stem Cells* (Dordrecht: Springer, 2007) 1-16.

[41] On this, see Gretchen V, 'U.K. Approves Europe's First Embryonic Stem Cell Clinical Trial', *ScienceInsider* (22 September 2011) http://news.sciencemag.org/scienceinsider/2011/09/uk-approves-europes-first-embryonic.html acc. 12 June 2012; also see Connor S, 'Stem Cells: The First Human Trial', *The Independent* (20 November, 2009) http://www.independent.co.uk/news/science/stem-cells-the-first-human-trial-1824099.html acc. 12 June 2012.

[42] Scientists have succeeded in reprogramming ASC from the skin into a pluripotential stage; in other words, iPSCs appear to have the renewing potentiality of embryonic SCs, yet this is still to be scientifically corroborated. See Takahashi K et al, 'Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors', *Cell* 131 (5) (2007) 861-72; Yu J et al, 'Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells', *Science* 318 (5858) (2007) 1917-20.

[43] In the US, the FDA has authorised the Neuralstem and StemCells companies to proceed with neural stem cell clinical trials; these applications are promising but are still in phase I; see Trounson A, 'New Perspectives in Human Stem Cell Therapeutic Research', *BMC Medicine* 7 (1) (2009) 29.

at the end of November 2011 it abandoned the trial.[44] In Europe, similarly, the biotech company ReNeuron has obtained approval to conduct the first clinical trial of the use of genetically engineered neural SCs to treat neuron disease.[45] Clinical trials conducted in the above-mentioned developed countries (where research is largely regulated) have revealed moderate benefits, but ground-breaking therapeutic advances have not yet been made.[46] Such trials should be approached with caution, since some clinical trials carried out on animals using hESCs and iPSCs have indicated a high risk of forming malignant teratomas (collections of carcinogenic cells), in other words the development of tumours.[47]

While global SC tourism has flourished due to the media hype and enthusiasm for innovative SCS,[48] this growth should spur governments to enhance policies, education and communication between physicians and patients.[49] Countries which have taken a strong stand on the SC tourism phenomenon and unproven treatment enterprises include Costa Rica,[50] while Germany is in the process of reforming its legislation.[51] The Chinese Ministry of Health has announced that the State Food and Drug Administration will more closely supervise SC clinical trials on foreign patients as standard therapies for profit.[52] In these cases, SC doctors and clinics have been prevented from engaging in this risky practice by medical authorities and governmental regulatory agencies.

In Mexico, most SC therapies are commercialised in private facilities and applied outside controlled clinical trials or official monitoring, thus lacking efficacy and safety control measures (see Table 7.2). These providers claim to

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[44] The news of Geron's decision to withdraw its embryonic SC research programmes appeared during the writing of this paper. This may represent a slowdown of hESC therapies. See Mack GS, 'Reneuron and Stem Cells Get Green Light for Neural Stem Cell Trials', *Nature Biotechnology* 29 (2) (2011) 95-7.

[45] See Baker M, 'Stem-Cell Pioneer Bows Out: Geron Halts First-of-its-Kind Clinical Trial for Spinal Therapy', *Nature News* 479 (7374) (22 November 2011) http://www.nature.com/news/stem-cell-pioneer-bows-out-1.9407 acc. 14 June 2012.

[46] So far, most clinical applications and trials in SCS have been conducted on ASCs and have focused on neurodegenerative, cardiovascular, muscular and blood disorders, i.e. ALS, muscular dystrophy, leukaemia, skin burns, as well as diabetes, oncological and genetic diseases; for more on the state of the art of translational SCS, see Hug K and Hermerén G (Eds) *Translational Stem Cell Research: Issues Beyond the Debate on the Moral Status of the Human Embryo* (New York: Humana Press, 2011).

[47] See Sugarman J and Sipp D, 'Ethical Aspects of Stem Cell-Based Clinical Translation: Research, Innovation, and Developing Unproven Interventions', in Hug K and Hemerén (Eds), *op. cit.* above note 46 at 127.

[48] See Braude P, Minger S and Warwick RM, 'Stem Cell Therapy: Hope or Hype?' *BMJ* 330 (7501) (2005) 1159-60.

[49] See Master Z and Resnik DB, 'Hype and Public Trust in Science' *Science and Engineering Ethics* (2011) 1-15.

[50] See Joseph L, 'Costa Rica puts Brakes on Popular Stem Cell Tourism', *Reuters* (7 June 2011) http://www.reuters.com/article/2010/06/07/us-costarica-stemcells-idUSTRE6516UR20100607 acc. 14 June 2012.

[51] See Tuffs A, 'Stem Cell Treatment in Germany is Under Scrutiny After Child's Death', *BMJ* (341) (2010).

[52] See Durfee D and Huang S, 'China Stops Unapproved Stem Cell Treatments', *Reuters* (10 January 2012), http://www.reuters.com/article/2012/01/10/us-china-health-stem-cell-idUSTRE8090GA20120110 acc. 14 June 2012.

treat and cure fatal and degenerative diseases.[53] The false claims associated with unregulated SC treatments generate serious ethical and legal concerns and can potentially harm patients financially and physically.[54] This situation also creates false expectations among desperate SC tourists (e.g. terminally and chronically ill patients), potentially worsening their suffering and putting their health at serious risk.[55] There is no clear evidence of whether there is a comparison between a control group of patients or attempts to evaluate the possibility of a placebo effect; nor is there any proof that providers are complying with international scientific and ethical standards.[56] Furthermore, there is no indication of follow-up monitoring of patients in order to assess benefits or adverse effects. These issues are addressed in the case studies analysed below.

In the context of free trade in medical goods and services, as well as the government's commitment to fostering medical tourism in the country, many private facilities have emerged as a common source of medical services, including experimental SC therapies.[57] Certainly, SC tourists may expose themselves to serious health risks when undertaking unregulated but easily available SC therapies. In addition, due to the lack of harmonised practices and legal systems, prospective SC tourists may need to sacrifice legal remedies which are otherwise available in their home countries.[58]

Mexico is a convenient healthcare service destination for medical tourists from nearby countries (mostly Mexican-American (Hispanic) and US citizens).[59] Arguably, the main reasons for these patients seeking treatment abroad are geographic proximity, affordable costs, rapid access and the availability of SC

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[53] For example, it is not clear whether private SC clinics follow international legal instruments that are established to ensure best practices in clinical research (e.g. the Helsinki Declaration — last reviewed in 2008), the International Ethical Guidelines for Biomedical Research Involving Human Subjects (1993, revised 2002) adopted by the World Health Organization or the International Conference on Harmonization for Good Clinical Practices (1990). The fact that unauthorised SC treatment providers claim to alleviate more than 40 diseases which, so far, are incurable medical conditions, is also problematic. See further Ryan KA et al, 'Tracking the Rise of Stem Cell Tourism', *Regenerative Medicine* 5 (1) (2010) 27-33

[54] See Lodi D, Iannitti T and Palmieri B, 'Stem Cells in Clinical Practice: Applications and Warnings', *Journal of Experimental & Clinical Cancer Research* 30 (1) (2011) 9.

[55] See Caplan A and Levine B, 'Hope, Hype and Help: Ethically Assessing the Growing Market in Stem Cell Therapies', *The American Journal of Bioethics* 10 (5) (2010) 24-5; Kelland K, 'Health Experts Warn of "Stem Cell Tourism Dangers"', *Reuters* (01 September 2010) *available at* http://www.reuters.com/article/2010/09/01/us-stemcells-tourism-idUSTRE67U4VK20100901 acc. 14 June 2012.

[56] For example, those issued by the ISSCR, *supra* note 27.

[57] Ibid, *supra* notes 10 and 11.

[58] For an illuminating analysis of the remedies medical travellers may need to give up in looking for medical services in developing countries, such as Thailand, Singapore and Mexico, see Cortez N, 'Recalibrating the Legal Risks of Cross-Border Health Care', *Yale Journal of Health Policy, Law, and Ethics* (1) (2010) 89.

[59] See Reisman D, *op. cit. supra* note 5; it is also documented that patients are motivated to cross national borders seeking medical treatments because they are cheaper, because they can avoid the long waiting list at home, and because they may easily access SC therapies that are not yet authorised or approved in their health jurisdictions; see Connell J, *Medical Tourism* (UK: CABI, 2011).

therapies that are not approved in their home countries. Although many issues of regulatory harmonisation, safety and security have yet to be resolved since the adoption by Canada, Mexico and the US of the North American Free Trade Agreement (NAFTA, 1994),[60] trade in healthcare goods and services has increased remarkably, mainly across the northern border regions of Mexico.[61] Therefore, within the context of healthcare globalisation, private healthcare providers perceive prospective SC tourists as patients who can freely decide to travel across borders in order to undergo any available medical treatment.[62]

7.4. The Need for a Change in Mexico's Existing Biomedical Regulatory Landscape

The lack of specific legislation overseeing basic and applied SCS in Mexico can be explained in terms of the extensive dispute about the moral status of the embryo which has hampered the adoption of adequate governance in this field.[63] Mexican legislators may have lost sight of the inadequate regulatory status of SCS and its clinical applications, including the insufficiency of the legal tools available to regulate the development of novel biomedical technologies. This section demonstrates the need for an in-depth revision of the existing regulatory regime to identify improvements in its scope and create targeted regulation of SC innovations. This should be accompanied by tougher measures of compliance to be implemented by the relevant regulatory agency, since the enforcement of existing rules has been negligible to date. To this end, this section examines the current regulatory regime for healthcare and biomedical

[60] In Spanish, *Tratado de Libre Comercio de América del Norte* (TLCAN). An extensive study of the impact of this treaty in Mexico goes beyond the scope of this chapter, so it is referenced as background data. NAFTA's Chapters Eleven, Twelve, Fourteen, Sixteen and Seventeen, which are relevant and directly linked to trade in healthcare service, contain provisions addressing investment, cross-border and financial services, temporary entry of business people and intellectual property issues; *available at* http://www.nafta-sec-alena.org/en/view.aspx?x=343 acc. 14 June 2012.

[61] See Judkins G, 'Persistence of the U.S. - Mexico Border: Expansion of Medical-Tourism amid Trade Liberalization', *Journal of Latin American Geography* 6 (2) (2007) 11-32. In fact, Tijuana has been targeted as one of the most promising Mexican regions for innovation in the biotech and healthcare industries. The US-Mexican cross-border alliance to foster health and life sciences research links between the two countries, which is called "The Life Sciences Initiative: Mexico-San Diego", has issued recommendations to promote growth in a few identified clusters of biotech innovation in the country, including Monterrey (Nuevo León), Guadalajara (Jalisco), Irapuato (Guanajuato) & DF (Mexico City). See San Diego Crossborder Group Inc and Merck Sharp & Dohme (MSD), *San Diego Dialogue: Borderless Biotech & Mexico's Emerging Life Sciences Industry* (May 2007) http://www.sandiegodialogue.org/pdfs/Borderless_Biotech.pdf and Council on Competitiveness & Global Bioeconomy Consulting, 'Catalyzing Cross-Border Innovation: The Mexican Life Sciences Initiative', *Phase I Report* (December 2005) http://www.compete.org/images/uploads/File/PDF%20Files/2-_Mexico_Life_Sciences_Initiative-Phase_I_Report_2005.pdf acc. 14 June 2012.

[62] See Horton S and Cole S, 'Medical Returns: Seeking Health Care in Mexico', *Social Science & Medicine* 72 (11) (2011) 1846-52; also see Medical Tourism Magazine, 'Medical Tourism from U.S. To Border Region of Mexico - Current Status and Future Prospects', (18 December 2009) http://www.medicaltourismmag.com/detail.php?Req=319&issue=14 acc. 14 June 2012.

[63] See Chapters 5 and 6.

activities, including the regulatory authority responsible for overseeing the transplantation of human biological material and its use in clinical research.

7.4.1. Overview of Biomedical Legislation

As stated in the introductory chapter of this thesis, in Mexico, the legal framework that delineates public policies and norms regulating the constitutionally sanctioned right to healthcare protection is the GHA.[64] All matters related to health care are largely governed by this act in general terms. The GHA stipulates that the MoH shall create the necessary public policies on health, granting statutory power to create and issue NOMs[65] in order to administer the national system of health and implement the relevant policies.[66]

Secondary regulations derived from the GHA govern biomedical research and are, arguably, generally applicable to the clinical utilisation of experimental SC treatments. The GHA sets forth the following associated secondary regulations: the Biomedical Research Regulation, which stipulates the conditions required to perform clinical trials on human subjects, including research involving the use of human organs, tissues and derivatives;[67] and the Sanitary Disposal of Human Organs, Tissues and Cadavers Regulation,[68] hereinafter referred to as the Tissue Regulation, which provides general rules concerning the removal, utilisation and transplantation of organs and tissues, including their components and derivatives from living and deceased individuals. However, it is not clear whether its scope extends to the regulation of ASCs derived from tissues for therapeutic and research purposes. The Tissue Regulation explicitly incorporates neither substantial nor procedural rules for

[64] The GHA can be consulted in Spanish at http://www.diputados.gob.mx/LeyesBiblio/pdf/142.pdf acc. 14 June 2012.

[65] Mexican Official Norms (NOMs) are technical or administrative rules that are enacted to specify, provide parameters or apply particular norms to further regulate certain areas. The Mexican federal congress does not discuss or vote to approve these administrative norms. See Chapter 2, Section 2.3.

[66] This is in accordance with the GHA and the Organic Law of the Federal Public Administration (*Ley Orgánica de la Administración Pública Federal) available at*: http://www.diputados.gob.mx/LeyesBiblio/pdf/153.pdf acc. 14 June 2012.

[67] The Biomedical Research Regulation can be found in Spanish at http://info4.juridicas.unam.mx/ijure/nrm/1/387/default.htm?s=iste acc. 14 June 2012. It is worth highlighting that the Biomedical Regulation was enacted when new innovative drugs and advanced therapeutic practices were not conceived, so legislation is either limited or obsolete in the face of new biotechnological emerging innovations.

[68] The Tissue Regulation is *available at* http://www.salud.gob.mx/unidades/cdi/nom/compi/rlgsmcsdotcsh.html acc. 14 June 2012. There is also a Mexican Official Norm (NOM-003-SSA2-1993) that regulates the therapeutic use of blood and its components. However, it makes no reference to the treatment and utilisation of SCs derived from umbilical cord blood or from any other source. This official standard also fails to establish particular requirements for the therapeutic use of haematopoietic SCs or any other type of SCs. The absence of specific guidelines for the use of SC lines procured from UCB has been pointed out by Serrano-Delgado VM et al, 'Ethical Issues Relating to the Banking of Umbilical Cord Blood in Mexico', *BMC Medical Ethics* 10 (1) (2009) 12.

the use of tissues or cells, nor any criteria to establish what activities utilising this human raw material are permitted.

The overall legal provisions that apply to cells within the existing federal health regulations are wide in scope, but certain descriptions may be applicable to SCs. For instance, Article 314, Section I of Chapter XIV of the GHA[69] specifies that "***germinal cells*** are those male and female gametes able to give rise to an embryo."[70] However, the definition of germinal cells or gametes is very specific and refers to the category of cells that may give rise to an entire living human, whereas a broader understanding of SCs indicates that "stem cells are those that have the capacity to self-renew (make more stem cells by cell division) as well as to differentiate into mature, specialized cells".[71] Further, section III of this article states that "***components*** are the organs, tissues, cells and all substances of which the human body is composed, excluding the products".[72] Section XI refers to ***products*** as "all tissues or substances extruded, excreted or expelled from the human body as a result of normal physiological processes. For the purposes of this section the placenta, skin and its appendages will be considered as ***products.***"[73] As regards a definition of tissues, section XIII provides that a ***tissue*** is a "morphological entity composed of a group of cells of identical nature, which are regularly ordered and perform the same role".[74]

The above provisions do not offer a generic definition of cells, or more precisely of SCs. However, the references found within the GHA in relation to human tissues and cells are fairly general and open to interpretation. By applying a purposive approach to interpretation of the law, it is plausible to infer that the definition of tissues found in the legislation ought to be interpreted as including cells, in fulfilling the purposes of the GHA and the associated secondary Tissue Regulation, Article 1 of which establishes that its object is to regulate the use of human organs, tissues and their components (cells), derivatives and products.[75] This interpretation is corroborated by the

[69] Chapter XIV of the GHA is entitled "Donation, Transplantation and End of Life" and comprises articles 313 to 350, *supra* note 64.
[70] SCs are classified according to their plasticity; *germinal cells* are considered to be *totipotent* and can give rise to a complete organism or human being. See Panno J, *Stem Cell Research: Medical Applications and Ethical Controversy* (New York: Facts on File Science Library, 2005).
[71] Retrieved from the ISSCR's website, ibid*, supra* note 27.
[72] The GHA, *supra* note 64.
[73] Ibid; skin appendages are located in the dermis with the exception of nails, and include hair and several types of glands. See Standring S and Gray H, '8. Systemic Overview: Skin and its Appendages', in *Gray's Anatomy: The Anatomical Basis Of Clinical Practice*, 40th Edition (Edinburgh: Churchill Livingstone, 2008).
[74] The GHA, *supra* note 64.
[75] The Tissue Regulation, *supra* note 68. In biological terms, tissues are conformed by cells and most SCs are derived from tissues; for example, human fat or adipose tissue is a rich source of somatic SCs. See

content of the provisions of the GHA, Article 341, which states that blood, the bloodstream and its derivatives, making explicit reference to ***haematopoietic stem cells* (HSCs),**[76] shall be considered ***tissues***.[77] As mentioned earlier and as is shown in what follows, the current health legislation and the related secondary regulations are broadly framed, with the result that the authorities find themselves helpless in overseeing this area, given the complete lack of precision regarding what is allowed and prohibited in research and therapeutic settings involving the utilisation of human biological material such as tissues, cells and their derivatives.

Importantly, Article 327 of the GHA ***proscribes the commercial use of human organs, tissues and cells***, but it allows the commercial private storage of umbilical cord blood (UCB).[78] Furthermore, Article 21 the Tissue Regulation establishes that the disposition of organs and tissues for therapeutic purposes shall be ***gratuitous***; thus, Article 22 of the Tissue Regulation also stipulates that the commercialisation of organs and tissues is forbidden.[79]

Given that law proscribes the commercial transplantation or application of tissues and cells, public health centres authorised to store and transplant human tissues (including HSCs and SCs derived from UCB) should operate under the principles of altruism, confidentiality, non-profit and solidarity, in accordance with Article 327 of the GHA.[80] The public and private storage of UCB is relevant in the context of SC research, since it constitutes a unique source of procurement of HSCs for future clinical applications.[81] Further, Article

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Zuk PA, 'Human Adipose Tissue is a Source of Multipotent Stem Cells', *Molecular Biology of the Cell* 13 (12) (2002) 4279-95.

[76] HSCs are those which have the ability to replicate into different types of blood cells (i.e. red blood cells, platelets, granulocytes, macrophages and B and T lymphocytes) and are successfully used to treat blood disorders such as leukaemia and other blood-related cancers. See Appasani K and Appasani RK, *Stem Cells & Regenerative Medicine: From Molecular Embryology to Tissue Engineering* (New York: Humana Press, 2011) at vii.

[77] The GHA, *supra* note 64.

[78] The GHA, *supra* note 64. For a doctrinal account of the Mexican provision establishing a clear prohibition to commercialize human organ, tissues and cells, see Casas Martínez MdL, 'Análisis e Implicaciones en la Ley General de Salud Mexicana sobre la Propiedad del Cuerpo en los Trasplantes Cardiacos. Aspectos Bioéticos de los Transplantes *in Mortis'* (*Analysis of the Implications of the Mexican General Health Law on the Property of the Body for Heart Transplantations in Mortis), Revista de Derecho Privado del IIJ-UNAM* (4) (2003) 3-33.

[79] The Tissue Regulation, *supra* note 68.

[80] The GHA, *supra* note 64; also see Canovas Pérez-Abreu E and Dib-Kuri A, 'Aspectos Bioéticos en la Prestación de los Servicios Públicos de Salud: Trasplante de Órganos y Tejidos' *(Bioethical Aspects on the Provision of Public Health Services: Organs and Tissues Transplantation)*, in Brena Sesma I (Ed) *Panorama Internacional en Salud y Derecho. Culturas y Sistemas Jurídicos Comparados (International Panorama on Health and Law. Comparative Legal Systems and Cultures)* (Mexico: IIJ-UNAM, 2007) 177-204.

[81] Commercial biobanking dominates this arena; for-profit biobanks promote their services to the public as biological insurance, thus exaggerating claims by affirming that the storage of these tissues will guarantee the future health of their children in providing cellular therapies for several diseases. See Serrano-Delgado VM et al, *supra* note 68. In Canada, similar situations are experienced due to the variety of practices of private and public biobanking and therapies derived from the tissues and cells storage. See further Bordet

323 stipulates that express written consent must be obtained from donors of human organs, tissues and cells.[82] The associated Biomedical Research Regulation, in Articles 20 to 27, delineates broad parameters for obtaining consent from human research subjects, organ and tissue providers.[83] When permitted by the general law, bio-banking and non-profit use in research of these raw biological material is in effect self-regulated by providers, medical practitioners and researchers, since the GHA and connected Biomedical Research and Tissue Regulations lack specific procedural rules or remedial measures and sanctions in cases of harm to research participants and patients.

7.4.2. OVERSIGHT COMMITTEES

The MoH, through an independent governmental authority called the Federal Commission for the Protection against Sanitary Risk (COFEPRIS).[84] Article 340 of the GHA establishes that COFEPRIS has the exclusive statutory competence to oversee the inspection, approval and authorisation of activities concerning the use, storage and transplantation of UCB[85] and derived HSCs. However, there is an absence of standards (NOMs) or legal guidelines for COFEPRIS to implement and enforce when evaluating, authorising and monitoring research and therapeutic activities involving human tissues and cells.

COFEPRIS in coordination with the National Transplant Centre (CENATRA)[86] and the National Centre for Blood Transfusion (CNTS),[87] is also

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S et al, 'Use of Umbilical Cord Blood for Stem Cell Research', *Journal of Obstetrics and Gynecology Canada* 31 (1) (2010) 58-61.

[82] The GHA, *supra* note 64.

[83] The Biomedical Research Regulation, *supra* note 67. For an in-depth analysis of the failings of the current rules in force relating to the granting of consent in biomedical research, see Verastegui E, 'Consenting of the Vulnerable: The Informed Consent Procedure in Advanced Cancer Patients in Mexico', *BMC Medical Ethics* 7 (1) (2006) 13; also see López de la Peña XA, 'Informed Consent and Institutional Review Board Approval in Mexican Medical Research', *Revista de Investigación Clínica* 47 (1995) 399-404.

[84] In Spanish: *Comisión Federal para la Protección contra Riesgos Sanitarios, available at* www.cofepris.gob.mx acc. 14 June 2012*;* COFEPRIS can be regarded as the Mexican equivalent of the US FDA. Among the issues under COFEPRIS vigilance are the scrutiny of environmental risks, publicity on health and supplies, sanitary surveillance on food and connected aliments, assessment of pharmaceutical products and so forth. On this see Gómez Dantés O et al., , 'Health System in Mexico', *Salud Pública de México* 53 (Supp 2) (2011) at S229.

[85] UCB units are a unique source of HSCs. These tissues are rich in HSCs, which can be differentiated into many other specialised cells, i.e. cardiac, cartilage, fat, hepatic and neural cells, which are of enormous value for regenerative medicine. See Forraz N and Mcguckin CP, 'The Umbilical Cord: A Rich and Ethical Stem Cell Source to Advance Regenerative Medicine', *Cell Proliferation* (44) (2011) 69-9; also see Horwitz ME and Chao N, 'Umbilical Cord Hematopoietic Stem Cell Transplantation', in Soiffer JR (Ed) *Hematopoietic Stem Cell Transplantation* (Humana Press, 2008) 267-88.

[86] See National Transplant Centre's website at: www.cenatra.salud.gob.mx acc. 14 June 2012; also see Sánchez Ramírez O, 'Donación y Trasplante de Órganos y Tejidos' (*Donation and Transplant of Organ and Tissues)*, in Brena Sesma I and Teboul G (Coords) *Hacia un Instrumento Regional Interamericano sobre la Bioética: Experiencias y Expectativas (Towards and Interamerican Regional Instrument on Bioethics)* (Mexico: IIJ-UNAM, 2009) 233-78.

responsible for overseeing, supervising and establishing public policies related to the donation, disposition and transplantation of human organs, tissues and cells.[88] Further, Article 338 of the GHA establishes that CENATRA has the authority to establish a registry of all allogeneic use and transplantations of human organs and tissues, being exclusively responsible for monitoring and applying this nationally.[89] This article explicitly excludes CENATRA from the control and monitoring of autologous transplantation.[90] Hence, CENATRA and the CNTS have no role in supervising the use or transplantation, whether for research or therapeutic purposes, of blood or any SCs derived from blood or human biological material (e.g. BMW, dental pulp and adipose tissues).

According to Article 17 of the GHA, COFEPRIS is also responsible for enforcing clinical research rules in research and treatment settings. Significantly, it has the authority to control and oversee clinical trials and therapeutic activities involving human subjects and to monitor the development of new drugs, medicines and therapies entering the Mexican marketplace and their advertising, [91] thus supervising, scrutinising and auditing healthcare establishments and issuing sanctions.[92] Section VIII of the same article (related to the provision of Article 340 GHA) establishes that COFEPRIS exerts control and vigilance over the disposal and transplantation of organs, ***tissues*** and ***cells***

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[87] The CNTS runs the National Centre for Blood Transfusion, which has a national public repository of UCB called CordMx. It is noteworthy that this public bank complies with the international standards set by the worldwide NetCord foundation; this organisation is affiliated with and accredits UCB banking globally and establishes some guidelines to be observed by affiliated biobanks. See Netcord-Fact, 'International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection, and Release for Administration', *available at:* http://www.lifeline.com.cy/downloads/faqs_netcord-fact_guidelines2006_3rdedition.pdf acc. 14 June 2012. Also see Calderón-Garcidueñas ED, 'Evaluación del Programa de Sangre Plancetaria CordMX. Logros y Expectativas' *(Evaluation of the Programme of Umbilical Cord Blood CordMx. Achievements and Expectations)*, *Revista Médica del Instituto Mexicano del Seguro Social* 43 (Suppl 1) (2005) 127-9.

[88] Articles 313 and 340 of the GHA, ibid, *supra* note 64. All government health offices detailed in this paper originate from and operate hierarchically under the MoH and all of them enjoy administrative, technical and operative independence.

[89] Allogeneic transplantation refers to SC transplants from one person to another, whereas autologous implantation relates to the re-injection or transplanting of a person's own SCs; see Taupin P, *Stem Cells and Regenerative Medicine: Patents and Clinical Trials* (New York: Nova Science Publishers, 2010) at 108.

[90] The GHA, *supra* note 64. CENATRA administers a National System and Registry of Transplants, which oversees and records all allogeneic transplants carried out in the country, as well as a list of people waiting for organ transplants and donors. See Dib-Kuri A et al, 'Organ and Tissue Transplants in Mexico' (English Abstract), *Revista de Investigación Clínica* 57 (2005) 163-69.

[91] In 2010, COFEPRIS was very successful in taking off the market several fake products that were advertised as "miraculous medicine", some of which caused cancer in patients. On this, see Murillo-Godínez G, 'Cáncer por Medicamentos: Tres Casos Recientes' *(Cancer Caused by Medicines: Three Recent Cases)*, *Medicina Interna de México* 27 (2) (2011) 179-81. Note that this rigorous vigilance and effective enforcement of legal provisions applied to fraudulent medical products occasioned the resignation of the Commissioner of COFEPRIS. This was also attributed to the enormous pressure pharmaceutical companies put on him to resign as a result of the removal of the medical products. See Cruz Martínez Á, 'México. Saldrá Miguel Ángel Toscano de la COFEPRIS por Inconformidades de las Farmacéuticas' *(Mexico. Miguel Ángel Toscano Quits COFEPRIS due to Pharmaceutical Companies' Complaints)*, *Fármacos* 14 (2) (2011) 87-8 http://www.saludyfarmacos.org/boletin-farmacos/ acc. 14 June 2012.

[92] The GHA, *supra* note 64.

of human beings.[93] Further, Article 315 of the GHA provides that all establishments which perform activities involving the procurement, analysis, preparation and disposal of organs, ***tissues*** and ***cells*** shall obtain a licence and authorisation from COFEPRIS.[94]

In accordance with the internal normative guidelines of COFEPRIS, which further regulate its supervisory and licensing activities, Article 14, Section VIII stipulates that the commission shall:

> Approve, extend or cancel projects that involve the application of pharmaceutical drugs, supplies, medical devices, experimental activities or procedures in human beings aimed to pursue scientific knowledge, and with regard to which there is ***not enough scientific evidence to prove their preventive, therapeutic and regenerative efficiency.***[95]

The assumption underlying the above provision is that current regulations stipulate no margin of discretion for physicians or scientists who are offering experimental treatments — in this case, using tissues and cells. Thus, given that COFEPRIS is responsible for the authorisation and licensing of the functioning of establishments which conduct medical procedures and clinical research involving human beings, all defined protocols must be submitted to, assessed by and approved by this agency before any medical or experimental activity is undertaken. Therefore, formal research protocols, clinical trials and experimental medical treatments being conducted in the country, including experimental SC therapies,[96] must obtain an authorisation or licence, which should be registered with and monitored by COFEPRIS.

7.4.3. THE CURRENT STATE OF CLINICAL RESEARCH

According to official notes obtained from COFEPRIS following the request to the Mexican government's portal of access to information, to date it has authorised 369 healthcare establishments for the disposition of organs, tissues and cells, of which 206 are private and 103 are in the public healthcare sector.[97] These healthcare centres not only collect and store tissues and cells, but also perform clinical trials and administer experimental medicine to human beings

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[93] Ibid.
[94] Ibid.
[95] The internal regulation of COFEPRIS can be consulted at http://www.diputados.gob.mx/LeyesBiblio/regla/29.PDF (emphasis added) acc. 14 June 2012.
[96] It has been pointed out that unorthodox SC therapies available worldwide put patients' safety at great risk with potentially adverse and lethal consequences; see MacReady N, 'The Murky Ethics of Stem-Cell Tourism', *The Lancet Oncology* 10 (4) (2009) 317.
[97] Official notes obtained from COFEPRIS through the Infomex website on 5 January 2012.

to treat diverse blood diseases such as acute limb ischemia, acute lymphoid and myeloid leukaemia, aplastic and Fanconi's anaemia, multiple myeloma, inherited or Kostman's neutropenia, thalassemia and Wiscott-Aldrich syndrome, among other immune-system diseases.[98] Table 7.1 presents an overview of the clinical trials involving the transplantation of tissues and cells currently being conducted in healthcare centres in Mexico and which are therefore not authorised to be marketed and offered to the public as standardised medical treatments.[99]

It is relevant that in the official notes obtained from COFEPRIS, this regulatory authority highlights the fact that it has authorised the research use in clinical trials of the following specific cells: germinal cells for assisted reproductive purposes, hematopoietic endothelial SCs, endothelial SCs, autologous mesenchymal SCs, neural SCs, autologous myoblast SCs, mesenchymal SCs derived from placentae and HSCs derived from BMW, UCB and the bloodstream. It thus specifies that all licensed activities involving the employment of the above-listed cells are exclusively authorised for research purposes, since the use of these cells in advanced medical therapies, medicaments, generalised treatments or standard medical treatments are not authorised by COFEPRIS at all.[100]

As noted earlier, COFEPRIS has the duty to evaluate, approve and monitor biomedical research and experimental medical applications.[101] This is troublesome, as it opens the door to potential conflicts of interest. It has been pointed out that COFEPRIS "requests 'blind' evaluations and leaves actual decision making to institutional research ethics committees (RECs) in the host organisations.[102] The responsibility for ethically evaluating research protocols often falls upon 'key' persons: the dean of teaching programmes or the service head of the host organisation."[103] Therefore, it is questionable whether ethics

[98] Ibid.
[99] This data was obtained from the online web search and corroborated with the official notes obtained from the MoH through the Health Research Policies Director's Offices on 17 November 2011.
[100] Ibid.
[101] For a general overview of the provisions concerning biomedical research in Mexico and Latin America, as well as a critique of the inadequacy and outdated state of the clinical research regulatory framework in Mexico, see Feinholz D, 'Las Investigaciones Biomédicas' *(Biomedical Research)*, in Brena Sesma I and Teboul G (Eds) *Hacia un Instrumento Regional Interamericano sobre la Bioética: Experiencias y Expectativas (Towards and Interamerican Regional Instrument on Bioethics)* (Mexico: IIJ-UNAM, 2009) 233-78.
[102] See Santiago-Rodríguez F, 'Governing Ethical Clinical Research in Developing Countries: Exploring the Case of Mexico', *Science and Public Policy* 37 (8) (2010) 580-96 at 590.
[103] Ibid.

research committees are independent evaluation bodies.[104] There is a risk of bias, since physicians are acting as judges and jury in the same (clinical) trial.[105]

It is well documented in empirical studies that COFEPRIS is "poorly financed and empowered".[106] For example, in relation to the oversight of clinical trials, empirical studies have revealed that "...'COFEPRIS does not follow up on the success or failure of clinical trials'; the expectation is that firms would make any research results publicly available. The US FDA has pointed out to the COFEPRIS that the lack of monitoring is unacceptable; a minimal level of surveillance is needed even if only on a random basis."[107] Limited financial budgets, infrastructure and human resources inhibit its optimal regulatory performance in enforcing the available biomedical legal provisions and monitoring experimental medical activities.[108] Certainly, COFEPRIS needs to be financially sound and staffed by highly qualified personnel in order to oversee effectively the experimental and mainly unsubstantiated SC-based therapies which are now extensively commercialised across the country (see Table 7.2).

Healthcare centre certification is also identified as an essential component of the monitoring of clinics, hospitals, and physicians and, in general, health facilities and providers which host medical tourism activities.[109] According to Articles 41bis and 98 of the GHA, public and private healthcare centres in Mexico must establish RECs and bioethics committees in order to obtain official certification and to operate legally in the country, as well as to assess and approve any research protocols for the conduct of investigations involving human beings.[110] Thus, it is established as official public policy that

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[104] RECs in Mexico are not regulated; proposals have been made for the enactment of an official Mexican NOM or national guideline to oversee these bodies. For instance, see Hernández M, 'La Necesidad de Regulación de los Comités de Ética de Investigación Biomédica en Países en Desarrollo como México', (*The Need to Regulate Ethics Committees for Biomedical Research in Developing Countries like Mexico)* in Keyeux G, Penschaszadeh V and Saada A (Eds) *Ética de la Investigación en los Seres Humanos y Políticas de Salud Pública (Research Ethics on Human Beings and Public Health Policies)* (Vol 2; Colombia: RedBioética & UNESCO, 2006) 285-316.

[105] See Valdez-Martínez E et al, 'Understanding the Structure and Practices of Research Ethics Committees through Research and Audit: A Study from Mexico', *Health Policy* 74 (2005) 56-68.

[106] Ibid, *supra* note 102 at 590-1.

[107] Ibid.

[108] See Santiago-Rodríguez F, 'Facing the Trial of Internationalizing Clinical Research to Developing Countries: Evidence from Mexico', in Dolfsma W, Duysters G and Costa I (Eds) *Multinationals and Emerging Economies: The Quest for Innovation and Sustainability* (Edward Elgar Publishing, 2009) 58-74.

[109] See Turner LG, 'Quality in Health Care and Globalization of Health Services: Accreditation and Regulatory Oversight of Medical Tourism Companies', *International Journal for Quality in Health Care* 23 (2011) 1-7.

[110] A snapshot of the certification status of public and private hospitals delivering SC therapies in the country is found in Tables 7.1 and 7.2. The General Health Council, through its Committee for the Certification of Healthcare Service Establishments, is the government department responsible for issuing authorisation and certification to all healthcare facilities in the country according to the Internal Regulation of the Committee for the Certification of Healthcare Service Establishments (2003) and the Internal Regulation of the National System to Certify Healthcare Establishments (2003). On the new scheme for

conventional[111] medical activities in Mexico must be based on evidence.[112] It is not clear whether there are set parameters that determine the guiding ethical principles to be followed by medical practitioners. The National Commission of Bioethics[113] has issued recommendations (the implementation of which is voluntary, however) for the establishment of clinical RECs and bioethics committees, proposing as guiding ethical principles, at least in this context, those of beneficence, non-maleficence, autonomy and justice.[114] It is also worth noting that as of 2008, at least 83% of public healthcare centres in Mexico had failed to establish RECs.[115] Furthermore, it has been shown that the existing RECs in public healthcare centres are more concerned with enacting bureaucratic procedures and improving training and research than with a commitment to the safety and adequate treatment of the subjects of clinical research.[116]

While there are a few regulatory provisions and agencies overseeing biomedical activities, the level of surveillance of SC providers is still negligible. It is precisely the combination of two elements, the weak enforcement status of COFEPRIS and the absence of targeted regulation for the therapeutic use of tissues and cells (not to mention for SCS and its clinical application), that may help us to understand the expansion of uncontrolled and unsafe SC therapies across the country. The existing inadequate regulatory regime and deficient surveillance potentially foster unethical behaviour prompted by economic and

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the certification of healthcare centres in Mexico, see Ruelas Barajas E, 'A New Era of Hospital Accreditation in Mexico', *Cirujía y Cirujanos* 73 (3) (2010) 201-2.

[111] The use of alternative medicines in Mexico (e.g. herbal, holistic, homeopathic, acupuncture, etc.) shall also be authorised and monitored by COFEPRIS and guided by particular criteria; such medicines are defined in article 224, section B and adhere to the rules established in the Regulation on Health Suppliers. For a closer review of these issues, see Gómez Castellanos R, 'El Ambiente Regulatorio de los Medicamentos Herbolarios en México. Antecedentes, Situación Actual y Perspectivas al Año 2005' *(The Regulatory Status of Herbalist Medicines in Mexico. Antecedents, Current Situation and Perspectives for 2005)*, *Boletín Latinoaméricano y del Caribe de Plantas Medicinales y Aromáticas* 8 (2009) 33-40.

[112] See Frenk J, 'Global Lessons of the Mexican Health Reform: Empowerment Through the Use of Evidence' (English Abstract), *Revista Peruana de Medicina Experimental y Salud Pública* 27 (3) (2010) 412-8; Frenk J et al, 'Evidence-Based Health Policy: Three Generations of Reform in Mexico', *The Lancet* 362 (9396) (2003) 1667-71.

[113] For a deeper review of the role and functions of this commission, see Luengas I, Feinholz D and Soberón G, 'National Bioethics Commission: Its Mandate and Approach', *Bioethical Debate* (2) (2007) 43.

[114] See Feinholz D, 'National Guidelines for the Organization and Operation of Research Ethics Committees', edited by Comisión Nacional de Bioética (México: CONBIOÉTICA, 2009) 57 http://cnb-mexico.salud.gob.mx/descargas/pdf/publicaciones/docutec/guiachbingles.pdf acc. 14 June 2012; for a theoretical account of these principles, see Beauchamp TL and Childress JF, *Principles of Biomedical Ethics,* 6th Edition (New York: Oxford University Press, 2009).

[115] This is corroborated by the official notes obtained from COFEPRIS, since its official files list only 114 registered RECs. This is worrisome, since the number of public and private healthcare establishments in Mexico greatly surpasses that number. Also see Valdez-Martínez E, 'Institutional Ethics Committees in Mexico: The Ambiguous Boundary between Healthcare Ethics and Research Ethics', *Revista Panamericana de Salud Pública* 24 (2008) 85-90.

[116] See Valdez-Martínez E et al, 'Descriptive Ethics: A Qualitative Study of Local Research Ethics Committees in Mexico', *Developing World Bioethics* 6 (2) (2006) 95-105.

commercial interests. Under this lax ethical and legal regulatory system, there is an absence of compulsion for SC providers to disclose the actual risks and benefits represented by experimental SC treatments, which have been administered to patients who eagerly seek relief from suffering irrespective of the cost.[117] Furthermore, SC therapies in the Mexican market lack evidence of quality, safety or regenerative efficacy. As the case studies analysed below reveal, most SC providers administer unsubstantiated therapies outside rigorous clinical trials.

7.5. CASE STUDIES: TRANSLATIONAL STEM CELL SCIENCE[118] IN MEXICO

In this context, the field of SCS has not received particular attention and, in addition, the budget for biomedical activities has been reduced. [119] Notwithstanding limited federal funding and the absence of specific governance in this area, various research projects involving SCs are currently being conducted in public national research centres.[120] At the other end of the clinical spectrum, allogeneic and autologous transplantations of certain types of SCs which are harvested mainly from BMW,[121] donated peripheral blood and UCB units are established practices to treat a variety of blood and immune system disorders in public healthcare institutions in Mexico (see Table 7.1).[122]

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[117] It has been pointed out that even though patients are informed about the risks associated with the application of unproven SC therapies, they ultimately decide to engage in these experimental procedures in a last desperate attempt to alleviate their suffering; see Einsiedel EF and Adamson H. 'Stem Cell Tourism and Future Stem Cell Tourists: Policy and Ethical Implications', *Developing World Bioethics* 12 (1) (2012) 35-44.

[118] Throughout this chapter, 'translational stem cell science' is used to focus "...not in the first place on stem cell research aiming at new, basic knowledge of stem cell biology. Instead, the focus is on ethical, legal, and social aspects of research, which aims at paving the way for clinical applications and translating the results of stem cell research into diagnostic and therapeutic applications", Hug and Hermerén, *op.cit. supra* note 46, at v.

[119] In Chapter 2, section 2.6, it is highlighted the limited funding for science in Mexico. Impotantly, most of the basic scientific research in Mexico is conducted in public educational and health research centres and it has been indicated that public funding for this biomedical research, not only in this country but also across the Latin American region, is very limited; however, despite the financial constraints under which stem cell researchers work, this work has increased and promises to keep flourishing. See Borbolla-Escoboza JR, 'Stem Cells and Development in Latin America', *Stem Cells and Development* 19 (3) (2010) 283-4.

[120] For a succinct review of the basic SC research being carried out so far in public research institutions, see Mayani H, 'Células Troncales y Medicina Regenerativa en México', (*Stem Cells and Regenerative Medicine in Mexico)*, in Pelayo R, Santa-Olalla J and Velasco I (Eds) *Células Troncales y Medicina Regenerativa (Stem Cells and Regenerative Medicine)* (Mexico: UNAM, 2011) 347-60.

[121] BMW transplantation is another well-established procedure in national health research centres. On this subject see Ruíz-Argüelles GJ, 'History of Bone Marrow Transplant in Mexico', *Revista Biomédica* 16 (3) (2005) 207-13; also see Ruíz-Argüelles GJ and Gómez-Almaguer D, 'Making Allogeneic Bone Marrow Transplantation Available to Patients in Developing Countries: The Mexican Experience', *The Open Haematology Journal* (2) (2008) 67-73.

[122] Even though there are a few public health centres conducting HSC transplants, according to Mexican physicians the development of this clinical setting is lagging behind the global standards; see Ruíz-Argüelles GJ, Cazares-Ordoñez Y and Ruíz-Delgado GJ, 'Algunas Observaciones sobre el Rezago en la Práctica de los Trasplantes Hematopoyéticos en México' *(Some Observations about the Backwardness of*

On the private healthcare side, the online search retrieved more than twenty illegitimate profiteering SC clinics which extensively advertise dubious SC-based treatments all over the country as standardised, advanced medical treatments and claim to treat a variety of chronic illnesses, including congestive heart failure, multiple sclerosis, type 2 diabetes, autism, Alzheimer's and Parkinson's diseases (see Table 7.2).[123] Most SC therapies available on the private market involve autologous ASC transplantation and lack clinical evidence of their quality, efficacy and safety.[124] Examples from the case studies are SC injections extracted from patients' own BMW, adipose tissues and teeth. As explained above, the regulatory system allows the storage of tissues and cells to be licensed by COFEPRIS, but the commercial use of human organs, tissues and cells is banned by the general law and secondary regulation; thus, according to the official data obtained from COFEPRIS, there has to date been no authorisation of commercialised SC-based therapies as standard medical treatments or practices.[125]

It remains problematic that experimental SC therapies are commonly marketed on a commercial basis all over the country (see Table 7.2). Patients are paying for expensive SC therapies in Mexico.[126] Private hospitals providing SC therapies are not under stringent ethical and legal control. The following sub-sections explore the provision of some of the SC therapies available in private Mexican healthcare establishments. These case studies exemplify the failure of the relevant regulatory agency to apply the existing legal norms to such establishments.

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the Practice of Hematopoietic Transplants in Mexico), *Revista de Hematología de México* 12 (1) (2011) 1-4.

[123] It must be acknowledged that the data presented concerning the type of cells and issues utilised by SC therapy providers are self-reported by clinic websites and in the literature. Therefore, one of the limitations of this paper is that the origin or nature of the SC used by public and private healthcare providers is not independently verified by further empirical work by the author, so it may also be the case that clinics herein mentioned are not injecting or using SC at all.

[124] McReady N, *op. cit. supra* 96.

[125] Ibid, *supra* note 97.

[126] A special investigation carried out by US journalists who revealed the fraud committed by US physicians when offering unsubstantiated and expensive SC-based treatments on the border of Mexico (particularly in Monterrey, NL), *CBS' 60 minutes (US) 2010 segment* '21st Century Snakeoil', (9 September 9 2011) *available at:* http://www.cbsnews.com/stories/2010/09/09/60minutes/main6850496.shtml?tag=mncol;lst;3 acc. 14 June 2012. Likewise, in Canada, a segment was broadcasted highlighting the marketing of untested SC therapies offered in Mexico by a physician who lost his licence to work in the USA. See *Global News 16x9 The Bigger Picture* 'Selling Hope', (15 January 15 2012) *available at: http://www.globalnews.ca/16x9/video/169+story++selling+hope/video.html?v=2187241991&p=1&s=dd#video* acc. 14 June 2012.

7.5.1. CASE I: THE TOOTH FAIRY?

Private biobanks have found a niche opportunity for economic profit by marketing SC storage as biological life insurance,[127] since these biobanks are important tissue containers for the procurement of SCs. A number of private clinics and biobanks have deliberately exploited the lack of public awareness in relation to the current state of scientific progress concerning the clinical use of the patient's own SCs.[128] This is the case of BioEDEN Inc,[129] an international biotech company which opened a branch in Mexico in 2009.[130] In Mexico, this company focuses on the collection and storage of dental tissues, such as children's milk teeth and adult wisdom teeth, in order to later procure mesenchymal stem cells (MSCs).[131] This private dental biobank has also publicly reported surgical interventions or transplants, applying autologous somatic SCs or MSCs harvested from deciduous teeth and dental pulp tissues to human patients.[132] Globally, no clinical application using human SCs isolated from teeth has to date been authorised as an advanced SC-based therapy.[133]

The claims made by BioEDEN Mexico via its web portal are supported by literature reporting pre-clinical results on animals, but lack documentary

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[127] Many private biobanks worldwide, particularly those collecting UCB, advertise the storage of these tissues as a biological insurance to obtain future SC-based therapies. Many ethical issues are raised, concerning for example the real possibility that the stored tissue will really be needed for a future treatment. See further Hofmann B, Solbakk JH and Holm S, 'The Use of Analogical Reasoning in Umbilical Cord Blood Biobanking', in Solbakk JH, Holm S and Hofmann B (Eds) *The Ethics of Research Biobanking* (Springer, 2009) 159-72.

[128] To date the therapeutic application of autologous SCs therapies is still limited, and as mentioned earlier clinical trials are under way, but no standardized SC-based treatment is available yet, with the exception of the well-established HSC transplants to treat blood disorders. On this, see Power C and Rasko JEJ, 'Promises and Challenges of Stem Cell Research for Regenerative Medicine', *Annals of Internal Medicine* 155 (10) (2011) 706-13; also see Master Z and Resnik DB, 'Stem-Cell Tourism and Scientific Responsibility', *EMBO Reports* (12) (2011) 992-5.

[129] BioEDEN in the UK has patented the procedure of SC isolation from teeth; see BioEDEN UK, 'BioEDEN Stem Cell Research of Mesenchymal Stem Cells (MSCs) Case Study', (20 August 2010) http://www.daresburysic.co.uk/case-studies/bioeden-case-study.aspx acc. 14 June 2012.

[130] See BioEDEN's website at: http://www.celulasdentales.com/ acc. 14 June 2012.

[131] MSCs are somatic SCs normally found in BMW and are also known as stromal cells; under adequate conditions, they have the hypothetical capacity to differentiate into diverse cell lineages, including muscle, bone, cartilage, fat tissues and connected cells from which these were extracted. See see Vemuri MC, Chase LG and Rao MS, *Mesenchymal Stem Cell Assays and Applications* (Humana Press, 2011) 107-122.

[132] This information was retrieved from the procedures self-reported on BioEDEN Mexico's website and YouTube channel. TV broadcasts are also available. These have reported the transplantations and surgical interventions carried out by this company of SCs harvested from deciduous teeth and dental pulp; see http://www.youtube.com/user/BioEDENMexico?feature=watch acc. 4 April 2012.

[133] Until now, well-designed pre-clinical studies in animals using deciduous teeth and dental pulp have been promising in the orthopaedics and maxillofacial areas, but clinical trials involving human beings have not been approved yet, therefore dental SCs clinical and commercial application still have a long way to go; see Yamada Y, Ito K, Nakamura S, Ueda M and Nagasaka T, 'Promising Cell-Based Therapy for Bone Regeneration Using Stem Cells From Deciduous Teeth, Dental Pulp, and Bone Marrow', *Cell Transplantation* 20 (7) (2011) 1003-13; also see D'aquino R, Papaccio G, Laino G and Graziano A, 'Dental Pulp Stem Cells: A Promising Tool for Bone Regeneration', *Stem Cell Reviews and Reports* 4 (2008) 21-6. Thus, experiments with human dental SC are still at a laboratory level, this is to say, researchers are initially investigating how these cells work and can be differentiated;

evidence reporting clinical trials or applications involving human beings.[134] In 2010, a letter to the *British Dental Journal* reported that the BioEDEN branch in Mexico, along with many others including in Italy, had succeeded in applying therapies to regenerate diverse tissues and maxillofacial bone cells by utilising dental pulp SCs.[135]

In the local media in Mexico, the BioEDEN enterprise announced this newly applied tooth cell-based therapy as a worldwide medical breakthrough.[136] However, the media and BioEDEN's physicians have failed to disclose to the general public and patients what the real potential of these cells is, since to date the therapeutic use of tooth SCs is still at an experimental stage; moreover, these SCs have the potential to be used only in dentistry.[137] The national media positively welcomed this therapeutic procedure and TV programmes included special features presenting these SCs interventions to the public as a marvellous scientific discovery, claiming that these cells could regenerate not only maxillofacial bones, but also any bone, tissue and skin in the human body.[138]

Prospective SC patients considering preserving their teeth and undertaking dental SC therapies are in a vulnerable position, since any consent given to undergoing these procedures would be based on misleading and incomplete information provided by the media and SC providers. This is in breach of Articles 20 and 21 of the Biomedical Research Regulation, which state that patients who give consent are required to have an accurate and complete understanding of the benefits and risks of the procedures they are subjected to.[139]

The Mexican franchise of BioEDEN has taken gross advantage of the ethical, religious and legal disputes over SCS prevailing in the country by stating that it is applying non-controversial somatic (bodily) ASCs harvested from teeth, as opposed to those embryonic SCs procured from embryos which

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[134] The scientific section of the BioEDEN Mexico website lists a very large amount of scientific literature reporting clinical research and therapies with stem cells procured from teeth and tested on animals, but not yet on humans; see http://www.celulasdentales.com/area-profesional/portal-de-dentistas-del-equipo-bioeden-mexico/articulos-cientificos-sobre-celulas-madre/ acc. 4 April 2012.
[135] See James D, 'Stem Cell Visits', *British Dental Journal* 209 (6) (2010) 263.
[136] Ibid, *supra* note 132.
[137] See Inanç B and Elçin YM, 'Stem Cell in Tooth Tissue Regeneration–Challenges and Limitations', *Stem Cell Reviews and Reports* (2011).
[138] This transplant was reported in a news broadcast available in Spanish at http://www.youtube.com/watch?v=PqrL-GpGABo&feature=related acc. 4 April 2012.
[139] Ibid, *supra* note 67.

involve their destruction.[140] The company claims to be using non-controversial sources of SCs contained in the pulp of deciduous teeth and that these have proven to be more beneficial than others, such as those procured from embryos and UCB. Such claims are unsound because they are not backed by conclusive scientific data. Furthermore, the company has infringed Article 327 of the GHA and the related Articles 21 and 22 of the Tissue Regulation, which provide that human tissues and their derivatives may not be the object of commercialisation and that any therapeutic activity involving tissues, cells and their products shall be free of any charge.[141]

On its website, BioEDEN states that it has authorisations from the US FDA and the UK HTA, without specifying the nature of the activities supposedly authorised by these foreign regulatory bodies.[142] In fact, neither the FDA nor the HTA has authorised SC therapies for commercial use.[143] In addition, in Mexico BioEDEN must comply with the national regulations, so, according to the data gathered from the official notes obtained through CENATRA and COFEPRIS, this private biobank has no licence to transplant tissues and cells (in this case SCs derived from tooth tissues). Moreover, COFEPRIS's registry of existing RECs in private and public healthcare institutions reveals that BioEDEN lacks any ethical oversight body to assess and approve any protocol or therapeutic activity involving tissues and cells, as required by Articles 41 bis and 98 of the GHA. Likewise, according to Article 17 of the internal regulation of COFEPRIS, BioEDEN needs to obtain authorisation to carry out experimental medical activities or to test new therapies or medical products. It is uncertain whether the company has obtained a licence to conduct research and therapeutic activities involving tissues and cells, since COFEPRIS reserves such information as confidential. However, what is clear—and is

[140] This capitalization of the moral controversies prevailing over the status of the embryo in favour of the use of ASCs as a preferable source for therapies has been applied in similar lax regulatory contexts where unproven SC therapies have proliferated without stringent control; for example, see Song P, 'The Proliferation of Stem Cell Therapies in Post-Mao China: Problematizing Ethical Regulation', *New Genetics and Society* 30 (2) (2011) 141-53.

[141] The GHA, *supra* note 64 and Tissue Regulation, *supra* note 68.

[142] Information is retrieved from BioEDEN's web portal section 'Stem Cells, the Process, Who We Are', available in Spanish at: http://www.celulasdentales.com/el-proceso/quienes-somos/ acc. 4 April 2012.

[143] The FDA has warned people about illegal commercialisation of SC therapies that are being offered worldwide without governmental approval, *available at:* http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm286155.htm acc. 4 April 2012. At a European level, the Advanced Therapy Medicinal Products regulation and the European Medicines Agency regulates the introduction of novel therapies arising from SCS. In the UK, the body authorising the introduction of advanced SC therapies is the MHRA. Relevantly, these agencies emphasize that no advanced SC therapies have yet met their approval as medicines and that they are years away from being authorized as safe and effective treatments; *available at* http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000471.jsp&murl=menus/special_topics/special_topics.jsp&mid=WC0b01ac058022857d acc. 4 April 2012.

confirmed by COFEPRIS's official notes—is that to date there has been no authorisation to commercialise any medical or therapeutic intervention utilising SCs.

This case evidences the failure of COFEPRIS to monitor and sanction not only the illegitimate profit-seeking delivery of experimental dental SC therapies, but also the misleading statements widely broadcast by this biobank. It also sheds light on the weak oversight of these practices in Mexico, leaving prospective patients vulnerable to physical and financial harm. Indeed, patients are deprived of any ethical and practical safeguards, assistance or resources to seek legal remedies. The case thus demonstrates the urgent need to enhance existing norms so as to comprehensively regulate the investigative procedures and therapeutic activities carried out with tissues, cells and their derivatives, in particular the area of SC research and its therapeutic applications, since the use of allogeneic or autologous ASC transplantation on a non-profit basis remains unregulated.

7.5.2. CASE II: STEM CELL THERAPY FOR AMYOTROPHIC LATERAL SCLEROSIS

Mexico is a pioneer in regenerative medicine.[144] However, it is uncertain whether this is subject to the requisite stringent oversight. Evidence to the contrary comes from the SC transplants performed at a private university medical facility, the San José Hospital (HSJ) of the Medical Technology School of Monterey (ITESM).[145] This is one of the largest, wealthiest and most reputable private healthcare facilities in the country, globally renowned for its innovative high-tech medical care, clinical research and application of quality and safety standards.[146] The HSJ is accredited by the relevant health authorities and has a licence from COFEPRIS to operate a healthcare establishment and a public biobank. However, it is not authorised to market SC-based interventions as generalised and standard medical treatments or therapeutic procedures.[147]

Amyotrophic lateral sclerosis (ALS), which is also called Lou Gehrig's disease, is a lethal neurodegenerative disorder which rapidly attacks the motor

[144] See Editorial, 'Biotech Round the World: Focus on Mexico', *Biotechnology Journal* 3 (9-10) (2008) 1131-34.
[145] The HSJ Technology School of Monterrey is considered to be an optimal place for clinical studies due to its structural capabilities with a broad human and material infrastructure.
[146] See Vequist DG and Valdez E, 'Medical Tourism Economic Report: Monterrey, Mexico', *Medical Tourism Magazine* (4) (2008) 20-1 http://globalhealthcaremagazine.com/issue.php?Id=4 acc. 4 April 2012. In the years to come, "Monterrey healthcare city" as it is named by the International Medical Tourism Association, is likely to undergo dramatic growth in medical services and stem cell therapies, since this northern area is heavily supported by private investment and has constantly adapted its infrastructure and social endeavour to serve US firms outsourcing healthcare services.
[147] Ibid, *supra* note 97.

neuron cells of the brain and spinal cord and which later obstructs muscular functioning; an in-depth understanding of this illness has yet to be acquired.[148] Since 2006, the HSJ has conducted clinical trials to test SC-based treatments involving endoscopic injections of autologous somatic SCs, which are harvested from patient's own circulating BMW blood and then injected into the frontal motor cortex (a region located in the front of brain) in order to treat ALS.[149] These interventions have been reported by the HSJ in peer-reviewed publications, which provide an account of its ALS treatment and outcomes.[150] The HSJ has reported that its protocols and patient recruitment are reviewed and approved by its institutional REC, as described in its publication. The informed consent of patients and families is also sought after the internal REC has granted permission to proceed.[151] According to COFEPRIS's official notes, this hospital has a registered REC and bioethics committee, in compliance with the requirement of Articles 41bis and 98 of the GHA. However, as noted in the overview of the current regulatory regime, there are as yet no clear and compulsory guidelines for the operation, functioning and integration of RECs in Mexico.[152]

The data gathered for this study indicate that the HSJ makes no financial gain from these SC-based therapies, since the procedures are performed in a research setting. Although the hospital has complied with the existing legal requirements related to clinical trials, there are no clear rules to follow regarding the therapeutic use and transplantations of SCs. Notably, the scientific publication of the outcomes of this experimental SC therapy constitutes a positive feature in favour of the HSJ, since it shows its transparency in publishing its research results. In addition, the HSJ can be seen as seeking to maintain its medical prestige and trustworthiness by adopting a transparent operational approach through the disclosure of its results in a peer-reviewed scientific publication.[153] The hospital and its staff have shown transparency, ethical conduct and commitment to developing evidence-based

[148] See Sipp D, *supra* note 22.
[149] See Martínez HR et al, 'Stem-Cell Transplantation into the Frontal Motor Cortex in Amyotrophic Lateral Sclerosis Patients', *Cytotherapy* 11 (2009) 26-34.
[150] Ibid.
[151] According to article 19 of the 2008 amended Helsinki Declaration, there is a prospective obligation to register clinical trials on a public database before they are conducted. Further, article 30 provides the ethical duty to publish the outcomes of the research, whether positive or negative. At least this ethical obligation has been fulfilled by the HSJ's team; see World Medical Association (WMA), *Declaration of Helsinki: Ethical Principles for Medical Research involving Human Subjects* (1964) (7th version 2008).
[152] Ibid, *supra* note 97.
[153] This is contrary to what has occurred in many other similar cases in Mexico and in many other countries, where unregulated and unproven SC therapies to treat ALS have been performed without any ethical or regulatory oversight; see Sipp D, *supra* note 22.

knowledge on the clinical application of SCs, notwithstanding the absence of comprehensive regulation of the therapeutic and research uses of tissues, cells and their derivatives.

A growing body of non-governmental patient groups has investigated and appraised unregulated SC therapies marketed worldwide. For example, in the USA, the ALSUntangled group (ALSU)[154] is a watchdog organisation which supports ALS patients and their families in tracking and evaluating these SC-based therapies. The experiences reported to ALSU by patients who have undergone SC therapies at the HSJ, together with the findings of independent investigations conducted by ALSU, are published by way of summaries in the ALS Journal.[155] The patients' narratives indicate that they decided to undergo unregulated SC therapies because they had nothing to lose and all to gain; patients noted that the rapid progress of this neurodegenerative disease had notably decreased. However, significant improvements were not experienced.[156] The ALSU summary report also raised serious concerns regarding the lack of safety of the procedures and the failure to provide an objective appraisal of adverse outcomes.[157] Furthermore, one in ten patients died within ten days of the transplant and a major exploration of the possible reasons was ignored. Nor was there any clear justification for transplanting or injecting SCs into the frontal cortex region of the brain, despite it being a procedure with the potential to affect cognitive function. Finally, the report states that the efficacy of the therapies was poorly communicated, that the standard cell dosage was not provided and that clinical tests were not randomised or blinded.[158]

This case exemplifies the need to adopt adequate guidelines when conducting research and therapeutic applications of SCS by non-profit healthcare establishments. This should be accompanied by effective monitoring

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[154] It is worth mentioning the valuable support offered by ALSUntangled to patients suffering from ALS. This initiative makes use of social networking, such as Twitter, in order to provide patients, clinicians and scientists with carefully scrutinised, up-to-date information on alternative or off-label ALS treatments. This is an innovative way to actively share knowledge among interested parties as well as bringing openness to investigations. The website and internet strategies used by ALSU are *available at:* http://www.alsuntangled.com/ acc. 14 June 2012.

[155] See Bedlack R and Hardiman O, 'ALSUntangled (ALSU): A Scientific Approach to Off-Label Treatment Options for People with ALS Using Tweets and Twitters', *Amyotrophic Lateral Sclerosis* 10 (3) (2009) 129-30.

[156] See Gornall J, 'Stem Cell Renegades or Pioneers?' *British Medical Journal* 340 (8) (2010) 1002-05.

[157] For example, no reference is made to the well-documented and scientifically disseminated case of a young patient who died due to the development of lethal tumours in the brain and spinal cord after having received a foetal neural SC transplantation; although the SCs injected are embryonic, similar risks and adverse effects can appear using ASC. See Amariglio N et al, 'Donor-Derived Brain Tumour Following Neural Stem Cell Transplantation in an Ataxia Telangiectasia Patient', *PlosMedicine* 6 (2) (2009) 0221-31; also see Tuffs A, 'Stem Cell Treatment in Germany is Under Scrutiny After Child's Death', *BMJ* (341) (2010).

[158] See ALSUntangled G, 'ALSUuntangled Update 3: Investigating Stem Cell Transplants at the Hospital San Jose Tecnologico de Monterrey', *Amyotrophic Lateral Sclerosis* 11 (1-2) (2010) 248-9.

mechanisms to guarantee the proper implementation of established procedures and to overcome the current difficulties faced by COFEPRIS when overseeing emerging and innovative biomedical practices.

7.5.3. CASE III: STEM CELL-BASED HEART REPAIR THERAPY

The Mexican state of Baja California (BC) has traditionally occupied a niche as a destination for US citizens seeking cheap and easily accessible healthcare.[159] The geographical proximity of the border city of Tijuana to the USA has led to this city having the largest number of private healthcare providers, with a substantial number of foreign patients being treated each year.[160] Among these private medical facilities is the Regenerative Medicine Institute of Hospital Angeles of Tijuana (referred to as the Angeles Regenerative Institute).[161]

According to the official data gathered for the present study, Hospital Angeles of Tijuana runs an institutional REC and has a licence issued by COFEPRIS to bank germinal cells for reproductive purposes.[162] Additionally, COFEPRIS has authorised the hospital to procure and use tissues and cells for therapeutic purposes. As earlier alluded to, COFEPRIS has authorised no public or private healthcare establishment to commercialise SC-based therapies as medicines, standard treatments or advanced therapies.[163]

The Angeles Regenerative Institute offers an alternative to SC therapies not yet approved by the US FDA, as advertised on its website.[164] It commercialises autologous SC-based therapies, consisting of the autologous transplantation of ASCs harvested from patients' adipose (fatty) tissue.[165] These adipose ASCs are obtained by liposuction, then re-injected, using a needle catheter, into the patient's heart.[166] The special catheter used, called MyoCath, is

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[159] See Cortez N, 'Patients Without Borders: The Emerging Global Market for Patients and the Evolution of Modern Health Care', *Indiana Law Journal* 83 (2008).
[160] See Vargas Hernández JG, 'An Exploration of Tijuana-San Diego Marketing Environment and Marketing Border of Health Service in Tijuana', *International Business Research* 3 (2) (2010) 162-8.
[161] In Spanish, *Instituto de Medicina Regenerativa S.A. de C.V., available at* http://www.regenerativemedicine.mx/ acc. 4 April 2012.
[162] Ibid, *supra* note 97.
[163] Ibid.
[164] The web address is shown in Table 7.2. Situated a few minutes' distance from the US border city of San Diego, it is one of the hospitals belonging to the national private healthcare company 'Angeles Group Health Services', having 23 Angeles hospitals across Mexico which enjoy a world-established medical recognition. In 2007, this group started an international programme to provide patients with English-fluent attention and medical advice. See further Grupo Angeles, 'Hospital Angeles How They Changed Private Healthcare in Mexico', *Medical Tourism Magazine* 17 (2010) 13-6.
[165] For a list of the illnesses for which treatment is offered and prices, go to http://www.angeleshealth.com/procedures/stem-cell/pricing.aspx acc. 14 June 2012.
[166] See Hotkar A and Balinsky W, 'Stem Cells in the Treatment of Cardiovascular Disease—An Overview', *Stem Cell Reviews and Reports* (2011) 1-9.

fabricated by the US Bioheart company.[167] According to the Angeles Regenerative Institute website, the aim of this SC therapy is to regenerate heart muscle tissue and to improve the working of the heart and the carrying of blood to it. In this case, the increased capacity of patients to walk longer distances allowed a heart functioning measure to assess the improvements following re-injection of patients' SCs.[168] To date, preclinical studies using adipose ASCs have been conducted in animal models, while controlled testing of safety and efficacy in humans is still pending, since more pre-clinical studies are required in order to understand the mechanisms of differentiation of adipose SCs, according to the literature reviewed.[169] Notwithstanding the lack of sound scientific evidence of the safety and effectiveness of these SC therapies in humans, the Angeles Regenerative Institute has reported, in an online database, positive results and improvements in health in the cases of two patients with congestive heart failure.[170] However, a cause for concern is that there is no trace of any attempt to measure the possible placebo effect.

According to the international clinicaltrials.gov database, the Angeles Regenerative Institute has been registered as conducting at least four clinical trials to test the safety and effects of autologous adipose-derived stromal cells delivered to patients with stroke, type II diabetes, diffuse lesions in the brain, renal failure and Parkinson's disease.[171] The status of these studies is given as "currently recruiting participants".[172] As previously indicated, according to the Mexican biomedical regulatory regime, non-profit experimental therapeutic activities are permissible provided that COFEPRIS grants authorisation. However, the Angeles Regenerative Institute not only conducts clinical trials, but also commercialises these experimental autologous ASC transplants as standard therapy. The hospital markets experimental SC-based therapies, meaning that research subjects undergoing experimental medical practices are being charged for their involvement, as if they were consuming proven medical treatments. This application of experimental SC therapies for financial gain

[167] Bioheart Inc. is a US company associated with the Regenerative Medicine Institute of Angeles Hospital; according to this company website, this centre is the first in Latin America of more than five planned to be conducted outside US-controlled clinical trials. Information available from www.bioheartinc.com acc. 18 June 2012.
[168] See 'Bioheart Reports Significant Improvements in Heart Failure Patients from Center of Excellence Program', August 24, 2010, *available at:* www.bioheartinc.com/newsandevents.html acc. 18 June 2012.
[169] See Illouz Y and Aris S, *Adipose Stem Cells and Regenerative Medicine* (Springer-Verlag Berlin Heidelberg, 2011).
[170] See 'Bioheart Commenced Successful Regenerative Stem Cell Treatments with Latin American Patients Having Congestive Heart Failure', (14 April 2010) ibid, *supra* note 167.
[171] This data was retrieved from the www.clinicaltrials.gov website and the information was last updated in October 2011, *available at:* http://clinicaltrials.gov/ct2/show/NCT01453751 acc. 18 June 2012.
[172] Ibid.

carried out by Angeles Regenerative Institute is in contravention of Article 327 of the GHA, which bans the commercialisation of tissues and cells, as well as of Articles 21 and 22 of the Tissue Regulation and the related provisions of the biomedical regulation, which forbid the charging of patients who enter clinical trials or who receive therapy derived from tissues, cells and their products.

In seeking to demonstrate a certain adherence to some guidelines and self-regulatory measures, the Angeles Regenerative Institute website informs patients that it is certified in the US by the ICMS, a private medical organisation.[173] At the beginning of 2011, the ICMS accredited and certified Angeles Regenerative Institute as the first private healthcare facility in Latin America where autologous ASC transplants could be performed.[174] However, as mentioned in previous sections, the reliability of the ICMS is highly contested, as its role as a private certifier of autologous SC-based treatments has raised concerns among the academic community and has been challenged by the FDA.[175] Hence, its legal status as an organisation legitimately entitled to certify SC medical practices is disputed. Some of the fundamental concerns about the ICMS are that it is not rigorous in certifying clinics, since sound scientific evidence or pre-clinical and clinical trial data are not required to obtain this certification for the later commercial application of SC-based therapies in humans.[176]

This case study demonstrates the lack of surveillance exercised by COFEPRIS. It is also asserted that the building of a substantial infrastructure of governance for SCS and its translation to the clinical setting are urgently needed, along with its effective oversight. Until now, physicians have taken advantage of the lack of SC-specific regulations and have tried to confuse the public by switching terms and activities; for example, failing to distinguish surgical interventions that may require rigorous clinical trials from those concerned solely with the practice of medicine or medical care. This is certainly

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[173] Ibid, *supra* note 29; also see International Cellular Medicine Society ICMS, 'Open Letter to Stem Cell Clinics', (2011) http://www.cellmedicinesociety.org/attachments/233_Open%20Letter%20To%20Stem%20Cell%20Clinics%20v2.pdf acc. 14 June 2012.

[174] See ICMS, 'Mexico-Based Stem Cell Clinic Advances in Accreditation Process' *BioPortafolio* (15 July 2011) http://www.bioportfolio.com/news/article/742367/Mexico-based-Stem-Cell-Clinic-Advances-In-Accreditation-Process.html acc. 14 June 2012; a second Mexican SC clinic, located in the paradisiacal beach resort, Cancún, has undergone the ICMS accreditation programme. See ICMS 'World Stem Cells Second Participant in ICMS Stem Cell Clinic Accreditation Program', (19 May 2011) www.cellmedicinesociety.org/home/news/press-releases acc. 14 June 2012.

[175] See Mitka M, 'Troubled by "Stem Cell Tourism" Claims, Group Launches Web-Based Guidance', *JAMA: The Journal of the American Medical Association* 304 (12) (2010) 1315-6.

[176] On this see Editorial, 'Order from Chaos', *Nature 446* (2010).

problematic, since experimental SC therapies can be marketed and offered to the public without the close monitoring and security measures needed to prevent the generation of carcinogenic cells and infections, among many other precautions. Certainly, before SC therapies become easily available in the medical marketplace, it is essential that they undergo clinical trials. The clinical application of SC therapies is in its initial stages and conclusive scientific evidence of quality, security and efficacy is not yet available, with the result that these interventions cannot be treated as simple medical activities with the frivolous SC treatment purveyor's intention of gaining economic profit from desperate and misinformed patients. This situation places patients in an extremely vulnerable position, which is aggravated when purveyors of SC therapies and clinics are certified by dubious private medical bodies.

As explored in previous sections, to date, the MoH has not issued targeted NOMs or specific guidelines for the non-profit use of tissues and cells or derived biological raw material for research or/and therapeutic purposes. Ideally, the introduction of a NOM to standardise this area should specify the principal purposes to be licensed by the regulatory body, establish supervisory and compliance mechanisms, create criteria to identify deviations and overall guidelines to assure the quality and proper operation of clinical trials and any experimental therapeutic activity utilising tissues, cells and their derivatives, as well as assessing the introduction of SC therapies as advanced biological medicines and treatments.[177] The absence of more targeted regulations, official standards or guidelines makes it difficult for the supervisory authority to effectively implement the existing laws, which are broad and vague in relation to their ambit of regulation; therefore, legislation is inadequate and its enforcement dysfunctional.

7.6. CONCLUDING REMARKS

Experimental SC therapies are easily available and commercialised all over Mexico without appropriate legal constraint and monitoring, in clear breach of the law. The GHA explicitly prohibits the commercial use of human tissues and cells and their derivatives; furthermore, any therapeutic procedures involving this human material must be *gratuitous*. The law also stipulates that healthcare providers and establishments must be licensed and authorised by COFEPRIS if they are to administer or conduct experimental medical procedures. However,

[177] See Chapter 4 on the normative proposals which I advocate for in this thesis.

no article in the legal system directly addresses the clinical application of SCS-derived products, that is to say the use of either allogeneic or autologous SC transplantation in medical, experimental or therapeutic activities (e.g. the procurement, origin or derivation of SCs, patents, testing, scientific qualifications, follow-up and ethical monitoring of SC transplants).

The current norms, which are wide and vague in scope, are inadequate, since when they were enacted the legislators did not have in mind the current scientific developments, so legislation is out-dated and enforcement is therefore dysfunctional. Hence, the problem in Mexico concerning the marketing of unsubstantiated SC treatment is not limited to the absence of targeted legal provisions, but extends to the enforcement of the existing rules, which has been negligible to date. There is a legal vacuum concerning the regulation of the allogeneic and autologous use, storage and application, for therapeutic and research purposes, of SCs derived from human tissues. Notwithstanding the prevailing legal lacuna, the relevant law explicitly prohibits the profit-seeking utilisation of tissues and cells. Furthermore, clinical trials must be free according to the biomedical regulations and good medical practice, so if purveyors of experimental SC treatments are charging human subjects to take part in these experimental treatments, they are clearly infringing domestic and internationally established regulations. Patients (and/or research subjects) should not be charged as if they were consuming merchandise; their participation in unproven and untested SC treatments, whose risks and benefits are subject to inherent uncertainty, must be closely controlled and must yield no economic profit.

The current *laisser-faire* regime has allowed the spread of experimental SC therapies all over the country, putting at risk patients' wellbeing and giving rise to significant ethical and legal challenges.[178] Although autologous ASC transplantation presents less controversial ethical dilemmas and social concerns (since it does not involve embryonic destruction), its unorthodox applicability imposes a burden on physicians, clinicians and practitioners to carefully measure the existing clinical risks involved, thus ensuring the safety and security of patients, while allowing progress and maintaining the best practices and reputation of this growing field.[179] The current inefficacy of available norms

[178] For a detailed review of these issues, see Hyun I, 'Allowing Innovative Stem Cell-Based Therapies Outside of Clinical Trials: Ethical and Policy Challenges', *Journal of Law, Medicine and Ethics* 38 (2) (2010) 277-85.

[179] See Herberts C, Kwa M and Hermsen H, 'Risk Factors in the Development of Stem Cell Therapy', *Journal of Translational Medicine* 9 (2011).

in dealing with the risks associated with the appearance of dubious SC treatments in Mexico cannot prevail and their scope is bound to change. The effective governance of SCS applications is a "delicate balancing act between minimizing overregulation while still assuring adequate protection of research subjects".[180]

The regulatory agency has failed to effectively monitor, supervise and sanction healthcare providers and purveyors of dubious SC treatments that are clearly infringing the current legal provisions concerning the commercial use of tissues and cells. The ineffective enforcement of the law is partially explained by the current regulatory authorities being overstretched, underfunded and lacking compliance mechanisms, so that existing legal provisions are difficult to apply rigorously, a situation not helped by the lack of more targeted legislation to govern the SCS field as a whole. The unsuccessful supervision by COFEPRIS may be also attributed to a shortage of well-trained and experienced personnel to effectively monitor the emergence of experimental SC therapies and providers, as required. It is true that the enactment of targeted regulations alone cannot solve the problem, but if stringent rules for compliance are also promulgated, the law may cease to be a dead letter in this domain.

As provisional measures, the existing regulatory system should incorporate internationally accepted scientific guidelines and standards—for instance, those established by the ISSCR—and ensure that COFEPRIS enforces them effectively, in coordination with other relevant authorities (e.g. the Ministry of Tourism and medical tourism outsourcing agencies) until more sophisticated regulation is in place. Stronger regulatory agencies are crucial in order to implement international guidelines and standards in this area. This must be combined with the implementation of an adequate financial budget and trained personnel for the regulatory authority to efficiently monitor clinical trials and experimental medical practices, as well as to effectively enforce the legislative provisions adopted. Once COFEPRIS is better funded, a coordinated network, organised dialogue and interaction between relevant organisations and the head of this governmental authority would guarantee better surveillance of emerging SC therapies. Collaboration is crucial in order to disseminate accurate information among prospective SC patients in relation to the current status of SC clinical applications in the country. This is necessary if the current government's goal is the consolidation of Mexico as a reputable and

[180] See Isasi RM and Knoppers BM, 'From Banking to International Governance: Fostering Innovation in Stem Cell Research', *Stem Cells International* (2011).

secure place for medical tourism activities, ensuring the wellbeing and safety of those pursuing experimental SC therapies. There is no doubt that adequate mechanisms of compliance combined with more targeted regulatory provisions are necessary if Mexico is to invest seriously in trading its reputation as a medical destination for patients who are willing to undergo experimental therapies in the hope of alleviating their suffering.

Table 7.1: Snapshot of Stem Cell Clinical Trials in Public Healthcare Centres			
Healthcare Facility	**Clinical Trials (CTs)* and Stem Cell Transplants****	**Status**	**Ethics Committee/ Accreditations (♣†‡)**
1. "La Raza" Medical Centre of the Mexican Institute for Social Security (IMSS-CBB) (case I)	**SCT ** in ALL, AML, AA, THA, FA, GS, IN, OP, GVHD and WAS**	In progress	REC-ECOT/ ‡
2. National Institute of Medical Science and Nutrition "Dr. Salvador Subirán"	Haematopoietic SCT in AA	In progress	REC-ECOT/ ‡
3. UCB-BB of the University Hospital of Monterrey, Nuevo León "Dr. Jose Eleuterio Gonzalez"	CT*: Haematopoietic stem cell transplantation in type 1 diabetes mellitus	Recruiting participants	REC-ECOT/♣‡
4. National Institute of Oncology (INCAN)	SCT in MM	In progress	BC-REC-ECOT/‡
5. National Medical Centre "Manuel Avila Camacho" IMSS. Puebla	SCT in ALL, AML, AA, THA, FA and GVHD	In progress	REC-ECOT/‡
6. National Medical Centre "20 de Noviembre"	SCT in ALI	In progress	REC-ECOT/‡
7. National Institute of Paediatrics	SC in ALL and GVHD	In progress	REC-ECOT/♣‡
8. Children's Hospital of Mexico "Federico Gómez"	Xenotransplantation SC in type I diabetes	In progress	REC/‡
9. National Centre for Blood Transfusion (CNTS) of the Ministry of Health (MoH) and its "CordMex" biobank	CT*: "Intracoronary Autologous Stem Cell Transplantation in ST Elevation Myocardial Infarction: Tracia Study"	Recruiting participants	REC-ECOT/ ‡
10. National Institute of Cardiology "Ignacio Chávez" Mexico	CT*: "Intracoronary Autologous Stem Cell Transplantation in ST Elevation Myocardial Infarction: Tracia Study"	Recruiting participants	REC-ECOT/♣‡ Joint International Commission
11. Hospital Civil of Guadalajara, Jalisco "Fray Antonio Alcalde"	SCT in ALL, AML, AA and GVHD	In progress	REC-ECOT/‡
12. National Rehabilitation Centre	SCT in SCI	In progress	BC-REC-ECOT/♣‡
13. Hospital Juaréz of Mexico	SCT in type II Diabetes, IC and MBR	In progress	REC-ECOT/♣‡

Abbreviations: ALI: Acute limb ischemia; ALL: Acute lymphoid leukaemia; AML: Acute myeloid leukaemia; AA: Aplastic anaemia; BB: Biobank; BC: Bioethics committee; BMW: Bone marrow; ECOT: Ethics Committee of Organ and Tissue Transplantation; FA: Fanconi anaemia; GVHD: Graft-versus-host-disease; GS: Griselly syndrome; IC: Ischemic cardiopathy; IN: Inherited neutropenia; MBR: Maxillofacial bone regeneration; MM: Multiple myeloma; OP: Osteoporosis; REC: Research ethics committee; (SCI) Spinal cord injury; THA: Thalassemia; UCB: Umbilical cord blood; WAS: Wiscott-Aldrich syndrome.

Sources: * Clinical trials and their current status were adapted from the information registered and retrieved from www.clinicaltrials.gov.

** Only one SCT transplant and its status are indicated per healthcare centre, but in many cases more than one SC transplant or medical trial was being conducted, according to the online search and literature review.

• Hospitals are certified and registered by the National System of Certification of Healthcare Establishments (SiNaCEAM); the data was obtained from the General Health Council's website.

† Licence to carry out transplants and BB granted by the Federal Commission for the Protection against Sanitary Risks (COFEPRIS).

‡ Authorised to procure and transplant HSC (BMW, peripheral blood and UCB) by the National Transplant Centre (CENATRA).

Note: Additional information was obtained through the Mexican government's portal for transparency and access to information (IFAI). All data was up to date on 28 October 2011.

Table 7.2. Stem Cell Therapy Providers in Mexico*	
Private Facility and Website•	**REC/COFEPRIS†**
Dental Pulp/Tooth	
1. BioEDEN México (Biobank) (case I)**: http://www.celulasdentales.com**	***
Bone Marrow (BMW)/Adipose tissue	
2. Hospital San José Technologic of Monterey (case II)**: http://international.hsj.com.mx**	REC – COFEPRIS
3. Regenerative Institute Tijuana (case III): http://www.regenerativemedicine.mx/	REC – COFEPRIS - ICMS
4. Haematology Centre and Internal Medicine of Puebla www.clinicaruiz.com	REC – COFEPRIS
5. OCA Hospital: http://www.ocahospital.com.mx	REC - COFEPRIS
6. Hospital ABC: http://www.abchospital.com/	REC- COFEPRIS
7. Centro Médico Excel: http://stemcellmexico.org	REC - COFEPRIS
8. Advanced Cellular Clinical Medicine: www.advancedcellularmedicineclinic.mx	***
9. ProgenCell, Stem Cell Therapies: http://progencell.com	***
10. Nova Cells Institute of Mexico: http://www.novacellsinstitute.com	***
11. ZITROMED Regenerative Medicine: http://www.zitromed.com.mx	***
12. Institute for Biomedical Research: www.iibmed.com	***
13. BioCare Hospital & Health Centre www.biocarehospital.com	***
14. Cancun Stem Cell Clinic www.cancunstemcellclinic.com	***
Peripheral and Umbilical Cord Blood	
15. Regenecell: www.regenecell.com	***
16. BioLife-Medical Centre ABC: http://www.biolife.com.mx	***
Placenta and Foetal Tissue/Alternative Medicine (acupuncture, herbal, holistic, etc.)	
17. Integra Medical Center ISCI: www.integramedicalcenter.com	***
18. REGENTHERAPY http://stemcell-therapy-mexico.com/	***
19. Bamboo www.bamboobelleza.com	***
Xenotransplantation (blue shark, pig SC, etc.)/Alternative Medicine	
20. Mexico Stem Cells www.mexicostemcellssite.com	***
21. The Center for Holistic Life Extension: www.extendlife.com	***
22. Perfection, makeover & laser centre: www.perfection.com.mx	***
23. XSTEM TECH: http://blancaes.stemtechbiz.com	***
SC Source Unpublicised	
24. Aesthetic & Anti-Aging: medicinaesteticaenreynosa.blogspot.com	***
25. Cellular Medicine: www.medicinacelular.com.mx	***
26. Cell Therapy Regeneration: http://terapiacelular.blogspot.com	***

Source: Most data is self-reported by SC providers' websites; information was also adapted from the online search and literature review, and data obtained from the Mexican government's portal for transparency and access to information (IFAI); information gathered was up to date in June 2012.

Notes: • Clinics claim to treat more than 40 health conditions, including Alzheimer's disease, amyotrophic lateral sclerosis, ageing, autism, arthritis, cerebral palsy, diabetes, mitochondrial, heart and immune disorders, multiple sclerosis, stroke, traumatic brain injury, spinal cord injury and Parkinson's disease.

† The Federal Commission for the Protection against Sanitary Risks (COFEPRIS) has granted a licence to function as a healthcare establishment but not as a provider of SC-based therapies.

Abbreviations: ICMS: International Cellular Medicine Society; REC: Research ethics committee.

*** Clinics lack ethics committees and accreditation or certification.

PART III: CONCLUDING SECTION

CHAPTER 8

CONCLUSIONS, FUTURE DIRECTION AND REGULATORY IMPLICATIONS

Everything which is not forbidden is allowed.[1]

8.1. CONCLUSIONS

In this final chapter, the main purposes and contributions of this doctoral study are reviewed; suggestions are made for future research and tentative proposals for policy-making and regulation in the area of SCS in Mexico. The primary goal of this thesis has been to portray the current ethical, legal and socio-cultural elements and concerns shaping the discussion of SCS regulation in Mexico as a case study. It has also aimed to explore the importance of having a well-developed and adequately enforced system of regulation governing the fast-moving area of SCS.

In order to realise the development of novel therapies that may potentially help those people suffering fatal diseases, that is to say, seeking to fulfil a 'social utility aim'[2] of SCS it is necessary to create targeted regulation. This study has suggested the adoption of a functional model of governance for Mexico similar to that followed in the UK. What is novel in this thesis is the proposal of a principles-based approach to SCS governance as an effective and facilitative form of regulation in Mexico.[3] This investigation has also shed light on the risks of under-regulation of SCS activities, which has led to the commercialisation of unsubstantiated SC-based therapies across the country. It therefore urges the imposition of better forms of governance that would allow efficient regulatory approaches and more rigorous means of enforcement to deal with unanticipated and novel discoveries, while providing certainty to scientists and clinicians involved in these activities, as well as guaranteeing adequate safeguards for those who are willing to participate in SC clinical trials in Mexico.

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[1] Maxim of the law. The Belgium regulation on research on human embryos adopted this rule as its core regulatory principle, this as a way of allowing the progress of medical scientific research, on this see further Pennings G, 'New Belgian Law on Research on Human Embryos: Trust in Progress Through Medical Science', *Journal of Assisted Reproduction and Genetics* 20 (8) (2003) 343-6.

[2] As it is argued for in Devaney S, 'Regulate to Innovate: Principles-Based Regulation of Stem Cell Research', *Medical Law International* 11 (2011) 53-68.

[3] I have benefited greatly from the insightful comments of Sarah Devaney on this point.

8.2. INNOVATING TROUGH EFFECTIVE ETHICAL AND LEGAL OVERSIGHT

The theme common to all three papers forming the basis of this doctoral study is the legal vacuum relating to SCS in Mexico. I have provided a reflexive explanation of the main factors behind the political and legal inertias regarding SCS regulation in this context. I have also provided interlinked theoretical, empirical and normative contributions to the understanding of better regulation in the area of SCS. It is crucial to acknowledge that although the research and therapeutic settings of SCS possess myriad promises, these also engender a great deal of uncertainty and many of the SCS therapeutic facets remain unproven. Notwithstanding that SCS research and therapeutic discoveries have a long way to go before being realised, I advocate for the adoption of permissive policies on SCS and the creation of targeted legislation through principles-based regulation, complemented with stringent ethical oversight mechanisms.

I have shed light on the fact that although thousands of *in vitro*-created embryos (from ART clinics) are kept frozen for an undetermined time and with an uncertain fate, these activities remain unregulated. These spare embryos will be indefinitely frozen; many will never be implanted, destined simply to perish. It is, I argue, imperative to treat the thousands of discarded IVF embryos with due regard, and this may be achievable by employing them for purposeful and worthy ends, such as research aimed at the elimination of human suffering. Under these circumstances, a moral compromise is suggested for the ethical conduct of SCS in Mexico as set out in Chapters 3 and 6.

I advance that the use of embryos for research could be approved under stringent ethical supervision to derive embryonic SCs lines. In the view of some scientists, active public engagement by scientists, making ethical and science sides of research understandable and accessible to the wider community should accompany this.[4] Furthermore, there should be ethical limits to the creation and use of embryos for particular purposes,[5] as well as restrictions to effectively avoid the social and ethical risks involved in the procurement of women's gametes for the creation of embryos.[6] Considering the strict observance and

[4] See McLaren A, 'A Scientist's View of the Ethics of Human Embryonic Stem Cell Research', *Cell Stem Cell* 1 (1) (2007) 23-6.
[5] See Brock DW, 'Creating Embryos for Use in Stem Cell Research', *The Journal of Law, Medicine & Ethics* 38 (2) (2001) 229-37; Steinbock B, 'What Does "Respect for Embryos" Mean in the Context of Stem Cell Research?' *Women's Health Issues* 10 (3) (2000) 127.
[6] This is desirable in order to prevent unethical and illicit activities involving the encouragement of a market for human oocytes, which may lead to the exploitation of vulnerable women. See Carroll K and Waldby C,

control of these safeguards, depriving ill people of the potential benefits of SCS research and applications would be immoral and unnecessary, whereas the use of existing frozen embryos and their creation solely for research and therapeutic purposes may be seen as ethically acceptable, because the outcomes of the research might potentially save many lives in the near future.[7]

I have also argued that it is essential to explicate the relevant concerns that surround the ethical use of hESCs and ASCs, as well as the ethical conduct of clinical trials of SC-based therapies.[8] In addition, it is imperative to ensure the adoption of ethical standards that guarantee the safety and integrity of research subjects and prevent wrongdoing by unscrupulous physicians who engage in and recruit patients for experimental clinical practices.[9] Issues related to ethical misconduct in SC research setting are also crucial in this discussion.[10] Protecting patients' safety should be paramount when planning and designing SC clinical trials.[11] It is important that ethical clinical practices[12] are in place to ensure that participants have a realistic picture of the research when they grant their consent, so they can take part without false expectations or therapeutic misconceptions.[13]

All SC clinical research activities require sound empirical data before moving to clinical trials involving human subjects.[14] Scientists and physicians also carry an important burden in the clinical setting of SC research.[15] They must provide adequate information and advise patients concerning the formal SC clinical trials available to prevent them from engaging, uninformed, in risky

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'Informed Consent and Fresh Egg Donation for Stem Cell Research', *Journal of Bioethical Inquiry* (2011) 1-11.

[7] See Berjis M, 'Human Embryonic Stem Cell Research and Surplus Embryos: A Moral Argument', *Mississippi College Law Review* 29 (2010) 427-44.

[8] See Lodi D, Iannitti T and Palmieri B, 'Stem Cells in Clinical Practice: Applications and Warnings', *Journal of Experimental & Clinical Cancer Research* 30 (1) (2011) 9.

[9] See Martell K, Trounson A and Baum E, 'Stem Cell Therapies in Clinical Trials: Workshop on Best Practices and the Need for Harmonization', *Cell Stem Cell* 7 (4) (2010) 451-4.

[10] See Hviid NT, 'What Happened to the Stem Cells?' *Journal of Medical Ethics* 34 (12) (2008) 852-7.

[11] See Sugarman J, 'Human Stem Cell Ethics: Beyond the Embryo', *Cell Stem Cell* 2 (6) (2008) 529-33.

[12] See Lo B, Kriegstein A and Grady D, 'Clinical Trials in Stem Cell Transplantation: Guidelines for Scientific and Ethical Review', *Clinical Trials* 5 (5) (2008) 517-22; also see Emanuel EJ, Wendler D, Killen J and Grady C, 'What Makes Clinical Research Ethical?' *JAMA: The Journal of the American Medical Association* 283 (20) (2000) 2701-11 and 'What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research', *Journal of Infectious Diseases* 189 (5) (2004) 930-7.

[13] See Lo B et al, 'A New Era in the Ethics of Human Embryonic Stem Cell Research', *Stem Cells* 23 (10) (2005) 1454-59.

[14] See See London AJ, Kimmelman J and Emborg ME, 'Beyond Access vs. Protection in Trials of Innovative Therapies', *Science* 328 (5980) (2010) 829-30; Isasi RM, 'Beyond the Permissibility of Embryonic and Stem Cell Research: Substantive Requirements and Procedural Safeguards', *Human Reproduction* 21 (10) (2006) 2474-81.

[15] On this, see further Master Z and Resnik DB, 'Stem-Cell Tourism and Scientific Responsibility', *EMBO Reports* (12) (2011) 992-5.

medical endeavours.[16] The clinical application of SCS is still in its infancy. Therefore, as there is an imperative to prevent physical harm to prospective patients, it is paramount that governments import adequate ethical and legal safeguards into clinical settings.

In democratic societies, where a plurality of moral viewpoints are held, the search for an ethical compromise to further SCS might guarantee that ethical oversight of these activities is correctly in place. This, in turn, ensures the ethical integrity of stakeholders, the moral community, regulators and scientific innovation itself. Master and Crozier conclude that

> …a moral compromise is not indicative of compromising on deep moral beliefs, but engaging in a process of reciprocal appreciation and understanding of different positions in a liberal democracy and attempting to resolve the issue to reach mutually satisfactory interests.[17]

Therefore, scientists, citizens and relevant policymakers should engage in public deliberation by which different ethical standpoints can be heard and equally appreciated in order to achieve consensus and moral compromise. This policy consultation process must be pursued in order to accommodate the ethical points agreed upon into any policy or legislation that attempts to oversee ethically and effectively the responsible progress of this area of biotechnology.

While in Chapter 5, I present extensive evidence that a deliberative dialogue is currently difficult to achieve, mainly because of the enduring religious, scientific and political disputes, there is also a need for regulation to prevent scientific misconduct and potential harm to present and prospective patients. In the more heavily populated regions of the country (e.g. Mexico City), the move towards a more secular society which opposes the political influence of religious organisations may potentially enhance the acceptability of more scientifically progressive and socially liberal policies and regulations.[18] In this context, such policies or legislative initiatives are more likely to be formulated. Indeed, as I have aimed to demonstrate, it is possible to provide certainty and legitimacy to activities involving SC research and therapy, on the

[16] See Sugarman J and Sipp D, 'Ethical Aspects of Stem Cell-Based Clinical Translation: Research, Innovation, and Developing Unproven Interventions', in Hug K and Hermerén G (Eds) *Translational Stem Cell Research: Issues Beyond the Debate on the Moral Status of the Human Embryo* (New York: Humana Press, 2011) 125-36.
[17] Master Z and Crozier G, 'The Ethics of Moral Compromise for Stem Cell Research Policy', *Health Care Analysis* 20 (1) (2012) 50-65 at 58.
[18] Also see Chapter 2, section 2.2.

basis of the constitutional right to healthcare protection and freedom of research. Despite the existence of these paramount fundamental and constitutional rights to regulate the field, the formulation of legislative proposals depends on both the support for and opposition to SCS from the government, policymakers and legislators, as well as a number of other key stakeholders.

In Chapter 7 it is argued that despite the lack of specific regulations for the use, storage, transplantation and medical application of SCs, explicit norms stipulate the banning of profit-seeking use and transplantation of tissues and cells. Furthermore, all clinical trials and therapeutic activities involving tissues and cells in Mexico must be free of any charge, according to biomedical regulations in force.[19] Thus, if purveyors of experimental SC treatments charge human subjects participating in these trials, they are clearly violating the law. Patients or research subjects should not be charged as if they were paying for consumer merchandise. Their participation in medical experiments should be free and voluntary, with adequate information about the risks posed by these interventions. However, in Mexico, SC therapeutic and research activities not only suffer a lack of rules; there is also a problem of enforcement, which has been negligible to date. The existing norms are not adequate. Legislation is outdated and enforcement is dysfunctional. Moreover, legislators remain reluctant to regulate these matters.

As I have discussed in Chapter 4, it would be naïve to assert that a liberal and progressive legal framework for SCS research and therapeutic activities, such as that of the UK, could be adopted in a foreign territory marked by religious battlegrounds and distinct legal traditions, such as Mexico. In a highly religiously contested context, permitting experimentation on embryos may be extremely difficult, but still feasible if a moral and political compromise is approached in the right way. In any case, the implementation of targeted rules, adequate mechanisms of compliance and stronger regulatory agencies to manage some of the SC clinical activities conducted in the country so far should be attempted. Nevertheless, lessons can be learnt when public legislative debates and policy-making processes are commenced to regulate the uncertain and controversial area of SCS. At this time, guiding principles and compliance mechanisms to be applied by a neutral expert body composed of trustworthy lay people should be proposed. This approach has been shown to be successful

[19] See the GHA, Article 327 and the Tissue Regulation, Articles 21 and 22.

in the UK's paradigmatic example of good and effective governance in the SC research field and its clinical settings.

8.3. Future Direction and Regulatory Implications

This doctoral investigation has critically analysed the policy debates and regulatory challenges in relation to SCS in Mexico. It has also explored the regulatory model of the UK for some aspect of SCS as well as its research and therapeutic application. The exploration of the UK regulatory regime has helped me to identify the main elements that can be emulated to better regulate the emerging area of SCS in Mexico. Suggestions for future research lie in the need to conduct broader empirical studies in the Latin American context which examine the risks and uncertainty of emerging biotechnologies. It would be beneficial for regulators and policy-makers to consider the convergences and divergences across comparable nations in this context, in order to develop strategies of governance for new technologies, securing scientific growth and guaranteeing people's safety. Moreover, further research on the risks and uncertainties posed by the biotechnologies themselves, as well as those engendered by the lack of targeted regulation would enable regulators to find better ways of good governance, as well as to build up theoretical frames for this specific context. I finally suggest for future research that a critical assessment of the relationship between policy-making and bioethics advice in developing good governance in this context is needed.

Finally, I hope that the conclusions drawn by this investigation, if adopted as proposed and acted upon, will enable legislators and policy-makers to develop an appropriate regulatory mechanism and ensure its enforcement. This is necessary, in order to make the best of responsible SC scientific, clinical research and new therapies which contribute to the eradication of disease and the alleviation of human suffering.

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APPENDIX A: LETTERS AND QUESTIONNAIRES ADDRESSED TO KEY STAKEHOLDERS IN MEXICO

Note: Letters and questionnaire were sent in English and Spanish versions. The English version was elaborated for the purposes of the internal approval of the Ethics Committee in the School of Law. As the mother tongue of all participants was Spanish, all interviews were conducted in that language. However, for the purposes of accuracy, some who also spoke English requested a copy of the English language version of the questionnaires, in addition to the Spanish one.

i) Invitation Letter (English version)

August 10, 2009

Dear Sir/Madam

By this means I would like to extend my recognition also expressed by the National and International scientific community, due to your commendable work in favour of scientific development.

In the meantime I would like to invite you to be part and participate as an interviewee in a research study conducted by Maria de Jesus Medina Arellano, a Lawyer who graduated as a Master of Philosophy and Pedagogy of Law from the Postgraduate Law Division at the UNAM, currently a PhD research student at the University of Manchester within the Doctoral Programme of Bioethics and Medical Jurisprudence. The purpose of this research is to carry out an in-depth ethical, philosophical and legal study to lead us to propose the most appropriate form of governance for stem cell science in Mexico. In order to gain a deep understanding of the legal framework and policy which Mexico needs to follow with regard to stem cell research, it is necessary to carry out qualitative research, based on the recent federal legal initiatives to amend the constitution, in contrast with the political and academic debates held by the Mexican Government and the academic community in favour of biotechnological research. Consequently, I have become aware of the necessity to evaluate the social, economic, cultural, religious and political environment in Mexico, in order to construct a theoretical framework and a legal platform for the governance of stem cell research there. This research will also compare the policymaking process initially followed in the UK and that begun in Mexico. The results of the case study will be used to suggest some steps ahead in the governance of stem cell research.

By carrying out interviews I am trying to find out about the perceptions, understanding and points of view concerning this issue among the social, political and religious communities in Mexico, mainly because within qualitative research the semi-structured interview method is a way of discovering and interpreting certain phenomena within a selected context. If you choose to participate, I am asking you to be involved in an interview for the purposes of the aforementioned case study. I am planning to go to Mexico to carry out the interviews from the end of November until the end of January. Your participation in this case study is of some importance and it is relevant to assure you that all the information will remain confidential. Also, if you are concerned about any risk, you have the right not to answer any undesirable

question and to end your participation at any time. There is even the possibility of missing out any question that you do not feel comfortable with. You can request the results of your interview, as well as details of the progress of the research, at any time.

The outcome of this research will help to identify the requirements and steps which need to be taken in order to create an appropriate legal framework for stem cell research in Mexico. I would really appreciate your acceptance of this invitation to participate and will be happy to conduct the interview at a time convenient to you during the months mentioned above. If you decide to participate, I would also request that you complete and sign the enclosed consent form.

Kindest regards,

ii) Invitation Letter (Spanish version)

Respetable Doctor/a:

Por medio del presente, me sumo al reconocimiento extendido por académicos y sociedad en general dentro y fuera del país, respecto de su loable labor dentro de la investigación científica en México.

De la misma manera, me permito invitarlo a participar como entrevistado dentro del proyecto de investigación que se lleva a cabo por la suscrita María de Jesús Medina Arellano, para lo cual me atrevo a introducir mis datos como Licenciada en Derecho, con Maestría en Filosofía y Pedagogía del Derecho, egresada de la División de Estudios de Posgrado en Derecho de la UNAM, actualmente me encuentro inscrita como estudiante investigadora de Doctorado en la Universidad de Manchester, Reino Unido, dentro del programa doctoral en Bioética y Medicina Legal.

El propósito de la investigación es llevar a cabo un estudio y análisis socio-ético y legal detallado que nos lleve a proponer la gobernabilidad adecuada al contexto social, político y legal de nuestro país sobre la investigación con células troncales. La investigación fue iniciada en el mes de enero del año 2008 y se planea concluir a finales del mes de diciembre de 2010. En este sentido, se ha considerado necesario incluir investigación cualitativa dentro de la investigación, puesto que se trata de un estudio socio-legal, de esta manera los métodos que se emplearán siguiendo una metodología cualitativa dentro de la investigación serán: elaboración de entrevistas semi-estructuradas, estudio comparado, tomando a México como nuestro caso de estudio frente a la legislación del Reino Unido, la cual nos servirá de referencia en conjunto con el proceso previo a la creación de su legislación para formular una propuesta tentativa de gobernabilidad en México sobre la investigación con células troncales. Este enfoque metodológico de la investigación se fundamenta en las recientes iniciativas de reforma constitucional presentadas ante la Cámara de Senadores del Congreso de la Unión, respecto a la prohibición de la investigación con células troncales de origen embrionario, así como la protección del embrión desde el momento de la concepción. Puesto que estas iniciativas de ley, resultan contrastantes con las políticas gubernamentales actuales, aunado a los posicionamientos y llamamientos por parte de la comunidad académica a una legislación responsable, se considera viable la elaboración del presente trabajo académico para la evaluación del contexto social, económico, cultural y

político en México respecto del tema, ya que la existencia de un estudio previo de esta naturaleza es escasa. Consecuentemente, este estudio me podrá situar en mejores condiciones para la elaboración de una propuesta tentativa de marco teórico y plataforma legal para la gobernabilidad de la investigación con células troncales en México, ahora demandada por los vastos progresos en la arena internacional en biotecnología aplicada a la medicina.

A través de la práctica de la entrevista propuesta, me planteo localizar la percepción, entendimiento, posiciones y puntos de vista respecto de este caso de estudio, tomando en consideración los distintos actores activos dentro del ámbito académico, social, político, legal y religioso en México. Lo anterior se justifica metodológicamente, en virtud a que dentro de cualquier investigación cualitativa para un caso de estudio sociológico, ético y legal resulta crucial llevar a cabo entrevistas semi-estructuradas como método para llegar a conocer e interpretar la realidad social de ciertos fenómenos dentro de un contexto determinado.

Bajo esta tesitura y por las razones antes descritas, le extiendo esta invitación para llevar a cabo una entrevista con usted por medio de un cuestionario semi-estructurado (el cual se anexa para su análisis previo a la aceptación y consentimiento de la entrevista, es importante explicitar que los temas y cuestionamientos que se plantean son sólo un esquema para poder dar pauta al desarrollo de la misma) para el propósito del avance del caso de estudio descrito. Si usted decide hacerlo, previo a la lectura del cuestionario e información relevante, así como de cualquier mayor información requerida por su parte, le solicito sirva expresar por escrito su consentimiento (encontrará anexo la carta de consentimiento respectiva) para ser parte y llevar a cabo la misma.

Su participación resulta crucial para apoyar la culminación del presente proyecto de doctorado, puesto que su contribución en la opinión y análisis de los temas que se plantean en el proyecto de tesis doctoral será generadora de conocimiento contextual y cercano a la necesidad real para la elaboración de la propuesta de gobernabilidad en la investigación con células troncales en México. Es importante hacer notar que la información permanecerá en extrema confidencialidad, si usted así lo requiere puede solicitar que su nombre no sea mencionado en el cuerpo de la tesis doctoral y solo se haga referencia a su entrevista a través de un seudónimo. De igual forma, si usted

tiene algún inconveniente respecto del cualquier riesgo o conflicto de intereses, se le reserva el derecho de no responder alguna pregunta que considere innecesaria, incomoda o simplemente que no se desea responder, así mismo podrá suspender su participación en la entrevista en cualquier momento, además de la posibilidad de eliminar cualquier pregunta. Finalmente, previo al análisis del resultado de la entrevista, usted tendrá acceso a la verificación de la transcripción que se haga de la misma, para efectos de su veracidad, de igual manera usted podrá tener acceso en cualquier momento al análisis del resultado de la misma, así como la contribución al proyecto de la investigación.

Resulta relevante mencionar que actualmente radico en la ciudad de Manchester, en el Reino Unido, sin embargo por los requerimientos exigidos por la presente investigación en cuanto a la metodología cualitativa adoptada, se tiene programado dentro de mi plan de investigación realizar una estancia de investigación por dos meses en México, para la realización de la investigación de campo, esto es la recopilación de material bibliográfico y hemerográfico relevante, así como la celebración de las entrevistas semi-estructuradas. En este sentido, el periodo de mi estancia en México comprenderá las fechas *del 23 de Noviembre de 2009 al 23 de Enero del 2010*, apunto este señalamiento en razón de poder facilitar la obtención de un espacio en su agenda dentro de este periodo y de esta forma hacer posible la celebración de nuestra entrevista.

Los resultados del proyecto de investigación doctoral podrán contribuir a conocer algunas necesidades y pasos a seguir para la creación de una plataforma legal congruente, así como de un análisis ético y filosófico necesario para la gobernabilidad de la investigación con células troncales en México. Bajo la expectativa de encontrar una respuesta positiva a la presente invitación, reciba de antemano mi más sincero agradecimiento por su tiempo, atención y colaboración.

Sin otro en particular, le reitero mi disponibilidad para cualquier información que el caso amerite.

Atentamente,

María de Jesús Medina Arellano

iii) Semi-structured Interview (English Version)

1) **Innovation in Biotechnology Applied to Medicine**

- To what extent is biotechnology innovation applied to medicine crucial for an emerging economy in a developing country such as Mexico?
- Do you think that it is important to understand and represent public opinion on scientific innovation prior to developing regulations?
- Do you know what kind of initiatives the Mexican Government has taken to create an economic and legal platform to stimulate biotechnology and biomedicine research?
- Should the biotechnology industry in Mexico be part of the decentralized government, or should it be kept exclusively for private investment? If so, why?

2) **Bioethics and Bioethics Committees**

- Do you consider it necessary to form a body of expertise in bioethics to provide pragmatic ways to deal with bioethical issues surrounding biotechnology research applied to medicine, such as stem cell research?
- In your view, which is the most appropriate school of thought on bioethics that our society should attempt to follow? For example, the American Beauchamp and Childress principles or European values on bioethics, such as solidarity, dignity, autonomy, etc. Why?
- What has been the role played by the National Council of Bioethics since its creation? Has it created any kind of specialized report in order to provide support for the policymaking process?

3) **Abortion and the Right to Life**

- Do you think that the rules on abortion could be a constraint on human embryonic stem cell research?
- Do you consider it necessary to construct more flexible norms to allow human embryonic stem cell research?
- Do you consider that the legal reasoning of the Supreme Court with regard to the unconstitutional action against the abortion rules of the Mexico City Criminal Code issued in August 2008 is in accordance with our social reality and regulatory needs? If so, why?
- Do you think that life should be protected from the initial stages of embryo formation, such as the unicellular level?

- ❖ Do you consider it important to accommodate religious points of view within a legal framework regarding issues of abortion or the beginning of life?

4) The Right to have a Family and Artificial Reproductive Techniques

- ❖ How could the government guarantee the right to have a family, established as fundamental within the Mexican Constitution?
- ❖ Which sorts of artificial reproductive techniques are available within the National Health System?
- ❖ Do you think that there are enough techniques of artificial reproduction to cover the demand of infertile couples?
- ❖ Do you think it appropriate to allow ART practices, which will result in some embryos being discarded, at the same time as having restrictive norms on abortion issues?

5) Stem Cell Science

- ❖ Can you identify the potential therapeutic benefits of using stem cells for regenerative medicine?
- ❖ Could you list some types of sources from which stem cells can be procured?
- ❖ Which sources of stem cells do you consider acceptable and which do you consider unacceptable for use in this country?

6) Human Embryonic Stem Cell Research – Ethical, Legal and Economic Issues

- ❖ Do you think that the use of human embryos for research could be justifiable? On what grounds?
- ❖ Are there any ethical issues with regard to the use of human embryos that you would like to highlight?
- ❖ How can the use of embryos be covered or justified in light of the various ethical dilemmas within a partially conservative community?
- ❖ From your point of view, which interests are it more important to protect: those of a community which considers the embryo as part of the human species and therefore entitled to protection, or those of individuals needing specialist treatment?
- ❖ If you think that human embryonic stem cell research should be allowed, what limits should be set?

7) Genomic Medicine

- ❖ What do you understand by "genomic medicine"?

- ❖ What hopes and disappointments for the Mexican government and society are associated with the investment made five years ago in genomic medicine?
- ❖ How useful for Mexican society has the creation of the National Institute for Genomic Medicine been?

8) **Access to and Allocation of the New Genetic Therapies and Healthcare Resources**

- ❖ Given the conflicting principles of distributive justice, which approach would be the best for access: an individualistic approach, meeting health needs; a utilitarian approach, maximising health gain; or an egalitarian approach, reducing inequalities in health?
- ❖ How could the rationing of healthcare be decided?
- ❖ To improve existing treatment options, how should healthcare staff proceed when providing these new therapies? What kind of procedural justice should be looked for?

9) **Policymaking and Economic Interests–Comparative Approach**

- ❖ Do you think that a consultative and deliberative style of communicating through position papers, open public consultations and white papers, as in the UK, would be an option to help in the process of making policy on biotechnology and biomedicine?
- ❖ What kind of economic impact would the development of this style of communication have in a developing country?
- ❖ To what extent do you think public attitudes (evidence of public support or opposition) regarding human embryonic stem cell research should be taken into account when developing regulations on stem cell research? Is a public dialogue necessary, such as that called for by the Supreme Court in August 2008?

10) **Constitutional and Cultural Values**

- ❖ Is the protection and guarantee of human dignity an important goal to achieve within our constitutional law?
- ❖ What do you understand by human dignity? Where we can obtain it and how might we lose it?
- ❖ To what extent might multiculturalism and religious points of view permeate regulations and national policies dealing with life sciences?
- ❖ Is the notion of human dignity within the constitution vague enough to allow human embryonic stem cell research? This concerns respect for the

human dignity of terminal ill people needing treatments emerging from this research.

- Do you think that the notion of human dignity as it is will be used by conservative groups (whether in the constitution or in secondary regulations) to prevent human embryonic stem cell research in Mexico?

iv) Semi-Structured Interview (Spanish Version)

1) **<u>Innovación en Biotecnología Aplicada a la Medicina (Investigación en la Salud)</u>**
   - ¿En qué medida la innovación en biotecnología aplicada a la medicina resulta ser fundamental para una economía emergente en un país en vías de desarrollo, como México?
   - ¿Considera importante entender y representar la opinión publica respecto de la innovación biotecnológica aplicada a la medicina, previo a la creación de cualquier tipo de regulación en la materia?
   - ¿Conoce las iniciativas legislativas que ha impulsado el gobierno Mexicano para la creación de una plataforma económica y legal para el estimulo de la investigación biotecnológica aplicada a la medicina? ¿Considera que estas son congruentes con las actuales iniciativas dentro del senado sobre el inicio de la vida y la clonación reproductiva y terapéutica?
   - ¿Cree que la industria biotecnológica aplicada a la medicina debería ser parte del gobierno centralizado? O bien, ¿Debería ser reservada para la iniciativa privada? ¿Por qué?
2) **<u>Bioética y Comités de Bioética</u>**
   - ¿Considera que el rol de la actual Comisión Nacional de Bioética debería ser más dinámico e influyente dentro del ámbito legislativo y judicial, frente a las discusiones y reflexiones éticas acerca de los debates en biotecnología aplicada a la medicina, por ejemplo, la prohibición o permisión de la investigación con células troncales?
   - Bajo su criterio, ¿Cuáles son los principios bioéticos que nuestra sociedad podría adoptar? Por ejemplo, los principios bioéticos de la escuela americana de Beauchamp y Childress, o bien los valores bioéticos Europeos, como son solidaridad, dignidad y autonomía; en cuanto a línea del pensamiento bioético: el deontológico, utilitarista o consecuencialista, por mencionar algunos, ¿Por qué?
   - ¿Cuál es la función que ha desempeñado la Comisión Nacional de Bioética desde su creación en temas como el de la investigación con células troncales? ¿Existe a la fecha algún reporte especializado acerca del tema creado por la Comisión?

- ¿Es necesario que la Comisión Nacional de Bioética genere influencia sobre la legislación que se pueda adoptar respecto de la investigación con células troncales? ¿Porqué?

3) **Aborto y Derecho a la Vida**
   - ¿Cree usted que las normas relativas al aborto pueden resultar una limitante para permitir la investigación con células troncales de origen embrionario?
   - ¿Deberíamos construir normas relativas al aborto más flexibles para poder dar paso a la investigación con células troncales de origen embrionario?
   - ¿Cuál es su opinión respecto de la resolución tomada por la Suprema Corte de Justicia de la Nación en Agosto del año 2008 respecto a la controversia constitucional presentada en contra las reformas al Código Penal del D.F. en materia de aborto?
   - ¿Considera que el derecho a la vida debe de ser garantizado y protegido desde las iniciales etapas embrionarias, es decir a nivel unicelular?
   - ¿Estima necesario incluir el punto de vista religioso dentro de las normas relativas al aborto y el inicio de la vida? ¿Cómo puede evitarse, a la luz de la influencia actual de la iglesia Católica en los actores legislativos?

4) **El derecho a Formar una Familia y las Técnicas de Reproducción Asistida**
   - ¿Estima necesario que el gobierno a través de la Secretaria de Salud proporcione los medios necesarios para todas las personas para formar una familia, en específico para aquellas parejas infértiles, puesto que este derecho se encuentra establecido como fundamental dentro de la Constitución mexicana?
   - ¿Conoce usted que tipo de técnicas de reproducción asistida están disponibles y accesibles para los ciudadanos dentro del sistema nacional de salud?
   - ¿Cree usted que se beberían de implementar más técnicas de reproducción artificial, aun cuando ello implique la no implantación de algunos embriones por no ser viables para reproducción?

5) **Investigación con Células Troncales**
   - ¿Podría identificar cuáles son los beneficios potenciales resultantes de la creación y obtención de células troncales de origen embrionario para la medicina regenerativa?
   - ¿Podría enlistar algunos de las fuentes de obtención de células troncales?

- ¿Desde su visión cual seria la problemática ética y moral que representa el uso de estas fuentes?
- ¿Qué tipo de fuente de obtención y utilización de células troncales estaría usted dispuesto a aceptar o viceversa rechazar dentro de nuestro marco legislativo y actividad científica?

6) **Investigación con Células Troncales de Origen Embrionario –Cuestiones Éticas, Legales y Económicas-**
   - ¿Juzga usted que la creación de embriones humanos para fines de investigación sea justificable? En caso de ser justificable, ¿Cuáles principios deberán regular la creación de embriones?
   - ¿Existen algunos dilemas éticos o morales en relación a la creación y uso de embriones humanos para fines de investigación que a usted le gustaría resaltar o considerar como de mayor relevancia?
   - ¿Cómo puede ser justificado, si es el caso, la creación, uso y aplicación de embriones con fines de investigación a la luz de los dilemas éticos y morales que enfrenta dentro de una comunidad multicultural y plural?
   - ¿Cuál de los bienes seria mas importante garantizar, el comunitario mediante la defensa de la vida inicial embrionaria como perteneciente a la humanidad o bien el individual para aquellas personas sufriendo enfermedades crónicas y terminales, cuya única esperanza son las terapias derivadas de la investigación con células troncales?
   - ¿Cuál sería el límite de desarrollo embrionario que usted cree podría ser justificable para la obtención e investigación con células troncales embrionarias?

7) **Medicina Genómica**
   - ¿Cómo define a la medicina genómica?
   - ¿Cuáles son las esperanzas y retos que representa para el gobierno mexicano y para la sociedad en general la inversión en medicina genómica realizada hace cinco años?
   - ¿Percibe los beneficioso ha traído consigo para la sociedad Mexicana la creación del Instituto de Investigación de Medicina Genómica?

8) **Acceso y Distribución de Nuevas Terapias y Tratamientos en el Sistema de Salud**
   - ¿Qué tipo de enfoque será el más adecuado para el acceso a las terapias génicas: un enfoque individualista, el cual conoce las necesidades de salud, un enfoque utilitario, el cual maximiza la obtención de salud o

bien un enfoque igualitario, por el cual se reduzcan las inequidades en el acceso a la salud?

- ¿Cuál sería la manera más viable de distribución de servicios de salud en cuestión de aplicación de terapias génicas?
- Hablando acerca del mejoramiento del acceso a los nuevos tratamientos: ¿Cómo deberán actuar los profesionales de la salud para proporcionar el acceso a las nuevas terapias? ¿Qué tipo de justicia procedimental deberán de implementar?

9) **Proceso Legislativo y Creación de Políticas Públicas –Enfoque Comparativo -**

- ¿Considera usted que un estilo de consulta y deliberativo de comunicación, mediante documentos de toma de posicionamiento, consultas publicas –mediante la expedición de reportes especializados, como sucedió con el reporte Warnock en el Reino Unido- pueda ser una herramienta adecuada y eficiente para enfrentar los dilemas éticos y legales en relación a la biotecnología aplicada a la medicina?
- ¿Qué clase de impacto económico podría tener para un país en vías de desarrollo este estilo de comunicación en tratándose de temas de relevancia global, como es la investigación con células troncales?
- ¿En qué medida la opinión pública debe de ser tomada en cuenta en relación a la investigación con células troncales embrionarias para adoptar alguna plataforma política y legislativa? ¿Es necesario un diálogo público, similar al convocado por la Suprema Corte de Justicia de la Nación en Agosto del año 2008?

10) **Valores Constitucionales y Culturales**

- ¿La garantía y protección de la dignidad humana constituye un valor constitucional crucial a alcanzar desde su perspectiva?
- ¿Que se entiende por dignidad humana? ¿Desde cuando se obtiene la dignidad humana y como se pierde? ¿A quien va dirigida la protección de la Dignidad Humana?
- ¿Considera que la noción de dignidad humana es un valor constitucional lo suficientemente vago para ser empleado en la construcción de un marco legal permisivo para la investigación con células troncales de origen embrionario? De ser así, ¿Podría ser apoyado bajo los fundamentos del respeto a la dignidad humana de aquellas personas con enfermedades crónicas o en etapa terminal?

- ¿La noción de dignidad humana es tan vaga, que podría constituir un argumento a favor dentro de la regulación para grupos conservadores con la intención de prohibir la investigación con células troncales embrionarias?
- ¿Cree usted que concebir a un cigoto como poseedor de dignidad humana sea un argumento valido?

APPENDIX B: PUBLISHED ARTICLES

1. 'Commentary: The Need for Balancing the Reproductive Rights of Women and the Unborn in the Mexican Courtroom', *Medical Law Review* 19 (3) (2010) 427-433.
2. 'Stem Cell Regulation in Mexico: Present and Future Challenges', *Electronic Journal of Studies in Ethics, Law, and Technology* 5 (1) (2011) Article 2.
3. 'Ética, Derecho y Desarrollo: Desafíos para la Consolidación de la Regulación de las Células Troncales en México', in *Derecho, Instituciones y Desarrollo. Temas Selectos (Law, Institutions and Development. Selected Themes)* (Mexico: ITAM-PORRUA, 2012).
4. 'Contested Secularity: Stem Cell Governance in Mexico', *Science and Public Policy* 39 (3) (2012).
5. Medina-Arellano MdJ, 'Stem Cell Regulation in Mexico: Current Debates and Future Challenges', *Studies in Ethics, Law and Technology* 5 (1) (2011) Article 2.

Medical Law Review, 18, Autumn 2010, pp. 427–433
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Commentary

THE NEED FOR BALANCING THE REPRODUCTIVE RIGHTS OF WOMEN AND THE UNBORN IN THE MEXICAN COURTROOM

Unconstitutional Claim 146/2007 and the Appended 147/2007

Introduction

On 28 August 2008, the plenary session of the Supreme Court of Mexico endorsed a groundbreaking judgment on abortion law in Mexico.[1] It upheld as constitutional the amendment of the local Criminal Code by the Mexico City Legislative Assembly in April 2007. The amending provisions permitted elective termination of pregnancy before the end of the twelfth week of gestation.[2] It also added clauses 16 Bis 6 and 14 Bis 8 to the local health law act stipulating that the Mexico City Ministry of Health, through its health providers (i.e. public hospitals and clinics), should provide first-trimester abortion services at no cost to Mexico City residents and for a moderate fee to women from outside the city.

Historically, abortion in Mexico City has been severely restricted; it was not allowed even in cases of rape. From 2000 onwards, however, gradual changes to the local Criminal Code were implemented when feminist and pro-choice groups initiated strong campaigns supporting the right of women to make decisions about their own bodies. In August 2000, abortion was exempted from penalty when the mother's life was at risk or when there was a severe congenital conditions affecting the foetus.[3] A further key change was in January 2004, when the Criminal Code advanced the notion that women's consent was central to abortion issues by incorporating a clause providing that abortion was permissible when a woman is artificially inseminated without her consent. It also incorporated the right of conscientious objection for health providers.[4] Campaigners highlighted the high number of 'back-

[1] Mexican Supreme Court of Justice, *Unconstitutional Claim 146/2007 and Its Appended 147/2007*, February 2009, 1421. Available at <http://www.gire.org.mx/publica2/SentenciaAbortoDF_SCJN_Feb09.pdf>. Mexico operates under a federal legal system; each member state has its own local constitution, but the Federal Constitution overrides all of the lower sources of law at all times. Additionally, each of the thirty-one states in Mexico has its own laws regarding abortion.

[2] Articles 145–7.

[3] Mexico City Criminal Code Articles 265 and 266.

[4] Article 148.

street' abortions sought by poor, rural, adolescent, and indigenous women and stressed the significance of this as a social problem. The most recent Mexico City Criminal Code amendments were considered a major step in reducing maternal mortality by eliminating the need for women to seek clandestine abortions.

The claim before the Supreme Court was brought by the President of the National Human Rights Commission and the Attorney General of the Federal Government, who were opposed to the decriminalisation of abortion in Mexico City. They challenged the reforms by arguing that they were wholly contrary to the provisions of the Federal Constitution concerning the protection of human life and dignity. It is perhaps unsurprising that this constitutional challenge reflects concerns of political and religious conservative groups in Mexico, since both the President of the Human Rights Commission and the Attorney General of the Federal Government were appointed by the President of Mexico, himself a member of the right-wing party in Mexico, with strong links to the Catholic Church. Although the Supreme Court could be considered to be acting as a mediator between liberal and conservative forces in Mexico, its judgment should be seen as progressive in that it upheld the constitutionality of abortion on demand in Mexico City and denied the existence of a right to life from conception.

This commentary focuses on three remarkable features of the judgment; first, a brief exploration of how the Court dealt with the arguments expressed by the petitioners in their claims; secondly the innovative decision-making process embraced by the Supreme Court with regard to the holding of public hearings prior to publishing its judgment; and finally, a detailed examination of Clause 8 in the Court's final ruling, which sets out the reasoning of the Court. This ruling is likely to stand as a remarkable precedent within the Mexican legal system in the area of resolving deeply conflictual societal issues such as those concerning the unborn and women's reproductive rights. Additionally, this ruling heralded important political and constitutional changes throughout Mexico, exemplifying the legal, ethical, and political divergence in the area.

The Right to Life and Human Dignity

The central arguments adduced by the claimants were based on the premise that life is constitutionally protected from the outset;[5] accordingly, decriminalising abortion in Mexico City infringed the basic right to life of the embryo and the unborn. Furthermore, the reforms

[5] N 1. It is important to highlight here that neither the claimants nor the Supreme Court made a clear distinction between the terms embryo/foetus and the unborn, but rather used these terms interchangeably.

were said to transgress the human dignity possessed by embryos, since life begins to matter morally and legally from the outset and it is from that point onwards that the embryo is in possession of full human rights and human dignity, notwithstanding the numerous alternative positions on this question. In addition, the constitutional challenge was grounded in many international treaties and covenants that Mexico had signed and ratified, such as the International Covenant on Civil and Political Rights in relation to the protection of life and prohibition to its deprivation and Article 4 of the American Convention on Human Rights, which referred to the right to life from the moment of conception.

The notion of human dignity appeared in the Mexican Federal Constitution in 1917, making it one of the first constitutions to adopt this principle.[6] Article 1 states:

> ... Discrimination based on ethnic or national origin, as well as discrimination based on gender, age, disabilities or any kind social status, health condition ... or any other reason which threatens *human dignity* and which is directed to either eliminate or restrict the *individual's* privileges and immunities shall be prohibited.

Nonetheless, there is neither an agreed interpretation, nor an explicit definition of the principle of human dignity. It can be subject to a range of religious and secular interpretations, so that dignity can be seen to be linked to humans as rational beings, as sentient beings, as created beings, or as beings with genetic constitutions typical of the members of the human species. Consequently, it is by no means clear that a straightforward assertion can be made from a reading of the Federal Constitution that human dignity is extended to or possessed by embryos. What is clear is that respect for human dignity is guaranteed to Mexican individuals as a part of their fundamental rights established under the Federal Constitution.

Innovation in the Courtroom

The Supreme Court reached its final judgment after making a public call for all interested parties to express their opinions regarding the constitutional challenge that had been made. It held six public hearings, a remarkable and unusual mechanism, in order to take into account the views of all interested parties, given the national relevance and legal impact of the issue. This process is fully authorised by its internal statutes and the Federal Constitution, in particular the

[6] M Häyry, 'Another Look at Dignity' (2004) 13 Cambridge Quarterly of Healthcare Ethics 7, 7–14.

Amparo Act[7] and the Federal Procedural Civil Code. At the six hearings, which took place in various courtrooms and were broadcast via the Supreme Court's website, more than eighty speakers from diverse sectors of the population, from the most secular to the most conservative, presented arguments for and against the decriminalisation of abortion. Among the questions addressed during these proceedings were whether the right to life is constitutionally protected from the moment of conception and whether the proposed reforms transgressed the constitutional principle of equality.[8] Among the strongest arguments made in favour of the decriminalisation of abortion were those that held that a woman's freedom over her physical and mental health should prevail over other concerns and that religious values concerning the protection of the embryo can and should be put aside when determining secular legal matters.[9] Conversely, the conservative position was that each embryo is a sentient being with a genetic constitution typical of the human species, making the embryo part of humanity and consequently deserving of the protection of its human dignity and life.[10]

Balancing Rights: The Embryo/Foetus and Women's Reproductive Rights

Before analysing the Supreme Court's written judgment in further detail, it is worth highlighting that the Court had previously ruled on this issue for the first time in 2002. In this earlier judgment, it had ruled that women's safety may in some cases prevail over that of the embryo/foetus. It also recognised that the interest of the unborn child is protected under civil norms in the legal system.[11] Notwithstanding this earlier seminal judgment, however, the Supreme preferred on this occasion to focus more on women's reproductive rights and the

[7] This Act establishes inter alia, procedural requirements for the judicial protection of fundamental rights in Mexico, in Spanish widely known as 'Amparo'. For further information about this judicial tool, see JUC Tinoco, 'Domestic and International Judicial Protection of Fundamental Rights: A Latin American Comparative Perspective', in Oliveira, Jorge Costa and Paulo Cardinal (eds), *One Country, Two Systems, Three Legal Orders - Perspectives of Evolution* (Springer, 2009) 339–57.

[8] Article 1 of the Federal Constitution.

[9] See further: N Ubaldi Garcete, *Constitutionality of the Abortion Law in Mexico City* (Information Group on Reproductive Choice, GIRE, Mexico 2010) 30–35.

[10] See, for example: C Fernández del Castillo Sánchez, 'Interrupción legal del embarazo o asesinato con autorización de la ley' (2008) 9 Ginecología y Obstetricia de México, 566–8.

[11] Mexican Supreme Court of Justice, 'The Right to Life of the Product of the Conception, Its Protection Derived from Mexican Constitution, International Treaties and Federal Local Regulations' (author's translation), February 2002, 588. Available at <http://www2.scjn.gob.mx/ius2006/UnaTesisLnkTmp.asp?nIus=187817 > .

constitutional status of the embryo/foetus, rather than on civil norms protecting the interest of the unborn. In sum, Clause 8 of the final judgment refers to 'the right to life, its nature and existence'.[12] Here, the Court established that life was a necessary condition for the existence of fundamental rights; however, this did not imply that the right to life should prevail over other fundamental rights, given that fundamental rights are not absolutes and that when they conflict, the balancing of rights is necessary.[13] The Court asserted that, from a plain reading of the Federal Constitution, there is no explicit text that grounds the argument that a foetus has a right to life; consequently, it ruled that there was no constitutional obligation to defend life from conception, in particular through the criminal law.[14]

The Court acknowledged that laws regarding the protection of life were derived from international covenants and treaties, but noted that the majority of these legal documents do not establish when life begins or from what moment it should be protected. Although the American Convention on Human Rights provides in Article 4 that 'life shall be protected by law, in general, from the moment of conception', the Court ruled that Mexico should not be bound by that specific stipulation. This is perhaps not surprising, given the reservation made by the Mexican government at ratification that decision-making on whether or not to protect life from the time of conception is to be reserved to the Mexican state.

In addition, the Court found that the Mexico City reforms were intended to combat violence against women, in conformity with international agreements signed by Mexico, such as the Inter-American Convention on the Prevention, Punishment and Eradication of Violence against Women (*Convention Belem Do Para*).[15] Furthermore, the Court held that the measure adopted by Mexico City was important for protecting women's health. It recognised that, in reforming the law, Mexico City was giving effect to the guarantee established in Article 4 of the Federal Constitution regarding women's responsibility for and freedom over their own bodies, their physical and mental health, and their lives. The Court noted that even if there were an aspiration to protect the foetus, the complete criminalisation of abortion did not ensure the due development of pregnancy, given the social context of poor, marginalised, and rural women who cannot achieve the best conditions for their pregnancy; indeed, such

[12] N 1 at [152–91].
[13] At [154–5].
[14] At [153].
[15] At [178–80].

a measure would only serve to perpetuate discrimination against women.[16]

In responding to the argument posed by the claimants in relation to Article 1 of the Federal Constitution regarding equality under the law, the Court asserted that women and men have equal rights before the constitution in connection with decisions regarding their offspring, but that questions about equality under the law are different from those situations that affect women in particular, concerning their bodies, their sexuality, and reproduction. In matters of reproduction, men cannot be considered to have an equal claim to decide over women's body. The Court considered that equality in the context of child protection and parental rights is different from the question of whether or not women can terminate pregnancy.[17] The judgment condemned forced motherhood and affirmed that reproduction must not occur against a woman's will.[18] Significantly, the Supreme Court validated the incorporation within the abortion debate in Mexico of a consideration of women's health rights and decisions regarding their bodies.

Recent Developments

Mexico City's Criminal Code and Health Law are now considered to be the most progressive in Latin America in terms of promoting self-determination in relation to women's health and reproductive rights. This judgment is an example of how courts may or indeed should take account of the prevailing social values and conditions in the context of their rulings on issues such as abortion and the right to life. For this reason, the decision on the part of the Mexican Supreme Court to call for public hearings prior to judgment represents an innovative and progressive approach to examining the social and political context to this issue.

However, the question of the legal status of the embryo continues to be disputed in Mexico. In federal political systems such as the one that operates in Mexico, there are differences between federal-level and state-level legislation; there is diversity between states as to the legal status of the embryo, as well as in abortion and reproductive rights. While progressive steps in favour of reproductive rights and choices were taken at the federal judicial level, it is possible to discern a different trend at the state level, where a counter-movement has emerged, leading to the reform of state

[16] At [181–3]. Article 4 of the Federal Constitution establishes: '... every person has the right to decide in a free, mature and informed way, the number and spacing of their children'.

[17] At [185–91].

[18] At [192].

constitutions to enshrine the protection of the unborn from conception. This has had a widespread impact, with seventeen states to date already having amended their constitutions to this effect. Though there were some variations between individual states, they all established that 'life shall be protected from the moment of conception until the natural end of life'.[19] This action can also be seen as a first step to revise the Federal Constitution. This requires, according to Article 135 of the Constitution, the approval of the majority of the local legislatures, along with the approval by two-thirds out of the attending members of the session established for that purpose.[20] This can also be seen as an indicator of the direct influence still exercised by the Catholic Church on many political parties in Mexico, demonstrating that a *de facto* separation of law and religious belief is far from reality. These reforms seem to be pre-emptive measures to prevent Mexican legislators from liberalising the rules on abortion and to halt any further development derived from this liberalisation. Fortunately, there has been no further reform to bring local Criminal Codes into line with these amendments to state constitutions, so that abortion continues to be allowed in many states in cases of rape or when the mother's life is at risk.

At the time of writing, the Mexican Supreme Court is set to decide again whether the protection of life from the moment of conception and the refusal to grant women the right to decide about the termination of pregnancy are consistent with the Federal Constitution. The Human Rights Commissioner in the state of Baja California has brought a further challenge to the amendment of its state Constitution regarding the protection of the life of the unborn. The Commissioner is claiming that the State Constitution impinges on the reproductive rights of women, as established by the Federal Constitution and affirmed by the 2008 Supreme Court ruling. While the Supreme Court's 2008 ruling may be seen as a landmark decision, it is not clear that this will remain the case given this second constitutional challenge and the rearguard action that has taken place at the state level. It remains to be seen whether a progressive or a restrictive approach will prevail in Mexico.

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[19] R Tapia Ibargüengoytia, 'Religion and Local Constitutions' (2009) La crónica de hoy. Available in Spanish at: <http://www.ccc.gob.mx/opiniones/676-la-religion-y-las-constituciones-estatales?format=pdf > .

[20] To date, there is a federal legislative proposal brought by a member of the right-wing political party to amend the Federal Constitution, which is identical to the reforms of the local constitutions. The proposal has not been discussed yet in the Federal Congress, however, further developments are expected.

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Stem Cell Regulation in Mexico: Current Debates and Future Challenges

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Stem Cell Regulation in Mexico: Current Debates and Future Challenges

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Abstract

The closely related debates concerning abortion, the protection of the embryo and stem cell science have captured the legislative agenda in Mexico in recent years. This paper examines some contemporary debates related to stem cell science and the legal and political action that has followed in the wake of the latest Supreme Court judgment on abortion, which debates are directly linked to the degrees of protection of the embryo stipulated in the Mexican Constitution. While some Mexican states have opted to take no further action, others, where conservative political forces are in the majority, have been very active in seeking to ensure that their constitutions are amended to protect human life from conception onwards. This intense legislative activity has not, however, been repeated at the federal level, where there is currently no overarching national regulatory framework governing stem cell research. Although major efforts have been made by the conservative block within the Senate to bring forward legislative proposals for the prohibition of human embryonic stem cell research, and despite the public expression by the federal government of its commitment to encourage inward investment and innovation in the area of biotechnology, stem cell science has, so far, remained unregulated. The legislative challenge is to resist the pressure that has been injected by religious leaders and to act in accordance with the values and principles adopted by the community in the Mexican Constitution. In the final analysis, Mexico faces particular difficulties in accommodating conservative political forces on one hand, while recognising on the other its need, as an emerging economy, to promote a progressive approach to innovation in biotechnology.

KEYWORDS: abortion, embryo, stem cell, regulation, religion, Supreme Court of Justice, Mexico

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INTRODUCTION

The successful work announced by Thompson et al. and Gearhart in 1998, when they isolated human embryonic stem cell lines derived from human blastocysts, dramatically revolutionised the field of biomedical science. The discovery of human embryonic stem cells (hESC) as a potential resource for treating and curing chronic diseases caused great excitement among the scientific community, the general public and the press. In subsequent years, this research has impacted not only biotechnology, but also the fields of social sciences and the humanities, given the legal, ethical and philosophical analysis about this activity *per se*. A number of benefits have emerged from the potential use of hESC to treat diseases such as Parkinson's, diabetes and cancer. However, scientists have expressed measured and balanced views, stressing that the development of treatments and their translation to clinical use is still a long way off.[1] Meanwhile, others are concerned about the use and creation of embryos for stem cell research, and this has been a hotly debated issue in bioethics for more than a decade.

In Latin American developing nations such as Mexico, Argentina and Brazil, the discussion regarding the regulation of stem cell research is closely interlinked to the debate of many other activities, such as abortion and assisted reproduction issues, whose acceptability depends on what the "moral status" of the embryo is deemed to be.[2] In this context, sometimes these discussions are conducted in terms of 'When does life begin?' or, more specifically, 'When does life begin to matter morally?' At other times, the moral and legal status of the embryo is discussed in terms of the applicability of human rights of embryos. Currently, in Mexico the debate is often about whether the concept of human dignity applies to the objects of the research, for example, embryos and also women who are the donors of eggs for stem cell research. Thus, stem cell science and possible future treatments continue to cause ethical and legal problems. In this context, the main dilemmas are the questions of the moral and legal status of the embryo and the protection of life.

By discussing the interlinking abortion and stem cell debates that are closely intertwined in Mexico, this paper attempts to show that any regulation adopted will still depend upon the position taken regarding the protection of life. The position regarding the protection of life and stem cell research has been established by constitutional courts, at least in Latin America, as observed in

[1] See, for example: Majlinda, L. (2010).
[2] This interlinking feature results common and shared by developing countries in Latin America, where the discussion about abortion, assisted reproduction and embryonic stem cell research are conducted in parallel. On this, see further: Diniz, D. (2008).

Brazil that has already regulated the practice.[3] Similarly, because of this synergistic nature between embryonic stem cell research, abortion and assisted reproduction issues, the position that Mexico has adopted in relation to abortion will be crucial in determining the viability of the development of a legal platform for stem cell research. It must be emphasised that the injection of significant federal government funding for biotechnology research in the country notwithstanding, no legal framework in relation to stem cell research has yet been established. Nevertheless, for almost a decade now, the academic community in Mexico has publicly argued for the need to adopt a systematic and comprehensive set of ethical and legal norms for basic stem cell research.[4] The adoption of regulation will prevent fraud, abuse and stem cell tourism in the country.[5] However, the debate and legislative efforts to regulate this emerging activity are complex because the status and protection of the embryo are characterised by impassioned discussion and conflicting interests among judges, religious leaders, members of the scientific community and politicians.

Against this background, the aim of this paper is to analyse the legal, political and religious difficulties and discrepancies in regulating stem cell research in an emerging economy such as Mexico. I argue in this paper that the challenges that legislators face in a democratic process such as regulation are not simple. In establishing a set of norms for stem cell research, they need to accommodate informed views of the wider community. This would be expressed in public discussions, as demonstrated by the public hearings held by the Supreme Court when ruling about abortion, while resisting the pressure of lobbying applied mainly by leaders of the Catholic Church. Therefore, what is expected in a plural society with a secular form of government is that the regulation that is to be brought into force must be isolated as much as possible from a particular religious influence. The regulation should follow the secular principles adopted by the Federal Constitution,[6] in accordance to what is provided by the constitutional

[3] This is in accordance with what occurred in Brazil, where the permission of stem cell research was ruled as constitutional by the decision of the Supreme Court of Justice on the issue. See Diniz, D. and Avelino, D. (2009).

[4] Arguments in favour of stem cell research in the Country are formulated based on its therapeutic potential in regenerative medicine. See, for example: Lisker, R. (2003).

[5] Stem cell tourism is identified as a sub-category of the so-called medical tourism; this subcategory is defined as that activity concerning the travelling of patients from one country to another looking to acquire stem cell treatments and therapies. Mexico, among other Latin-American countries, has been identified as a targeted place for patients/consumers who seek reproductive and regenerative medical services. See Smith, E. et al. (2009).

[6] Hereinafter I shall refer to the Political Constitution of the Mexican United States as the "Federal Constitution". It is worth noting that Mexico operates under a federal legal system. Each member state has its own local constitution, but the Federal Constitution plays a major role. It overrides all of the lower sources of law at all times, and these should always be in accordance with its provisions. The Mexican Federal Republic is composed of 31 states plus the Federal District of

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clause 3 section I, and clause 130 which provide that education and government shall be secular and free of any religious orientation.[7]

To analyse the conflicting issues surrounding the regulation of biotechnology, in particular that which is concerned with stem cell science in Mexico, this paper will first explore the initial steps taken by some members of the research community and politicians to discuss stem cell research, and the preliminary legislative proposals initiated as a result. Some clerical leaders highly influence the initial and current debates by lobbying the federal legislature.[8] Legislators, whose aim it is to achieve a desirable legal framework free of any particular religious doctrine, thus face the pressure interjected by members of the Catholic church. To counteract this interference of clerical lobbying, certain legistlative actions have been taken by some political leaders, with more liberal views on the issue, in order to reject the incorporation of religious beliefs into the law-making process. Despite the efforts in the past decade to regulate stem cell science,[9] no legal setting has been adopted with respect to this issue, or with respect to regulating related activities associated with the use of human embryos. Accordingly, I explore the scrutiny of the current legal provisions related to biotechnology, in accordance to their relevance, influence and connection to the stem cell debate in Mexico.

Subsequently, this paper explores two seminal rulings issued by the Mexican Supreme Court on abortion closely related to the constitutional protection of life. The first ruling established the existence of the right to life under constitutional norms. It is adequate to highlight that this first judgment granted a high level of protection to the embryo, yet this ruling had little influence on the latest one, since the Supreme Court considerably diverged from its earlier

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Mexico City, which are free to organise their internal regimes and regulations in certain matters that are not determined at the federal level, and to vary their local constitutions, but they are united and coordinated as a federation. Since it is a concurrent system, local constitutions may never challenge what is stated within the Federal Constitution. The Federal Constitution provides, in articles 39 to 41, the form of government and integration of the Federal Republic. An English version of the Federal Constitution is available at http://www.juridicas.unam.mx/infjur/leg/constmex/pdf/consting.pdf, translated by Carlos Pérez Vázquez, accessed January, 2010.

[7] Clause 130 of the Federal Constitution gave birth to a secondary regulation *"Ley de Asociaciones Religiosas y Culto Público"* by which the attribute of Mexico as a secular country is ratified and endorsed. See Vázquez, R. (2010).

[8] In this local context, this intercession exerted by cleric leaders from the Catholic Church within the stem cell debate is also pointed out in Blancarte, R. (2010), at 33.

[9] In 2006, the Commission of Science and Technology within the National Chamber of Deputies in Mexico, in conjunction with the Science and Technology Advisory Forum, organised a workshop that put together members of the legislature, scientific community and medical lawyers. This workshop analysed and discussed the regulation of human cloning and stem cell science. Afterwards, a final report was issued: Foro Consultivo Científico y Tecnológico (2006).

reasoning on that point. The latest ruling constitutes a groundbreaking decision reached after a historic and innovative process of resolution never before seen within the Court, whereby the highest court in Mexico publicly called for all who were interested, along with experts, to express their opinions about abortion laws in Mexico. Due to the important role of the Supreme Court of Justice in deciding on legal parameters when there is an absence of political agreement or political inertia, it has been suggested that the Court will create a minimal legal setting for the practice of stem cell science in the near future. After the recent ruling on abortion, local constitutional implications were brought to light. Thus, senate members of the conservative political party formulated, at the federal level, two private bills seeking to protect life from the moment of conception[10] to prohibit human cloning and restrictive provisions for stem cell science. In the final section, this paper argues that the lack of a regulatory framework reveals the complexity of the conflicting political interests and understandings concerning the status of the embryo, and the legitimacy of biotechnology research into aspects of stem cell science.

BACKGROUND

Abortion politics and the associated debate in Mexico are just the beginning of the long process of regulating new technologies and are a part of the divergence between religious and social values. It has been pointed out that the moral position regarding abortion is one of the issues to take into account before moving forward in stem cell science.[11] To date, there is no legal framework with respect to stem cell science, or any other activity involving the use of human embryos such as in assisted human reproduction.[12] Although the debate about regulating stem cell science in the country had been initiated in 2004 by some legislators in the Chamber of Deputies of the General Congress of the Union in Mexico,[13] they

[10] Here, it is important to note that the concept of the "conception" emerged from within the doctrine of the faith of Catholic Church, thus this concept in Mexico in the political and public debate regarding abortion and embryo research has been used and understood within that context.

[11] See Holm, S. (2002).

[12] Here, I am not going to discuss the issue of assisted reproduction in Mexico, which is currently practiced by private and public clinics. Albeit they also involve the use and destruction of human embryos for the sake of assisted reproduction, a legal lacuna is also visible in this area. Therefore, a special analysis regarding this current state of affairs is due for a separate but connected future discussion.

[13] Hereinafter referred to as the "Federal Congress", -in accordance with article 105 of the Federal Constitution, the federal legislative power in Mexico operates as follows: "The legislative power at a Federal level operates a bicameral system composed of the Senate and the Chamber of Deputies"- The bicameral Federal Congress in Mexico is called the Congress of the Union and is composed of a Senate and a Chamber of Deputies, which act in coordination to create, discuss and approve federal law, initiated by their members or by the Mexican President. Apart from the

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failed to reach any legal framework. This result was mainly because religious values of the Catholic Church had also been introduced into the debate. The Roman Catholic Church has a strong presence in most Latin American nations and coincidentally, the most conservative sector of the catholic tradition has tried to determine the underlying morality to be reflected in the law regarding stem cell research, although without much success.[14] Accordingly, when talking about the liberalisation of abortion or the permissibility of the procurement of embryos for stem cell research, the protection of the embryo remains a fundamental feature of societies that are presupposed to have strong pressure from the more conservative sector of the Catholic Church. Among plural societies, diversity of views is tolerable and also desirable in order to achieve a democracy. However, what is occasionally not acceptable is that any particular religious doctrine be reflected in the law, thereby undermining the constitutional foundations of a secular nation.[15]

It is clear that this discussion constitutes an enormous legislative challenge, since the debate is centred on whether life from the outset is something that deserves protection in the legal system, as well as the degrees of protection accorded to the embryo. Currently, those issues are actively being disputed and are a point of tension and conflict among politicians and catholic religious leaders, with a significant impact on local legislatures across Mexico. As noted above, the Mexican Republic was constituted as a secular state. However, the influence of

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legislative functions of the Federal Congress, the Senate and Chamber of Deputies enjoy different functions. The Senate plays a crucial role in conducting foreign affairs and it approves international treaties signed by the federal government and ratifies diplomatic appointments made by the executive. The Chamber of Deputies approves the annual national budgets and determines the system of taxation.

[14] Here it is important to highlight that the presence and predominance of the Roman Catholic Church in some Latin American developing nations do not imply that there is homogeneity among the views and beliefs held by the members of this religion. However, it must be acknowledged that Catholicism is the predominant religion in Mexico, and that the opposition to abortion and embryo research debate is dominated by the more conservative teaching of the doctrine of this faith. In a similar context, such as that related to the Argentinean stem cell debate, these important features and nuances of the conservative Catholic intervention have been meticulously explored in: Luna, F. and Salles, A. (2010).

[15] Although the analysis of the historical linkage between the Catholic Church and Mexico goes beyond the scope of this article, one point must be highlighted. Mexico has undertaken major wars in order to achieve the independence and separation of the Catholic Church and state. In brief, during the Presidency of Benito Juárez García were incorporated the so-called "*leyes de reforma"* were incorporated, by which the freedom of worship and Mexico as a secular state were established. However, it was not until the new Constitution of 1917 (still in force) that the separation of church and state and the expansion of anti-clerical laws were first established. This led to a civil war commonly known as the "Cristero religious war" led by Catholics and clerics fighting in the name of Christ against secularism in Mexico. Two years later, they were defeated by the Mexican government of the time. For an in-depth exploration of this topic, see further information here: Galeana, P. (2010), Wilkie, J.W. (1966). Also see Mabry, D.J. (1978).

the more conservative Catholic leaders on the political and legal agenda has been visible during the last decade in which the federal government has been headed by the National Action Party (PAN), considered to be a conservative political party in the country.[16] In contrast, other local legislatures composed mainly of members of the Party of the Democratic Revolution (PRD), who hold more liberal views, have assumed their constitutional commitment to reject any view or belief that religious leaders attempt to inject into the legislative process.[17] Here, it is pertinent to point out that Mexico was separated from the Catholic Church more than a hundred years ago, when it was declared that religious values should be put aside when deciding secular state and legal matters.

HUMAN DIGNITY AND THE STATUS OF HUMAN EMBRYOS

Conservative political leaders attempt to defend the protection of embryos based on the presumption that they deserve the protection of their human dignity as granted by the Federal Constitution. It is true that one of the key constitutional principles in Mexico is that of human dignity. In 1917, the notion of human dignity appeared in the Mexican Federal Constitution, making it one of the first constitutions to adopt this principle.[18] The first article of the Federal Constitution establishes the following:

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[16] To set the political scene, it is relevant to point out that the federal government is currently headed by the National Action Party (hereinafter, referred to by its acronym in Spanish, PAN), which is considered to have a more conservative ideology, at least regarding topics of the beginning and end of life. The PAN has historic links to the Catholic Church, which can be inferred from its extensive literature and its professed doctrine, defending life from the moment of conception in the terms of the catholic doctrine. For a more detailed exploration of the political and religious changes in Mexico since the coming to power at the federal level of the PAN, with its links to the Catholic Church, see further: Ard, M. J. (2003).

[17] This position, defended by the Party of the Democratic Revolution (hereinafter, referred to by its acronym in Spanish, PRD), is grounded in constitutional provisions, such as those establishing that education and the form of government must be free of any religious influence. This political party in Mexico is considered to hold a liberal ideology regarding issues of the beginning and end of life. Likewise, the PRD enjoys a majority within some local legislatures, allowing it to implement its own legal agenda, which is considered to be the more progressive and liberal in the country. An example of this is Mexico City, which is currently headed by the PRD, where innovative and liberal legislation has been passed, such as abortion on demand in 2007, the marriage between couples of the same sex in 2006, implementing the regulation of advance directives in 2008, and, more recently, in December, 2009, couples of the same sex being given the right to adopt a child.

[18] See Häyry, M. (2004). The question of the role that human dignity plays in the Mexican legal system is a matter for another paper, which will need to discuss whether a legal interpretation and understanding of this principle can be extended to the protection of embryonic life.

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> …Discrimination based on ethnic or national origin, as well as discrimination based on gender, age, disabilities or any kind social status, health condition…or any other reason which attempts against *human dignity* and which is directed to either cancel or restrain the *individual's* privileges and immunities shall be prohibited.

Nonetheless, while the concept is invoked in the Federal Constitution, there is neither an agreed interpretation nor an explicit definition of the principle of human dignity. Various religious and secular interpretations can be made, such that dignity can be seen to be linked to humans as rational beings, as sentient beings, as created beings or as beings with genetic constitutions typical of the members of the human species. Consequently, it is by no means clear that a straightforward assertion can be made from a reading of the Federal Constitution that human dignity is extended to, or possessed by, embryos. What is clear is that respect for human dignity is guaranteed to Mexican citizens as a part of their fundamental rights established under the Federal Constitution.[19]

THE INFLUENCE OF THE ROMAN CATHOLIC DOCTRINE

In spite of all the major efforts of conservative forces to implant religious values within the law, the legislative battle appears to have just begun. Recently, in the national Chamber of Deputies, members of the PRD put forward a legislative proposal to block any constitutional and legal changes based on religious values. The legislative proposal embodies the amendment of article 40, which makes explicit the constitutional status of the Mexican Republic as a secular state, adding that, by no means, shall any norms reflect religious interest and values.[20] This legislative action is an attempt by liberal members of the PRD to incorporate the principle of *"secularity"*. It also seeks to reinforce the separation of religious interests from the law in a pluralistic democracy. This is due to the necessity to resist the recent lobbying by the Catholic Church among other political actors,

[19] The Federal Constitution adopted an articulated catalogue of fundamental rights contained in articles 1 to 29. The protection of the right to life, among other basic rights, is contained within this catalogue. See Carmona-Tinoco, J.U. (2009). Thus, human dignity is a principle contained in this catalogue, yet it is claimed that its definition and legal scope in the Mexican legal system is still in the process of formulation. See Valadés, D. and Carpizo, J. (2009), at 129-122.

[20] This bill has been approved by the National Chamber of Deputies and now passes to the Senate, where the formal proceedings to amend the Federal Constitution require it to be discussed and approved by a majority vote. A synopsis of this proposed bill is available on line at: http://www.diputados.gob.mx/servicios/datorele/LXI_LEG/Sinopsis_dictamenes_sesion.pdf, accessed May, 2010. For a closer examination of the motives that prompted this constitutional reform, see García Ramírez, S. (2010).

thus making clear the necessity to establish the *de facto* separation of religion from state matters.

Due to the constant and forceful actions against abortion and stem cell research on the part of pro-life and religious groups, the brief history of attempts to regulate stem cell science has been marked by defeats and partial victories amongst congressmen, judges and the vast majority of civil society. The result is that, to date, these attempts have been frustrated. The first manoeuvre to discuss and regulate stem cell research in Mexico occurred in 2003, when a private bill that proposed amending the general health law to prohibit human cloning and embryonic stem cell research, was brought to the Chamber of Deputies by a legislator from the PAN. However, this legislative proposal was never accepted.[21] As a result, legislators in this chamber began an intensive campaign to discuss this topic and many others linked to it, such as the human genome, genomic medicine and stem cell research. To that end, the Chamber of Deputies took the initiative of inviting the Scientific and Technological Council Forum of Mexico to jointly organise a seminar where experts debated and expressed their scientific and ethical views regarding these scientific activities. In spite of this positive initiative, the outcomes of the seminars seemed not to be legally fruitful, due to their failure to adopt any clearly articulated legal framework within which to regulate cloning or stem cell research, in particular. The publication of a final report was a valuable product extracted from this seminar. The report optimistically and moderately conveyed to legislators the scientific side of stem cell research.[22]

Although it was the first step taken in an attempt to regulate stem cell research in Mexico, it was not until the latest ruling by the Supreme Court of Mexico in relation to abortion issues, when local legislatures and political leaders decided to undertake legislative actions in order to protect embryonic life. Before examining the seminal rulings and proposals dealing with the protection of the embryo and their political repercussions across the nation, it is appropriate to describe the current legal setting regarding biotechnology in the country, as well as the investment recently made by governmental and private investors in this field.

REGULATING BIOTECHNOLOGY IN MEXICO: AN OVERVIEW

To offer a current and up-to-date overview of biotechnology research in Mexico and its regulation is not an easy task. The task seems more complicated if one considers biotechnology investment according to aspects of stem cell research, which is at its initial stage of development in this country. It is at this stage that this sort of investment will face political, cultural and potentially constitutional

[21] See Brena Sesma, I. (2006).
[22] Ibid, note 9.

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questions as to whether life should be protected from the outset and onwards, and whether embryo research in general, and stem cell science in particular, should proceed. A national legal framework for stem cell research does not yet exist. Legislation regarding some other issues related to it, such as science, biotechnology and innovation has a different regulatory status.

With regard to a legal definition of an embryo and its protection, the Federal Constitution is silent. The document does not provide any reference to it, yet its secondary legislation establishes a definition as to what is to be understood by "embryo."[23] First, it is necessary to point out that the promotion of science, biotechnology and innovation are exclusively regulated by federal legislation, yet local states have concurrent jurisdiction, in accordance with each specific regulation.[24] The basic regulation dealing with biotechnology research is the General Health Law (1984), by means of statutes called the Regulation on Sanitary Disposal of Human Organs, Tissues and Cadavers (1985) and the Regulation on Scientific Health Research (1987), along with regulations put forth by the National Institutes of Health Law (2000). The first statute provides the definition of concepts such as cells, tissues and what is understood to comprise artificial reproduction. Although there are some concepts that are relevant to the stem cell debate, this statute does not establish a specific route to be followed by researchers in the mentioned areas of research.[25] The second statute makes brief reference to the issue of assisted reproduction, which is also not widely regulated, and simply establishes that research is permissible only when there is no other means to solve infertility problems and when this activity is performed in line with the moral, cultural and social perceptions of the couple.[26] The last statute regulates the functioning of the National Institutes of Health in the country. This is connected to the recent creation of the National Institute of Genomic Medicine (INMEGEN).

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[23] In clause 314, subsection VIII of the General Health Law it is established that under this regulation embryo is to be understood as: "…the product of the conception from that point onwards, and up to the end of the twelfth week of gestation."

[24] In accordance with article 3 of the Federal Constitution, one of the goals that the federal government shall pursue is the development and strengthening of scientific and biotechnological research. Article 2 of the Law on Science and Technology, the particular body of norms that regulates this responsibility of the federal government, establishes that it is federal state policy to increase the scientific and technological capabilities and the training of researchers in order to solve essential national problems, which in turn will contribute to the advance and growth of community wellbeing.

[25] See further: Muñoz de Alba, M. (2006).

[26] At the time of writing, further legislative development are expected in the Federal Congress regarding the regulation of assisted reproduction in the Country, activity as previously mentioned that remains unregulated as well. This legislative proposal has been discussed and consequently modified several times in the Federal Congress, at the moment this has not been passed yet.

Most of the legislative proposals and policies created in favour of biotechnology, however, have been presented by members of the PAN. The federal government has publicly expressed its commitment to encouraging inward investment and innovation in the area of biotechnology, although it has not explicitly addressed the development of stem cell science. An example is the creation in 2004 of the INMEGEN, which is directly subordinate to the Ministry of Health. The federal government, through the Ministry of Health, had invested heavily here, particularly in the development of a platform for genomic medicine as a key area in which to develop biotechnology and healthcare innovation.[27] This institute was created based on the premise that building a legal and research platform for genomic medicine was justified on the grounds that it promised the amelioration of health problems. This was to be done by means of the promotion, regulation, development and utilisation of the research and medical applications derived from the knowledge of the human genome.[28]

The INMEGEN was recognised as a national research institute authorised to conduct research into genomic medicine. Article 7 bis provides that the "…National Health Institutes Regulations basically consist of obligations to carry out clinical and experimental research into fundamental technology development within the area of genomic medicine; to promote safety measures in its specialised area; to further the links between national and international institutions in order to create a research network in the field of genomic medicine; to foster innovation and technological projects for creating means of diagnosis, genomic medicine and genetic therapy; to be the National Reference Centre for issues related to studies on genomic medicine and its applications."

This advance in biotechnology research has been recognised as an excellent result of lobbying by the director of INMEGEN, who organised several workshops and seminars in the Federal Congress in order to convince legislators and the federal authorities to invest in this innovative research.[29] In order to create INMEGEN, the General Health Law and the regulations concerning the national health institutes were modified. Therefore, the section 'biotechnology products' was first introduced into law in order to regulate common biotechnological goods. Article 281 bis establishes that "…biotechnological products are those nutrients, ingredients, additives, raw materials, health inputs, pesticides, toxic or dangerous substances, and their rights, involved in processes within living organisms or part of them, modified by a traditional technique or by genetic engineering." This wording suffers from a lack of clarity with respect to modification by traditional techniques, suggesting that the modification of living beings by means of non-

[27] See Isasi, R. M., et al. (2004).
[28] See Jimenez-Sanchez, G. (2003).
[29] See Seguin, B., et al. (2008).

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traditional techniques is allowed. However, this is the only norm that makes reference to the modification of living organism and biotechnology.

This important advance in biotechnology notwithstanding, there is a clear dichotomy as to the government's view of stem cell research. On one hand, the federal government invests a considerable sum of money into genomic research. On the other, this research centre is prevented from conducting embryonic stem cell research, in accordance with its internal regulation, as stipulated in article 3, section I, which provides that "...no research of any kind will be carried out on human stem cells derived from live embryos, or those procured by nuclear cell replacement…"[30] Although there is a clear prohibition of certain types of stem cell research, other important ways of procuring embryonic stem cells are not contemplated, nor is the possible use of these cells. In addition, this prohibition applies only to INMEGEN, not to any of the other public and private research centres in the country capable of developing biotechnology, especially with respect to stem cell science.

The monetary investment has been visible by the creation of an infrastructure and legal platforms for genomic medicine under the pretext of the achievement of economic and social development, thereby fostering policy actions across issues and borders. However, although this shows that the federal government is eager to advance science and biotechnology on one hand, on the other hand, the government is maintaining restrictive policies in relation to stem cell science as provided by the internal regulations of INMEGEN. Moreover, restrictive parliamentary proposals have been put forward by members of the PAN to prohibit stem cell research in the country. This point will be further explored in the following sections of the paper.

Nevertheless, it is important to note the fact that the government is not the only player to have injected financial resources into biotechnology and life science research in the country. Lately, Mexico has seen increasing interest from private foreign companies in nurturing this area of research, creating international transnational alliances between countries and research institutes.[31] The influence of private forces, such as biotech and pharmaceutical companies, transcends the borders that conservative groups have intended to place around the country. At

[30] Statutory bill of the National Institute of Genomic Medicine, March 2007, (author´s translation), available online from http://portaltransparencia.gob.mx/pdf/123701000564.pdf. accessed on April 22, 2010.

[31] According to a study entitled "Catalyzing Cross-Border Innovation: The Mexican Life Sciences Initiative" carried out in 2005 by the Council on Competitiveness and Global Bioeconomy Consulting, *life science* is to be understood as "…broadly defined to include all biological technologies and applications. This includes: biotechnology, pharmaceuticals, plant and animal technologies, medical devices, healthcare (e.g. translational research, clinical trials), biological related information technology (e.g. bioinformatics, telemedicine), as well as biological-related production and manufacturing." See San Diego Dialogue, (2007), at 3.

the moment, at least one major private alliance with foreign investment has been formed, the Life Sciences Gateway Initiative, and it is composed of some key regions in Mexico that have an emerging potential to develop biotechnology, including certain stem cell research activities.[32] This alliance is enhanced further by links with the University of California-San Diego and Merck, Sharp & Dohme in promoting life science research within so-called Mexican bio-clusters. The Mexican states involved in this alliance are Morelos, Guanajuato, Guadalajara and Monterrey. These clusters have different strengths and activities. While the Morelos Institute specialises in research, Guanajuato has the largest agri-biotech cluster. Guadalajara, known as the Silicon Valley of Mexico, already practices the utilisation of stem cells from umbilical cord blood and spare embryos from fertility treatments. In Monterrey, technology and clinical research centres are undertaking the same work.[33] The main goal of the alliance is to link health and life science research and enterprise in Southern California with these Mexican regions.

One of the researchers involved in the alliance points out that Mexico has the infrastructure and maintains the quality and standards of the US or Europe, with the added advantage of having more patients for research and more room for clinical trials, highlighting the point that many clinical research locations in the United States are overbooked. In addition, he claims that the migratory policies in Mexico are more flexible and that a lack of regulation fosters freedom, but that the infrastructure is primitive and there are not enough researchers.[34] This last point raises the strong need to develop a platform for stem cell research in order to achieve desirable conditions for all stakeholders in this research activity.

Furthermore, key actors in the scientific community in Mexico, such as national researchers, have publicly called the attention of the Federal Congress to their concern regarding the potentially inadequate regulation of stem cell science. As a result of this legal uncertainty, the academic community issued a public letter requesting that the national legislators avoid the adoption of any legislation seeking to prohibit all kinds of stem cell science practices. This position among scientists and national researchers reiterates their ethical affirmation and the relevant principle of the freedom of research to promote knowledge as a public good within a democratic state, as expressed in one of the editorial of issues of the National Academy of Sciences journal.[35] The National Academy of Sciences plays a crucial role in developing scientific research in the country. The Academy, which enjoys the most prestigious and honourable public status, brings together the whole scientific community working in public and private research centres.

[32] For instance, see (2008) "Biotech round the world: Focus on Mexico."
[33] See further: Meade, C. (2008).
[34] Ibid, note 32, at 8.
[35] Ruiz-Gutiérrez, R. (2009).

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Therefore, research projects and interests are at the heart of this organisation. However, their claim is based on a line of thinking followed by a minority of the population, largely restricted to the academic sector.

THE CONSTITUTIONAL RIGHT TO LIFE IN THE SUPREME COURT OF MEXICO

The Supreme Court of Justice has played an important role in interpreting the Federal Constitution.[36] Hence, it is relevant to analyse its interpretations regarding the legal status of the embryo.[37] The Court has addressed the issue on two occasions, although in both cases it has failed to provide an accurate interpretation of the protection due the embryo, if any, derived from constitutional principles and fundamental rights. In order to address the extent of legal protection offered by the highest court with regard to the embryo, it is also significant to point out that both judgments were issued as a result of modifications to the abortion law reforms approved by the local legislature of Mexico City. This local legislature is mainly composed of members of the PRD who advocate liberal policies on issues regarding the beginning and end of life. This latest point denotes the fact that the political context and the lack of predominance of religious influence may be the deciding factors in liberalising the regulation of certain activities such as abortion. Consequently, it has been suggested that in the near future, this may extend to the regulation of stem cell research due to its interruption of pregnancy as related to the extent of legal protection deserved by the embryo. This is because the Court has recently been acting as a broker between the federal government, legislators and society with respect to outstanding issues, based upon the divergent views that they can neither accommodate nor conciliate.

The reforms to its criminal code, approved by the legislative assembly of Mexico City in 2000, extended the exemption from penalty in cases of abortion when the mother's life was at risk and when there were severe congenital conditions affecting the foetus. It is argued that this reform seemed to constitute a significant achievement in incorporating a new language into the public discourse,

[36] See, for instance: Cossío-Díaz, J.R. (2009).

[37] The Mexican Supreme Court of Justice is the highest judicial authority. One of its functions is to exercise constitutional control, when unconstitutionality is claimed, which is no more than the Court´s power to strike down any bill or secondary body of norms that may contradict or contest any provision of the Federal constitution, or otherwise to pronounce the legality of the bill or norms challenged. Rulings issued by this Court are called *jurisprudence* or *judicial precedent* and can be considered similar to *case law* in common law systems. In order to create jurisprudence or judicial precedent, as a formal requirement, eight of the members of the Court must agree on the main points of any judgment. The Court's judicial precedents are binding on all lower courts, due to its hierarchical supremacy as a constitutional court over all the Courts within the judicial system.

such as sexual and reproductive rights.[38] However, this reform was contested immediately after its approval by a minority of congressmen within the local legislative assembly who were conservative members of the PAN. They challenged the constitutionality of this reform, arguing that the exemptions added to the criminal code in order to allow abortion where there were genetic or congenital malformations of the foetus, violated the foetal constitutional right to life. Here, it is pertinent to point out that both the claimants and the Supreme Court allude to the protection of the product of the conception, the embryo, foetus and unborn, without establishing any distinction between them.[39]

Subsequently, in January, 2002, the Supreme Court, upheld the first judicial precedent regarding abortion norms and the protection of the unborn. In doing so, the Court attempted to interpret the constitutional provisions and civil norms related to the protection of the product of conception. The Court endorsed the constitutionality of the reforms based on the argument that the crime of abortion remained intact, and that the exemptions were incorporated for socially accepted reasons. In addition, it held that the reforms did not authorise the interruption of the life of the product of conception. It merely conceded the possibility of exempting a woman from criminal punishment when an abortion was performed under the circumstances stated in the criminal code. Thus, the constitutional right to life of the product of conception remained intact.[40] The Court interpreted constitutional articles 14 and 22 of the Federal Constitution as providing the following, respectively: "...no one shall be deprived of her life…" and the "...death penalty is forbidden…" Accordingly, the constitution "protects any manifestation of human life, regardless of the current biological development."[41] On the other hand, within the Federal Constitution, there is no special provision referring literally or indirectly to the product of conception, the embryo, foetus or unborn. However, the Court asserted that since article 123 provides the protection of working rights for pregnant women by allowing maternity leave for them, the aim of the constitution is to protect life from the outset.[42]

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[38] See further: Madrazo, A. (2009).

[39] See Claim of unconstitutionality 10/2000. Claimant: Deputy Members of the Mexico City's Legislative Assembly (author's translation), http://www.scjn.gob.mx/SiteCollectionDocuments/PortalSCJN/MediosPub/AsuntosRelevantes/2000/Acci%C3%B3n%20de%20inconstitucionalidad%2010-%202000%20de%20Pleno.pdf, accessed on January 2010.

[40] Tesis: P./J. 14/2002, 'The right to life of the product of the conception, its protection derived from Mexican Constitution, International Treaties and Federal and Local regulations' (author's translation).

[41] Ibid, note 39, at 87.

[42] Idem, at 100-103.

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In addition, the Court recognised that under the Federal Constitution, all human beings have the right to life, and that the product of conception is an early manifestation of life. The constitution's aim, therefore, is to protect life from conception onwards. Nonetheless, the Court was ambiguous by ruling in that way, since it did not explain, in lay terms, what conception means or how one can determine when conception starts. Finally, the Court agreed that the product of conception is not only protected under national civil norms, but also by international treaties signed and ratified by the Mexican government, such as the UN Convention on the Rights of the Child (1990) and the American Convention of Human Rights (1978), commonly known as the Pact of Santa Fe Costa Rica, signed and ratified by Latin-American and Caribbean countries. The first establishes the protection of children before and after birth, and the last provides the fundamental right to life. At that time, the Court did not make it clear that the federal government had issued an exception to the Pact of Santa Fe regarding the protection of life from conception onwards. However, this point was covered by the latest ruling of the Court, explored later in this section. The judges also asserted that federal civil norms provide that the unborn child has the potential to invoke inheritance and donation rights, so it must be considered a bearer of rights, and therefore must be protected from the moment of conception.

To a certain extent, the ruling was significant in acknowledging the constitutional right to life.[43] Nonetheless, the Court acknowledged the right to life of the product of conception. It does not, however, provide a clear explanation about the consequences of that safeguard. In other words, it merely analysed the constitutionality of the norms contested without providing a clear pragmatic explanation about why and how life from conception onwards is deemed to be protected. The judgment is legally flawed, since there is a lack of legal reasoning by which the Court explains why it is inferred that life should be protected from the outset. It only focused on the potential of the "unborn" to become a bearer of rights. It did not provide further and stronger reasoning to understand and accept that, somehow, diverse fundamental rights such as women's autonomy and right to decide over their body should be put aside to protect life from conception, even in cases of unwanted pregnancies.[44] The Court granted high constitutional protection to the product of conception, failing to establish an accurate account of its implications not only in the case of abortion exemptions, but in broader terms when talking about relevant areas such as the protection of spare embryos procured for artificial reproduction techniques already in practice. However, the

[43]For a discussion see: Ordóñez, J. (2002).

[44] This is not to say that we have an argument in favour of abortion on demand as a result of unprotected sex. This is just to highlight that judges needed to be clearer when balancing conflicting basic rights, such as those concerned with the right to life and the ability to decide about our own offspring.

Court drastically changed this ruling a second time in further reforms on abortion law in Mexico City. This time, the highest judicial authority provided expanded reasons to carefully figure out the degrees of protection accorded to the embryo.

Once again, in April, 2007, the local assembly of Mexico City amended its criminal code and the local health law, decriminalising abortion before the end of the twelfth week of pregnancy.[45] In addition to the legalisation of elective termination of pregnancy up to twelve weeks of gestation, the reforms also added clauses to the local Health Law. These clauses stipulated that the Mexico City Ministry of Health, through health providers (i.e., public hospitals and clinics), must ensure access to first-trimester abortion services at no cost to Mexico city inhabitants and for a moderate fee for women from outside the city. However, difficulties arose immediately upon the approval of the aforementioned reforms when the President of the National Human Rights Commission and the Attorney General of the Mexican Republic, separately, initiated claims of unconstitutionality against the reforms made to the criminal code and local health law.[46] The central arguments, adduced by the petitioners, were based on the premise that life is constitutionally protected from the outset. Accordingly, decriminalising abortion in Mexico City infringed upon the basic right to life of the embryo and the unborn. Furthermore, the reforms were said to transgress the human dignity possessed by embryos, since life begins to matter morally and legally from the outset. The petitioners further asserted that it is from conception onwards that the embryo is in possession of full human rights and human dignity, the numerous alternative positions on this question notwithstanding.[47] In addition, the allegation was again grounded in many international treaties and covenants

[45] Presently, abortion in cases of rape can be carried out in all 32 states. In 29 states when pregnancy ends by miscarriage, women are exempted from penalty in contrast to other states, where it is not considered an exemption from punishment; in 28 states when the woman´s life is at risk; in 11 states due to foetal impairments; in six states when there is insemination by a donor without the consent of the woman; and in one state for socio-economic reasons (for women with three or more children).

[46] Suprema Corte de Justicia de la Nación, (2008a). It should be pointed out that the President of the Human Rights Commission acted under his own authority and initiative, without the approval of the majority of the collegiate advisory council within the commission, although half of the members of the council expressed their disapproval in alleging any claim of unconstitutionality against the Mexico City reform. See further: Serrano-Migallón, F. (2008). Another relevant point is that both authorities who contested those reforms are appointed by the President of the Mexico and in the case of the Attorney General, he takes direct orders from the President. Additionally, as previously indicated, the Mexican President was brought to power by the conservative PAN.

[47] Here, it is pertinent to note that the doctrine of the PAN states that: "Human beings possess an inner dignity and have material and spiritual ends to fulfil; therefore the community and its organs shall guarantee the freedom and the means to accomplish that destiny with dignity" (author's translation). Cautiously, we can infer that the claims of unconstitutionality were not grounded in constitutional norms, but rather were based on the doctrine of a conservative political party. Principios de doctrina del Partido Acción Nacional, (2002).

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that Mexico had signed and ratified. Consequently, the Supreme Court was called again to decide about the constitutionality of those reforms and issued another landmark ruling in this area.

On August 28, 2008, the plenary session of the Supreme Court of Mexico issued a ground-breaking judgment on abortion law, upholding the constitutionality of abortion on demand in Mexico City. Its earlier judgment notwithstanding, however, the Court decided to rule differently this time, changing its previous seminal ruling in 2002.[48] As a result, the Court preferred, on this occasion, to focus predominantly on women's reproductive rights. Secondarily, but in more detail than in its previous judgment, it focused on the extent of protection of the constitutional right to life rather than of the civil law, which protects the interests and rights of the *unborn*.

In order to reach a final judgment, the Supreme Court made a public call for all interested parties to express their opinions regarding the constitutional challenge. It issued a document that established the formal requirements for holding public hearings.[49] Subsequently, the Supreme Court held six of these public hearings, a remarkable and unusual mechanism, in order to take into account the views of all interested parties, given the national relevance and legal impact of the issue. At the six hearings, which took place in courtrooms and were broadcast internationally through the Court's special website, more than 40 speakers from diverse sectors of the population, from the most secular to the most conservative, presented arguments for and against decriminalisation.[50] Amongst the strongest arguments made in favour of the decriminalisation of abortion were those that held that a woman's freedom over her physical and mental health should prevail over other concerns.[51] These arguments also pleaded that religious values concerning the protection of the embryo can and should be put aside when determining secular legal matters. Conversely, the conservative position was that

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[48] The Court is authorised to change and vary its judicial reasoning and judgment from time to time, in accordance with the current social circumstances and based on accurate arguments. See further: Sodero, E. (2004).

[49] Suprema Corte de Justicia de la Nación, (2008b). "General Agreement 2/2008, of the Plenary of the Supreme Court of Justice of the Nation by which are established the guidelines to follow in order to celebrate public hearings concerning relevant issues with legal interest and national importance" (author´s translation). http://www.ordenjuridico.gob.mx/Federal/PJ/SCJN/Acuerdos/2008/02042008%281%29.pdf, accessed on July, 13, 2010.

[50] In order to provide transparency, as well as to inform society as to the process of arriving at the final ruling, the Court created a micro-website where people could access all the particulars of the public hearings, the documents presented by the speakers and recordings of the speeches made before the Court, as well as the final ruling and the dissenting comments made by judges. This website was available online until February, 2010, more than a year after the final ruling of the Court. This information was sourced from http://informa.scjn.gob.mx/, accessed February 7, 2010.

[51] See further: Ubaldi Garcete, N. (2008).

each embryo is a sentient being with a genetic constitution typical of the human species, making the embryo part of humanity and, consequently, deserving of the protection of its human dignity and life.[52] During the final hearing, in a groundbreaking judgment, eight of the eleven judges orally and publicly upheld the constitutionality of the decriminalisation of abortion in Mexico City.[53] Subsequently, six months after its oral ruling, the Court published a written judgment on the matter in March 2009.[54]

In sum, clause eight of the final judgment refers to 'the right to life, its nature and existence.' In addressing the allegation put forward by the claimants, the Court established that "life is a necessary condition for the actual existence of fundamental rights; however, this does not imply that the right to life should prevail over other fundamental rights, given that fundamental rights are not absolutes and that when they conflict, the appraisal of rights is necessary."[55] The Court asserted that "from a plain reading of the Federal Constitution there is no explicit text which grounds the argument that a foetus has a right to life; moreover, there is there is no constitutional obligation to defend life from conception, in particular through the criminal law."[56] Once more, the Court failed to provide more clarity on the use of the language applied to the *embryo/foetus/unborn and the product of the conception,* so this ambiguity persists in this ruling, yet it conclusively stated that life is not protected from conception under constitutional norms.

The Court continued its reasoning, establishing that laws regarding the protection of life were derived from international covenants and treaties, and then indicated that the majority of these legal documents do not establish when life begins or from what moment it should be protected. It also considered that, although Article 4 of the American Covenant of Human Rights establishes when life is considered to begin, Mexico should not be bound by that specific stipulation. This is because of the reservation made by the Mexican government when ratifying this covenant, which acknowledges that decision making on whether or not to protect life "in general" from the time of conception is to be reserved by each Mexican state.[57] Furthermore, the Court is not constrained to protect life from the outset, not even from a particular point, under international

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[52] See, for example: Fernández del Castillo Sánchez, C. (2008).
[53] Any ruling passed by a majority of eight judges' votes out of the 11 judges sitting *en banc* creates *precedent,* which is binding on all Federal and lower courts in Mexico, in accordance with article 43, *Ley de Amparo*.
[54] Ibid, note 46. It is noteworthy here that the Supreme Court of Justice also had the power to completely overrule the amendments made to the Penal Code and the Health Law if it had been found contrary to the provisions of the Constitution.
[55] Idem, at 151 (author´s translation).
[56] At 153 (author´s translation).
[57] At 158-174.

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norms. This time, the Court successfully provided a clear explanation of the binding status of the Latin-American Covenant of Human Rights, which in its earlier seminal ruling, failed to be invoked. In other words, the Court affirmed that there is no right to life in itself. However, the Court does, ultimately, have an interest in promoting and protecting life, for instance, the right to health care is provided by constitutional norms.

Furthermore, the Court held that the measure adopted by Mexico City was important for protecting women's health. It recognised that in enacting this reform, Mexico City was assuring article 4 of the Federal Constitution regarding women's responsibility for and freedom over their own bodies, their physical and mental health and their lives. The Court affirmed that even if there were an aspiration to protect the foetus, the complete criminalisation of abortion would not ensure the due development of pregnancy, given the social context of poor, marginalised and rural women who cannot achieve the best conditions for their pregnancy. Further, if abortion remains as a crime, it would only serve to perpetuate discrimination against women, by not giving them control over their bodies.[58]

A relevant point to make here is that it does not follow that by allowing the interruption of pregnancy before the twelfth week, the Court or the states renounce any interest in protecting embryonic and foetal life. Sensibly, the Court indirectly initiated gradual protection deemed appropriate to the embryo, such as after the twelfth week of gestation. However, the issue about the treatment of the embryos before that period of development remained unaddressed.[59] Thus, the Court failed to consider whether embryos created in vitro for artificial reproduction enjoy the same level of protection as those produced by conception. Furthermore, in accordance with the ruling, one can infer that in the constitutional system, life starts to matter and is deemed to be protected after the twelfth week of embryonic gestation; therefore, this interpretation by the Court suggested that embryonic research could proceed before the window of legality for interrupting embryonic development.

A valuable feature of this ruling is that the public proceedings held by the Supreme Court of Justice of Mexico constitute an important example of how prevailing social values and conditions should be taken into account in order to reflect the real needs of a population in the construction of the law. Hence, the Court's decision to assess these values by encouraging their expression at public hearings regarding the status of the embryo and women's reproductive rights. This public engagement shows the necessity of the law to reflect the real context within a community, as well as the rights and interests to be considered before legislating on sensitive issues such as abortion and stem cell research. An

[58] At 182-183. Article 4 of the Federal Constitution establishes that '…every person has the right to decide in a free, mature and informed way, the number and spacing of their children'.
[59] See Medina Arellano, M.D.J. (2010).

important final remark concerning this judgment is that the Supreme Court's authorisation of abortion on demand makes it easier to consistently endorse a framework for human embryonic stem cell research, since the barrier of the moral standing of the embryo can be overcome.

Interestingly, it might be the case that in the near future, the Supreme Court of Justice of Mexico will establish the legal parameters regarding stem cell regulation, as has occurred in many other areas of the law where there is an absence of political agreement, lack of regulation and a great inertia to legislate. Legal parameters would also reflect the experience of other developing countries such as Brazil, with legal, religious and political contexts very similar to those of Mexico. In Brazil, was the Supreme Court that ended up deciding the legality of stem cell research, therefore it shall proceed, since this scientific activity does not contest any constitutional norm.[60]

However, in the case of the Supreme Court of Mexico, the discussion with regard to the legal status of the embryo is extremely unrefined. Nonetheless, the positive features of its legal ruling on abortion and its potentially crucial role as a mediator of political, legal and religious forces are significant. The Court did not articulate the extent of protection between the initial stages of embryo development (such as zygotes and blastocysts) and foetus. Its lack of certainty and limited arguments regarding the degree of protection accorded to the embryo opened the door to transplant this debate to the political and legislative arena, though, as suggested, just temporally, as it provoked political and legal responses across the country, creating legislative repercussions for abortion and stem cell science.

POLITICAL AND LEGAL IMPLICATIONS FOR STEM CELL SCIENCE AND ITS REGULATION

Immediately after this latest Supreme Court ruling on abortion, reactionary stances were taken by some political and clerical figures in order to construct a legal shield that would prevent the adoption of abortion laws elsewhere like those endorsed in Mexico City. In the Senate, a major reform was promoted and initiated by conservative members of the PAN to amend the Federal Constitution, strengthening the protection of life from conception. Additionally, they put forward additions to the General Health Law seeking to implement a total ban not only on abortion, but also on any activity related to the use and destruction of embryos, including human cloning. These reforms, promoted by members of the PAN, were denounced as linked to religious ground by some members of the Chambers of Deputies. For example, Jaime Cardenas publicly stated that: "the

[60] Ibid, note 3.

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church promotes reforms and laws in several States and it is opposition to others."[61] Subsequently, in local legislatures, actions were taken to modify local constitutions and guarantee the right to life from conception, given that there is a lack of an explicit norm in the Federal Constitution protecting life from the outset as recently asserted by the Supreme Court.

These local constitutional changes were immediately visible and had a widespread impact, for they were translated across 17 states, all of which amended their local constitutions. While there were variations in legislation among the states, they all established that "*life shall be protected from the moment of conception until the natural end of life"* and reforms of this type are still being enacted at the time of this writing. Here, by incorporating local constitutions concepts derived from the catholic doctrine, it can be noted the direct influence still exercised by the hierarchy of the Catholic Church on many political groups in Mexico, demonstrating that there is far from being a *de facto* separation of law and religious belief.[62]

What is of great importance here is that, as mentioned before, these reforms seem to be pre-emptive measures to prevent Mexican legislators from liberalising the rules on abortion and to halt any further development, such as embryo research. The question of the legal status of the embryo continues to be disputed. It remains a point of tension and conflict among social, political and legal groups. A relevant political coalition is worth noting here. Most of the legislatures that have modified their local constitutions are not dominated by members of the PAN, the political party that brought the current president of Mexico to power. Rather, they are members of the Institutional Revolutionary Party (PRI),[63] without whose support the reforms of the local constitutions would ever have become possible. These reforms were based on the same arguments put

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[61] Author´s translation from Faesler, J. (April, 2010).

[62] By comparing the text added to the local constitution with recent document issued by the Congregation for the Doctrine of the faith, called "Instruction Dignitas Personae for certain bioethical questions" it is found the great similarity in both documents regarding the protection of life. The last document establishes: "1. The dignity of a person must be recognized in every human being *from conception to natural death"*...and, ..."12. ...new medical techniques must respect three fundamental goods: a) the right to life and to physical integrity of every human being *from conception to natural death*..." (Emphasis added). Document available on line at: http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html, accessed on October 20, 2010. This point has been noted several times by Ricardo Tapia in various writings, see further: Tapia, R. (2009a) (2009b).

[63] Known by the Spanish acronym PRI, this political party ruled at the federal level for seven decades until the PAN came to power in 2000. Members of this political party are also supposed to hold more liberal views, since its founders were the one who sought the separation of the Church from the State. For a deeper insight regarding the political ideologies, developments and agendas pursued by the three main political parties (PAN, PRD & PRI) in Mexico, *see*: Wuhs, S.T. (2008).

forward by the federal authorities that contested the Mexico City's criminal code reforms. Consequently, the political rejection of the Court's decision, which was anticipated, is a clear movement organised by the hidden coalition of the political parties PAN and PRI in Mexico, at least on this issue. The local reforms are expressions of the powerful influence of religious beliefs among those political leaders, especially given the historical links between the Catholic Church and the governing party in Mexico, PAN, which has acquired new political allies to strengthen its cause.[64]

It has been suggested that this political alliance is motivated by the political parties' interest to attract votes in the future elections from the Catholic population, as well as to seek further national legislative reform.[65] A member of the Chamber of Deputies Leticia Contreras (PRD) publicly condemned in the media that the main purpose of these local constitutional changes is to call for an amendment to the Federal Constitution.[66] Not surprisingly, it may well become a reality, since one of the ways to amend the national constitution is by seeking the approval of an amendment with the majority of local legislatures.[67] The local legislative reforms are grounded in the catholic teaching, since they stated that life begins at conception, leading this concept to be perceived in a religious context throughout the country since Catholicism is the predominant religious doctrine in the region. As previously agreed, in a plural community constitutionally established under secular principles, any attempt to inject religious values into the law is considered to be a clear affront to the basic principles of the Federal Constitution. Controversially, by legislating in this way, members of the local legislatures are contravening the foundations of the secular state.

After the latest ruling of the Supreme Court of Justice on abortion, and the local legislature's amendments regarding the protection of life from the outset, the issues about cloning, stem cell research and the status of the embryo emerged on the federal legislative agenda. Therefore, members of the conservative wing in the Senate made it a crucial priority matter to propose amendments to the Federal

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[64] Recently, the PRI has allied itself with the PAN with regard to this mission. Without its support, the proposals of the PAN to amend local constitutions would not have been approved by local congresses. Only in the few states where the PRD controls the legislature have these amendments failed, in favour of more progressive regulations like those passed by Mexico City's Legislative Assembly.

[65] See further: Tapia, R. (2009c).

[66] See González López, G. (2009).

[67] This in accordance with article 135 of the Federal Constitution, entitled "Constitutional Reforms". This literally provides that "This constitution can be amended or reformed by two thirds of the attending members of the Federal Congress at the respective session. Such amendments and reforms shall be valid when ratified by the majority of the State Legislatures. Either the Congress or the Permanent Commission during congressional recesses shall compute the State Legislature´s votes and declare the approval of the respective amendments and reforms."

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Constitution and the General Health Law in order to provide clearer rules about the protection of life, embryo research and related issues.

To date, two private bills have been brought before the Senate by legislators from the PAN. The first legislative proposal seeks to amend the Federal Constitution with regard to the protection of life from the moment of conception. The parallel bill contains provisions to be added to the General Health Law, placing a total ban on human embryonic stem cell research, as well as very tight restrictions on the use of adult stem cells. The motives behind these private bills as previously mentioned are suggested to be grounded in pseudo-scientific arguments, as well as inspired and supported by Catholic values related to the beginning of life and the moral status of the embryo.[68]

In general terms, the legislative proposal to amend the constitution rests on the modification of article 1 of the Federal Constitution regarding the beginning of life and its protection. The content of this amendment is as follows:

> "In the Mexican United States all individuals shall be entitled, *from the moment of conception,* to the privileges and guarantees granted by this Constitution. Such privileges and guarantees shall not be restricted or suspended except in the cases and under the conditions established by this Constitution itself."[69]

As can be seen, this text proposed to be added to the Federal Constitution is not very distinct from the postulate of the doctrine of the Roman Catholic Church with regard to the protection of life. This point generated divergence in the Senate and, presently, the discussion of this private bill has not been even initiated. It is very unlikely that both bills are going to be passed in the Congress in the near future, since currently, as previously noted, diverse liberal political actors are pushing forward legislative actions to avoid religious influence on the law. In addition, a similar amendment to the local constitution of Baja California is currently being contested and its ruling by the Supreme Court of Justice is pending.[70] If the Supreme Court of Justice upholds the unconstitutionality of this amendment, the natural legal consequence is the reversal of all the local constitutional changes and the refusal of the above-mentioned federal legislative proposal.

Consequently, it is also crucial for the members of the conservative political forces in the country to modify the secondary legislation. That is to say, the General Health Law, in order to provide clearer rules about embryonic research and related issues. Basically, this second bill presented before the Senate

[68] Ibid, note 65.
[69] Emphasis added. See Leal Angulo, A.C. (2009).
[70] See Conesa Labastida, L. (2010).

seeks to establish a total ban on human cloning and contain very restrictive clauses on stem cell research and therapies. A relevant fact to note here is that this legislative proposal is identical to the one previously rejected by the Chamber of Deputies in 2003. In short, the proposal consists of four clauses to be added to the General Health Law that would, in essence, prohibit research, manipulation or any intervention in order to carry out human cloning. It also states what is to be understood by human cloning and prohibits the procurement of embryos by cloning, as well as the combination of any human cell with any other species, that is to say the creation of animal-human chimeras.[71]

Here, it is relevant to highlight that this proposal does not provide any further normative rules to follow regarding those embryonic stem cells obtained from supernumerary embryos,[72] from in vitro fertilisation treatment or from umbilical cord blood; both are already being practiced in public and private clinics across Mexico. This last point raises several questions as to what is currently occurring in the biomedical field. Mexican doctors are allegedly using stem cells to treat ill national and foreign patients, as well as creating umbilical cord blood bio-banks, activities are not covered by the law.[73] Finally, the proposed bill also stipulates very tight restrictions on the use of adult stem cells, particularly those procured from bone marrow. The proposed punishment for anyone conducting human cloning and embryonic stem cell research would range from one to eight years of imprisonment, as well as the permanent cancellation of his or her licence to work in the medical profession.

On the other side of the argument, certain well-known scientists who are members of the National Academy of Sciences and of the Scientific and Technological Council Forum of Mexico, have claimed and called for public attention to promote more liberal regulations and investment in embryonic stem cell research, under the banner of 'medical progress with responsibility.'[74] By supporting the permissibility of stem cell research, it is argued that the investment in it is urgent, since it is an investment in scientific progress and enhancement of health services and treatments. Well known researchers in Mexico widely

[71] The text of the legislative proposal does not make a particular reference to a scientific definition of animal-human chimeras. It is also restricted to state that any combination of genes different to the human species to create embryos is prohibited. The legislator is ambiguous when talking about this kind of embryo. However, the reference made corresponds to the avoidance of procuring admixed embryos, the definition of which is relevant here: "human admixed embryos refer to embryos that involve a mixture of human and animal material but are nevertheless predominantly human." See further: Homer, H. and Davies, M. (2009).

[72] Surplus or supernumerary embryos are those that were not transferred to a woman´s uterus in assisted reproduction treatments. A brief analysis of the ethical and social implications of the use of this type of embryo goes beyond the scope of this article. See Robertson, J.A. (2001).

[73] See Dhar, D. (2009).

[74] Ibid, note 35.

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disseminate academic work by which they explain the importance of scientific development in the country.[75] Mexican scientists suggest that the ethical limitations must be observed when conducting their laboratory activities. Then, research on embryos is not promoted in all circumstances. Initially, national researchers proposed that research on embryos can be allowed before the 14th day of embryonic development, because after that point, life is morally relevant since the primitive streak develops.[76] Therefore, the use of early embryos for research is reasonable and desirable with regard to the advancement and development of knowledge in an emerging economy, along with the search for new ways to alleviate illness.[77]

CONCLUDING REMARKS

For almost a decade, there has been considerable, if limitless, public discussion about stem cell research among legislators and within the scientific and legal community. Much of the legislative effort has focused on prohibiting such research, yet no law has been enacted, leaving a legal lacuna in this area.[78] Stem cell research remains unregulated, leaving scientists and private clinics to initiate work in the field with great ethical and legal freedom, uncertainty and likely indifference about what is permitted in the country.[79] Consequently, there is an urgent need to create a legal framework to avoid fraud, abuse and stem cell tourism in the country. The unsuccessful debate involving the regulation of stem cell science that has taken place in the Congress for more than a decade now, and the associated discussion regarding the constitutional protection of life, are just the beginning of the long process of regulating new technologies and are part of the interaction between religious and public moralities.

This paper appraised political, ethical and legal issues affecting stem cell research in Mexico. Closely linked to it is the issue of the constitutional protection of life, which has prompted numerous political interventions in the law. Conflicting social and constitutional values were brought to the public sphere when the constitutionality of abortion laws in Mexico City was challenged. The Supreme Court of Justice needed to clarify and interpret the Federal Constitution to provide legal certainty about the protection of life in a Mexican constitutional framework. The question of the status of the embryo is still debated and remains important in this context. The tension involved is highly emotional and surrounded by conflicting interests among the research, religious, legal and

[75] See Tapia, R. (2008).
[76] See, for a discussion: Tapia, R. (2009d).
[77] See Lisker, R. and Tapia, R. (2006).
[78] See LeRoy, W. (2008).
[79] See González Martín, N. (2006).

political communities. The interpretation adopted by the Supreme Court in relation to the lack of constitutional protection of life from the outset notwithstanding, opposing views tend to predominate across the country, whilst at a federal level, a minimum set of norms regulating stem cell research activity in the country is still pending.

The liberalisation of abortion in Mexico City has generated the social conditions for the outlining of an acceptable legal framework for the practice of stem cell science by the passing of legislation allowing embryonic stem cell research. . Although this legislation is important, the persistent lack of regulatory structure reveals the complexity of the conflicting political interests, views and understandings regarding the status of the embryo and the legitimacy of biotechnological research into aspects of stem cell science. A further issue to explore is that the Federal Congress governs the regulation of science, biotechnology and health matters, not the local constitutions.

At the time of this writing, the Mexican Supreme Court was set to decide again whether the modification of one of the local constitutions regarding the protection of life from conception is consistent with the federal one, since the local human rights commissioner in the state of Baja California has brought before it a claim of unconstitutionality. [80] The challenged amendment is claimed to be in opposition to what is established in the Federal Constitution, in accordance to what the highest court recently endorsed. For a third time, the Supreme Court of Justice is to lay down the rules related to the beginning and protection of life. Pro-choice groups, the scientific and academic communities, along with the secular population, may expect the reversal by the Court of the constitutional changes in the states, which are noticeably no longer in line with the provisions of the Federal Constitution. Finally, an important point to highlight here is that the Supreme Court has gained relevant social importance in the creation of the law by means of interpretation, clarification and application of the norms established within the Federal Constitution. Society relies on its final legal decisions as the ultimate and most reliable form of the administration of justice. The Court has played an important role in determining the final legal route to follow when congressmen and politicians fail considerably to address and elucidate the current social and legal issues. In the future, it might be the Supreme Court of Justice in Mexico that ends up deciding whether or not human embryonic stem cell research can proceed in accordance with constitutional norms.

In this particular scenario, the current regulation in this area seems to have been determined by the effectiveness of the lobbying of legislators by the hierarchy of the Catholic Church, albeit currently it does not seem plausible that this influence will be repeated in future debates. The debate is profoundly

[80] Ibid, note 71.

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dichotomous and sources of dissent have been suppressed and labelled as religious and archaic. On one hand, there are visible actions to encourage biotechnology in the country, while on the other, there is a strong tendency to maintain restrictive legislative proposals regarding particular biotechnology developments, such as that applied to stem cell research.

Arguably, it may be time to discuss the issue from a different perspective in social contexts where religious values still prevail. In order to take a new standpoint on how to deal with emerging problems in bioethics such as those related to embryonic stem cell regulation, an ordered dialogue should be established among all interested parties in the community. This would include stakeholders, politicians, religious and lay people. This indeed may be the time to discuss a new perspective on how to deal with bioethical problems emerging in the developing world.[81]

A call for the promotion of knowledge should also include an invitation to a national debate and the setting up of specialised bioethics committee, whose opinions and reports on stem cell science would take into account as many interested voices as possible. This would be done mainly to promote the progress of science and for the benefit of the health of Mexican society. Having contextualised the status of biotechnology in Mexico as relevant for stem cell science, we should adhere to the analysis of the seminal rulings issued by the Supreme Court regarding the protection of life and abortion issues. These judicial decisions marked the key points that denote the latest national discussion about the protection of life from conception and its intertwined debate regarding stem cell research.

It is important to acknowledge here that biotechnology research and some applications involving stem cells have commenced in Mexico, driven by an alliance of private investors and foreign biotech interests. This will continue to develop further without any ethical or legal provision being observed, putting people in a vulnerable position vis-à-vis those who operate stem cell clinics and offer treatments. Accordingly, it is time to take effective legislative action in accordance with the context and reality prevailing in this society. All in all, a crucial point should be highlighted: The enormous biotechnological potential and existing infrastructure for the conduct of medical research, combined with the lack of regulation of stem cell research and many other biotechnological issues, make it feasible and favourable for foreign alliances, along with private clinics and research centres in Mexico, to conduct these activities in the country without any observance of ethical guidelines and within a minimal legal setting.

[81] Ibid, note 2.

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Contested secularity: Governing stem cell science in Mexico

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This paper explores the factors influencing and hampering the consolidation of a legal framework for stem cell (SC) science in Mexico. Based on interview data from seven key stakeholders who can potentially influence future policy or legislation for emerging technologies in Mexico, this paper identifies pivotal topics that are presently shaping the political, regulatory, religious, and bioethical debates on the issue. It is acknowledged that there is a clear need for a broader and lengthier public discussion of the ethical and legal concerns involved in SC science. However, given the enduring conflict between scientifically minded, religious and political stakeholders, it remains uncertain whether such clarity and robust debate will be forthcoming, making it unlikely that a national regulatory framework for SC cell research will be adopted in Mexico in the short-to-medium term.

Keywords: stem cell science; regulation; politics; bioethics; religion; México.

1. Introduction

In the global economy, the governance of emerging technologies could substantially influence the scientific, legal and economic growth of any nation (Gottweis et al. 2009: 20). Mexico, among other Latin-American countries, is facing varied socio-cultural, religious and political battles pertaining to assisted reproductive technologies (ART) and stem cell (SC) science.[1] In this case, the emerging debate on the ethics and regulation of SC research is clearly divided between conservative and more liberal stances (Medina-Arellano 2011). This discussion has paralleled the disputes about the decriminalisation of abortion.[2] The central concern is the degree of protection deemed to be appropriate for the embryo with regard to its use and destruction, in order to obtain SCs for research.

Given the plurality of voices converging in the same space, this paper aims to portray the emerging struggles that have promoted a legal inertia and lack of political compromise to urge public dialogue, which will allow the establishment of governance for emerging technologies.[3] Thus, after describing some background data and the methodology utilised for this study, I seek to gain an insight into the core themes framing and influencing the debate, with regard to the ethics and regulation of SC research in Mexico. This analysis is drawn from the information elicited from seven semi-structured interviews with key Mexican stakeholders participating in the emerging SC science debate. In this account of stakeholders' perceptions, it is intended to present, as closely as the qualitative data allows, the main issues featured and the challenging questions of this domain. In so doing, this paper provides a brief examination of the regulatory milieu. It then explores the current cultural diversity, as well as the religious and political activism prevailing in this context, which have nuanced the emergent discussion on SC research. It is suggested that a clearer understanding of the science and issues arising out of SC science needs to be disseminated, clarified and further inspected by expert bodies and policy-makers if regulation in this area is ever to be achieved.

It is also argued that a flexible approach towards SC regulation is feasible based on constitutional provisions, such as the right to have access to health and to pursue scientific and technological progress, as well as the obligation to guarantee freedom of research, which will be discussed in more detail below (Brena Sesma 2005).[4] Notwithstanding that the Mexican legal system is theoretically permissive, it is acknowledged that, given the enduring conflicts between science, religion and political interests, it is unlikely that a national legal framework

will be adopted unless there is a genuine institutional and political compromise oriented to achieving sustainable economic growth parallel to the well-being of the community.

While the existing antagonistic views regarding the embryo represent the main difficulty in consolidating regulation in the area, to date, there has been substantial basic and clinical research on adult SCs in Mexico, but no evidence of research conducted on human embryonic stem cells (hESC) thus far (Mayani and Lisker 2007). Most interviewees articulated that they hold a gradualist approach regarding the protection of embryos. In view of this, it is feasible to advocate for a legal framework for SC science which allows the use of spare embryos from *in vitro* fertilisation (IVF) clinics, since otherwise, they will be discarded. Up to now, the final destiny of the now thousands of existing frozen embryos is not clear due to the legal vacuum in this area.[5]

Finally, it is stressed that the legal lacunae in this terrain should not remain simply because researchers and clinicians are uncertain about the ethics and regulations they are expected to follow. Furthermore, this unregulated scenario prevents researchers from engaging in sophisticated basic and clinical SC research, which may potentially assist myriad patients hoping to benefit from advances in regenerative medicine.[6]

2. Background

It is pertinent to provide background information on the latest developments shaping the SC controversy in Mexico. As highlighted before, this mirrors the complexities that some countries face where there is considerable Catholic influence and cultural pluralism when legislative initiatives to regulate emerging technologies are proposed.[7] Notably, debates on embryonic protection and SC science began as a result of religious politicisation encompassing the liberalisation of abortion, similar to those that have occurred in comparable contexts (e.g. the debates in the USA (Wertz 2002)). Similarly, in Mexico there have been two episodes where SC research was discussed in parliament[8]—just after legislative reforms on abortion laws in Mexico City and the related judicial decisions (Medina-Arellano 2011).[9] The aforementioned reforms were contested before the Mexican Supreme Court of Justice, which later upheld their constitutionality (Suprema Corte de Justicia de la Nación 2008). However, the Supreme Court cautiously neglected to enter a profound interpretation with regard to the scope of legal protection ascribable to *ex* or *in utero* embryos.[10]

On the other side of the spectrum, as a result of the judicial confirmation of the legality of the decriminalisation of abortion in Mexico City, a conservative campaign from religious (mainly Catholic) and right-wing political groups against these reforms and judicial decision was widely dispersed all across the country (Amuchástegui et. al. 2010). The concerns maintained by conservative groups regarding further liberalisation of abortion in other jurisdictions and progressive horizons for embryo and SC research regulation, led them to put forward constitutional amendments in states legislatures. Therefore, the local constitutions of some states were reformed to incorporate:

> . . . the protection of life from the moment of the 'conception' until its natural end.

This is manifestly in line with the wording used in Catholic doctrine (Tapia 2009a). To a great extent, these states constitutional reforms are troublesome, inasmuch as the conquest of secularity in Mexico was complicated and was achieved with many difficulties: it has cost many lives, as history recalls.[11] Furthermore, the religious influence over state affairs is a hazardous reality for a pluralistic nation, since it jeopardises and undermines the secular foundations of the country. Therefore, it is imperative to establish a comprehensive public dialogue in which stakeholders, politicians and religious actors can embrace the necessary legislative actions, in order to accommodate diverse lay views and cultural and religious plurality at the same time.

3. Methodology

A qualitative methodology is adopted with the aim of capturing the lived experiences of the interviewed stakeholders, which also allows for the generation of contextual and critical ethical analysis (Holm and Jonas 2004). Following qualitative methods, as applied to empirical bioethical inquiries, seven in-depth semi-structured interviews with an open-ended questionnaire were administered, in order to encourage the participants to converse about their individual perceptions and attitudes towards SC science (Sankar and Jones 2008).[12] Grounded theory procedures were applied when conducting the analysis (Corbin and Strauss 2008).

In keeping with the methods adopted, the selection of participants was as follows: all the respondents are from Mexico and are prominent stakeholders who can potentially shape and influence the policy-making process and governance for emerging biotechnologies. The criteria for the inclusion of the key stakeholders included a wide range of backgrounds. Whenever direct quotations are included, they are as follows: S1 (physiologist), S2 (judge), S3 (medical lawyer), S4 (medical lawyer), S5 (physician), S6 (senator), and S7 (chemist). All of these stakeholders have contributed to the emerging SC science discussions, plus they hold top positions in academic and government institutions participating in the discussion (see Table 1).[13] The quotations employed in the body of this paper were carefully chosen to be representative of the opinions elicited from the available sample. The direct citations

Table I. General description of interviews conducted as part of this study

Stakeholder	Professional background	Academic centre or institution	Duration of interview (minutes)
S1	Psychologist (PhD in bioethics)	Department of Psychology, Psychiatry and Mental Health, Faculty of Medicine, UNAM*	61
S2	Judge (PhD in law)	Mexican Supreme Court of Justice	46
S3	Medical lawyer (PhD in bioethics)	Institute for Legal Research, UNAM	70
S4	Medical lawyer (LLM bioethics)	National Institute of Genomic Medicine	86
S5	Physician (PhD in biochemistry)	Institute of Cellular Physiology, UNAM	120
S6	Senator (PhD in economics)	Mexican Senate, Federal Congress	68
S7	Chemist (PhD in biomedicine)	National Institute for Genomic Medicine	32

*UNAM National Autonomous University of Mexico

inserted are used to support the specific points and arguments introduced, as well as the particular claims sustained by stakeholders. With the permission of the participants, the interviews were digitally recorded and transcribed.[14] Transcripts were examined using qualitative content and thematic analysis, which also permitted the revision of every line of the transcription that was coded accordingly. This task was repeated and refined to assure accuracy and to incorporate emergent themes and information (Forman and Damschroder 2007). Follow-up electronic correspondence was continued with the participants, in order to seek feedback and agreement on the content transcribed from the interviews. In a few cases, additional data for the enrichment of the research was provided. The participants signed a consent form and were promised anonymity. They were notified that they possessed the right to refuse to participate and to withdraw their consent at any time, in order to safeguard their safety and confidentiality.

Some necessary limitations to this inquiry are acknowledged. Due to the small size of the sample that was used, wider community views cannot be claimed from the empirically generated representativeness, and the extent to which SC research is acceptable cannot be determined from this data. Nevertheless, the main issues being disputed can be identified. Notwithstanding the above-stated empirical constraints, the study aims to provide a point of reference and contribute to tracking the roots of the emergent discussion on SC science regulation.

4. A regulatory framework for SC science

The growing field of regenerative medicine across Mexico must incentivise government efforts to put adequate legal controls in place, especially when this field extends to commercial and therapeutic applications. As stated in Section 2 of this paper, the Mexican constitution is silent regarding the legal treatment of the embryo. Although there are some secondary provisions that mention this subject, they fall short of confronting the issues at stake. In what follows, the existing constitutional provisions are succinctly examined. Thus, as was also suggested by the stakeholders, diverse legal routes should be explored in attempting to consolidate a facilitative and flexible legal framework for SC science.

In June 2011, legislators of the Federal Congress passed a seminal constitutional reform concerning fundamental human rights. This constitutional reform incorporated the observance of internationally sanctioned human rights into the section previously known as 'fundamental rights', which contained the so-called individual guarantees of citizens; it has now been modified to contain 'human rights and guarantees'.[15] Accordingly, Article 1 expressly recognises the application of fundamental human rights and requires authorities to adhere and comply with the international human rights treaties signed and ratified by Mexico. Furthermore, Article 3, Sections V and VII, enshrine the obligation of the state to respect the freedom of research and to pursue the development of scientific and technological research.[16] Article 4, third paragraph, sets health protection as a constitutional right, it stipulates that:

> ... Every person has the right to *health protection* ... (emphasis added, Political Constitution of the United Mexican States 2008)

Accordingly and grounded on those constitutional provisions, the use of a human rights-based approach to advance SC science and its regulation appears to be feasible.[17]

As stated, according to Article 3 of the constitution, there is a burden on the state's government to promote freedom of research and investigation in science and technology. Furthermore, this freedom of research, as well as the right to enjoy the benefits of scientific progress and its application have also been endorsed as fundamental rights in international legal documents. For instance, these rights are established, respectively, in Article 12 of UNESCO's Universal Declaration on the Human Genome and Human Rights (1997) (Harmon 2005), in Article 2 of the Universal Declaration on Bioethics and Human Rights (2005) (Ten Have and Jean 2009) and Article 15, first paragraph of the UN International Convenant on Civil and Political Rights

(1996) (see Chapman 2009), all of which Mexico has agreed to. However, public policies have not yet addressed the issue of basic and clinical SC science, this in fulfilment of the constitutional norm, as must be if the fundamental right of freedom to pursue scientific research is to be realised (Ruffert 2011: 29–53). Some steps have been taken in order to draw legislative attention to this topic: for instance, seminars have been organised by legislators to bring together well-established investigators from different areas, who have been actively participating in the bioethical arena (Morales Aché 2006b). Regarding the political complexity to achieve regulation, one of the stakeholders (S3) stated:

> . . . here in the area of Health and Law, we have organised public debates, we have invited researchers . . . we had a public event about stem cells in 2004, where they came . . . the publication is of 2005, and they came in 2004, . . . experts came from everywhere in the world, from the United States, Europe, . . . and they talked about the topic, . . . I believe that it is very important to disseminate the knowledge (SC science); as long as there is no knowledge it is not possible to have an informed debate . . . unfortunately at the moment all topics are seen by the political parties as points to be compromised. In other words, you cede this to me and I cede to you another piece, like a piece within a political game, and in reality they are not realising how important these topics are for the population, and not only for the wider population but for individuals, since these are topics that also concern the privacy of the person.

On the other side of the spectrum, a crucial point was raised by the stakeholders: the necessity to establish clear aims in developing a platform for SC science, in addition to the transparency of the research process and products, if the research projects are deemed to be based on the potential health benefit they represent for the community.[18] The stakeholders felt that the failure to achieve a legal framework for this research activity and the lack of success in the creation of a legal framework are due to legislative inconclusiveness, as well as the lack of clarity of the objectives and goals to be pursued by researchers.[19] Stakeholder 3 affirmed:

> I think that the problem should not be centered only on the embryo, but the problem or part of the problem must be focused on the aim, and I believe that it is very important, the aim of the research on stem cells, if we take into account that research on stem cells is going to permit the advance of science, but also to a certain extent we cannot totally believe in what scientists are saying, that they are going to discover cures for all illnesses, so I believe that we have to be cautious, but to take into account what is the aim, what is the cost? What are we going to clarify? What are we going to get out of this research? And I believe that this point of view of what is the aim that is sought (SC research) is not present in the discussion.

On that same point, Stakeholder 6 stated:

> I believe that this has to be done (SC science) through very clear established projects which are related to the combat of illness, very well defined in . . . not only in our country but everywhere in the world, that is to say, the manipulation or work on stem cells must always be linked to a project that aims to attack the most serious illness in the country.

Stakeholders suggested that the regulation of SC science must be the result of a comprehensive public, plural and secular debate, given the diverse religious and cultural voices prevailing in this context. Moreover, any policy and regulation adopted regarding biosciences, specifically SC research, must look at the local context and the specific points that it is attempting to regulate. In doing so, a democratic deliberation regarding science, technology and innovation is more likely, which needs to be in line with the most recent advances in science, and which is to make best use of available resources.[20] Currently, not all voices are included in the limited discussion:

> The stem cell debates and regulation are being conducted without taking into account the researchers' voices. (S1)
> I am in favour of human embryonic stem cell research, but due to political pressures in my work, I cannot assume an open posture. (S4)
> I am in favour of a more progressive and permissive approach. (S6)

As a point of reference, the stakeholders indicated that the successful regulatory reforms of other countries must be followed, and permissive approaches were favoured.[21] Most of the stakeholders agreed with the establishment of an expert body, which would review and license any research on a case-by-case basis, as is the case in the UK (Warnock 1985).[22] Stakeholders indicated that the implementation of an expert regulatory and ethics committee meticulously deciding, case-by-case, on the SC treatments and experiments to be conducted in the country is desirable (Allyse 2010). The expertise of ethics regulatory bodies, as similar to the UK Human Fertilisation and Embryology Authority, would provide an example of how to regulate emerging technologies like embryonic SC research, while providing protection and a certain level of respect for embryos (Holm 2009). For instance, they indicated that, in order to be in accordance with this expertise and licensing model:

> . . . in principle . . . we need to express that it must be considered case by case (SC research), and it must be legislated accurately, this will allow us to determine what is valid or not. (S4)
> The research should be permitted upon approval of a specific committee that could guarantee transparency, responsibility and efficiency of the researchers. (S3)

Nevertheless, a few stakeholders acknowledged that SC science and its regulation in Mexico is not a priority in the legal, economic and political agendas. For example:

> Look, in accordance with the General Health Act, in terms of new technologies which impact health and its need for

> legislation, I find that there are 10 things more important to legislate before human stem cells (research). (S7)

In opposition to the secondary importance attributed by a few of the stakeholders to SC science regulation in Mexico, the majority of stakeholders expressed the view that organised ethical debates are needed before sophisticated SC scientific activities are undertaken. An open dialogue, which includes scientists and the wider community, is also called for, in order to evaluate the types of SC research and the benefits and potential harm this science represents. Nevertheless, as analysed from the elicited perceptions, due to the enduring divergence and battles between conservative, religious and secular positions, at the present, it is not clear whether the creation of any legal framework for SC science will be adopted. The enduring religious and political disputes over the regulation of certain scientific activities lead legislators to enact prohibite provisions that in the longer term obstruct the global scientific development and delays biotechnology innovation, see Marchant and Pope (2009). Notwithstanding that it is the state's duty to guarantee the freedom of scientific research and its progress, the federal legislature has failed to create an ordered debate that might culminate in an appropriate legal framework See Donders (2011).

5. Controversial cells in context

The overt opposition towards biomedical activities is characterised by the antagonistic discourses articulated by pro-life (conservative) groups and leaders of the Catholic Church (Tapia 2009b). On the other hand, the growth of opposing liberal stances represented by pro-choice (predominantly secularist) groups creates parallel endeavours. This situation makes it difficult to legislate on controversial bioethical issues, thus it has given rise to legal vacuums not only for SC research but also for ART and health-related bioethical issues (Tapia 2011). Based on the empirical data collected, this section outlines, in broader terms, the factors obstructing the establishment of a deliberative body, which would lead to the creation of concrete minimum legal standards for the advancement of SC science. It also provides a general overview of the policies promoted, so far, on innovation in biotechnology. The interview data suggests that the scientific and political course of events to regulate SC science activities are not very promising, at least for the moment. This unpromising scenario is marked by a lack of political interest to promote emerging biomedical technologies and innovation. The legislative inertia also reflects a reluctance to engage in an interdisciplinary and meaningful conversation over the status of embryos, even in the face of clear evidence that the fate of surplus embryos left over from fertility treatment is unknown.

5.1 The political and bioethical struggle: Catholicism versus secularism

The National Action Party (Spanish acronym PAN), currently in power in Mexico, has shown a conservative stance towards certain biomedical technologies, in specific SC science. This is mostly based on arguments extracted from Catholic doctrine (Blancarte 2010a). Furthermore, this political party has shown a particular reluctance to encourage the advancement of SC science or any closely related activity (Blancarte 2010b). However, the presence of legislators with Catholic views is not limited to the PAN: on the contrary, it is also present in other political parties that are supposed to uphold more secular views.[23] For example, members of the Institutional Revolutionary Party (Spanish acronym PRI) have joined conservative sectors to promote a prohibitive agenda on bioethical dilemmas, in order to obtain the sympathy and votes of the Catholic constituency. Following this conservative bioethical agenda, members of the federal and local legislatures (particularly those affiliated with the PAN and PRI) have pursued a dignitarian agenda on medico-legal issues.[24] Despite the strong hegemony of the Catholic Church and pro-life groups, the stakeholders stressed that their influence has not been translated into the enactment of any regulation on SC science, giving rise to the legal vacuum in this terrain (S1, S3–6).

In contrast to conservative stances, the members of the Democratic Revolution Party (Spanish acronym PRD) in the political arena are actively promoting more liberal stances towards the regulation of biomedical, sexual and reproductive themes, for instance, putting forward legislative initiatives that proposed the liberalisation of abortion, plus same-sex marriage and adoption in Mexico City (Unzelman 2011). Additionally, within the Federal Congress, there is also a diversity of ideological and ethical backgrounds, including the left-wing, liberals, socialists and ecologists. This plurality is due to the proportional representation system that is used for elections.[25] This ideological heterogeneity in the political arena explains the complexity of achieving a legislative compromise to govern innovations in health, science and biotechnology. Consequently, notwithstanding the considerable presence of Catholic beliefs among the legislators, a majority is not reached and obtaining majority approval to implement either radical conservative or progressive agendas is complicated, at least in the Federal Congress.

On the other hand, the initial academic discussion on bioethical issues has been mainly concentrated on the emergence of genomic medicine in the country (Jiménez-Sánchez et al. 2010). In the same manner as in the political arena, the bioethical academic discourses in Mexico feature a clash of antagonist ideologies, divided between liberal–secular (embodied by pro-choice groups) and

conservative (pro-life with a Catholic foundation) postures (Brena Sesma 2006). Blancarte (2009) points out that, in Latin America, the historical Catholic tradition has dominated the sphere that all religions could occupy in bioethical discussions, through monopolising and not recognising the plurality of stances among religions.

In brief, all stakeholders indicated that much of the initial SC science debate was dominated by Catholic members alongside those with conservative views within the government and legislatures. In addition, all expressed their disagreement with the interventions by religious groups and criticised the fact that the views on embryo research, assisted reproduction and abortion, which are held by politicians and local governments and which are guided by members of the PAN and PRI, are fuelled by the most conservative views of Catholic doctrine, which are later transplanted into the policy-making arena. All stakeholders' claim that there is undue interference by Catholic leaders, since the Catholic Church, along with conservative groups, has successfully persuaded the political party currently in power, as well as a few legislators in the Federal Congress, to maintain an outright ban on SC science. The Catholic lobbying over legislators seeking to forbid SC science activities has been common in many countries where this religion enjoys certain emphaty from the population. On this see Oakley (2002).

It is worth noting that the aforementioned situation is constantly evolving and that political control of the pro-life and religious alliances has somewhat lessened, due to the growth of divergent voices that have also gained ground in the debate. A gradual shift from the conservative debate to a secular discussion on bioethics has also arisen, which includes liberal reflections on the emerging biotechnologies and innovations.[26] Therefore, the academic discussion recently formulated by those scholars and civil society groups (i.e. pro-science) has favoured the advancement of science and biotechnology, particularly SC science, focusing on the achievement of a progressive legal framework, which facilitates the conduct of responsible scientific research (Tapia 2009c).

The stakeholders' opinions emphasised the importance of secularity within the bioethical discourse, while keeping a balanced account of the state of biotechnology and its ethical ramifications (S1, S4–7). Through explaining secularity, they argued in favour of a neutral common point, allowing the expression of varied voices and respect for the different ideas and beliefs which converge in a democratic state. Given the current ambivalence in the national bioethical discourse, embracing any legislation on the contested issues will be a complex task, unless an inclusive and ordered public dialogue can be established which includes the wider community, including civil society groups, academic associations, stakeholders and experts in bioethics.

5.2 Taking a glance at biotechnology and innovation

In 2003, well-established researchers at the Mexican National Academy of Science urged the government to implement public policies that could facilitate innovation, for example, in biotechnology applied to health (Bolivar Zapata 2003). The main recommendation was to inject more financial resources to create human resources with the capability of transforming this field in Mexico. It was also proposed that investments be increased in the existing public institutions that already had the infrastructure to develop biotechnology. The priority that was initially identified was the necessity to efficiently administer and expand the current resources. Likewise, the creation of laws, regulations and appropriate rules, which could provide efficient supervision, was also recommended. For this, all stakeholders stressed the need to strengthen the existing links between private and public research institutes and the governmental agencies, as a way of achieving better outcomes for R&D and its adequate regulation.

One important step in the advancement of biotechnology was registered in 2005 when, as a result of an ordered and inclusive dialogue, the Biosafety Act on Genetically Modified Organisms was passed in the Federal Congress. This regulation establishes clear rules for key stakeholders in this area, as well as guaranteeing a certain protection for consumers and the welfare of the community.[27] This experience showed that links between the stakeholders, scientific community, and policy-making sectors are crucial, in order to create public trust and construct adequate regulatory frameworks that would cover safety issues and measure the risks associated with the new technologies (Falkner and Gupta 2009). Interestingly, unconnected with the main issue being discussed and through extrapolating the worries of Mexican politicians over novel scientific activities, this regulation explicitly put aside the oversight of specific areas of biotechnology applied to medicine, such as SC science and assisted reproduction.[28]

Nonetheless, the fragmented investment in biomedical sciences was found to be a common concern shared by most of the stakeholders (S1, S3–5, S7). This worry lies in the urgent necessity to create efficient communication links between the academic sector, policy-makers and the scientific community. Furthermore, this need for links, as explained by the stakeholders, was also highlighted during the last national discussion concerning the regulation of biotechnology industries—namely genetically modified organisms (GMOs) in Mexico (S1, S3–5, S7). Moreover, as argued by the stakeholders, it is expected that a similar scenario to that which occurred in 2005 would have to occur in order to generate the necessary legal provisions for any activity involving embryos, SC research and ART practices. However, it appears that the ordered dialogue desired by stakeholders is not an easy task, since the status of the embryo continues to be a contentious topic about

which legislators and policy-makers avoid serious discussion.

The stakeholders have also drawn attention to the need to involve the private sector in the generation of scientific innovation. Therefore, adequate legislation is urged, particularly when taking on new biotechnologies. So far, private investment in biotechnology and interest by private industries in continuing to foster this activity are seen in the creation of research clusters in different regions of Mexico (Editorial 2008). Recently, private funds were allocated to biomedical research seeking to expand biotechnological incubators, particularly in molecular and genetic research (Vargas-Parada 2011).

In the biomedical field, in the last decade the Mexican government has invested in genomic medicine as a way to achieve health and welfare development and build up personalised medicine for the Mexican population. It was acknowledged by all stakeholders that the creation of the National Institute for Genomic Medicine (INMEGEN) was a positive step towards motivating further investment in many other areas of biotechnology. One of the main arguments that effectively worked towards the creation of this research centre was the shift from a society dependent on foreign economies and health developments to one capable of creating its own knowledge-based health economy (Jimenez-Sanchez 2003).

Equal to what was encountered with the regulation of GMOs, one of the main concerns raised by Mexican politicians, before the foundation of INMEGEN, was related to the possibility that members of this health research centre might conduct SC research and human cloning by members of the scientific community in the newly created biomedical research centres. So, in order to allay the fears held by certain politicians, the INMEGEN was created subject to the condition that any studies related to reproductive human cloning or embryo research were banned (R3). This is also documented in Schwartz Marín (2010). Unsurprisingly, this prohibition only confirms the reluctance of legislators to tackle the contested issue of embryo and SC science regulation. Furthermore, genomic medicine is not closely related to human cloning. The prohibition imposed on INMEGEN was perceived by stakeholders as a clear measure, in order to ease the fears of the hierarchy of the Catholic Church and conservative members of the Federal Congress (S1, S3–7) (Jimenez-Sanchez et al. 2008).

As a result of the investment in genomic medicine, there are huge expectations that this field could be a tool for economic growth in Mexico (Jiménez-Sánchez et al. 2011). Meanwhile, the stakeholders' concerns were focused on the transparency needed from all research centres, in order to generate more public trust.[29] Thus, research projects and the knowledge gained from these must be disseminated to the general and academic communities. As a consequence, as argued by stakeholders, there has been a lot of noise doubting the legitimacy and reliability of the research conducted in research centres (S3, S5, S6). This fact is not optimal for the advancement of new projects in biotechnology. According to the participants, there is a compelling fear that, in the future, SC research might be conducted by private research centres, since there is no monitoring and legal oversight in the area. First and foremost, the claim made by the interviewees, in relation to the consolidation of scientific projects, which must be characterised by transparency in the process of creation and communication of knowledge, is an important element in advancing SC science.

Notwithstanding the aforementioned governmental support to GMO and genomic medicine research, public investment in many other areas of science, technology and innovation has not increased during the last two periods of federal government, as was affirmed by the stakeholders (S1, S3–5). The disconnection between the advances of science and technology and the public policies pursued by the federal government is visible. According to the stakeholders, at present Mexican science and technology lacks adequate support and public funding in many areas of knowledge. Additionally, it has been pointed out that institutionalised politics, which obstruct the creation of science within research centres and institutes in Mexico, might stop the flow of developments in biotechnology. For instance, in 2010, the OECD reported that Mexico has the lowest R&D expenditure among OECD members (OECD 2010). It was recommended that a revision of Mexico's strategies to establish effective governance and implementation of renewed innovation policies at federal and state levels be added to the aim of adequate funds to support R&D. Thus, in the area of SC science, public calls by academic and scientific organisations have been made to urge investments in this field, in order to prevent obstructions to biomedical innovation (Tapia 2009d). Certainly, to date, there has been a growing research potential for SC science, as well as public and private interest in this field.

6. Human embryonic SCs: The status of the embryo

A set of stakeholders' perceptions concerning the status of embryos is highlighted in this section. The following sub-themes emerged and shaped this section:

- whether or not *ex* and *in utero* embryos are viewed as sacrosanct, bearing life, or special entities that required to be treated with dignity
- claims about a gradualist approach to protecting the embryo
- whether or not spare embryos from IVF clinics are regarded as viable for research since, to date, there have been no clear details about their final destiny

- whether or not embryonic and adult SC research constitutes a legitimate means to improve health and alleviate people's suffering

Interestingly, most of the stakeholders considered embryos to be special entities which should be treated with due respect in accordance with their stage of development (S1, S2–4, S7). A minority of the respondents maintained that early embryos must be seen as just a bunch of cells useful for scientific purposes (S5, S6).[30]

6.1 Sanctity of life and human dignity

The opposition to SC research, in this context, finds its rationale in the protection of early embryonic life. On the basis of this position, embryonic creation and destruction should be prohibited.[31] In that case, the fundamental question concerns when life begins and from what point it is significant, morally and legally speaking. The Catholic Church has issued encyclical letters establishing that human life begins at and is worthy of protection from the moment of conception. Therefore, embryos are human beings to be afforded protection of life and dignity, as is indicated in the instruction *Dignitas Personae: On certain bioethical questions*[32] issued by the Congregation for the Doctrine of the Faith. Often, this stance is transplanted into the legal and political spheres, where politicians holding this view defend the protection of embryos as bearers of human rights and dignity: thus, their use and destruction is not acceptable (President's Council on Bioethics 2008). In the Mexican scenario, conservative members of the PAN have followed this religious belief, inasmuch as it is also indicated within the statutes of the ruling political party, which promotes the sanctity of life and dignity of humankind from conception.

Most of the stakeholders agreed that human dignity is an inalienable principle granted in the constitution, but limited to individuals and citizens, and open to diverse interpretations. Therefore, the concept of 'personal dignity' emerged in the interviews (S1–4, S6, S7). According to the Mexican Constitution of 1917, human dignity is one of the paramount principles within the catalogue of fundamental rights adopted therein. Notwithstanding this, the principle is centred on the protection of an individual understood as a 'person'. The meaning and significance of the notion of human dignity has been explored at length in different areas and contexts, for instance, in the role it plays within the bioethical, human rights and healthcare arenas (Andorno 2009). Attention has also been drawn to the significance of this notion in the policy-making debates on SC research across the globe (Caulfield and Brownsword 2006). In Mexico, legal scholars and philosophers have affirmed that human dignity is a valuable principle in bioethical debates (González Valenzuela 2005). However, as was pointed out by the stakeholders, this constitutional principle of human dignity in a secular state cannot be read as a religious concept (S1, S3–7). Instead, it should be understood as a legal principle that needs to be filled with meaningful content agreed by the community (Valadés 2009: 137–50). It is precisely the vagueness of this notion that allows its interpretation as either a facilitative or restrictive conceptual tool, for or against emerging technologies in biomedicine (Brownsword 2008b: 30).

Although it was affirmed in the interviews that human dignity is of paramount value in the Mexican constitutional system, it was also recognised that human dignity is seen as a barrier in the discussion of SC science. For example:

> It should not be incorporated into the stem cell debate . . . It's a concept for a citizen that implies pride, honour, and respect . . . Social and religious prejudices cannot be guiding our legal system anymore. (S6)

In this context, it seems that human dignity is deemed to be a unique value attached to individuals and citizens but not to other entities, for example, early embryos. However, the notion of human dignity will continue to be an abstract notion within the legal system that is not encountered in biological terms,[33] as expressed by the respondents:

> Human dignity does not have any relation to biology at all. (S1)
>
> It is a cultural concept; at the end of the day it signifies the possibility for human beings to make their own decisions . . . the importance of this notion in legal systems is increasing every day. (S2)

According to the stakeholders, it might be risky to include this principle in any secondary regulation dealing with embryo research, if some guidance about its interpretation has not been previously provided.[34] This guidance must serve as a pathway, which could provide enough flexibility for the use of this principle in the process of authorising research. Without a doubt, this principle is an abstract legal term that grounds fundamental rights which cannot be taken away, and the notion should remain and be interpreted in secular terms. As the respondents argued:

> It is important but separated from any kind of religious interpretation . . . It must signify respect for each other as individuals. (S3)
>
> It is a subjective principle, it is important in our legal system, and if you consider that an embryo is a human being, then human dignity should be protected. (S5)

Ultimately, it appears to be crucial in this context to take into consideration the plurality of views converging in the arena. However, the incorporation of divergent voices is not an easy task but will greatly strengthen the regulatory legitimacy (Brownsword 2007, 2008a). Following this, a clearer understanding, or broader interpretation, of human dignity needs to be delineated, either by the court

or legislators, if this notion is to be deemed useful in any future regulation addressing embryonic and SC research, as long as it is clearly determined who are the recipients of this notion (Schroeder 2010).[35] This might provide a balance among the wider religious views and secular community, given that Catholicism is not the only religion in the country and, up until now, the claims for respecting human dignity of the embryo are mainly based on religious grounds.

6.2 Gradualist stances

For some supporters of embryonic SC research, embryos are deemed to be special entities worthy of respect and with a commensurable moral status, depending on the stage of biological embryonic development (see Mulkay (1997) on the debate in the UK). Many of the stakeholders support this middle position by which legal protection and respect for embryos increased in proportion to the stage of embryonic growth (S1–5, S7) (Fox 2000). When the participants commented on this point, for example, they said:

> It has special status, but it is not as a human being. It is deemed to be protected, but not in the same category as human beings and persons. (S3)
> I opted for a gradualist protection of the embryo, in accordance with the social imagination. (S4)

These asserted ethical positions reveal that embryonic research might be morally justifiable by stakeholders in this context. The embryo is seen as a potential human being, which is entitled to some degree of legal protection but not equal to that possessed by individuals (McLachlan 2002). From a biological point of view, a renowned researcher who has actively advocated for SC research in the country, Ruben Lisker (2003), has also advanced two arguments supporting this position. First, he argues that the impact of the loss of a family member is different depending on the stage of development of human life, which is why it is not the same thing to have a miscarriage (Lisker 2003). He continues by focusing on the misfortune of the death of a newborn, or tragically losing a five-year-old child (Lisker 2003: 609). Lisker also asserts that an embryo, which is created for the sole purpose of harvesting SC, lacks the potential to become a human being, since it was not created for that purpose (Gruen et al. 2007). Finally, he proposes that, within the Mexican context, life should be counted as morally and legally relevant from birth onwards (Bortolotti and Harris 2005). This position is maintained overall by interviewees, as is shown by the following elicited response:

> The creation of embryos to procure stem cells should proceed, I am in favour of a more permissive approach . . . I cannot see the limits since embryos are created for research purposes but not for reproductive cloning . . . It is byzantine to think that an embryo before the twelfth week of gestation is a human being; protection should be adapted accordingly to modern times. (S5)

For the minority of stakeholders, an early embryo, e.g. a zygote, is not a human being but possesses the potential to become viable and create human life (Holm 2002). This position is assumed as follows:

> It is not human life; viability is an important point of reference. (S2)

Notwithstanding the above view, the stakeholders indicated that the procurement of SCs from early embryos is not translated as undue respect for the embryo. On the contrary, the establishment of a timeline indicates that there is a limit and respect for the early manifestation of life.[36] It is inferred that the generation of an informed and open debate is essential, in order to engage the public in a dialogue to establish the limits on the use of early embryos (Ho et al. 2010). Within the public dialogue, cultural and local circumstances are crucial to establish proper and monitored use of early embryos, since the moral and pragmatic problems, which the use of hESC implied, are difficult to compromise on (Holland et al. 2001). On the above points, stakeholders considered that:

> An informed debated is needed to draw a limit or period for the protection of embryos . . . Early embryonic development cannot be considered human life. (S3)
> The embryo could be protected after the cellular division, that is to say, after the 14th day of development . . . the embryo is a special form of life. (S1)
> The timeframe should be determined in accordance with cultural conditions. (S4)

The participants also maintained that the use of early embryos is not seen as a lack of respect for human life, as long as there is a clear limitation and safe conditions for the use and procurement of embryos for research, since the action could ameliorate human life and health (McGee and Caplan 1999). In addition, the participants agreed that the establishment of a timeline for conducting research on SC is feasible and will draw the boundaries for research:

> We cannot talk about life, but better we can talk about a form of life of cell . . . once this cell is obtained, then the spare material is discarded, but on the seventh day of development (embryonic development) . . . then again the argument is that these cells are discarded biological material. (S5)
> My personal opinion is that we cannot consider them as human life (early stage of embryonic development) . . . It is a process of development. (S4)

In the view of a minority of the stakeholders, it seems feasible that research can be allowed within the first 14 days of embryonic development, since it is at this point that the primitive streak of the embryo is formed.[37]

> No . . . they are a bunch of cells until the nervous system is developed right after the fourteen day of development

> (embryonic)... This is my point of view... there are a lot of references where this claim can be validated. (S5)
> I think that the creation of clear projects to conduct stem cell research must be established seeking to combat chronic and severe illness... through well-defined projects it can be possible to disappear not only the health the suffering of ill people this country but in many other regions around the world... We need to pursue research on SC to develop treatments and alleviate the most worrisome illness in the country. (S7)

On this basis—as was also agreed by the stakeholders—since embryos are not analogous to human beings, a higher moral commitment is due to those patients who are suffering from chronic diseases and who base their hopes on the development of treatments and cures from hESC research (Devolder and Savulescu 2006).

6.3 Spare *in vitro* fertilisation embryos

As highlighted earlier, despite the fact that ART procedures have been available in Mexico for many years, no specific law has yet been enacted (Mendoza Cárdenas 2011). The area is only vaguely addressed in general secondary provisions. Thus, the treatment of the embryo, the number that should be created and implanted, as well as the rate of successful final fertilisations are not closely controlled and overseen: their fate and final destiny in Mexico is unknown (Moctezuma Barragán 1998). Moreover, ethical and legal guidelines for research on gametes and embryos discarded from IVF clinics have not yet been issued. So far, very little is known about the mechanisms and requirements of gamete and embryo donation, as was pointed out in the interview:

> The point is that mechanisms should be established: From where do we procure the germ cells? Authorisation must be granted to create a number of IVF embryos... if they are spare embryos from *in vitro* fertilisation: Where are they? Are they destroyed?... As an option, informed consent and authorisation from the parents can be obtained to use IVF spare embryos for research. (S4)

On the point of allowing research on frozen IVF and embryos:

> ...it is not justifiable to prohibit research on embryonic stem cells on spare embryos from assisted reproduction... It must be a very important part of the rules because, on the one hand, there are thousands of supernumerary embryos frozen in IVF clinics; we already have a lot of spare embryos but we do not know their final destination. (S1)

It is worth noting that, under this unregulated context, research on supernumerary IVF embryos to procure SCs for therapeutic purposes in Mexico is already conducted (Cuneo et al. 2004). IVF and SC procurement practices are carried out without any specific regulation or guidelines to be followed. Here, most of the interviewees agreed that the procurement of embryonic cells from discarded IVF embryos, if available, should proceed instead of leaving the embryos to perish (Franklin 2006):

> In relation to assisted reproduction techniques,... for this kind of embryo (supernumerary), the only final destination is its destruction, otherwise it could be used for research; or perhaps because of the long time that it was stored, it may not be viable to be used for any purpose anymore,... In this case, my way of thinking is that it is better to use them (spare embryos) for research if they can help in developing therapies... Instead of putting them in boiling water, as it has been done, I would prefer that they (spare embryos) are used for research; I prefer they are used for research. (S3)

All of the stakeholders agreed that assisted reproduction and SC research are equally valid medical mechanisms to alleviate health disorders (Devolder 2005); these therapies are directed towards accomplishing the fundamental rights established within the Federal Constitution, as provided within the fundamental rights catalogue under Clause 4: 'the right to access to health and to reproduce'. As was pointed out by the stakeholders, these are both treatments and it is contradictory to prohibit one and not the other: if that is so, the justification for permission or banning must be clear:

> It is completely contradictory (prohibition of research on spare embryos)... since embryos are already created for therapies (ART technologies)... and, since there is no specific legislation on assisted reproduction and the generation of *in vitro* embryos, in a strict sense there must be a legislation that establishes what is legal or illegal to do with those embryos, for instance, if they can be sold or not, or issues about ownership of tissues, if IVF embryos can be destroyed or not, and if so, then it would be better to permit their utilisation to procure stem cells and conduct any kind of research, provided that there are specific rules and limits to be observed, etc. like in civilised countries! (S4)

Most stakeholders (S1, S3–7) perceived the use of surplus embryos as not morally contested but as a complex activity to be monitored and regulated. Additionally, they suggested that transparent rules be provided, from which society can benefit and by which it can participate in this debate. Issues about consent from the couples whose gametes were used to create embryos have not even been considered in the public health agenda (Svendsen and Koch 2008). Notwithstanding the ethical controversies and moral divergence on embryonic research, it has been pointed out that the creation of adequate legal norms, by which risk and safety issues are clearly established and must be rigorously observed when conducting research on these spare embryos and cells can be delineated, must be encouraged (Cohen et al. 2008). However, the stakeholders recognised that the wider community is not yet well-informed or aware about the social, health and ethical implications of conducting SC research. Nevertheless, it is essential to begin the discussion

concerning assisted reproduction techniques and a growing unregulated market, such as SC-based therapies.[38]

7. Conclusions

Drawing on empirical data, this paper has explored the crucial conflicts that seem to be deciding factors in developing any governance over emerging technologies, particularly SC science. I have outlined the fact that the political party currently heading the Mexican Federal Government maintains a strongly conservative stance. Furthermore, the lobbying of politicians and policy-makers by the hierarchy of the Catholic Church to implement its own views and ethical beliefs on the issue hamper the consolidation of any legal setting. Drawing on stakeholders' opinions, it is expected that a change in the political context would open the door to the adoption of a permissive legal framework. This change in the political arena must allow the inclusion of diverse voices in an inclusive, public and ordered policy-making process. A wider examination of the ethical and legal issues involving SC research is necessary, and it has been shown that it is the disconnection between the scientific community, policy-makers and bioethics experts, which overshadows the future of SC science in Mexico.

The recent antagonistic discussions and the absence of any consensus regarding the protection accorded to the embryo, if any, represent a major complexity translated into legal vacuums in this area. On the other hand, the current normative provisions fall short of providing guidelines to follow regarding emerging technologies and innovations in healthcare. However, it is feasible to adopt a flexible legislation grounded on constitutional norms, such as the right to have access to health care, freedom of research, and pursuit of scientific development. On the other hand, the aim of any legislation regarding emerging technologies must be to promote responsible, fair and humanitarian research. The legislative inertia cannot remain, since there is a high potential to contribute to the growth of the economy by encouraging biotechnology research, particularly given the EU ban on patenting SC therapies which Mexico could take advantage of (Callaway 2011). As the stakeholders have suggested, one step towards adopting any regulation is by learning from the experiences of countries where the policy-making process has been successfully established, like the UK.

Finally, it should be kept in mind that, in order to construct an accurate legal setting in accordance with the local context, a truly deliberative process, which includes the various social players interested in developing bioethical and legal governance over this issue, must be established (Salter and Salter 2010). A minimum basic ethical reference point for the discussion of SC research should be prepared, while making possible the inclusion of diverse ethical stands. Even countries with a strong Catholic influence have adopted a regulatory regime for SC science: why not Mexico?

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Notes

1. For example, in August, 2011, Costa-Rica's government was sued before the Inter-American Court of Human Rights (IACtHR), see No 91/11, IACHR takes case involving Costa Rica to Inter-American Court, <http://www.cidh.oas.org/Comunicados/English/2011/91-11eng.htm> accessed 30 September 2011; Costa Rica maintains a continued ban of ART, this prohibition has extensively based on religious arguments advanced by the Catholic Church and other religious groups in the country which maintain that assisted reproduction constitutes a violation of the embryo's right to life (Shearer and Vanderpoel 2011). It is certainly the case that whatever decision is adopted by the IACtHR over this case will influence the regulation of ART and SC fields in the region.
2. During the writing of this paper, in September 2011, the Mexican Supreme Court of Justice uphold the constitutionality of Baja California and San Luis Potosi's State constitutions that protect life from the outset, this ruling has only a minor impact on the general arguments stated herein, see <http://www.bbc.co.uk/news/world-latin-america-15104022> accessed 22 October 2011.
3. In analogous socio-cultural plural endeavours, based on qualitative studies, the remarkable constraints within the scientific, social and cultural configuration toward achieving regulation for emerging technologies have been shown. Thus, proposals have been made to establish public dialogue and engagement in seeking to achieve facilitative regulation in a context where science is a goal to be pursued, as it is in the Argentinean case (Harmon 2011a, 2011b).
4. For a concise introduction to the promising research on SCs being conducted in Latin America, see (Borbolla-Escoboza 2010). On an international scale, it has also been reported that, despite the absence of legislation for SC science in Mexico, it actually has a

'flourishing stem cell industry' (Dhar and Hsi-en Ho 2009: 115).

5. ART technologies have now been available in Mexico for more than three decades, without ethical and legal oversight (Morales Aché 2006a). Up until now, uncontrolled creation and vitritification of embryos for assisted reproduction purposes is a common practice in Mexico (González-Santos 2011). More recently, in May 2011, an attempt to regulate ART in the country was made in the Federal Congress. However, this legislative initiative was not passed and has not yet actually been discussed (Damián and Valadez 2011). For the purposes of scope and space this legislative initiative is not analysed in detail here, however major points of connected issues are laid out.
6. The absence of specific regulation also actualises the potential harms to patients currently undertaking uncontrolled SC therapies offered across Mexico. This issue deserves fuller analysis, but that is beyond the scope of the present paper.
7. In Mexico, according to data from the Population and Housing Census 2010 carried out by the National Institute of Statistics and Geography (Mexico), 83.9% of the population is Catholic; however, most of this population self-reported being mainly non-practicing Catholics, as opposed to committed followers of the most conservative teachings of the Catholic faith. The data also showed that the Catholic population has gradually decreased in the last ten years from 88% to the current 83.9%. For some, this gradual decrement was due to the growing religious diversity and cultural pluralism, in addition to a few scandals related to child abuse involving clerics of the Catholic Church (Barranco 2011).
8. It should be noted that these legislative attempts to regulate the area were expected to be inclined to liberalise SC policies in Mexico. However, that has not occurred (Isasi and Knoppers 2006: 20).
9. It is worth noting that the legislators who passed these reforms in Mexico City are considered to maintain leftist and progressive ideologies (Carrillo 2007).
10. Since the issue at stake was not the legal status of human embryos but rather the reproductive rights of women, it is understandable to a limited extent that the moderate discussion undertaken by the Mexican Supreme Court did not extensively include human embryo matters (Ubaldi Garcete 2010).
11. For an historical account of the struggles between the Catholic Church and the Mexican State, which at some point erupted in a lamentable battle widely known as the 'Cristero War' (Wilkie 1966).
12. Socio-bioethical inquiries pertaining to the study of contested issues surrounding basic and translational SC science are valuable methodological instruments to identify emergent themes gaining relevance in this field, including the identification of areas of understanding or disagreement; an example of an empirical investigation conducted to reflect on the ethical issues relating to SC clinical settings can be found in Williams and Wainwright (2010).
13. In some cases, when explicitly asked I was fully authorised to use the name of the interviewees, but although permission had been obtained, it was decided to use the above-listed anonyms for the sake of the neutrality of the research being conducted. However, professions and institutional affiliations are provided in Table 1 in order to shed light on the backgrounds shaping the context and emerging discussion. It is worth mentioning that two Catholic priests and the president of the most active pro-life organisation in Mexico were invited to participate in this inquiry; however, neither a negative nor a positive response was obtained from them.
14. Interviewees were recruited by personal invitation mailed electronically following the approval of the internal ethics committee of the School of Law, University of Manchester. The interviews lasted between 45 and 115 minutes. The author personally conducted the interviews in Spanish between November 2009 and January 2010. All participant's quotations used in this investigation are the author's own translation unless otherwise indicated, therefore all transliteration oddness remain as my own errors.
15. See the Official Decree published in June 2011, <http://www.dof.gob.mx/nota_to_imagen_fs.php?codnota=5194486&fecha=10/06/2011&cod_diario=237901> accessed 25 March 2012. The constitutional section that was reformed resembles the commonly said dogmatic part of the majority of civil law constitutions. In other words, it is the section that generally contains a catalogue of fundamental and inalienable human rights and grounding principles of the legal system. The dogmatic section of the constitution is comprised of 29 articles. The Federal Constitution in Spanish, as amended, can be found at <http://info4.juridicas.unam.mx/ijure/fed/9/> accessed 25 March 2012..
16. The Federal Constitution sets forth in Section V of Article 3 that '... the State ... *shall support scientific and technologic research,* shall strength and promote the country's culture', thus Section VII stipulates that 'Universities and other higher education institutions upon which the Law has conferred autonomy, shall ... carry out their purposes of educating, *doing research* and promoting culture in accordance with the principles established in this Article, *respecting freedom to teach and to do research and freedom to analyze and discuss ideas* ...' (emphasis added) (Political Constitution of the United Mexican States 2008). This constitutional right to promote science and

technologic research is further regulated by its secondary regulation, the Science and Technology Act.

17. The idea of connecting and adopting a human rights-based approach to regulation of certain health matters in Latin America has already been advanced, in particular, as a tool for tobacco control (Cabrera and Madrazo 2010).
18. This argument which is based on the potential contribution of SC research and technologies to alleviate health suffering, the social utility aim, has been used to generate the production of SC biovalue to advance this field (Waldby 2002).
19. The importance of achieving transparency and clarity on the objectives pursued when conducting SC research has been highlighted as a necessary step in order to gain the necessary accountability and trust to effectively develop and regulate this field while at the same time, it guarantees the integrity of scientists and encourages the sharing of the sci*ent*ific knowledge generated (Devaney 2011; Knoppers et al. 2010).
20. In democratic societies all voices need to be heard in looking an agreement or middle point about contended issues such as SC research, particularly when it involves the use of early embryos or its creation solely for research purposes (Cohen 2007).
21. It is acknowledged that an effective regulatory solution for the challenges actualised by SC science is difficult to achieve. However, it is possible to improve the norms in any regime that is adopted (see Brownsword and Yeung, 2008).
22. As indicated by Franklin (2010), the British legislative initiative may allow fruitful regulatory lessons to create a preferable legal setting rather than no legislation at all.
23. Similarly, in the case of Germany and the USA, where policies regarding hESC research are informed not only by minority religious articulations but also by a broader secular population that inserted into the SC discourses voices of scepticism and notes of caution regarding emergent technologies (Jasanoff 2007).
24. Here, I am referring to a dignitarian agenda in terms of an ethos derived from the most conservative doctrine of the Catholic teaching that promotes respect for human dignity as a sacred value inherent to all human beings (Campbell 2005). The dignitarian agenda pursued by MPs in the Federal Congress also differs from that advanced by the 'dignitarian alliance', which promotes the principle of human dignity as a paramount foundation of human rights (Beyleveld and Brownsword 2001; Brownsword 2003).
25. At the time of writing, the current political parties in the Federal Congress 'are the PRD (Party of the Democratic Revolution), PT (Worker;s Party), PVEM (Ecological Green Party), COM (Convergence Party), and PANAL (New Alliance Party). For an overview and examination of the composition and seats occupied by the members of the existing political parties in the Federal Congress up to the latest federal elections of 2009 (see Klesner (2009)).
26. The growing liberal approach to bioethical reflection is represented in the following literature: González Valenzuela 2007, 2008; Ortiz Millán 2009; Pérez Tamayo et al. 2007; Vázquez 2004.
27. As a measure to closely observe and support actions on activities related to GMO and the implementation of the Biosafety Act on GMO and its regulation, the CIBIOGEM, the Inter-Sectorial Commission on Biosafety of Genetically Modified Organisms, was created; the Biosafety Act and related regulation can be found at <http://www.cibiogem.gob.mx/eng/Paginas/Home.aspx> accessed 3 April 2011.
28. Article 6 provides that: 'The following are excluded from the realm of application of this Law: . . . II. The utilization of *in vitro* fertilisation techniques, conjugation, transduction, transformation or any other natural process, as well as polyploid induction, as long as no molecules of recombinant deoxyribonucleic acid (DNA), nor genetically modified organisms are employed; . . . V. The human genome, human stem cell cultures, modification of human stem cells and the biosafety in hospitals, whose regulation corresponds to the General Law of Health, and to the International Treatises in which the United Mexican States is a participant . . .' http://www.cibiogem.gob.mx/eng/Documents/Ing_LBOGM_P.pdf> accessed 13 July 2011 (English translation).
29. The necessity to generate public awareness and engagement in scientific endeavours seeking to foster trust between SC science and the wider community has been elaborated by Bates et al. (2010).
30. This moral standing is close to the arguments which purpose that early embryos are just a bunch of cells that do not have any difference from any other human cells, e.g. skin, hair etc. (Harris 2004).
31. For a concise revision of the divergent postures towards SC science and human cloning, see Salles (2008).
32. In this document the Roman Catholic doctrine expressed its total opposition to embryonic SC research and placed very narrow restrictions on adult SC research <http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html> accessed 11 April 2011.
33. This abstract understanding of the principle of dignity is closely related to what has been described as the mystery of its meaning that might be keep it unravelled, on this account of the notion of dignity see further Gurnham (2005).
34. The religious use and interpretation of the notion of human dignity, as well as its utility in bioethical and

policy-making debates has also been hotly debated and criticised from diverse philosophical standing points, on this see Macklin (2003), Pinker (2008) and Shuklenk (2010).

35. Lately, the Mexican Supreme Court of Justice has denoted dignity as foundational for human rights stating that it is the 'basis and condition of all others: the right to always be acknowledged as a human person. Thus, from human dignity all other rights stem, insofar as they are necessary for man to integrally develop his personality', text quoted in Madrazo and Vela (2011).
36. This is not an easy task, since even in countries with permissive SC legal frameworks, the time line to be drawn for the use of early embryo in research remains contested (Greely 2006).
37. This argument has been advanced in most countries where there is a liberal and facilitative approach to SC research (Chalmers 2010; LeRoy 2008); this liberal ethical position in the Mexican context has been introduced by Lisker and Tapia (2006).
38. Mexico has been identified as one of the places in Latin America where untested SC therapies are being marketed (Ryan et al. 2010); the ethical and legal implications of the marketing of these therapies fall outside the scope of this study.

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