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Stem Cell Tourism: The Challenge and Promise of International Regulation of Embryonic Stem Cell- Based Therapies

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**STEM CELL TOURISM:
THE CHALLENGE AND PROMISE OF INTERNATIONAL REGULATION OF
EMBRYONIC STEM CELL-BASED THERAPIES**

*Lesley N. DeRenzo**

Most cells in the human body are committed to fulfilling a single function. In contrast, embryonic stem cells have the ability to become over 200 distinct cell types. Because of this distinctive characteristic, embryonic stem cells hold vast promise to treat a variety of diseases and disorders. Nevertheless, scientific experts concede that substantial advances in basic biology and clinical technique are essential before embryonic stem cells are readily available for clinical use. Despite the lack of safety and efficacy testing in humans, there are clinics around the world charging patients thousands of dollars for embryonic stem cell-based therapy. As a result, scientists have reported instances of patients suffering adverse outcomes after receiving unregulated stem cell-based therapies. Recognizing the global nature of science and medicine, this Note explores various solutions the United Nations can take to regulate the use of embryonic stem cells in clinical practice.

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I. INTRODUCTION

Stem cell-based therapies have existed since 1968 when clinicians performed the first bone marrow transplantation.¹ Thirty years later, Dr. James A. Thomson, Director of Regenerative Biology for the Morgridge Institute for Research, derived the first human embryonic stem cell (hESC)

¹ Fritz H. Bach et al., *Bone-Marrow Transplantation in a Patient with the Wiskott-Aldrich Syndrome*, 2 THE LANCET 1364 (1968) (discussing a bone marrow transplant to replace abnormal cells with healthy cells capable of making normal platelets, T cells, and B cells); see also Robert A. Good et al., *Immunological Reconstitution of Sex-Linked Lymphopenic Immunological Deficiency*, 2 THE LANCET 1366 (1968) (discussing a bone marrow transplant procedure for an individual with combined T-cell and B-cell immunodeficiency). A bone marrow transplant delivers healthy bone marrow stem cells into a patient and replaces bone marrow that is either not working properly or has been destroyed (i.e., ablated) by chemotherapy or radiation. See U.S. Nat'l Library of Med., *Bone Marrow Transplantation*, MEDLINEPLUS, <http://www.nlm.nih.gov/medlineplus/bonemarrowtransplantation.html> (last updated Mar. 28, 2011).

lines² from left-over, pre-implantation human embryos (donated to biomedical research).³ Dr. Thomson theorized that his findings could revolutionize medicine by generating unlimited sources of human cells for transplantation therapies.⁴ However, he cautioned that “*substantial advances* in basic developmental biology” were essential before hESC-based therapies would be ready for clinical applications.⁵ Indeed, scientific experts maintain that the only established, stem cell-based treatment in clinical practice is bone marrow transplantation, which incorporates the use of hematopoietic stem cells.⁶

² Human embryonic stem cells [hESCs] are: (1) derived from human embryos, (2) can self-replicate indefinitely, and (3) can develop into cells and tissues of the three primary germ layers (i.e., endoderm, mesoderm, and ectoderm). *See infra* Appendix B & D; *see also* James A. Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 SCI. 1145, 1145 (1998) (discussing the generation of cardiomyocytes from the first human embryonic stem cell lines derived from blastocysts). Furthermore, a hESC line is a population of cells isolated from cryopreserved, pre-implantation human embryos (usually four- or five-days old) that can be grown indefinitely in vitro. *See* DEP’T OF HEALTH AND HUMAN SERVICES, NAT’L INSTITUTES OF HEALTH, *STEM CELLS: SCIENTIFIC PROGRESS AND FUTURE RESEARCH DIRECTIONS* 13 (2001), available at <http://stemcells.nih.gov/staticresources/info/scireport/PDFs/fullrptstem.pdf>; *see also infra* Appendix D.

³ Thomson et al., *supra* note 2, at 1145. Individuals that had undergone in vitro fertilization [IVF] and no longer needed their left-over embryos donated their embryos for use in Dr. Thomson’s study. *Id.* “[IVF] is the joining of a[n] . . . egg and . . . sperm in a [petri] dish.” U.S. Nat’l Library of Med., *In Vitro Fertilization (IVF)*, MEDLINEPLUS, <http://www.nlm.nih.gov/medlineplus/ency/article/007279.htm> (last updated Jan. 25, 2011) (stating that “[i]n vitro means ‘outside the body[,]’ [and] [f]ertilization means the sperm has attached to and entered the egg.”).

⁴ Thomson et al., *supra* note 2, at 1146–47.

⁵ *Id.* at 1147 (emphasis added).

⁶ Bone marrow transplantations are used primarily to treat diseases of the blood system (e.g., treatment for leukemia and similar blood-related cancers). *See, e.g.*, George Daley et al., *Mapping the Road to the Clinical Translation of Stem Cells*, 2 CELL STEM CELL 139, 139 (2008). Hematopoietic (i.e., blood-forming) stem cells are extracted from bone marrow and are used to replace blood cells destroyed from high doses of chemotherapy. *See, e.g.*, Jos Domen et al., *Bone Marrow (Hematopoietic) Stem Cells*, in U.S. DEP’T OF HEALTH AND HUMAN SERVICES, *REGENERATIVE MEDICINE* 22 (2006), available at http://stemcells.nih.gov/staticresources/info/scireport/PDFs/Regenerative_Medicine_2006.pdf. Hematopoietic stem cells are different from embryonic stem cells. More specifically, embryonic stem cells can develop into nearly every type of cell in the body, whereas hematopoietic stem cells divide to form more blood-forming stem cells, or can mature into one of three types of blood cells (i.e., white blood cells, which fight infection; red blood cells, which carry oxygen; and platelets, which help the blood to clot). *See generally* U.S. DEP’T OF HEALTH AND HUMAN SERVICES, *STEM CELL BASICS* (2009), available at <http://stemcells.nih.gov/staticresources/info/basics/SCprimer2009.pdf> (a comprehensive review on the state of the science on stem cell research).

Once human cellular-based and tissue-based products⁷ became available for therapeutic applications, Congress assigned regulatory responsibility of these products to the U.S. Food and Drug Administration (FDA).⁸ The FDA identifies a broad spectrum of safety concerns related to hESC-based products for use in human transplantation.⁹ More specifically, the FDA asserts that hESCs—and their derivatives—pose the risk for: (i) spontaneous formation of tumors after injection of hESCs into a human subject; (ii) migration of hESCs to a different site in the human body than what was originally intended; and (iii) development of immunogenicity because of the body's reaction to the foreign material expressed from the human proteins on the hESC product.¹⁰

Moreover, it is essential that all left-over, pre-implantation embryos donated for clinical applications are screened for infectious diseases.¹¹ Accordingly, without standardized safety screening of hESCs for infectious diseases, hESC-based therapies pose the risk of transmitting infectious diseases such as Hepatitis B and HIV/AIDS to the recipients.¹² While hESC research has many safety challenges, the FDA states that the goal of facili-

⁷ FDA regulations define cellular-based and tissue-based products as “articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.” 21 C.F.R. § 1271.3(d) (2010).

⁸ See generally 21 C.F.R. § 1271 (2010) (outlining FDA's good tissue practice requirements).

Of FDA's many responsibilities for human health and security, the FDA is responsible for assuring the safety, efficacy, and security of biological products. What Does FDA Do?, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194877.htm> (last updated Dec. 17, 2010).

⁹ Donald W. Fink Jr., *FDA Regulation of Stem Cell-Based Products*, 324 SCI. 1662 (2009) (presenting how the FDA ensures subjects enrolled in clinical studies involving stem cell-based products are not exposed to significant and unreasonable risk due to the FDA's review of medical and scientific information to determine whether there is sufficient safety assurance to permit initiation of human clinical studies); see also Dina Gould Halme & David A. Kessler, *FDA Regulation of Stem-Cell-Based Therapies*, 355 NEW ENG. J. MED. 1730 (2006) (articulating how the FDA's promulgated regulations regarding human cells, tissues, and cellular-based and tissue-based products, provide an appropriate regulatory structure for the wide range of stem cell-based products that may be developed to replace or repair damaged tissue).

¹⁰ Fink Jr., *supra* note 9, at 1662; see also *Stem Cell Science: The Foundation of Future Cures: Before the Subcomm. on Health, U.S. House of Representatives' Comm. on Energy and Commerce*, 110th Cong. (2008) (statement of Dr. Elias A. Zerhouni, Dir. of the Nat'l Institutes of Health, U.S. Dep't of Health and Human Services).

¹¹ See 21 C.F.R. §§ 1270.21, 1271.75(a)(1)(i)–(v), 1271.85(a)(1)–(5) (2010).

¹² In the United States, any human tissue intended for transplantation must be tested for the following communicable viruses: (1) HIV, (2) Hepatitis B, and (3) Hepatitis C. 21 C.F.R. § 1270.21(a)(1)–(4) (2010); see also discussion *infra* Part III(A) (discussing threats posed by the potential use of modern molecular technology to produce biological weapons and the use of stem cells as a critical link to both evade and produce such weapons).

tating the development of safe and effective hESC-based products is attainable.¹³ And, the FDA emphasizes that cooperative, interdisciplinary efforts are essential to ensure patient safety.¹⁴

Despite well-documented safety risks, there are clinics throughout the world, and outside of the FDA's jurisdiction, offering unregulated hESC-based therapies.¹⁵ Unregulated clinics increase the probability that vulnerable patient populations receiving these treatments will experience adverse outcomes.¹⁶ The risks of patients suffering harm from unsubstantiated hESC-based treatments are mitigated within the United States, and in other developed countries, because Federal agencies actively regulate against unsafe medical practices.¹⁷ Unfortunately, at this time, there is no international governing body authorized to set and enforce regulations on the use of hESCs in medical practice.¹⁸ Thus, the burden of regulating hESC-based therapies is dependent on the enforcement mechanisms of individual countries.¹⁹

As stem cell treatments emerge as a developing area of medical tourism, scientific experts are becoming increasingly concerned with the potential adverse impacts of hESC-based treatments offered without regulatory oversight.²⁰ Because of this concern, the International Society for Stem

¹³ Fink Jr., *supra* note 9, at 1663.

¹⁴ *Id.*

¹⁵ Daley et al., *supra* note 6, at 139.

¹⁶ *See id.*

¹⁷ Sorapap Kiatpongsan & Douglas Sipp, Commentary, *Offshore Stem Cell Treatments*, NATURE REP. STEM CELLS (Dec. 3, 2008), <http://www.nature.com/stemcells/2008/0812/081203/full/stemcells.2008.151.html> (analyzing how the market approach to experimental medicine, in which doctors and entrepreneurs exploit patient trust and take advantage of the dearth of cell therapy regulations in many countries, is destined to end badly unless there are clear and enforceable rules to regulate such behavior).

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ Medical tourism is defined as travel with the aim of improving one's health. *See* MILICA Z. BOOKMAN & KARLA R. BOOKMAN, MEDICAL TOURISM IN DEVELOPING COUNTRIES 1 (2007); *see also* Eliza Barclay, *Stem-Cell Experts Raise Concerns About Medical Tourism*, 373 THE LANCET 883 (2009) (investigating how stem cell therapies are emerging as a growing area of medical tourism, even while research is still in its early stages); Olle Lindvall & Insoo Hyun, *Medical Innovation Versus Stem Cell Tourism*, 324 SCI. 1664 (2009) ("Stem cell tourism is criticized on grounds of consumer fraud, blatant lack of scientific justification, and patient safety" and the "conditions under which 'unproven' therapies may be offered to patients outside of regular clinical trials"). The World Health Organization [WHO] identifies medical tourism as trending upward. BOOKMAN & BOOKMAN, *supra* note 20, at 2 (citing David Woodward et al., *Globalization, Global Public Goods and Health*, in WHO, TRADE IN HEALTH SERVICES: GLOBAL, REGIONAL AND COUNTRY PERSPECTIVES 3, 7 (2002). Further, a 2008 survey of health care consumers found that the frequency of patients traveling abroad to obtain health care is increasing. DELOITTE CENTER FOR HEALTH SOLUTIONS, DELOITTE, 2008 SURVEY OF HEALTH CARE CONSUMERS (2008), available at

Cell Research (ISSCR) issued guidelines targeting “stem cell tourism.”²¹ The ISSCR’s guidelines highlight the need for well-designed clinical trials as an essential element for administering any proposed hESC-based “therapy.”²² While the ISSCR acknowledges a place for investigator-led medical innovation, it does so with the caveat that such interventions must be conducted in line with the ethical obligation to do no harm.²³

Although the guidelines advocate for an international framework, they carry no legal force.²⁴ Moreover, despite the efforts of a well-intentioned international professional society, the guidelines are easily ignored by unregulated clinics.²⁵

Therefore, Part II of this Note examines the promise of hESC-based therapies and highlights the challenges, or potential dangers, of stem cell tourism without an international regulatory framework. Part III explores a range of effective solutions to combat administering unsafe hESC-based therapies. Specifically, this includes the analysis and application of: (i) a binding U.N. Security Council (Security Council) Resolution to effectuate immediate action in the interest of national security and public health; (ii) a

http://www.deloitte.com/assets/DcomUnitedStates/Local%20Assets/Documents/us_chs_ConsumerSurveyExecutiveSummary_200208.pdf (highlighting that patients traveling to a new location for the purpose of obtaining quality health care at a lower price is becoming more prevalent and will likely continue as an emerging trend in accessing health care).

²¹ See INT’L SOC’Y FOR STEM CELL RES. [ISSCR], *Guidelines for the Clinical Translation of Stem Cells* (2008), available at http://www.isscr.org/clinical_trans/pdfs/ISSCRGLClinicalTrans.pdf (presenting the international guidelines defining scientific, clinical, regulatory, ethical, and societal issues that must be addressed to ensure that basic stem cell research is responsibly transitioned into appropriate clinical applications for treating patients). ISSCR is “an independent, nonprofit organization established to promote and foster the exchange and dissemination of information and ideas relating to stem cells, to encourage the general field of research involving stem cells and to promote professional and public education in all areas of stem cell research and application.” *Mission Statement*, ISSCR, <http://www.isscr.org/mission/index.htm> (last updated Oct. 2, 2003). ISSCR members agree to abide by the ISSCR’s professional standards when conducting human embryonic stem cell research. *Join ISSCR*, ISSCR, <http://www.isscr.org/membership/index.htm> (last updated Nov. 16, 2010).

²² *Guidelines for the Clinical Translation of Stem Cells*, *supra* note 21. “[C]linical trials. . . are generally considered to be biomedical or health-related research studies in human beings that follow a pre-defined protocol.” *Understanding Clinical Trials*, CLINICALTRIALS.GOV, <http://clinicaltrials.gov/ct2/info/understand> (last updated Sept. 20, 2007).

²³ Kiatpongsan & Sipp, *supra* note 17.

²⁴ *Id.*

²⁵ See *id.* The most notorious example of clinicians and physicians disregarding medical guidelines in relation to human subjects research is demonstrated by the heinous acts carried out by Nazi doctors during World War II despite German regulations prohibiting such conduct. See, e.g., Michael A. Grodin, *Historical Origins of the Nuremberg Code*, in *THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION* 121, 130–31 (George J. Annas & Michael A. Grodin eds., 1992) (citing 11 *Reichs-Gesundheitsblatt* 174–75 (1931)).

resolution outside of the purview of biomedical regulations in which the World Health Organization (WHO) could issue a non-binding resolution; and (iii) model treaties and the codification of key portions of the ISSCR guidelines into the form of a draft treaty.

II. hESC THERAPIES—INSPIRED BY THE PROMISE, RESPECTFUL OF THE CHALLENGE, YET NAVIGATING WITHOUT A REGULATORY ROAD MAP

Human embryonic stem cells hold vast potential to treat a variety of diseases and disorders.²⁶ However, scientific experts concede that substantial advances in basic biology and clinical technique are critical before hESCs are readily available for use in clinical applications.²⁷ Despite the lack of safety and efficacy testing in humans, there are clinics around the world charging patients thousands of dollars for embryonic stem cell-based therapy.²⁸

As a result, patients lured by the promise of novel stem cell treatment have suffered adverse outcomes from unregulated therapies.²⁹ Many stem cell scientists agree that there is a need for systemic international regulation and oversight of hESC-based therapeutic treatments offered at various clinics around the world.³⁰

²⁶ See *infra* Appendix C for an illustration of the potential of stem cell-based research; see also discussion *infra* Part II(A) (discussing the promise of hESC-based research to allow for an understanding of human development and cell specialization, thereby maximizing the likelihood for the development of new therapies and treatments for human disease).

²⁷ Stephen Pincock, *Warning Against Stem Cell Tourism*, ABC SCI. ONLINE (June 22, 2007), <http://www.abc.net.au/science/news/stories/2007/1958206.htm> (discussing the potentially grave risks of traveling internationally in search of untested stem cell treatments); see also discussion *infra* Part II(A) (highlighting that there are several major hurdles to overcome before hESCs are available for clinical application, including: (1) generating large and defined populations of the desired hESCs, (2) promoting the survival of grafted hESC-derived cells after implantation, and (3) avoiding the formation of tumors or vigorous immune reactions caused by hESC-based therapy).

²⁸ *Online Briefing & Rapid Roundup: New Concern over Stem Cell Tourism*, AUSTL. SCI. MEDIA CTR. (Oct. 17, 2008), <http://www.aussmc.org/2008/10/rapid-roundup-new-concern-over-stem-cell-tourism-experts-respond/> (forum where experts discuss the danger of administering unproven hESC treatments to human subjects).

²⁹ See, e.g., Norra MacReady, *The Murky Ethics of Stem-Cell Tourism*, 10 THE LANCET ONCOLOGY 317 (2009) (highlighting recent cases of adverse outcomes from unproven stem cell treatments).

³⁰ See *Guidelines for the Clinical Translation of Stem Cells*, *supra* note 21.

A. *The Challenge and Promise of hESC-Based Therapies*

Over the past several years, scientists have made significant discoveries regarding the curative potential of hESCs.³¹ For example, in 2009, scientists demonstrated in mice that hESC-derived natural killer cells³² were better at destroying blood cancer and solid tumors (e.g., breast and prostate cancer) than natural killer cells derived from umbilical cord blood.³³ This finding could promote the use of hESC-derived natural killer cells in humans for cancer therapy.³⁴

Studies in mice have also shown the possibility of engineering cardiovascular tissue for transplantation in humans by inducing hESCs to become heart cells.³⁵ If successful in humans, this therapy could replace damaged heart tissue caused by heart disease.³⁶ Another study successfully demonstrated that hESC-derived neurons had the capability of repairing damage caused by a stroke in rats.³⁷ Rats that suffered mobility restrictions with their paws were able to use their paws again normally after transplanta-

³¹ See *infra* Appendix C for an illustration of the potential of hESC-based research.

³² A natural killer cell is “[a] type of immune cell that has granules (small particles) with enzymes that can kill tumor cells or cells infected with a virus.” *Definition of Natural Killer Cell*, NAT’L CANCER INST., <http://nci.nih.gov/dictionary/?CdrID=44062> (last visited Mar. 30, 2011).

³³ Peter S. Woll et al., *Human Embryonic Stem Cells Differentiate into a Homogeneous Population of Natural Killer Cells with Potent In Vivo Antitumor Activity*, 113 BLOOD 6094 (2009) (articulating that hESC-derived natural killer cells were better than umbilical cord-derived natural killer cells at destroying cancer in a research study with mice).

³⁴ *Id.*

³⁵ Lei Yang et al., *Human Cardiovascular Progenitor Cells Develop From a KDR⁺ Embryonic-Stem-Cell-Derived Population*, 453 NATURE 524 (2008) (highlighting how scientists verified that cardiomyocytes (i.e., heart cells) derived from embryonic stem cells expressed cardiac genes, conducted electrical currents, and had the ability to repair the pumping ability of mouse hearts damaged by induced heart attacks).

³⁶ *Id.*

³⁷ Marcel M. Daadi et al., *Adherent Self-Renewable Human Embryonic Stem Cell-Derived Neural Stem Cell Line: Functional Engraftment in Experimental Stroke Model*, 3 PLOS ONE 1 (2008) (discussing that post-mortem tissue sections of treated rats’ brains showed transplanted human neurons, derived from embryonic stem cells, grew towards the site of neuron loss and did not appear to generate any tumors over a two month observational period). Moreover, a “[s]troke is the third leading cause of death in the U.S. and a leading cause of serious, long-term disability in adults. A stroke . . . occurs when blood flow to the brain is interrupted [causing] brain cells in the immediate area . . . to die because they [lack] the oxygen and nutrients they need to function.” *Know Stroke. Know the Signs. Act in Time.*, NAT’L INST. OF NEUROLOGICAL DISORDERS & STROKE, <http://www.ninds.nih.gov/disorders/stroke/knowstroke.htm> (last updated May 21, 2010).

tion of the hESC-derived human neurons.³⁸ Scientists hope to one day use this treatment in humans who suffer mobility impairments from stroke.³⁹

Scientists also successfully improved the motor functions of rats with Parkinson's disease by injecting the rats with hESC-derived dopaminergic nerve cells.⁴⁰ Unfortunately, the rats developed brain cancer as a result of stem cell treatment.⁴¹ However, if scientists can learn to control the spontaneous cell differentiation that caused the brain cancer in the rats, hESCs may one day be a plausible source of dopaminergic nerve cells for humans suffering from Parkinson's disease.⁴²

While hESC studies demonstrate promising advancements for potential therapies,⁴³ they are not without significant scientific hurdles and potential risks.⁴⁴ For example, several studies have shown that hESC-based

³⁸ Daadi et al., *supra* note 37.

³⁹ See *Guidelines for the Clinical Translation of Stem Cells*, *supra* note 21.

⁴⁰ Neeta S. Roy et al., *Functional Engraftment of Human ES Cell-Derived Dopaminergic Neurons Enriched by Coculture with Telomerase-Immortalized Midbrain Astrocytes*, 12 NATURE MED. 1259 (2006) (articulating how a more efficient technique to derive dopaminergic neurons from hESCs allowed for the neurons to engraft into the brains of parkinsonian rats and significantly improve motor function). Additionally, "[p]arkinson's disease . . . result[s] [in the] loss of dopamine-producing brain cells . . . [and] . . . [t]he four primary symptoms . . . are tremor . . . ; rigidity . . . of the limbs and trunk; . . . slowness of movement; and postural instability . . . and coordination." *Parkinson's Disease Information Page*, NAT'L INST. OF NEUROLOGICAL DISORDERS & STROKE, http://www.ninds.nih.gov/disorders/parkinsons_disease/parkinsons_disease.htm (last updated Mar. 30, 2011).

⁴¹ Roy et al., *supra* note 40, at 1259.

⁴² *Id.*

⁴³ See, e.g., Testimony of the Director of the National Institutes of Health, Dr. Elias A. Zerhouni, *supra* note 10; Gordon Keller, *Embryonic Stem Cell Differentiation: Emergence of a New Era in Biology and Medicine*, 19 GENES DEV. 1129 (2005) (articulating that hESCs have great potential for clinical applications to replace damaged cells and tissues in humans); Gretchen Vogel, *Ready or Not? Human ES Cells Head Toward the Clinic*, 308 SCI. 1534 (2005) (discussing how dopamine-producing neurons derived from hESCs could provide an unlimited and well characterized source of cells for a variety of treatments in humans); Xianmin Zeng et al., *An In Vitro Model of Human Dopaminergic Neurons Derived from Embryonic Stem Cells: MPP⁺ Toxicity and GDNF Neuroprotection*, 31 NEUROPSYCHOPHARMACOLOGY 2708 (2006) (discussing how "the availability of human dopaminergic neurons, derived from hESCs, allows for the possibility of directly examining the unique features of human dopaminergic neurons with respect to their responses to pharmacological agents as well as to environmental and chemical toxins"); Hannes Hentz et al., *Cell Therapy and the Safety of Embryonic Stem Cell-Derived Grafts*, 25 TRENDS BIOTECH. 24 (2006) (identifying that hESCs, or their derivatives, have an unprecedented potential to cure degenerative disorders); Yang et al., *supra* note 35; and Daadi et al., *supra* note 37.

⁴⁴ See, e.g., Deepa M. Deshpande et al., *Recovery From Paralysis in Adult Rats Using Embryonic Stem Cells*, 60 ANNALS OF NEUROLOGY 32 (2006) (noting that while the hESCs mediated partial recovery from paralysis, hESCs have not been tested in large animals or humans and it is unclear whether hESCs will act the same way in a human host); Marcel Dihné et al., *Embryonic Stem Cell-Derived Neuronally Committed Precursor Cells with Reduced Teratoma Formation After Transplantation into the Lesioned Adult Mouse Brain*,

therapies can: (i) cause cancer in the host subject through spontaneous differentiation; (ii) induce immunogenicity responses in the host subject because of foreign human proteins expressed from the hESCs; and (iii) migrate to different areas of the body other than the intended injection site.⁴⁵

According to the National Institutes of Health (NIH),⁴⁶ before scientists can use hESCs in transplantation therapy, hESCs must: (i) proliferate extensively and generate sufficient quantities of specialized cells; (ii) differentiate into the desired cell type(s); (iii) survive in the recipient after transplant; (iv) integrate into the surrounding tissue after transplantation; (v) function appropriately for extended periods of time; and (vi) *avoid harming the recipient*.⁴⁷

One company is on the path to demonstrate that hESC-based therapy in humans can be safe and efficacious. On January 23, 2009, the FDA granted approval for the first study of hESC-based therapy in humans pursuant to a 21,000-page application submitted by Geron Corporation.⁴⁸ Ge-

24 STEM CELLS 1458 (2006) (illustrating that more than 70 percent of mice that received murine ESC-derived neural precursor cells develop tumors from the treatment); Rutger-Jan Swijnenburg et al., *Clinical Hurdles for the Transplantation of Cardiomyocytes Derived from Human Embryonic Stem Cells: Role of Molecular Imaging*, 18 CURRENT OP. IN BIOTECH. 38 (2006) (indicating how there remain significant hurdles before safe and successful translation of hESC-based treatments will be available for clinical therapy, including the need to assess cells following transplantation); Jia-Yi Li et al., *Critical Issues of Clinical Human Embryonic Stem Cell Therapy for Brain Repair*, 31 TRENDS IN NEUROSCI. 146 (2008) (highlighting that there are several major hurdles to overcome before hESCs are available for clinical application, including: (1) generating large and defined populations of the desired hESCs, (2) promoting the survival of grafted hESC-derived cells after implantation, and (3) avoiding the formation of tumors or vigorous immune reactions caused by hESC-based therapy); Bin Lu et al., *Long-Term Safety and Function of RPE from Human Embryonic Stem Cells in Preclinical Models of Macular Degeneration*, 27 STEM CELLS 2126 (2009) (reiterating that assessments of safety and efficacy are crucial before human hESC-based therapies can move into the clinic); Hannes Hentze et al., *Teratoma Formation by Human Embryonic Stem Cells: Evaluation of Essential Parameters for Future Safety Studies*, 2 STEM CELL RES. 198 (2009) (discussing that because transplantation of hESCs into immune-deficient mice will result in uncontrolled cell-differentiation, standard techniques for the administration of hESC-derived cells are crucial to establishing the use of hESCs in therapeutic applications in humans); and Roy et al., *supra* note 40.

⁴⁵ See sources cited *supra* note 44.

⁴⁶ The National Institutes of Health [NIH] is the primary Federal agency responsible for conducting and supporting medical research and supports over 300,000 extramural scientists and research personnel at more than 3,000 institutions nationwide. *About NIH*, NIH, <http://www.nih.gov/about/index.html> (last updated Oct. 27, 2010).

⁴⁷ Testimony of the Director of the National Institutes of Health, Dr. Elias A. Zerhouni, *supra* note 10, at 2 (emphasis added); see also sources cited *supra* note 44.

⁴⁸ *Geron Receives FDA Clearance to Begin World's First Human Clinical Trial of Embryonic Stem Cell-Based Therapy*, GERON CORP. (Jan. 23, 2009), <http://www.geron.com/>

ron's application described twenty-four separate animal studies that demonstrated the effective and safe use of hESC-derived treatments for spinal cord injuries in mice and rats.⁴⁹ According to Geron, the animal studies provided data showing that after the mice and rats received hESC-derived injections, they regained the ability to use their hind legs and did not develop tumors from the treatment.⁵⁰ In vitro studies further demonstrated that the animals' immune systems did not attack Geron's hESC-derived cells as a foreign tissue, minimizing the risk of immunogenicity.⁵¹

Despite the initial approval by the FDA, the project was placed on a clinical hold in August 2009 based on the FDA's review of a non-clinical, animal study.⁵² The animal study of concern to the FDA demonstrated that a high frequency of animals injected with Geron's hESC-based product developed cysts in the injury site.⁵³ In an effort to persuade the FDA to lift its clinical hold, investigators recently completed a confirmatory, preclinical study in rats to address the FDA's safety and efficacy concerns.⁵⁴ The FDA told Geron it would review the study's results and make a determination as to whether Geron's proposed Phase I clinical trial⁵⁵ can move forward.⁵⁶ On July 30, 2010, the FDA lifted its clinical hold on Geron's proposed Phase I

media/pressview.aspx?id=1148. Geron is a biopharmaceutical company based in California and endeavors to develop first-class treatments for cancer and chronic degenerative diseases, including spinal cord injury, heart failure and diabetes. *See id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Geron's IND for Spinal Cord Injury Put on Hold*, GERON CORP. (Aug. 18, 2009), <http://www.geron.com/media/pressview.aspx?id=1187> (discussing FDA's decision to place a clinical hold on Geron's proposed clinical trial). A clinical hold is an order issued by the FDA to delay a proposed clinical investigation or to suspend an ongoing investigation for the development of a new drug or biological product. 21 C.F.R. § 312.42(a)(2010).

⁵³ *Geron and FDA Reach Agreement on Clinical Hold*, GERON CORP. (Oct. 30, 2009), <http://www.geron.com/media/pressview.aspx?style=print&id=1195> (discussing Geron's agreement with FDA to submit additional safety and efficacy animal studies regarding their hESC-based product for spinal cord injuries).

⁵⁴ Jason Sharp et al, *Human Embryonic Stem Cell-Derived Oligodendrocyte Progenitor Cell Transplants Improve Recovery after Cervical Spinal Cord Injury*, 28 STEM CELLS 152 (2010) (discussing the ability of GRNOPC1, a proprietary hESC-derived population containing myelinating oligodendrocyte progenitor cells, to restore mobility to rats with cervical spinal cord injuries).

⁵⁵ Phase I studies "evaluate how a new treatment should be given, how often, and what dose is safe [and] usually enrolls only a small number of patients." *What is a Clinical Trial?*, NAT'L CANCER INST., <http://www.cancer.gov/clinicaltrials/learning/what-is-a-clinical-trial> (last updated Apr. 8, 2008).

⁵⁶ *See Geron and FDA Reach Agreement on Clinical Hold*, *supra* note 53.

clinical trial.⁵⁷ And, in October 2010, Geron enrolled its first patient to test the safety and efficacy of its proposed therapeutic application for spinal cord injuries.⁵⁸

Unfortunately, not all countries have stringent regulations on par with that of the FDA to ensure the safety and efficacy of investigational, new therapies.⁵⁹ Moreover, these deficiencies are exposed and expanded as individuals travel from a country with an effective regulatory regime to a country without effective governance, regulation, and safety practices—hopeful to find a novel treatment not available in their own country.

B. *Stem Cell Tourism*

Many stem cell scientists agree that there is a need for systemic international regulation and oversight of hESC-based therapeutic treatments offered at various clinics around the world.⁶⁰ The act of individuals traveling to another country in the hope of finding a stem cell-based therapy is known as “stem cell tourism.”⁶¹ Stem cell tourism has received intense scrutiny based on numerous reports of charlatanry, unsubstantiated claims in advertisements, and adverse medical outcomes.⁶²

Direct-to-consumer advertising via the internet is playing a significant role in attracting patients to seek stem cell therapies that turn out to be unsubstantiated.⁶³ Privately operated clinics around the world advertise,

⁵⁷ *Geron to Proceed with First Human Clinical Trial of Embryonic Stem Cell-Based Therapy*, GERON CORP. (July 30, 2009), <http://www.geron.com/media/pressview.aspx?id=1229>.

⁵⁸ Jodi Xu, *Geron Enrolls First Patient in Stem-Cell Treatment Study*, WALL ST. J. (Oct. 11, 2010, 3:33 P.M. EST), <http://online.wsj.com/article/SB10001424052748703794104575546371842991324.html>.

⁵⁹ Mark H. Wholey & Jordan D. Haller, *An Introduction to the Food and Drug Administration and How it Evaluates New Devices: Establishing Safety and Efficacy*, 18 *CARDIOVASCULAR & INTERVENTIONAL RADIOLOGY* 72 (1995) (discussing how FDA may need to compromise some of its stringent approval standards to avoid industry's migration to countries where the regulatory standards are less rigid).

⁶⁰ Barclay, *supra* note 20 at 883–84; *see also* Bryn Nelson, *Stem Cell Researchers Face Down Stem Cell Tourism*, *NATURE REPORTS STEM CELLS* (June 5, 2008), <http://www.nature.com/stemcells/2008/0806/080605/full/stemcells.2008.89.html> (analyzing “stem cell tourism” where people travel thousands of miles and pay thousands of dollars to receive unregulated care); Kiatpongsan & Sipp, *supra* note 17; MacReady, *supra* note 29.

⁶¹ *See* Kiatpongsan & Sipp, *supra* note 17.

⁶² *See id.*

⁶³ Darren Lau et al., *Stem Cell Clinics Online: The Direct-to-Consumer Portrayal of Stem Cell Medicine*, 3 *CELL STEM CELL* 591 (2008) (describing that despite the immature state of stem cell medicine, patients are seeking and accessing putative stem cell therapies in an “early market.”). The researchers analyzed stem cell clinic websites and found that “the portrayal of stem cell medicine on provider websites is optimistic and unsubstantiated by peer-reviewed literature.” *Id.* For an example of a clinic offering unsubstantiated stem cell therapies visit EmCell.com. EmCell.com is a website that makes contrary scientific claims

without citing to any substantiated peer-reviewed literature backing their practices, novel hESC-based therapies for many diseases in which conventional medicine is unavailable.⁶⁴ The cost of stem cell therapy averages \$21,500 per treatment, excluding travel and accommodation.⁶⁵ News reports from 2009 indicate that clinics in China are charging as much as \$69,420 per treatment.⁶⁶

Furthermore, there is potential for serious side effects after receiving unregulated stem cell treatments.⁶⁷ For example, in an observational study in China, fetal brain tissue was transplanted into the lesions of more than 400 patients with spinal cord injury at Beijing's Chaoyang and West Hills (Xishan) hospitals.⁶⁸ The visiting researchers could not find evidence of clinical improvement in any of the patients they observed and reported that several of the patients who received the treatment had developed meningitis from the stem cell injections.⁶⁹

In another adverse outcome report, Israeli researchers from Sheba Medical Center in Tel Aviv detailed the first case of a brain tumor that developed in a male child due to an unregulated stem cell transplantation therapy.⁷⁰ The child and his family had sought unconventional stem cell therapy

that certain stem cells can migrate to an individual's damaged site, engraft, proliferate, undergo specialization under regulation of a new host, and substitute lost or damaged cells, thus restoring the impaired body functions. For additional evidence of unsubstantiated stem cell treatment claims, visit StemCellsChina.com. StemCellChina.com is a website providing specious patient testimonials about stem cell treatments. Contrary to claims by EmCell and StemCellsChina, the FDA asserts that hESCs—and their derivatives—pose the risk for (1) spontaneous formation of tumors after injection of hESCs into a human subject; (2) migration of hESCs to a different site in the human body than what was originally intended; and (3) development of immunogenicity because of the body's reaction to the foreign material from the human proteins expressed from the hESC product. See Fink Jr., *supra* note 9, at 1662; see also Halme & Kessler, *supra* note 9, at 1730–31; see articles cited *supra* note 44.

⁶⁴ Lau et al., *supra* note 63, at 591.

⁶⁵ *Id.* at 592.

⁶⁶ Barclay, *supra* note 20, at 884.

⁶⁷ Bruce H. Dobkin et al., *Cellular Transplants in China: Observational Study from the Largest Human Experiment in Chronic Spinal Cord Injury*, 20 NEUROREHABILITATION & NEURAL REPAIR 5 (2006) (comparing available reports of patients who received preoperative and postoperative assessments before and up to one year after receiving biological cell-based implants in China).

⁶⁸ *Id.*

⁶⁹ *Id.* Meningitis is an inflammation of the membranes that cover the brain and spinal cord and is primarily caused by either a viral or bacterial infection. U.S. Nat'l Library of Med., *Meningitis*, MEDLINEPLUS, <http://www.nlm.nih.gov/medlineplus/meningitis.html> (last updated Mar. 25, 2011).

⁷⁰ Ninette Amariglio et al., *Donor-Derived Brain Tumor Following Neural Stem Cell Transplantation in an Ataxia Telangiectasia Patient*, 6 PLOS MED. 221(2009) (reporting on a human brain tumor complicating neural stem cell therapy and advocating that further work is urgently needed to assess the safety of certain stem cell-based therapies).

offered in Russia to treat a rare neurological disorder called ataxia telangiectasia, which causes severe disability.⁷¹ However, instead of the treatment improving the child's symptoms, he began to suffer from recurring headaches.⁷² When the child reported these new symptoms, researchers in Tel Aviv discovered that the headaches were a result of abnormal growths that developed in the child's brain and spinal cord from the stem cell-based injections.⁷³

In another report, police in Hungary arrested four people in a raid conducted on a suspected, rogue stem cell clinic.⁷⁴ The clinic was charging patients as much as \$25,000 per treatment and injecting patients with illegally obtained embryonic and fetal stem cells.⁷⁵ The cells used at the clinic were derived without authorization or safety testing, posing serious risks to the clinic's patients.⁷⁶

While nothing is inherently wrong with stem cell tourism, the lack of standards to prove safety and efficacy of hESC-based therapies is a valid reason why such treatments are not available in Canada, the United States, and many other nations.⁷⁷ Additionally, individuals suffering from debilitating conditions in which there are no conventional medical treatments are prime targets for clinics that market unregulated and potentially harmful stem cell therapies.⁷⁸ According to one stem cell tourist, “[w]hen you’ve

⁷¹ *Id.* at 223. “Ataxia telangiectasia is a primary immunodeficiency disease which affects a number of different organs in the body. *Ataxia Telangiectasia: Fact Sheet*, NAT'L CANCER INST., <http://www.cancer.gov/cancertopics/factsheet/risk/ataxia> (last updated Jan. 6, 2006). An immunodeficiency disease is one that causes the immune system to break down, making the body susceptible to diseases. *Id.* There is no cure for ataxia telangiectasia.” *Id.*

⁷² Amariglio et al., *supra* note 70, at 223.

⁷³ *Id.*

⁷⁴ *Stem Cell Tourism on the Rise*, CELL MED. (Aug. 13, 2009), <http://www.cellmedicine.com/tourism-caveat-emptor.asp> (discussing the risks associated with stem cell tourism).

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ Lori P. Knowles, *Stem Cell Hype and the Dangers of Stem Cell “Tourism”*, STEM CELL NETWORK/RÉSEAU DE CELLULES SOUCHES (2008), available at <http://www.stemcellnetwork.ca/uploads/File/whitepapers/Stem-Cell-Hype.pdf> (white paper discussing the dangers of stem cell tourism).

⁷⁸ See David Cyranoski, *Stem-cell Therapy Faces More Scrutiny in China but Regulations Remain Unclear for Companies that Supply Treatments*, 459 NATURE 146 (2009) (discussing China's attempt to designate all forms of stem cell therapy as “ethically problematic,” “high risk” or “still in need of clinical verification”); see also Patrick White, *Stem Cell Therapy: Cure or Hoax in China?* GLOBE & MAIL (Aug. 23, 2007, 9:11 AM EDT), <http://www.theglobeandmail.com/life/article778149.ece> (discussing individual patients that are side-stepping Canadian domestic regulations and traveling to China in hopes of a cure); Drew Griffin & David Fitzpatrick, *U.S. Patients Try Stem Cell Therapies Abroad*, CNN (June 2, 2009, 10:37 PM EDT), <http://www.cnn.com/2009/HEALTH/06/02/stem.cell.therapy>.

been in a wheel chair [sic] for 14 years, do you think it really worries [me] [sic] what treatment I receive?"⁷⁹

Another stem cell tourist discovered a website by Beike Biotechnology in China offering stem cell treatments to restore vision in blind children.⁸⁰ The family traveled to Hangzhou, China, with their blind, seven-month-old daughter and paid \$23,000 for their infant to have infusions of stem cells in her eyes.⁸¹ The doctors in China have told the parents that the therapy is working in their daughter.⁸² Despite the Chinese doctors' assertions, Dr. Bruce Dobkin, Director of the Neurologic Rehabilitation and Research Program at the University of California, Los Angeles stated that, "it is extreme nonsense to think that cells can be incorporated into the complex nervous system and do so much, when we cannot even get cells in mice and rats to do very much."⁸³ One Chinese scientist reasoned that, "we think money is mainly behind [the treatments offered by Beike Biotechnology]," and added his concern that Beike's advertised therapy will create a bad reputation for China's entire biotech industry.⁸⁴

Seriously ill individuals are often drawn to the promise of research or novel treatments because they believe it is a better alternative to standard treatment or better than no treatment at all.⁸⁵ When these individuals are in search of a cure or treatment, it can lead to a decreased ability to properly

⁷⁹ Interview by Jennifer Macey, reporter ABC, with Perry Cross, paraplegic stem cell tourist (Oct. 17, 2008).

⁸⁰ Louisa Lim, *Stem-Cell Therapy in China Draws Foreign Patients*, NPR (Mar. 18, 2008), <http://www.npr.org/templates/story/story.php?storyId=88123868>.

⁸¹ *Id.*

⁸² *Id.* Cf. Irana Klimanskaya et al., *Derivation and Comparative Assessment of Retinal Pigment Epithelium from Human Embryonic Stem Cells Using Transcriptomics*, 6 CLONING & STEM CELLS 217 (2004) (finding that with further research retinal pigment epithelium cells derived from hESCs might have the potential to successfully restore vision in animal models of age-related macular degeneration).

⁸³ Lim, *supra* note 80; see also Klimanskaya et al., *supra* note 82.

⁸⁴ Lim, *supra* note 80. According to one article, China's health ministry has ignored unauthorized stem cell therapies offered by hundreds of hospitals under its jurisdiction. *Stem Cells in China: Wild East or Scientific Feast?*, ECONOMIST (Jan. 14, 2010), <http://www.economist.com/node/15268869>. According to the article, Beike Biotechnology is infamous for its internet claims and marketing efforts in countries across the world. *Id.* Beike also openly claims to supply stem cells to more than two dozen hospitals in China and one in Thailand for treating a myriad of conditions. *Id.* Despite Beike's claims that it treats over 6,000 patients using novel stem cell therapies, the company has not published any papers in internationally recognized, peer-reviewed journals. *Id.*

⁸⁵ CARL H. COLEMAN ET AL., THE ETHICS AND REGULATIONS OF RESEARCH WITH HUMAN SUBJECTS 133 (2005). Medical vulnerability is identified by five categories of vulnerability: (1) communicative, (2) institutional, (3) deferential, (4) medical, and (5) social. See J. Koffman et al., *Vulnerability in Palliative Care Research: Findings from a Qualitative Study of Black Caribbean and White British Patients with Advanced Cancer*, 35 J. MED. ETHICS 440 (2009).

weigh the risks and potential benefits associated with proposed treatments.⁸⁶ This type of vulnerability increases the possibility that informed consent is based on misunderstanding potential benefits or motivated solely by the hope of finding a cure.⁸⁷ This vulnerability also increases the risk that such participants will be exploited, because either they have unreasonable expectations about the potential benefits or investigators mislead them about the risks in relation to any potential benefits.⁸⁸ Because of the lack of international regulation in this area, stem cell tourists who are harmed will find themselves lacking a clear path for legal recourse or other assistance.

C. *International Regulation*

1. Human subjects research

It is the responsibility of the medical profession to insist that major innovations, such as the application of hESCs in clinical practice, are first incorporated into formal research projects.⁸⁹ This is especially true given the World Medical Association's (WMA) International Code of Medical Ethics that states, "[a physician shall] respect human life [and] act in the patient's best interest when providing medical care."⁹⁰

Notably, "when a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research."⁹¹ Nonetheless, radically new procedures of this description must be incorporated into *formal research* protocols at an early stage in order to determine whether the procedures are safe and effective.⁹²

⁸⁶ COLEMAN ET AL., *supra* note 85.

⁸⁷ *Id.*

⁸⁸ *Id.* Federal regulations require Institutional Review Boards [IRBs] reviewing research protocols to ensure that before approving any protocol, "[r]isks to subjects are minimized" and "[r]isks to subjects are reasonable in relation to anticipated benefits, if any." 45 C.F.R. § 46.111(a)(1-2) (2011).

⁸⁹ REPORT OF THE NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, 44 Fed. Reg. 23192 (Apr. 18, 1979) (codified as 45 C.F.R. § 46) [hereinafter BELMONT REPORT].

⁹⁰ WORLD MED. ASSOC., WMA INT'L CODE OF MED. ETHICS (2006), available at <http://www.wma.net/en/30publications/10policies/c8/index.html>. The World Medical Association [WMA] was founded in 1947 by twenty-seven countries and represents physicians around the world. *About the WMA*, WORLD MED. ASSOC. (2011), <http://www.wma.net/en/60/about/index.html>.

⁹¹ BELMONT REPORT, *supra* note 89.

⁹² *Id.* (emphasis added). Regulatory approval of new therapies generally requires clear evidence of efficacy and safety and researchers can only obtain this evidence by well-designed and well-conducted randomized prospective clinical trials. See RICHARD CHIN & BRUCE Y. LEE, PRINCIPLES AND PRACTICE OF CLINICAL TRIAL MEDICINE 7 (reprint 2008) (1996).

Further, clinics must not classify hESC-based therapy as an available “treatment” until hESC-based therapy is generally recognized among experts as a “treatment.” Supporting this assertion, the U.S. Supreme Court held that a drug is effective if there is general recognition among experts, founded on substantial evidence, that the drug, in fact, produces the results claimed for it under prescribed conditions.⁹³ By parallel reasoning, experimental medical treatment must not be classified as an available treatment unless there is general recognition among experts, founded on substantial evidence, that the treatment, in fact, produces the results claimed under prescribed conditions. Thus, it is absolutely essential that a patient has the necessary information to make an informed decision when seeking information on whether to participate in novel “treatments.”

Having access to accurate and relevant information is essential to make an informed decision regarding novel medical treatment. Even one of the earliest known guidelines on human medical experimentation, promulgated in Germany in 1931, incorporated the concept of informed consent.⁹⁴ The guidelines, entitled, “Regulations on New Therapy and Human Experimentation,” were issued by the German government in a Reich Circular on February 28, 1931.⁹⁵ The guidelines stated that “[i]nnovative therapy may be carried out only after the subject or his legal representative has unambiguously consented to the procedure in the light of relevant information provided in advance.”⁹⁶

Germany’s guidelines proved futile, as it was the atrocious German human experimentations during World War II that led to the Nuremberg Doctors’ Trial of 1946 and the resulting Nuremberg Code—the first international research guidelines.⁹⁷ The very first line of the Nuremberg Code sets forth the essential tenant of informed consent by declaring that “[t]he voluntary consent of the human subject is absolutely essential.”⁹⁸

⁹³ U.S. v. Rutherford, 442 U.S. 544 (1979) (holding that a drug is unsafe for the terminally ill, as for anyone else, if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit).

⁹⁴ THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION, *supra* note 25, at 129; *see also* Robert M. Sade, *Publication of Unethical Research Studies: The Importance of Informed Consent*, 75 ANNALS OF THORACIC SURGERY 325 (2003).

⁹⁵ THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION, *supra* note 25, at 129.

⁹⁶ *Id.* at 130–31 (citing 11 *Reichs-Gesundheitsblatt* 174–75 (1931)); *see also* Sade, *supra* note 94.

⁹⁷ Sade, *supra* note 94, at 325.

⁹⁸ 2 TRIALS OF WAR CRIMINALS BEFORE THE NUERNBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10 181–82 (U.S. Gov’t Printing Office 1946-1949) [hereinafter NUREMBERG CODE].

Following the Nuremberg Code, the WMA approved the Declaration of Helsinki in 1964.⁹⁹ The Declaration of Helsinki asserts that, “every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject.”¹⁰⁰ Further, “[t]he degree of risk taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.”¹⁰¹

While the Nuremberg Code and the Declaration of Helsinki set international standards for treatment of human subjects when conducting medical research, neither mandate the regulation of novel biomedical interventions postured as available treatments.¹⁰² Even the Convention of Oviedo (Oviedo Convention), a prominent example of ethical rules related to the application of biology, medicine, and research in human subject experimentation, does not regulate biomedical research disguised as a curative therapy.¹⁰³

The Oviedo Convention, a legally binding instrument signed by most of the European States, mandates that all ratifying States implement a regulatory scheme to monitor biomedical research in relation to human subjects research.¹⁰⁴ Echoing the informed consent requirements of the Nuremberg Code and Declaration of Helsinki, Article 5 of the Oviedo Convention declares that, “[a]n [experimental medical] intervention . . . may only be carried out after the person concerned has given *free and informed consent*.”¹⁰⁵

Most importantly, Article 16 sets forth essential principles for the ethical conduct of human subjects research.¹⁰⁶ The Oviedo Convention mandates that research on a person may only be undertaken if all of the following conditions are met: (i) [t]here is no alternative of comparable effectiveness to research on humans; (ii) [t]he risks which may be incurred by that person are not disproportionate to the potential benefits of the research;

⁹⁹ Sade, *supra* note 94.

¹⁰⁰ World Med. Assoc., *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects* (June 1964), available at <http://history.nih.gov/research/downloads/helsinki.pdf> (a statement of ethical principles that offers guidance to participants in medical research involving human subjects) [hereinafter Declaration of Helsinki].

¹⁰¹ NUREMBERG CODE, *supra* note 98, at 182.

¹⁰² See generally Declaration of Helsinki, *supra* note 100; NUREMBERG CODE, *supra* note 98.

¹⁰³ Convention for the Protection of Human Rights and Human Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, 1997, C.E.T.S. No. 164 [hereinafter Oviedo Convention].

¹⁰⁴ *Id.*

¹⁰⁵ *Id.* art. 5 (emphasis added).

¹⁰⁶ *Id.* art. 16.

(iii) [t]he research project has been approved by [a] competent body after independent examination of its scientific merit . . . ; (iv) [t]he persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection; and (v) [t]he necessary consent as provided for under Article 5 has been given expressly . . . and is documented.¹⁰⁷

Because hESC-based therapies are not yet an acceptable curative treatment or therapy, any proposed intervention that uses hESC-based products must take place within the constraints of a carefully planned clinical trial.¹⁰⁸ This will ensure the administration of hESCs falls under the provisions of the Nuremberg Code, Declaration of Helsinki, and Oviedo Convention (where applicable).¹⁰⁹

2. A call for international regulations—Past, present, & future

Many clinics offering dubious hESC-based treatments are located in countries where regulations are less stringent regarding human subjects research.¹¹⁰ Stem cell scientists have expressed frustration with how the multi-jurisdictional nature of stem cell research makes it “tremendously” difficult to regulate.¹¹¹ One analysis detailed the lack of international mechanisms for accountability, transparency, and ethical oversight as the main reasons for scientific regulatory system failures.¹¹²

Because of the regulatory difficulties, professional groups have issued guidelines in relation to providing hESC-based therapies. In particular, the ISSCR issued guidelines entitled “Clinical Translation of Stem Cells” that provide acceptable ways in which researchers may provide hESC-based

¹⁰⁷ *Id.*

¹⁰⁸ Regulatory approval of new therapies generally requires clear evidence of efficacy and safety and researchers can only obtain this evidence by well-designed and well-conducted randomized prospective clinical trials. *See* CHIN & LEE, *supra* note 92, at 7.

¹⁰⁹ Notably, there are two additional, well-established guidelines that govern the use of human subjects research throughout the world. They are: (1) THE COUNCIL FOR INT’L ORGS. OF MED. SCIENCES, INT’L ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (2002) and (2) Universal Declaration on Bioethics and Human Rights, UNESCO Gen. Conf. Res., 33rd Sess., 33 C/Resolution 36 (Oct. 19, 2005).

¹¹⁰ Kiatpongsan & Sipp, *supra* note 17. Examples of countries with less stringent regulations include: China, India, Russia, and Thailand. *See id.*

¹¹¹ Monya Baker, *Stick to the Guidelines and Fewer Get Hurt*, NATURE REPORTS STEM CELLS (Dec 11, 2008), <http://www.nature.com/stemcells/2008/0812/081211/full/stemcells.2008.157.html> (discussing ISSCR’s hope that its guidelines will prompt regulators and governments to close “shady” clinics that offer unproven stem cell therapies); *see also Guidelines for the Clinical Translation of Stem Cells*, *supra* note 21.

¹¹² *See, e.g.,* Herbert Gottweis & Robert Triendl, *South Korean Policy Failure and the Hwang Debacle*, 24 NATURE BIOTECH. 141 (2006).

therapies.¹¹³ The ISSCR strongly condemns clinics that promote and administer unproven uses of stem cells, or their direct derivatives, to patients outside of a clinical trial—particularly when patients are charged for those services.¹¹⁴ Even so, the ISSCR concedes that it will not enforce the guidelines or evaluate individual clinics for compliance.¹¹⁵ Nonetheless, the ISSCR is hopeful that the publication of its guidelines will push countries to adopt and enforce harmonized regulatory standards.¹¹⁶

Another international professional society, the BIONET Expert Group (BIONET), warns that legal, political, social, and cultural differences between nations can lead to “multiple standards and even to gaps [between] governance regimes.”¹¹⁷ BIONET has called for a joint advisory body to monitor research practices internationally.¹¹⁸

Although setting common standards in the biomedical field can be an arduous task, it is possible because international human rights law presupposes that some basic principles of human rights transcend cultural diversity.¹¹⁹ Additionally, international organizations such as the ISSCR and BIONET provide a forum for discovering multinational standards in hESC research.¹²⁰

One example of collaboration in setting international scientific standards is the Universal Declaration on the Human Genome and Human Rights (Universal Declaration).¹²¹ The Universal Declaration publicized the immense potential of therapeutic applications related to gene therapy, but emphasized that any such research involving gene therapy should “fully respect human dignity, freedom[,] and human rights . . .”¹²²

¹¹³ *Guidelines for the Clinical Translation of Stem Cells*, *supra* note 21; *see also* Lindvall & Hyun, *supra* note 20, at 1665.

¹¹⁴ *Guidelines for the Clinical Translation of Stem Cells*, *supra* note 21.

¹¹⁵ *Stem-Cell Society Condemns Medical Tourism*, 453 NATURE 969 (2008) (announcing ISSCR’s official condemnation towards clinicians offering unproven stem-cell treatments to vulnerable patient populations).

¹¹⁶ *Id.*

¹¹⁷ Daniel Cressey, *Ethics Scrutiny Needed for Chinese-European Projects*, 461 NATURE 157 (2009).

¹¹⁸ *Id.*

¹¹⁹ Roberto Andorno, *Biomedicine and International Human Rights Law: In Search of a Global Consensus*, 80 BULL. OF THE WORLD HEALTH ORG. 959 (2002) (discussing the global challenges raised by biomedical advances).

¹²⁰ *Id.*

¹²¹ *Universal Declaration on the Human Genome and Human Rights*, G.C. Res. 16, U.N. ESCOR, 29th Sess., 26th plen. mtg. (Nov. 11, 1997).

¹²² *Id.*

The United Nations responded similarly when citizens worldwide learned that scientists had successfully cloned a sheep.¹²³ Concern quickly spread that scientists could apply the same technique to produce genetically identical human beings.¹²⁴ As a result, the French and German governments petitioned the United Nations to approve a worldwide ban on human cloning.¹²⁵ In response, on December 12, 2001, the U.N. General Assembly established the Ad Hoc Committee on an International Convention Against the Reproductive Cloning of Human Beings.¹²⁶ On March 8, 2005, the U.N. General Assembly adopted a non-binding resolution calling for the ban of all forms of human cloning contrary to human dignity.¹²⁷

Professional society guidelines and U.N. declarations have formed a directional point of origin to help determine the path forward in the regulation of hESC-based therapies. From here, a range of effective solutions emerge—each helping to fulfill the promise of ever-advancing hESC-based therapies. Specifically, this journey includes the analysis and application of: (i) a binding U.N. Security Council Resolution to effectuate immediate action in the interest of national security and public health; (ii) a resolution outside of the purview of biomedical regulation in which WHO could issue a non-binding resolution; and (iii) model treaties and the codification of key portions of the ISSCR guidelines into the form of a draft treaty.

III. HESC THERAPIES—A REGULATORY ROAD MAP TO HELP GUIDE THE JOURNEY

Scientific advances are dependent on collaborative, international research—as science is not constrained by geographic boundaries. The international community must implement a standardized ethical and regulatory framework to address the emerging and complex scientific and social challenges generated by hESC-based therapies. While there are various approaches the international community could take to regulate hESC thera-

¹²³ Andorno, *supra* note 119. The term cloning is used to describe the process of making duplicate biological material. Kathi E. Hanna, Cloning/Embryonic Stem Cells, NAT'L HUM. GENOME RES. INST. (Apr. 2006), <http://www.genome.gov/10004765>.

¹²⁴ Andorno, *supra* note 119.

¹²⁵ *Id.*

¹²⁶ U.N. Ad Hoc Committee on an Int'l Convention Against the Reproductive Cloning of Human Beings, U.N., <http://www.un.org/law/cloning/> (last updated May 15, 2005); *see also* Erika Check, *Call for Cloning Ban Splits UN*, 416 NATURE 3 (2002) (discussing international debate regarding the U.N.'s proposed global ban on human cloning); Nigel Williams, *UN Stalls on Human Cloning*, 14 CURRENT BIOLOGY R937 (articulating how the U.N.'s attempt to come up with a resolution on the issue of human cloning was postponed due to continued debate amongst countries over a world-wide human cloning ban).

¹²⁷ U.N. Declaration on Human Cloning, G.A. Res. 59/280, annex, U.N. Doc. A/RES/59/280 (Mar. 23, 2005).

pies, the establishment of a formal, international standard is the critical first step to advance the regulation of hESCs. This section explores three different options available for the regulation of hESC-based therapies.

A. *Leveraging a Binding U.N. Security Council Resolution – Immediate Action to Protect National Security and the Public Health*

1. The binding resolution—Lessons from 9/11

Under the U.N. Charter, the Security Council has primary responsibility for maintaining international peace and security.¹²⁸ Article 39 of the Charter allows the Security Council broad discretion to assess whether threats to peace exist, and Chapter VII provides for flexibility to decide on appropriate responses.¹²⁹ Article 25 of the Charter obligates member States to comply with the binding Resolutions adopted by the Security Council under its Chapter VII authority.¹³⁰

On September 28, 2001, weeks after the horrific 9/11 attacks on America, the Security Council adopted Resolution 1373—a “wide-ranging, comprehensive resolution with steps and strategies to combat international terrorism.”¹³¹ In effect, Resolution 1373 converted the International Convention for the Suppression of the Financing of Terrorism,¹³² which had not yet been universally ratified, into instant international law, binding on all 192 Members of the United Nations. The Security Council then adopted Resolution 1377 on November 28, 2001, reaffirming Resolution 1373.¹³³

¹²⁸ The U.N. Security Council has:

[P]rimary responsibility, under the Charter for the maintenance of international peace and security [A] representative of each of its members must be present at all times at United Nations Headquarters When a complaint concerning a threat to peace is brought before [the Council], the Council’s first action is usually to recommend to the parties to try to reach agreement by peaceful means. In some cases, the Council itself undertakes investigation and mediation. It may appoint special representatives or request the Secretary-General to do so It may set forth principles for a peaceful settlement.

U.N. Security Council: Background, U.N., http://www.un.org/Docs/sc/unsc_background.html (last visited Mar. 26, 2011).

¹²⁹ The U.N. Charter article 39 states “[t]he Security Council shall determine the existence of any threat to the peace, breach of the peace, or act of aggression and shall make recommendations, or decide what measures shall be taken in accordance with Articles 41 and 42, to maintain or restore international peace and security.”

¹³⁰ U.N. Charter art. 25.

¹³¹ S.C. Res. 1373, U.N. Doc. S/RES/1373 (Sept. 28, 2001); *see also* Press Release, Security Council Adopts Wide-Ranging Anti-Terrorism Resolution; Calls for Suppressing Financing, Improving International Cooperation, U.N. Press Release SC/7158 (Sept. 28, 2001).

¹³² G.A. Res. 54/109, U.N. Doc. A/RES/54/109 (Feb. 25, 2000).

¹³³ S.C. Res 1377, U.N. Doc. S/RES/1377 (Nov. 12, 2001).

Resolution 1377 tasked the States with, among other action items, promoting best -practices in the areas covered by Resolution 1373, including the preparation of model laws.¹³⁴ Because the Security Council adopted Resolution 1377 under Chapter VII of the U.N. Charter, Resolution 1377 imposes binding obligations (in contradistinction to voluntarily entering a treaty) on Member States to address the global issue of threats to peace and security represented by terrorism.¹³⁵

According to one scholar, the Security Council, for the first time, “[mandated] all [S]tates to take or to refrain from specified actions in a context not limited to disciplining a particular country.”¹³⁶ The U.N. Security Council can only bind Member States if a determination is made by the Security Council, under Article 39, that a threat to the peace, breach of the peace, or act of aggression exists.¹³⁷

2. Unregulated hESC-based therapies—A threat to peace?

Some experts warn that the major threat of hESC research is not the often cited violation of ethical norms, but the possibility that stem cells will be used to bring physical harm to the human race.¹³⁸ While some may scoff at the idea that this particular type of danger is possible, using biologics for human harm is not a new concept.¹³⁹ The deployment of biological agents is

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ Paul C. Szasz, *The Security Council Starts Legislating*, 96 AM. J. INT’L L. 901 (2002) (discussing how, for the first time, the United Nations Security Council used its Chapter VII powers under the Charter with its resolution to counter the threat of terrorism).

¹³⁷ See U.N. Charter, *supra* note 129 and accompanying text. The structure of the U.N. Security Council consists of five permanent members with veto power (i.e., China, France, Russia, the United Kingdom, and the United States) and ten elected non-permanent members that serve for two-year terms. U.N. Charter arts. 23 & 27.

¹³⁸ LEO FURCHT & WILLIAM HOFFMAN, *THE STEM CELL DILEMMA: BEACONS OF HOPE OR HARBINGERS OF DOOM?* 195 (2008) (indicating that while stem cells offer the hope of creating or repairing tissues lost to age, disease, and injury—because of this very ability—they hold the potential to incite an international biological arms race); see also Zach W. Hall, Resource Review, *Stem Cells and Leonardo’s Cave*, 2 CELL STEM CELL 536 (discussing how the authors of “The Stem Cell Dilemma: Beacons of Hope or Harbingers of Doom?” are rightly alarmed by the threats posed by the potential use of modern molecular technology to produce biological weapons and see stem cells as a critical link in efforts to both evade and produce such weapons).

¹³⁹ See *Amerithrax or Anthrax Investigation*, FEDERAL BUREAU OF INVESTIGATION [F.B.I.], <http://www.fbi.gov/anthrax/amerithraxlinks.htm>. “Soon after the terrorist attacks of 9/11/01, letters laced with anthrax began appearing in the U.S. mail. Five Americans were killed and 17 were sickened in what became the worst biological attacks in U.S. history.” *Id.*

no longer a hypothetical scenario, but a potentially life-threatening reality.¹⁴⁰

According to the NIH, the anthrax attacks, subsequent to 9/11, exposed vulnerabilities in the United States and abroad to unconventional weapons employed by terrorists.¹⁴¹ More specifically, the use of anthrax demonstrated that terrorists could use deadly pathogens and biologics to threaten the health and safety of citizens around the world.¹⁴² Given the enormity of the threat of a biological attack, NIH spent over \$1.7 billion in 2009 towards biodefense research, with projections showing plans to spend equivalent amounts in the following years.¹⁴³

Of great concern with bioterrorism is that civilian populations vary significantly in their susceptibility to exposure from harmful biological agents—mainly due to differences in age (e.g., infants to the elderly) and health (e.g., immunocompromised to healthy immune systems).¹⁴⁴ Countries around the world all face an uncertain, but real threat—the deliberate act of introducing re-emerging and emerging communicable diseases into the civilian population.¹⁴⁵ Additionally, authorities state that countries in the Middle East, South Asia, and Southeast Asia face the risk that transnational

¹⁴⁰ Reschma Agarwal et al., *Biological Warfare – An Emerging Threat*, J. OF THE ASS'NS OF PHYSICIANS OF INDIA (2004).

¹⁴¹ *The Role of NIH Biomedical Research in Responding to the Threats of Chemical, Biological, Radiological and Nuclear (CBRN) Terrorism: Hearing Before the H. Comm. on Gov't Reform, Subcomm. on Nat'l Sec., Emerging Threats, and Int'l Rel.*, 109th Cong. (2005) (statement of Anthony S. Fauci, M.D., Director, Nat'l Institute of Allergy and Infectious Diseases, Nat'l Institutes of Health, U.S. Dep't of Health and Hum. Services).

¹⁴² *Id.*

¹⁴³ *Research Portfolio Online Reporting Tools (RePORT), Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)*, NIH, <http://report.nih.gov/rcdc/categories/default.aspx> (last updated Feb. 14, 2011). NIH is the lead recipient of Federal biodefense dollars. See Crystal Franco, *Billions for Biodefense: Federal Agency Biodefense Funding, FY2008-FY2009*, 6 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRACTICE, & SCI. 131, 138 (2008) (analyzing the budgets and allocations for biodefense at the Departments of Health and Human Services, Homeland Security, Defense, Agriculture, and State and the Environmental Protection Agency and the National Science Foundation).

¹⁴⁴ Bioterrorism includes the use of “living organisms, whatever their nature, or infective material derived from them, which are used for hostile purposes and intended to cause disease or death in man, animals and plants, and which depend for their efforts on the ability to multiply in the person, animal or plant attacked.” See, e.g., Nicholas J. Beeching et al., *Biological Warfare and Bioterrorism*, 324 *BMJ* 336, 336 (2002); Anthony S. Fauci, *Bioterrorism: Defining a Research Agenda*, 57 *FOOD & DRUG L.J.* 413 (2002) (analyzing the laws, regulations, and policies affecting FDA-regulated products).

¹⁴⁵ See Fauci, *supra* note 144, at 420. Pandemic influenza is an example of a re-emerging disease. *Id.* In 1918, pandemic influenza killed an estimated twenty-five million people worldwide, including 750,000 in the United States. *Id.* HIV/AIDS, an example of an emerging disease, has now killed more than twenty-two million people and infected forty million others worldwide. *Id.*

terrorist groups can acquire biologics easily, as they have poorly secured biological laboratories and culture collections.¹⁴⁶

One al-Qaeda training manual advocates for the use of biologics in terrorist attacks.¹⁴⁷ However, rudimentary lab equipment and limited access to lethal strains hindered al-Qaeda's known bioweapons efforts.¹⁴⁸ Despite al-Qaeda's set-backs, some experts predict that a biological attack could occur by the end of 2013.¹⁴⁹ Even more, a news report from 2010 acknowledged the possibility that terrorist groups were selling fake pharmaceuticals on the black-market as a profit-making venture to fund terrorist activities for the purpose of implementing a biological attack.¹⁵⁰

The field of biotechnology is emerging and proliferating before the full impact is understood and "well before laws and policies are in place to ensure their use for peaceful purposes."¹⁵¹ As one scholar noted, "[e]very major technology—metallurgy, explosives, internal combustion, aviation, electronics, nuclear energy—has been intensively exploited, not only for peaceful purpose, but also for hostile ones."¹⁵²

One muggy Sunday in July 1939, physicists Leo Szilard and Eugene Wigner paid a visit to Albert Einstein at Little Peconic Bay on Long Island, where he was spending the summer. They broke the news to Einstein about the recent experimental work with neutrons. They suggested it would be possible to use a neutron, discovered only seven years earlier, to start a chain reaction in the uranium nucleus. His Response? "I never thought of that." The man who launched a revolution in physics had not imagined that his famous equation of 1905, $E=mc^2$, might be used to release massive amounts of energy in a weapon of war. Six years later to the day, July 16, 1945, the nuclear chain reaction that the world's greatest scientific mind had never considered was initiated at the "Trinity" atomic bomb test site on a desert flat north-west of Alamogordo, New Mexico.¹⁵³

Imagine a situation in which an unsuspecting stem cell tourist is injected with a communicable biological agent under the auspices of receiving hESC-based therapy. This innocent individual, paying upwards of \$65,000

¹⁴⁶ BOB GRAHAM ET AL., THE REPORT OF THE COMMISSION ON THE PREVENTION OF WMD PROLIFERATION AND TERRORISM xix (2008).

¹⁴⁷ Joby Warrick, *Officials Fear Toxic Ingredient in Botox Could Become Terrorist Tool*, WASH. POST (Jan. 25, 2010), <http://www.washingtonpost.com/wp-dyn/content/article/2010/01/24/AR2010012403013.html?hpid=topnews>.

¹⁴⁸ *Id.*

¹⁴⁹ GRAHAM ET AL., *supra* note 146, at xv.

¹⁵⁰ Warrick, *supra* note 147.

¹⁵¹ DANIEL M. GERSTEIN, BIOTERROR IN THE 21ST CENTURY 17 (2009).

¹⁵² *Id.* at 37 (citing NRC and the IOM, Globalization, Biosecurity, and the Future of the Life Sciences 49.).

¹⁵³ FURCHT & HOFFMAN, *supra* note 138, at 230.

for putative therapy, may not only serve as a potential human vector to transmit toxic biological agents, but may be unknowingly contributing to the financing of terrorist activities.¹⁵⁴ And, similar to worries articulated in the 2010 news report, these unregulated clinics may be using funding from stem cell tourists to advance other forms of bioweapons.¹⁵⁵

While the probability of the above hypothetical situation is unknown, so significant are the consequences that they cannot be left to chance.¹⁵⁶ Just as the world would not sit idly by as rouge scientists assembled the components of a nuclear weapon, the United Nations must act to ensure national security. As one atomic bomb historian prophetically asserted days leading up to the Manhattan Project, “[t]he bomb was latent in nature as a genome is latent in flesh.”¹⁵⁷ Thus, unregulated hESC-based therapies offered in rogue clinics around the world may fall under the purview of the Security Council’s Chapter VII authority. Furthermore, Security Council Resolution 1377 provides the United Nations flexibility to institute a standardized regulatory scheme for hESC-based therapy by binding Member States to “intensify their efforts to eliminate . . . international terrorism.”¹⁵⁸

3. Taking a proactive stance towards hESC regulation

While resolutions are typically non-binding legal instruments, the flexibility to impose binding resolutions can be extremely powerful in prompting individual States to act. For example, scholars assert that the international community’s agreement to refrain from directly or indirectly

¹⁵⁴ See, e.g., Warrick, *supra* note 147 (purchasing pharmaceuticals off the black-market may fund terrorist activities).

¹⁵⁵ See *id.*; Agarwal et al., *supra* note 140.

¹⁵⁶ The factors which effect the issue of biological weapons include:

the dual use problem involving materials, equipment, and knowledge which has both legitimate peaceful and (illegitimate) hostile applications; the biotechnology revolution and related developments (e.g. synthetic biology); globalization and the increase in trade; the inherent weaknesses in the existing law against the use and development of biological weapons in the 1925 Geneva Protocol and the 1972 Biological Weapons Convention [“BWC”]; . . . ; the threat posed by terrorists and non-state actors and their increased interest in biological weapons; public and government fear of biological weapons use (particularly in Western states) that may have an impact physically, economically, and psychologically well beyond any actual ‘success’ rate; renewed interest in incapacitating and disabling chemical and biological substances; and a crisis of legitimacy related to the actions and policies to counter the biological weapons threat.

JEZ LITTLEWOOD, *MANAGING THE BIOLOGICAL WEAPONS PROBLEM: FROM THE INDIVIDUAL TO THE INTERNATIONAL* 4 (2006).

¹⁵⁷ FURCHT & HOFFMAN, *supra* note 138, at 224.

¹⁵⁸ S.C. Res. 1377, U.N. Doc. S/RES/1377 (Nov. 12, 2001).

financing terrorist activities was successfully implemented through policies in the United States and overseas.¹⁵⁹ As a result, scholars declare that al-Qaeda suffered financially, inhibiting the ability to conduct terrorist activities.¹⁶⁰

Yet, other scholars in the international community profess that the United Nations resolution has had only a minimalistic impact on combating the financing of terrorist activities.¹⁶¹ In particular, a report by a Security Council monitoring group observed that al-Qaeda has sustained considerable financial resources despite international efforts to eliminate their funding.¹⁶²

One explanation for this is the possibility that terrorist financing is sustained by transferring funds through a corrupt organization that claims to have charitable, social, or cultural goals.¹⁶³ This may be further bolstered by a Security Council Resolution that creates a humanitarian exception to freezing financial assets if the assets are necessary to cover basic living expenses such as food, rent, mortgage, medicines, and *medical treatment*.¹⁶⁴

Similar to al-Qaeda terrorists that operate independent from any one foreign financial benefactor, raising their assets from legitimate and nondescript commercial entities, rogue stem cell clinics operate in various centers around the world—each with sources of revenue difficult to track and control.¹⁶⁵ Establishing an international regulatory framework is essential to promoting security awareness in the life sciences community and mitigates the ability of terrorists to employ biological technology for less than noble purposes.¹⁶⁶

As with any proposed solution, there will be difficulties in measuring its effectiveness. While there are conflicting reports about the level of effectiveness anti-terrorist financing campaigns have had on the reduction in terrorist activity, any positive effect, regardless of the size of the impact, is

¹⁵⁹ U.S. TREASURY DEP'T, CONTRIBUTION BY THE DEP'T OF THE TREASURY TO THE FINANCIAL WAR ON TERRORISM 5 (2002), available at <http://www.treas.gov/press/releases/reports/2002910184556291211.pdf>; but see U.N. Security Council, *Second Report of the Monitoring Group Established Pursuant to Security Council Resolution 1363 (2001) and Extended by Resolution 1390*, 3, U.N. Doc. S/2002/1050 (Sept. 20, 2002).

¹⁶⁰ U.S. TREASURY DEP'T, *supra* note 159.

¹⁶¹ U.N. Security Council, *supra* note 159, at 3.

¹⁶² *Id.*; but see U.S. TREASURY DEP'T, *supra* note 159, at 5.

¹⁶³ JIMMY GURULÉ, UNFUNDING TERROR: THE LEGAL RESPONSE TO THE FINANCING OF GLOBAL TERRORISM 104 (2008).

¹⁶⁴ S.C. Res. 1452, ¶1, U.N. Doc. S/RES/1452 (2002) (emphasis added).

¹⁶⁵ *Fund-Raising Methods and Procedures for Int'l Terrorist Orgs. Before the Subcomm. on Oversight and Investigations of the H. Comm. on Financial Services*, 107th Cong. (2002) (testimony of Steven Emerson, Exec. Dir. for the Investigative Project).

¹⁶⁶ GERSTEIN, *supra* note 151, at 8, 139.

meaningful. Therefore, leveraging the authority provided in Security Council Resolution 1377 is a critical first step to publicizing international consensus on hESC-based therapies.

However, if the Security Council is simply unable—due to lack of actionable information—to address this issue as one that poses a threat to national security, there are other necessary steps the United Nations should take to address the risks associated with receiving unregulated hESCs.

B. Implementation of a Non-Binding UN Resolution – Looking For Short Term Direction Outside of Biomedical Regulation

International consensus is critical to the success of mitigating the chance that patients will suffer an adverse outcome from putative hESC-based therapies or that nations will experience public health threats from untested biologics. While the lawmaking process is often accused of failing to keep up with scientific advances, standardized ethical principles withstand the passage of time.¹⁶⁷ Thus, the WHO must act to pass a non-binding resolution, at a minimum, regarding the international community's standards in relation to hESC-based therapies.¹⁶⁸ The WHO's constitution provides it the ability "to propose conventions, agreements and regulations, and make recommendations with respect to international health matters."¹⁶⁹ Thus, the WHO can act to promote a non-binding resolution that condemns clinics that offer unsafe hESC therapies.

While not topically analogous, the principles embodied in the U.N. Resolution on Human Rights and Terrorism is a model resolution adaptable by the WHO to the problem of clinics offering unsubstantiated hESC-based therapies. Through the United Nation's Resolution on Human Rights and Terrorism, the international community has spoken clearly, and without ambiguity, expressing "condemn[ation] [of] all acts, methods and practices

¹⁶⁷ Andorno, *supra* note 119.

¹⁶⁸ In 1948, the United Nations established the World Health Organization [WHO]. *History of WHO*, WHO, <http://www.who.int/about/history/en/index.html>. The WHO is the "directing and coordinating authority for health within the [U.N.] [and is] responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring[,] and assessing health trends." *About WHO*, WHO, <http://www.who.int/about/en/>. WHO acts "as the directing and coordinating authority on international health work." Const. of the WHO, art. 2(a), 62 Stat. 2679, 14 U.N.T.S. 185. The World Health Assembly [WHA] is comprised of 193 U.N. Member States and makes major policy decisions regarding the WHO's initiatives. *Countries*, WHO, [http://www.who.int/countries/en\(listing WHO member states\)](http://www.who.int/countries/en(listing%20WHO%20member%20states))(last visited Mar. 26, 2011).

¹⁶⁹ Const. of the WHO, *supra* note 168, art. 2(k).

of terrorism in all its forms and manifestations.”¹⁷⁰ The international community has further called upon States to “refrain from financing, . . . providing training for, or otherwise encouraging terrorist activities.”¹⁷¹

Both the statement of condemnation, and the call upon States to act, is essential for a hESC-based therapies resolution. Following the United Nation’s lead in addressing terrorism, the WHO, acting in its capacity as the specialized health agency of the United Nations, must issue a non-binding resolution that (i) condemns clinics that promote or administer unproven uses of stem cells to patients outside of a clinical trial and (ii) calls upon States to close down clinics and sensor individuals that violate hESC-based therapy guidelines.

While it is still too soon to know whether hESCs will offer the cures millions of people hope for, what is certain is that the power of biotechnology crosses international boundaries more freely than ever.¹⁷² And, the key to scientific progress is based on the “unification rather than fragmentation of knowledge.”¹⁷³ Thus, broader global cooperation among countries and their biological scientists may be the world’s best approach to promote scientific progress.¹⁷⁴

The impact of a resolution can help increase the safety, efficacy, and transparency of hESC-based therapies and, in the process, reduce the number of rouge stem cell clinics offering unregulated therapies.¹⁷⁵ A resolution would also, in effect, increase knowledge and awareness and help align stem cell tourists’ expectations with the promise of hESC-based therapies.¹⁷⁶ Thus, urging the regulation of hESC-based therapy can mean preventing susceptible patients in Hungary from paying thousands of dollars for unregulated stem cell injections.¹⁷⁷ Or, it could mean saving the child in Israel from suffering abnormal growths on his brain and spine due to irresponsible and ineffective cell-based treatment.¹⁷⁸

If countries adopt regulations based on the WHO’s guidance, then stem cell tourists can travel with additional confidence that they are pursuing hESC-based therapies that are regulated and, in the process, benefit from international cooperation in science.

¹⁷⁰ G.A. Res. 48/122, U.N. Doc. A/RES/48/122 (Dec. 20, 1993); *see also* G.A. Res. 49/185, U.N. Doc. A/RES/49/185 (Dec. 23, 1994).

¹⁷¹ *See* G.A. Res. 51/210, ¶ 3(f)(5), U.N. Doc. A/RES/51/210 (Dec. 17, 1996).

¹⁷² GERSTEIN, *supra* note 151, at 192.

¹⁷³ *Id.*

¹⁷⁴ *Id.* at 194

¹⁷⁵ *See* GREGORY D. KOBLENTZ, *LIVING WEAPONS: BIOLOGICAL WARFARE AND INTERNATIONAL SECURITY* 8 (2009).

¹⁷⁶ *See* GERSTEIN, *supra* note 151, at 143.

¹⁷⁷ *Stem Cell Tourism on the Rise*, *supra* note 74.

¹⁷⁸ Amariglio et al., *supra* note 70.

C. *Codifying the ISSCR Guidelines by Leveraging Principles from Model Treaties*

As previously discussed, hESC-based therapies have transcended the national stage into a global forum in need of international regulation.¹⁷⁹ And, if the U.N. Security Council does not leverage its powers under its binding resolution, and the WHO does not propose a non-binding resolution, there are additional steps the United Nations can take to regulate hESC-based therapies and mitigate the possibility of patients suffering adverse health outcomes from unregulated treatments.

1. ISSCR guidelines

The Task Force for the Clinical Translation of Stem Cells, a multi-disciplinary group of stem cell researchers, clinicians, ethicists, and regulatory officials from 13 countries, developed the ISSCR guidelines.¹⁸⁰ The ISSCR decided to take steps to prompt the international community to adopt uniform regulations for hESC-based therapies.¹⁸¹ This was largely due to the desire to mitigate the occurrence of adverse outcomes in vulnerable patient populations, persuaded by means of misleading advertising, to pursue unproven stem cell-based therapies abroad.¹⁸²

Because peer-reviewed scientific literature has not yet shown hESCs to be safe for transplantation into humans, the ISSCR strongly condemns clinics that promote and administer unproven uses of stem cells to patients outside of a clinical trial.¹⁸³ More specifically, the ISSCR guidelines specify that “all studies involving clinical applications of stem cells must be subject to independent review, approval, and ongoing monitoring by human subjects research oversight bodies.”¹⁸⁴ Further, the ISSCR reiterates the need for independent review and informed consent to maximize respect for the voluntary nature of any subject’s participation in clinical

¹⁷⁹ HERBERT GOTTSWEIS ET AL., *THE GLOBAL POLITICS OF HUMAN EMBRYONIC STEM CELL SCIENCE*, 189–90 (2009) (investigating the interaction between national regulatory formation and the global bio-politics of regenerative medicine and human embryonic stem cell science).

¹⁸⁰ Insoo Hyun et al., *Commentary, New ISSCR Guidelines Underscore Major Principles for Responsible Translational Stem Cell Research*, 3 *CELL STEM CELL* 607, 609 (2008) (discussing core principles that should guide the responsible transition of basic stem cell research into appropriate clinical applications).

¹⁸¹ *Id.*

¹⁸² Hyun et al., *supra* note 180, at 609.

¹⁸³ *Guidelines for the Clinical Translation of Stem Cells*, *supra* note 21.

¹⁸⁴ *Id.*

trials.¹⁸⁵ Fortunately, portions of the ISSCR guidelines are uniquely suited for adoption into treaty language.

2. Model treaties

The international community has come together to address many human rights and public health issues through treaties. For instance, in 2005, the WHO successfully implemented International Health Regulations to enhance the international community's ability to prevent and respond to acute public health risks.¹⁸⁶ The International Health Regulations are legally binding on all 194 WHO Member States, including the United States.¹⁸⁷

In June 1997, the WHO gained endorsements from the American Public Health Association and the 10th World Conference on Tobacco and Health to develop a treaty in response to the globalization of the tobacco epidemic.¹⁸⁸ On May 21, 2003, the World Health Assembly adopted the WHO Framework Convention on Tobacco Control (FCTC), which entered into force on February 27, 2005.¹⁸⁹ In 2009, the FCTC published guidelines on: (i) protecting public health policies with respect to tobacco control; (ii) protecting individuals from exposure to tobacco smoke; (iii) establishing packaging and labeling of tobacco products regulations; and (iv) banning tobacco advertising, promotion, and sponsorship.¹⁹⁰

Another treaty, the Convention on the Rights of Persons with Disabilities (CRPD), entered into force in May 2008 and serves as a successful model for international action.¹⁹¹ To date, 147 countries have signed the CRPD and 97 have ratified it.¹⁹² The CRPD treaty requires that States "adopt all appropriate legislation" to "ensure and promote the full realiza-

¹⁸⁵ *Id.*

¹⁸⁶ See *What are the International Health Regulations?*, WHO, <http://www.who.int/features/qa/39/en/index.html> (last updated Apr. 10, 2008).

¹⁸⁷ WHO, Revision of the International Health Regulations, WHO Doc. WHA58.3 (May 23, 2005).

¹⁸⁸ See Maureen Beuhly et al., *International Health Law*, 32 INT'L L. 539, 550 (1998) (discussing how WHO endeavored to build support for the development of a framework convention on tobacco and how the U.N. focal point on tobacco, established and strengthened contacts with governments, nongovernmental organizations, and over thirty U.N. organizations to garner international support).

¹⁸⁹ WHO Framework Convention on Tobacco Control, 42 I.L.M. 518 (May 21, 2003).

¹⁹⁰ WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL, GUIDELINES FOR IMPLEMENTATION: ARTICLE 5.3; ARTICLE 8; ARTICLE 11; ARTICLE 13 at 1 (2009) [hereinafter FCTC GUIDELINES FOR IMPLEMENTATION].

¹⁹¹ Convention on the Rights of Persons with Disabilities art. 1, G.A. Res. 61/106, U.N. Doc. A/RES/61/106 (Jan. 24, 2006).

¹⁹² U.N. Enable, U.N., <http://www.un.org/disabilities/> (follow link to "Signatories & Ratifications") (last visited Mar. 26, 2011).

tion of all human rights” for people with disabilities.¹⁹³ Additionally, States must modify or abolish all existing “laws, regulations, customs and practices that constitute discrimination” against people with disabilities.¹⁹⁴ The official United Nations interpretation of the CRPD requires States to include explicit protections in their legal instruments, both in national laws and constitutions.¹⁹⁵ And, according to the United Nations, the CRPD marks a “paradigm shift” in international attitudes and approaches to persons with disabilities.¹⁹⁶

An additional area of successful international action is demonstrated by the international regulation of child labor.¹⁹⁷ In 1999, the International Labour Organization (ILO), a tripartite U.N. agency that brings together governments, employers, and workers to promote international regulations, adopted the Worst Forms of Child Labour Convention as ILO Convention No. 182.¹⁹⁸ One hundred and seventy-three countries, including the United States, have ratified the ILO Convention.¹⁹⁹ The ILO Convention imparts the need to “reach out to the children at special risk” and prevent children from engaging in the worst forms of child labor.²⁰⁰ The ILO Convention further asserts that the “best interests of the child shall be a primary consideration.”²⁰¹

On the broader subject of protecting individual interests, medical treatment should not be classified as an available treatment unless there is general recognition among experts, founded on substantial evidence, that

¹⁹³ Convention on the Rights of Persons with Disabilities, *supra* note 191, art. 4, cl. 1.

¹⁹⁴ *Id.*

¹⁹⁵ ANDREW BYRNES ET AL., FROM EXCLUSION TO EQUALITY: HANDBOOK FOR PARLIAMENTARIANS ON THE CONVENTION FOR THE RIGHTS OF PEOPLE WITH DISABILITIES AND ITS OPTIONAL PROTOCOL III (2007).

¹⁹⁶ Joint Statement of Commitment to the Convention on the Rights of Persons with Disabilities, United Nations Inter-Agency Support Group for the Convention on the Rights of Persons with Disabilities (available online at www.un.org/disabilities/documents/iag/soc.pdf).

¹⁹⁷ See Jonathan P. Hiatt & Deborah Greenfield, *The Importance of Core Labor Rights in World Development*, 26 MICH. J. INT'L L. 39, 41 (2004) (articulating how labor and trade linkage provisions respect domestic labor law as well as core labor rights).

¹⁹⁸ See *Mission and Objectives*, ILO, <http://www.ilo.org/global/about-the-ilo/mission-and-objectives/lang--en/index.htm>; see also *ILOLEX Database of Int'l Labour Standards, Ratification by Country or by Convention*, ILO, <http://www.ilo.org/ilolex/english/newwratframeE.htm>.

¹⁹⁹ *ILOLEX Database of Int'l Labour Standards*, *supra* note 198.

²⁰⁰ ILO Convention (No. 182) Concerning the Prohibition and Immediate Action for the Elimination of the Worst Forms of Child Labour, art. 7(2)(d), June 17, 1999, S. Treaty Doc. No. 106-5 (1999), 2133 U.N.T.S. 151 [hereinafter Worst Forms of Child Labour Convention].

²⁰¹ *Id.* art. 7(2)(d).

the treatment, in fact, produces the results claimed under prescribed conditions.²⁰² As such, hESC-based therapy must be treated as experimental and conducted only in clinical trials until accepted as standard medical treatment.²⁰³ Once hESC-based therapies are categorized as research instead of treatment, the informed consent requirements of the Nuremberg Code and Declaration of Helsinki must apply. Additionally, Article 16 of the Oviedo Convention must be codified in international regulations to harmonize standards in determining when it is permissible to conduct research on human subjects.²⁰⁴ The principles from these treaties, taken with the ISSCR guidelines, form the basis to develop a comprehensive international regulatory framework.

3. Using the ISSCR guidelines and model treaties to create an international framework for regulating hESC-based therapy

To address vulnerable populations lured by deceptive and misleading advertising, the international community should adopt key principles from the WHO FCTC to ban all misleading advertising promoting hESC-based therapies.²⁰⁵ Certainly, it is inevitable that spotlighting this issue internationally will bring about heightened public awareness.

Proposed hESC regulations must also address the lack of international regulations²⁰⁶ by requiring each ratifying State to take legislative action, or promote existing laws, to address clinics offering unregulated hESC-based therapies.²⁰⁷

The draft hESC regulations (Draft Treaty), attached to this Note as Appendix A, is based on, and adapted from, the ISSCR guidelines and the previously discussed treaties.²⁰⁸ The Draft Treaty, if implemented, would require ratifying States to: (i) declare all hESC-based therapies as experi-

²⁰² *Rutherford*, *supra* note 93.

²⁰³ *See generally* INDIAN DEP'T OF BIOTECHNOLOGY & INDIAN COUNCIL OF MED. RESEARCH, GUIDELINES FOR STEM CELL RESEARCH AND THERAPY (2007). Despite India's guidelines, there are still reports that unregulated hESC therapies are offered at clinics in India. *See Kiatpongsan & Sipp*, *supra* note 17.

²⁰⁴ Oviedo Convention, *supra* note 103.

²⁰⁵ *See* WHO Framework Convention on Tobacco Control, *supra* note 189.

²⁰⁶ Kiatpongsan & Sipp, *supra* note 17.

²⁰⁷ *See, e.g.*, WHO, Revision of the International Health Regulations, *supra* note 187; WHO Framework Convention on Tobacco Control, *supra* note 189; Convention on the Rights of Persons with Disabilities, *supra* note 191; and Worst Forms of Child Labour Convention, *supra* note 200.

²⁰⁸ *See Guidelines for the Clinical Translation of Stem Cells*, *supra* note 21; *see also* Oviedo Convention, *supra* note 103; WHO, Revision of the International Health Regulations, *supra* note 187; WHO Framework Convention on Tobacco Control, *supra* note 189; Convention on the Rights of Persons with Disabilities, *supra* note 191; and Worst Forms of Child Labour Convention, *supra* note 200.

mental and allowable only in a clinical trial setting—until accepted as routine medical practice; (ii) promote public awareness regarding the medical efficacy and safety of hESC-based therapies; (iii) ban all misleading advertising promoting hESC-based therapies; and (iv) take legislative action to ensure criminal and civil liability for clinics offering unregulated hESC-based therapies.

And, while the attached Draft Treaty represents another key step towards regulating hESC-based therapies, there are potential roadblocks and objections to overcome.

4. Roadblocks to achieving international regulation

Because 13 different countries already approve the ISSCR guidelines, garnering further consensus through United Nations action is quite promising.²⁰⁹ At the same time, treaties can take a very long time to pass and presumably longer yet to implement. For example, it took 21 years from the inception of the CRPD to when it became international law.²¹⁰ While reaching consensus may be a time consuming process, the impact of global consensus can be instrumental in changing State practices. For instance, shortly after the passage of the Worst Forms of Child Labour Convention, Indonesia became one of the first countries to take action to end the employment of 1,900 children working on dangerous fishing platforms.²¹¹ Thus, criticizing the lawmaking process as slow is not sufficient reasoning for abandoning a solution altogether.

Of greater concern than the speed of implementation is the fact that the countries most likely to enter into a treaty are not likely to be the same countries that allow clinics to exploit vulnerable patient populations. While this is a relevant criticism, the very fact that international law condemns such practices will raise public awareness and help mitigate instances of

²⁰⁹ Hyun et al., *supra* note 180, at 609.

²¹⁰ Arthur O'Reilly, *A UN Convention on the Rights of Persons with Disabilities: the Next Steps*, 17 *DISABILITY WORLD* (2003), http://www.disabilityworld.org/01-03_03/news/unconvention.shtml.

²¹¹ Press Release, Int'l. Labour Org., *ILO Worst Forms of Child Labour Convention Comes into Force*, (Nov. 17, 2000) (available online at http://www.ilo.org/global/About_the_ILO/Media_and_public_information/Press_releases/lang--en/WCMS_007917/index.htm). The ILO highlights several other examples of the impact of the Worst Forms of Child Labour Convention. *Id.* Examples in the ILO's press release have included: (1) the establishment of child labour training courses for all officials of the education department in Bangladesh; (2) the development of a National Plan of Action for the eradication of the worst forms of child labour in South Africa; (3) large-scale projects on commercial agriculture and fireworks production; and (4) the development of large-scale projects on domestic service, child prostitution, mining and child soldiers. *Id.*

unsuspecting stem cell tourists traveling abroad to receive putative therapies.

The international community can infer from the FCTC's findings that exposure to tobacco advertisements increases the use of tobacco, and analogously, exposure to hESC-based therapy advertisements increases the occurrence of stem cell tourism.²¹² The FCTC chose to reduce the use of tobacco by advocating for a comprehensive ban on tobacco advertising, promotion, and sponsorship.²¹³ Here, by increasing public awareness about putative hESC-based therapies and decreasing the means of advertisement, promotion, and sponsorship, the rate of stem cell tourism for these types of therapies should decrease.

Also, it may be unfair to presume that all individuals and clinics offering putative hESC treatments have only financial or self-serving interests—some may truly believe that the treatments work. However, without clinical efficacy, mere belief that a treatment is effective, without valid proof, is not sufficient reasoning to expose patients to undue risk—regardless of the size of economic or career impact. Further, this violates the WMA's medical ethics guidelines to “act in the patient's best interest when providing medical care.”²¹⁴

Lastly, critics will argue that hESC-based therapy regulations will limit the freedom of choice for global citizens in the selection of medical care. However, this is not a sufficient reason to jeopardize the health and financial well-being of vulnerable patient populations or expose the public to unstable biological hazards. The ability and right of legislatures to protect the health, safety, and welfare of the public has been upheld time and time again.²¹⁵

IV. CONCLUSION

Unregulated hESC-based therapies have transcended the national stage into a global forum in need of international regulation. Several model declarations and treaties serve as effective examples to develop and imple-

²¹² FCTC GUIDELINES FOR IMPLEMENTATION, *supra* note 190, at 49–59.

²¹³ *Id.*

²¹⁴ WMA INT'L CODE OF MED. ETHICS, *supra* note 90.

²¹⁵ *See, e.g.*, *Dent v. West Virginia*, 129 U.S. 114 (1889) (examining the scope of the states' discretion to regulate the practice of medical care); *Lawton v. Steele*, 152 U.S. 133 (1892) (outlining the power of the state to abate nuisances under the police powers); *Austin v. Tennessee*, 179 U.S. 343 (1900) (upholding Tennessee's limits on the sale of cigarettes); *Compagnie Francaise de Navigation a Vapeur v. State Board of Health*, 186 U.S. 380 (1902) (upholding the state power to quarantine interstate commercial goods to protect the public); *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) (upholding the constitutionality of Massachusetts mandatory vaccination laws and declaring that persons are subjected to restraints and burdens in order to secure the general comfort, health, and prosperity of the State).

ment key portions of the ISSCR guidelines to protect human dignity and public health and promote the obligation of a physician to do no harm.

Action by the U.N. Security Council is one immediate solution to require States to mandate international regulation of hESC-based therapies. Additionally, the attached Draft Treaty is a step in the right direction to protect all man-kind.²¹⁶ All three solutions discussed can promote global best practices in—and accelerate the promise of—translational stem cell therapies, while protecting the public health. If any of the solutions are implemented, they will, at a minimum, reduce the number of unregulated clinics offering putative and potentially harmful hESC-based therapies.

The international community has come together to address many human rights and public health issues in the past. Now is the time for the United Nations to address clinics offering unsafe hESC-based therapies and prompt the collaboration of the international community to advance science while ensuring human dignity.

Just as science continues to quickly evolve, there are new regulatory pathways to explore. Further research should apply lessons learned from trade regulations and explore ways that international trade and commerce laws can reward model stem cell clinics and penalize rogue clinics that violate international regulations. Specific areas to advance include: strengthening enforcement mechanisms, enhancing border control techniques, establishing an international accreditation process, and imposing sanctions on countries that detract from the promise of hESC-based therapies.

APPENDIX A

DRAFT LANGUAGE OF A MODEL HESC TREATY²¹⁷

WHO Framework Convention on Human Embryonic Stem Cell-Based Therapies

Preamble

The Parties to this Convention,

Determined to give priority to their right to protect public health,

²¹⁶ See *infra* Appendix A.

²¹⁷ Author of this Note adopted and tailored language from the following guidelines and treaties: *Guidelines for the Clinical Translation of Stem Cells*, *supra* note 21; Oviedo Convention, *supra* note 103; WHO, Revision of the International Health Regulations, *supra* note 187; WHO Framework Convention on Tobacco Control, *supra* note 189; Convention on the Rights of Persons with Disabilities, *supra* note 191; and Worst Forms of Child Labour Convention, *supra* note 200.

Seriously concerned about the potential adverse impacts of human embryonic stem cell (hESC) based treatments offered without peer-reviewed safety and efficacy data from clinical trials,

Recognizing that cooperative action is necessary to protect patients from receiving unproven hESC-based therapies to mitigate the potential of suffering adverse health outcomes as a result,

Conscious of the valuable work being conducted by many States on hESC transplantation regulation and commending the leadership of the World Health Organization as well as the efforts of other organizations and bodies of the United Nations and other international and regional intergovernmental organizations in developing measures on regulating the clinical application of hESCs,

Recalling Article 12 of the International Covenant on Economic, Social and Cultural Rights, adopted by the United Nations General Assembly on 16 December 1966, which states that it is the right of everyone to the enjoyment of the highest attainable standard of physical and mental health,

Recalling also the preamble to the Constitution of the World Health Organization, which states that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition,

Determined to promote clinical translation of hESC-based therapies based on current and relevant scientific, technical and economic considerations,

Conscious that the misuse of biology and medicine may lead to acts endangering human dignity,

Stressing the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine,

Resolving to take measures as necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to the application of biology and medicine,

Have agreed, as follows:

Article 1

Allowing hESC-based Therapies in Approved Clinical Trials

The Parties undertake to develop and promote national research and to coordinate research programs at the regional and international levels in the field of hESC clinical applications. Each party shall only conduct hESC research on human subjects when:

- (a) there is no alternative of comparable effectiveness to research on humans;
- (b) the risks which may be incurred by that person are not disproportionate to the potential benefits of the research;
- (c) the research project has been approved by a competent institutional review board or other regulatory body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical ability;
- (d) the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection; and
- (e) the persons undergoing research have expressly given free and informed consent that is then documented.

Article 2

Education, Communication, and Public Awareness

Each party shall promote and strengthen public awareness of hESC-based therapies, using all communication tools, as appropriate. Towards this end, each Party shall adopt and implement effective legislative, executive, administrative or other measures to promote:

- (a) broad access to effective and comprehensive educational and public awareness programs on the health risks of receiving unregulated hESC-based therapies;
- (b) public access, in accordance with national law, to a wide range of information on hESC-based therapies; and
- (c) awareness and participation of public and private agencies and non-governmental organizations in developing and implementing intersectoral programs and strategies for hESC-based therapy regulation.

Article 3

Advertising, Promotion, and Sponsorship of hESC-based Therapies

1. Parties recognize that a comprehensive ban on advertising, promoting, and sponsorship of unregulated hESC-based therapies would reduce the availability of such unregulated hESC-based therapies to vulnerable patient populations.

2. Each Party shall, in accordance with its constitution or constitutional principles, undertake a comprehensive ban on all unregulated hESC-based therapy advertising, promotion, and sponsorship. This shall include a comprehensive ban on cross-border advertising, promotion, and sponsorship origination from its territory. In this respect, within the period of five years after entry into force of this Convention for that Party, each Party shall undertake appropriate legislative, executive, administrative or other measure to ban such advertisements, promotions, and sponsorships.

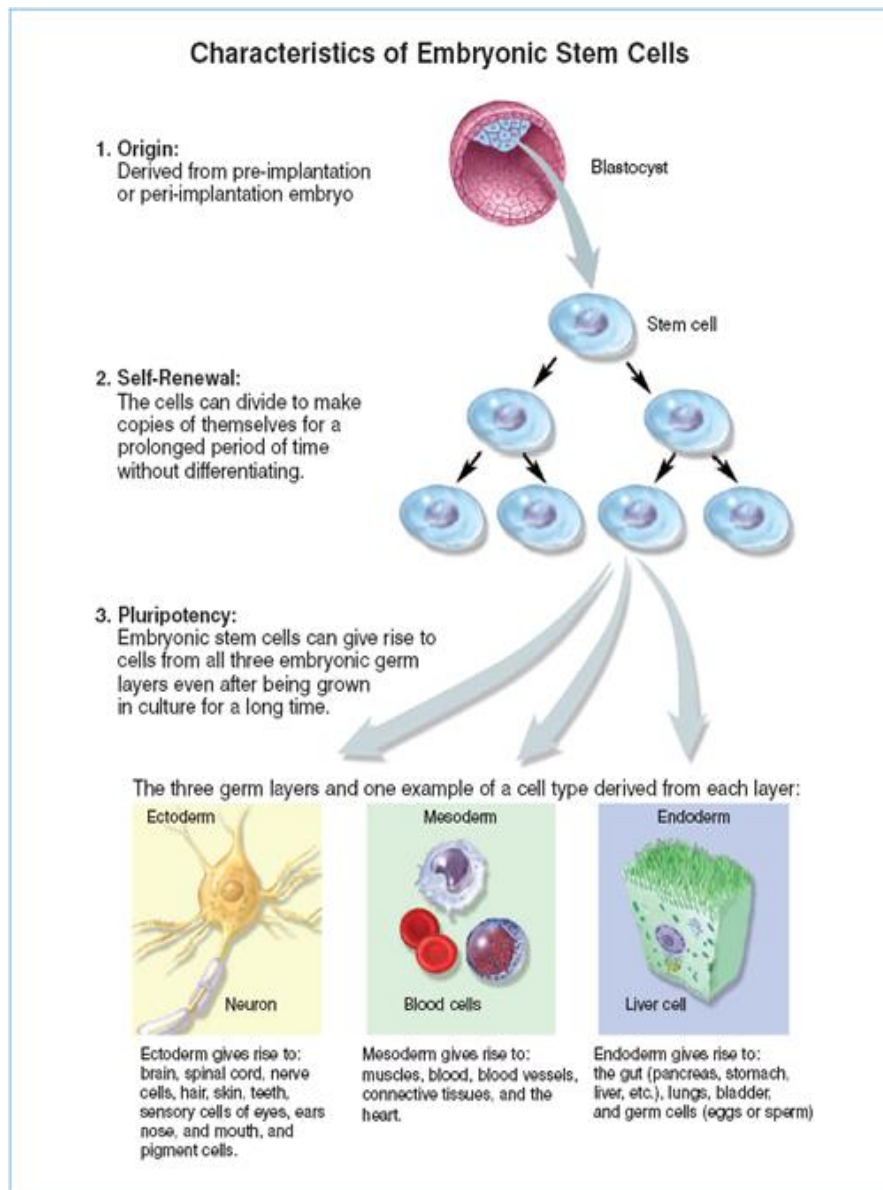
Article 4

Protection from Exposure to Unregulated hESC-based Therapies

1. Parties recognize that scientific evidence has not established the safety and efficacy of hESC-based therapies as standard medical treatment and until such data is available, any proposed hESC-based therapy must be conducted in a clinical trial setting that has been approved by an institutional review board.

2. Each Party shall adopt and implement in areas of existing national jurisdiction as determined by national law, and actively promote at other jurisdictional levels, the adoption and implementation of effective legislative, executive, administrative and other measures, providing for protection from unregulated hESC-based therapies.

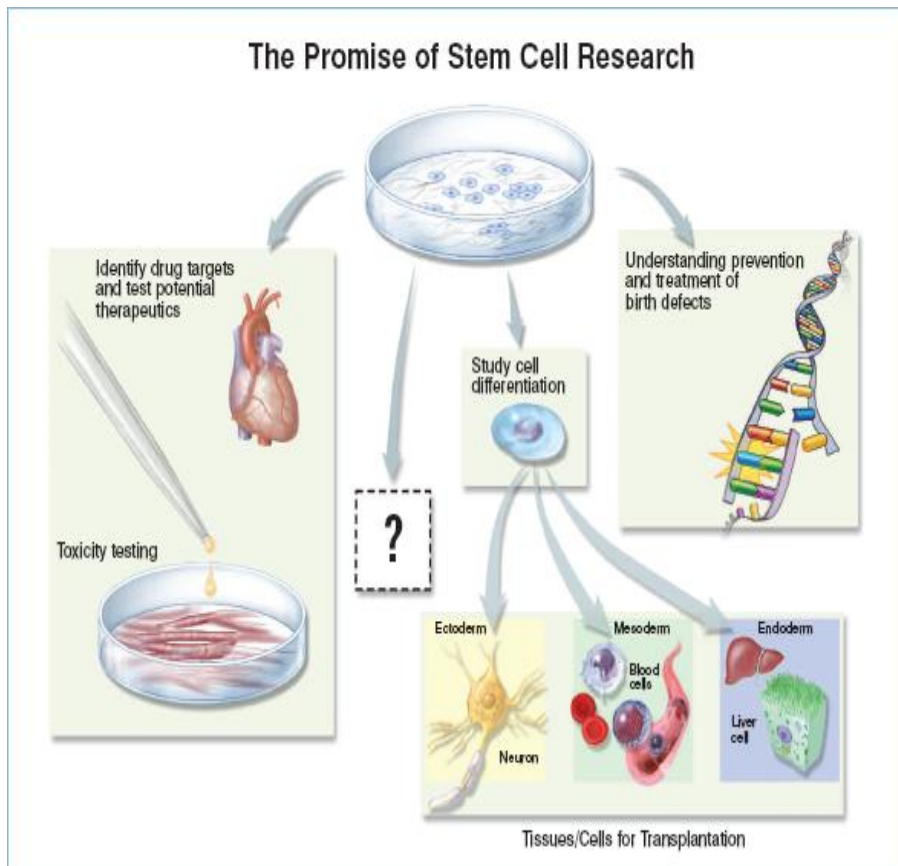
3. For the purpose of this Convention, the parties shall take legislative action or promote existing laws to deal with criminal and civil liability, including allowing compensation for individuals injured by unregulated hESC-based therapies where appropriate.

APPENDIX B²¹⁸

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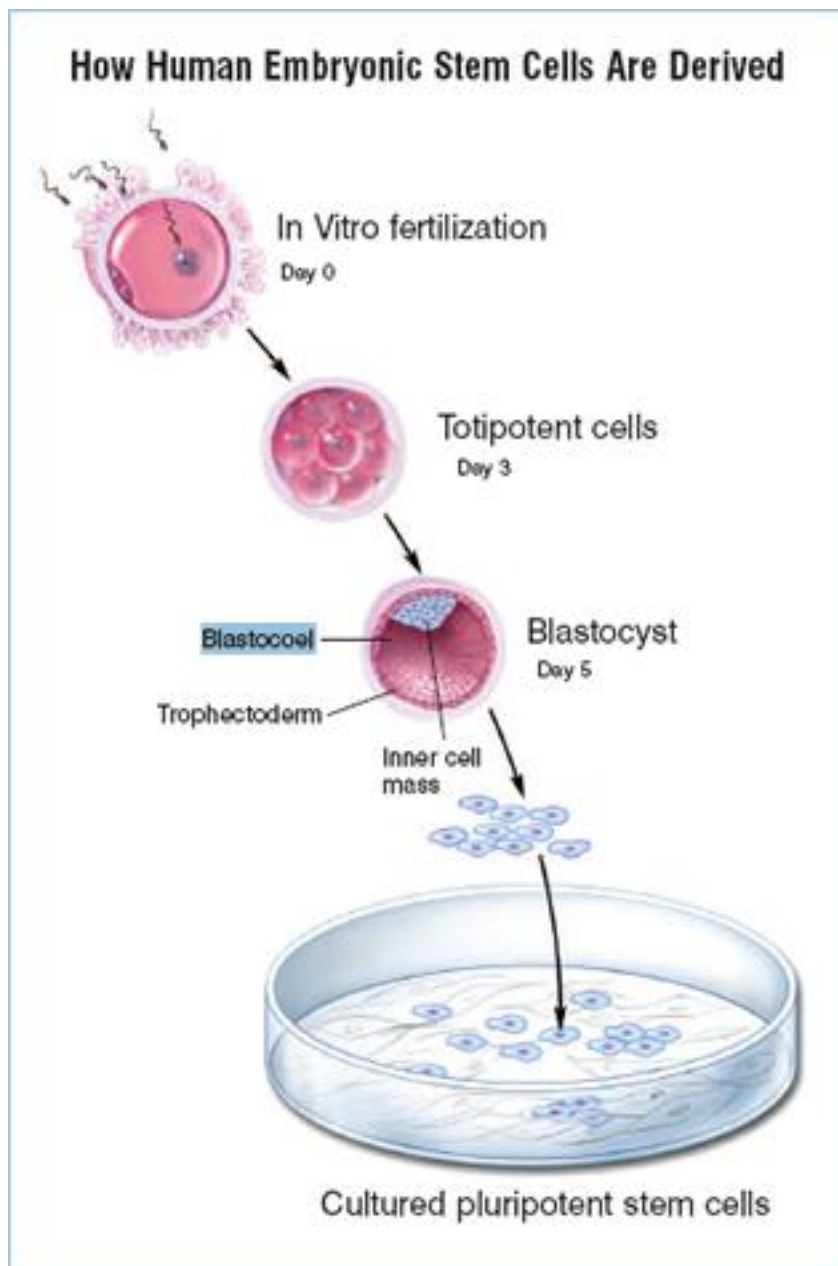
²¹⁸ U.S. DEP'T OF HEALTH AND HUMAN SERVICES, REGENERATIVE MEDICINE, *supra* note 6, at 2 fig. 1.2.

APPENDIX C²¹⁹



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²¹⁹ U.S. DEP'T OF HEALTH AND HUMAN SERVICES, REGENERATIVE MEDICINE, *supra* note 6, at 3 fig. 1.3.

APPENDIX D²²⁰

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²²⁰ U.S. DEP'T OF HEALTH AND HUMAN SERVICES, REGENERATIVE MEDICINE, *supra* note 6, at 1 fig. 1.1.