SMU Science and Technology Law Review

Volume 25 | Number 2 Article 7

2022

Creating a United Front: Harmonizing the United States Regulatory Policies Surrounding Human Embryonic Stem Cell Research

Sydney Kossow
Southern Methodist University, Dedman School of Law

Creating a United Front: Harmonizing the United States Regulatory Policies Surrounding Human Embryonic Stem Cell Research

*Sydney Kossow**

ABSTRACT

Stem cell therapy is an imperative development in science and medicine that is heavily regulated worldwide. With the potential to cure illnesses, help understand disease development, and advance regenerative medicine, a harmonized regulatory policy is crucial to capitalize on the benefits of stem cells. This article examines an important topic of discussion surrounding stem cell therapy and research: the political debate on how and when embryonic stem cells can be used. In addition to examining ethical challenges, this article discusses the legal challenges surrounding using embryonic stem cells to inform regenerative therapies. Specifically, this article will examine the National Institute of Health's Guidelines for Human Stem Cell Research and the historic avenues of federal and state legislation to regulate the use of these cells in research. This article discusses the internal and external inconsistencies of the United States' current regulation of embryonic stem cells and how the divide between states is problematic for the United States' completive stance in developmental science and medicine. Finally, this article contemplates a cohesive regulatory system influenced by individual states and other countries that currently lead the medical field, to form a united front in approaching the use of stem cells.

I. INTRODUCTION

In December 2012, Kyle and Carla Poppleton were expecting their first child.[1] The couple, who lived in Botswana, decided to collect their new baby's cord blood and tissue cells to take advantage of the new advanced form of medicine, stem cell therapy, and safeguard their new child's health.[2] In March 2013, the Poppletons welcomed their daughter Paige into the world.[3] Within just a year Paige was diagnosed with cerebral palsy, and by the next six months she could not sit up and kept her right hand in a fist shape most of the time.[4] In April 2014, Paige's umbilical cord blood stem cells were transferred to Duke University in North Carolina, where the cells

DOI: https://doi.org/10.25172/smustlr.25.2.7

* Sydney Kossow is a 2023 J.D. candidate at SMU Dedman School of Law.

1. Shamshad Ahmed, *How Stem Cell Therapy Changed Our Lives*, SMART CELLS (Dec. 19, 2017), https://www.smartcells.com/how-stem-cell-therapy-changed-our-lives-three-real-life-stories/ [https://perma.cc/8WY7-F6Z4].

2. *Id.*

3. *Id.*

4. *Id.*

were transplanted and reinfused into Paige's body.[5] Two months after the infusion Paige began crawling, pulling herself to stand up, and holding her parents hands once again.[6] This story, and thousands of others like it, is an encouraging endorsement of stem cell research and the life-changing healing powers it has and can continue to provide in the medical space.[7]

Stem cell therapy is a groundbreaking part of science and medicine taking over the globe.[8] Stem cells show great promise in aiding to find cures for illnesses, understand the development of diseases, and advance regenerative treatment in ways that no other scientific research has been able to do.[9] While certain aspects of stem cell therapy and research are legal in the U.S., the use of stem cells, and more specifically the use of embryonic stem cells, has been heavily restricted through legislation and regulation.[10] Although there is a bright future for human embryonic stem cell research, its development is halted by many legal and ethical challenges.[11] This article will first look at the history of stem cell research and its growing potential in the medical science realm. Next, this article will unpack legal issues surrounding the use of stem cells in regenerative research and therapy and introduce policy arguments for and against the legality of embryonic stem cell research. This article will also touch on how the internal and external inconsistencies of U.S. regulation surrounding stem cell research impede biotechnology advances.[12] Lastly, this article will focus on stem cell regulations across the globe and explore what a new regulation system in the U.S. might look like with the influence of other countries and individual states that are currently leading the medical field.

---

5. *Id.*

6. *Id.*

7. *See* Ahmed, *supra* note 1.

8. *See* Piotr Rewerski, *The Need for a New U.S. Stem Cell Research Policy: A Comparative Look at International Stem Cell Research Laws*, 2007 U. ILL. J.L. TECH. & POL'Y 415, 417–18 (2007).

9. *See id.*

10. *See id.* at 418.

11. Li Jiang, *Will Diversity Regulations Disadvantage Human Embryonic Stem Cell Research: A Comparison Between the European Union and the United States*, 25 DEPAUL J. ART, TECH. & INTELL. PROP. L. 53, 55 (2014).

12. *Id.*

II. WHAT IS STEM CELL THERAPY?

A. What Are Stem Cells?

A stem cell is a single cell from the human body with the capacity to replicate itself (self-renew) and differentiate itself into various cell types.[13] The characteristic of differentiating itself is also known as "specializing."[14] Stem cells are considered *unspecialized*, meaning they can transform into *specialized* types of cells like bone or muscle cells.[15]

There are two main types of stem cells: embryonic and adult.[16] Embryonic stem cells are derived from embryos and have virtually unlimited potential to replicate into every kind of cell in the body, a characteristic known as "pluripotent."[17] Deriving embryonic stem cells requires the embryo to be destroyed, which has sparked many of the legal and ethical arguments discussed later in this article.[18] Three types of embryos are currently being pursued when it comes to stem cell research: (1) embryos intended to create a child, (2) embryos created in the process of in vitro fertilization (IVF) but not implanted, and (3) embryos created specifically for research purposes.[19] The use of embryonic stem cells is legal in some states; however, it is heavily restricted, and this article will discuss this further in the following sections.[20]

On the other hand, adult stem cells can be extracted from certain types of tissue with minimal bodily intrusion.[21] The extraction of adult stem cells is thus less controversial because it does not require destroying any organism.[22] The drawback to adult stem cells is that they are "multipotent," meaning they can only replicate a limited number of other types of cells in comparison to

13. Sylvia E. Simson, *Breaking Barriers, Pushing Promise: America's Need for an Embryonic Stem Cell Regulatory Scheme*, 34 BROOK. J. INT'L L. 531, 537 (2009).

14. *Id.*

15. Allison B. Newhart, *The Intersection of Law and Medicine: The Case for Providing Federal Funding for Embryonic Stem Cell Research*, 49 VILL. L. REV. 329, 330 (2004).

16. *Id.*

17. Amy Miller, *The Effect of Federal Funding Restrictions for Embryonic Stem Cell Research on Colleges and Universities: The Need for Caution When Ethical Objections to Research Are Raised*, 41 J.C. & U.L. 147, 154–55 (2015).

18. *Id.* at 153.

19. Christopher Ogolla, *Reversing the United States Policy on Human Embryonic Stem Cell Research: A Case of Science, Law and Policy, or Just Plain Politics*, 35 T. MARSHALL L. REV. 91, 94 (2009).

20. *See generally* Rewerski, *supra* note 8.

21. Miller, *supra* note 17, at 154.

22. *Id.*

embryonic cells.[23] Scientists have recently succeeded in transforming adult cells into stem cells that act similarly to embryonic cells using genetic reprogramming.[24] While this provides exciting hope for the future of stem cell therapy, scientists have yet to ensure the safety of this process and cannot definitively say whether using reprogrammed adult cells will cause adverse effects on the human body.[25]

Without the reassurance that reprogrammed adult cells are safe to use in the human body, many researchers advocate for the use of embryonic stem cells.[26] Researchers tend to prefer the use of embryonic stem cells over adult stem cells for a few other main reasons: (1) embryonic stem cells are pluripotent and have the potential to differentiate into any specialized human cell type; (2) embryonic stem cells have the ability to grow into large numbers of specialized cells through a controlled laboratory setting; and (3) embryonic stem cells are abundant in comparison to adult cells.[27] While researchers have been surprised at the adaptability and promise of working with adult stem cells, adult stem cells are more likely to contain abnormalities and often carry a risk to humans due to the environmental hazards of cell replication.[28] These reasons weigh in favor of using embryonic stem cells over adult cells for the time being when it comes to regenerative medicine.[29]

B. How Do Stem Cells Work?

Stem "cell therapy focuses on aiding the regeneration process of the muscle cells" in the body.[30] Researchers can grow stem cells in a lab, manipulating them into specific types of cells to be used to repair the response system of diseased, dysfunctional, or injured tissue.[31] Most stem cells have the ability to transform by separating without limit, dividing, and transforming into a new kind of cell.[32]

---

23. Edward A. Fallone, *Funding Stem Cell Research: The Convergence of Science, Religion & Politics in the Formation of Public Health Policy*, 12 MARQ. ELDER'S ADVISOR 247, 253–54 (2011).

24. *Stem Cells: What They Are and What They Do*, MAYO CLINIC, (Mar. 19, 2022), https://www.mayoclinic.org/tests-procedures/bone-marrow-transplant/in-depth/stem-cells/art-20048117 [https://perma.cc/7FLS-AWKP].

25. *Id.*

26. *See id.*

27. Newhart, *supra* note 15, at 331.

28. MAYO CLINIC, *supra* note 24.

29. *See id.*

30. NEIL H. RIORDAN, STEM CELL THERAPY A RISING TIDE: HOW STEM CELLS ARE DISRUPTING MEDICINE AND TRANSFORMING LIVES 9 (2017).

31. MAYO CLINIC, *supra* note 24.

32. Samuel D. Hodge, Jr., *A Medical/Legal Perspective on Stem Cell Therapy: A Scientific Breakthrough or Snake Oil*, 83 ALB. L. REV. 89, 90 (2019–2020).

There are four outcomes that can happen with the life of a stem cell.[33] The first fate is a common one, being that the stem cell remains inactive, thus not dividing or differentiating into any other kind of cell.[34] The second fate of a stem cell is called symmetric self-renewal; in this situation the parent cell divides into two daughter cells that are exactly the same as the parent cell.[35] While this fate is not considered differentiation, it does increase the pool of specialized stem cells that can then be used for differentiation in the future.[36] Thirdly, a stem cell can participate in what is called asymmetric self-renewal.[37] Similar to symmetric self-renewal, asymmetric self-renewal results in a parent stem cell dividing into two daughter cells; however, in this instance, one daughter cell is a copy of the parent and the other is a more specialized cell named a progenitor cell.[38] This progenitor cell can then be used for natural tissue development or regeneration and also provides the benefit of maintaining the stem cell pool for the future.[39] The fourth fate of a stem cell is when a stem cell divides into two daughter cells, but both daughter cells are differentiated from the parent cell.[40] While this process does not maintain the stem cell pool it does result in a greater proliferation of differentiated cells for tissue development or regeneration.[41]

After a stem cell has been transformed into a specialized cell, through one of the processes described above, it can then be implanted into a person to start the regeneration process.[42]

C. Why Are Stem Cells Becoming Popular, And Why Does Anyone Care?

This form of medicine is making headlines because there are endless amounts of benefits derived from using stem cell therapy in the medicinal sphere.[43] These benefits include an increase in the understanding of how diseases occur, development and testing of new drugs, tissue regeneration, and

33. Jesse K. Biehl & Brenda Russell, *Introduction to Stem Cell Therapy*, NATIONAL INSTITUTES OF HEALTH PUBLIC ACCESS (July 21, 2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4104807/ [https://perma.cc/EW8U-ZLFR].

34. *Id.*

35. *Id.*

36. *Id.*

37. *Id.*

38. *Id.*

39. Biehl & Russell, *supra* note 33.

40. *Id.*

41. *Id.*

42. *See generally* MAYO CLINIC, *supra* note 24.

43. *Id.*

cures for diseases that are a significant area of focus for the medical community around the world.[44]

Researchers and doctors hope to better understand the processes in which diseases and conditions develop in the human body by watching stem cells mature into differentiated cells such as heart muscles, nerves, and other tissues or organs.[45] Additionally, by testing new drugs on stem cells, scientists and researchers can determine whether a new drug is safe for humans, which could potentially provide some solutions to ethical issues that surround drug and treatment testing on animals and humans.[46]

A wide range of people might benefit from stem cell therapies, including but not limited to people with spinal cord injuries, diabetes, Parkinson's disease, Alzheimer's disease, heart disease, cancer, strokes, and many more.[47] But stem cells do not only concern patients.[48] Stem cell research has become a popular and controversial topic because it "necessitates decisions from the political, legal, ethical, and religious realms," making it an important issue for many different groups of people outside of the medical field.[49]

III. LEGALITY AND REGULATORY CONCERNS REGARDING EMBRYONIC STEM CELLS

Most of the political and legislative debate surrounding stem cell research focuses on embryonic stem cells rather than adult stem cells.[50] This has allowed adult stem cells to be used in various clinical trials without much pushback.[51] While there is controversy in the scientific world regarding the capabilities of embryonic in comparison to adult stem cells, some scientists believe that adult stem cells have the power to do anything that can be accomplished with embryonic stem cells.[52] However, until scientists find a way to use adult stem cells in the same way that they could use embryonic stem cells, by transforming them into any type of cell, the superior therapeutic power of embryonic stem cells, and the debate regarding their legality, will continue in full force.[53]

---

44. *Id.*

45. *Id.*

46. *See id.*

47. *Id.*

48. *See* Chelsea L. Gulinson, *Embryonic Stem Cell Tourism*, 58 JURIMETRICS J. 17, 41 (2017).

49. *Id.*

50. Hodge, *supra* note 32, at 93.

51. *Id.* at 94.

52. Simson, *supra* note 13, at 539.

53. *See id.*

Due to the fact that there are extremely polarized beliefs regarding stem cell research, "political branches have been locked in a stalemate" for the past thirty years when it comes to administrative policy.[54] Furthermore, successive U.S. presidents have fallen on both sides of the polarized debate, leading to inconsistent administrative policies.[55]

The regulation of stem cell research and therapies in the U.S. thus operates at both the federal and state levels.[56] Because the U.S. has no uniform regulation at the federal level, state legislators took matters into their own hands by developing differentiated state regulations.[57] These varying policies create an incohesive system, hindering the ability of the U.S. to capitalize on this field of science and medicine.[58] Additionally the varying policies threaten cooperative attempts between the states to progress together in scientific studies of stem cells.[59]

A. National Institutes of Health Guidelines for Human Stem Cell Research

In 1985, Congress enacted a ban on most fetal research thereby banning research on embryonic stem cells.[60] Following the 1985 ban, Congress amended the National Institute of Health's (NIH) appropriations bill, which is the primary source of federal funding for medical and life science research projects throughout the U.S.[61] In 1995, the Dickey-Wicker Amendment was added to the NIH appropriations bill, which prohibited the use of any federal funds for any research that destroys or endangers human embryos.[62] To harvest new stem cells the embryo must be destroyed.[63] Therefore, the Dickey-Wicker Amendment meant that federal funding would be permitted only in cases where embryonic stem cells had already been extracted BEFORE the project's funding began.[64]

President Bush announced an executive order in 2001, easing the Dickey-Wicker strain on stem cell research and allowing federal funds to be

54. Gulinson, *supra* note 48, at 33.

55. *Id.*

56. Jiang, *supra* note 11, at 78.

57. *Id.* at 79.

58. *Id.*

59. *Id.* at 88.

60. Thomas W. Mayo, *Embryonic and Fetal-Cell Research*, 1 HEALTH L. PRAC. GUIDE § 15:20 (2022).

61. Miller, *supra* note 17, at 148–49.

62. *Id.*

63. *See id.* at 149.

64. *Id.*

awarded for research that used human embryonic stem cell lines.[65] However, to be awarded the federal funds, the embryonic stem cell lines had to meet certain criteria, for example, "when the life and death decision has already been made."[66] This expanded the ability of research to be done on some embryonic stem cells, yet only sixty cell lines met the specifications for this executive order.[67] Bush's policy did not affect private or state-funded research, nor did it affect adult stem cell research.[68]

A few years later, President Bush vetoed the Stem Cell Research Enhancement Act of 2007 (2007 Act), which was aimed at amending the Public Health Service Act to provide for human embryonic stem cell research.[69] The 2007 Act explicitly endorsed human embryonic stem cell research, stating that such research would be federally funded and the Secretary would conduct the research.[70] Had President Bush not vetoed the 2007 Act, federal funding for stem cell research would have expanded to include stem cells created for, but not used in, the in vitro fertilization (IVF) process.[71]

After Bush left office in 2009, President Obama issued an executive order which removed barriers created by President Bush's previous executive order.[72] Obama's executive order made room for federal funding from the NIH, but it did not come without limits.[73] President Obama placed three general restrictions on the use of embryos for stem cell research, including that research had to be (1) done responsibly, (2) scientifically worthy, and (3) permitted by law.[74]

In response to President Obama's executive order, the NIH published draft guidelines for federal funding using human embryonic stem cells in order to impose restrictions on research.[75] These restrictions stated that, in accordance with Dickey-Wicker, no NIH funding would be given to support the derivation of stem cells from human embryos, but funding would be granted for research done on embryonic stem cells that had already been

65. Ogolla, *supra* note 19, at 99.

66. Mayo, *supra* note 60.

67. *Id.*

68. *A Brief History of U.S. Stem Cell Policy*, Research America, https://www.researchamerica.org/advocacy-action/issues-researchamerica-advocates/stem-cell-research/brief-history-us-stem-cell (last visited September 7, 2022) [https://perma.cc/2TTQ-W7BQ].

69. Simson, *supra* note 13, at 551-52.

70. *Id.* at 551.

71. Research America, *supra* note 68.

72. *Id.*

73. *See* Miller, *supra* note 17, at 173.

74. *Id.*

75. *Id.* at 174.

derived.[76] Therefore, even after lifting the restrictions placed during Bush's presidency, President Obama's executive order was still being limited by the Dickey-Wicker Amendment.[77] The Dickey-Wicker Amendment remains the primary regulatory construct under which the federal government restricts funding regarding embryonic research today.[78]

The D.C. Circuit upheld the NIH's guidelines regarding embryonic stem cells in *Sherley v. Sebelius*.[79] In *Sebelius*, researchers brought a claim arguing the NIH guidelines violated the Dickey-Wicker Amendment because previous decisions by the NIH to fund embryonic stem cell research should be considered null and void.[80] The district court concluded that stem cell research did not violate the Dickey-Wicker Amendment.[81] The court reasoned that the Dickey-Wicker Amendment bars funding for the destruction of an embryo in the act of deriving an embryonic stem cell; however, it does not explicitly prohibit the funding of research in which an embryonic stem cell will be used.[82] In holding this, the D.C. Circuit stated that an embryonic stem cell that was previously derived from an embryo is not an "embryo" for the purposes of the Dickey-Wicker Amendment.[83]

Since President Obama's executive order in 2009, a few other noteworthy issues have been regulated.[84] In 2016, President Obama signed the 21st Century Cures Act into law, which in part provided to assure the timely review of regenerative therapies, including research done through stem cells.[85] Then in 2019, the Department of Health and Human Services (HHS) issued a new policy that ended the allowance under NIH for intermural fetal tissue research.[86] Additionally, the policy enacted by HHS established an Ethics Advisory Board that evaluates all future extramural fetal tissue research projects, including those involving stem cells, and determines whether the projects should receive federal funding.[87] In 2020, the Ethics Advisory Board evaluated fourteen "extramural research proposals involving fetal tissue,"

76. *Id.*

77. *Id.*

78. *See id.* at 149.

79. Miller, *supra* note 17, at 175.

80. E. Johnathan Mader, *The Wholesale Human: The Ineffectuality of Responsive Regulation to Advancements in Reproductive Biotechnology Post Roe v. Wade*, 42 U. ARK. LITTLE ROCK. L. REV. 203, 215 (2019).

81. *Id.*; Miller, *supra* note 17, at 175.

82. Sherley v. Sebelius, 644 F.3d 388, 390 (2011).

83. *Id.* at 395.

84. *See* RESEARCH AMERICA, *supra* note 68.

85. *Id.*

86. *Id.*

87. *Id.*

and only one of the fourteen proposals was recommended to receive federal funding.[88] Finally, and arguably most important, in 2021, HHS amended its 2019 policy to no longer require an Ethics Advisory Board review for fetal tissue research and also allowed intramural research involving fetal tissue to resume.[89]

B. Federal Legislation

1. *The FDA's Control over Stem Cells*

Today, the U.S. Food and Drug Administration (FDA) regulates the progress of stem cell research and therapy.[90] Scientists would argue that stem cell research should be governed as a practice of medicine rather than as a drug, but a U.S. Court of Appeals holds otherwise.[91] In 2014, the case of *United States v. Regenerative Sciences LLC et al.* was decided by a three-judge panel from the D.C. Court of Appeals.[92] The court held that a treatment made from a patient's own processed stem cells constitutes a drug and is subject to regulation by the FDA.[93]

In addition to the case noted above, three statutes give the FDA regulatory authority over stem cell treatments.[94] These three statutes are the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Public Health Services Act (PHSA), and the 21st Century Cures Act.[95] The FD&C Act allows the FDA to regulate any drugs or devices intended for use regarding diagnosis, cure, treatment, or prevention of disease, along with any effect to the structure or function of the body.[96] For a new drug to be approved under the FD&C Act, the drug or device must prove safe and effective through clinical trials.[97]

Section 351 of the PHSA gives the FDA the authority to regulate interstate commerce that involves biological products, including any product used to prevent, treat, or cure a disease or condition of a human.[98] Section 361 of

88. *Id.*

89. *Id.*

90. *See Appeals Court Affirms That Stem-Cell Therapy is a Drug: United States v. Regenerative Sciences*, 30 No. 1 WESTLAW J. PHARM. 5, Feb. 21, 2014, at 1.

91. *See id.*

92. *Id.*

93. *See id.*

94. Sydney Hope, Comment, *When Miracle Cures Go Bad: Regulators' Responses to Unproven Direct-to-Consumer Stem Cell Therapies*, 23 SMU SCI. & TECH. L. REV. 257, 263 (2020).

95. *Id.*

96. *Id.*

97. *Id.*

98. *Id.* at 264.

PHSA allows the FDA to regulate in a manner necessary to prevent the introduction, transmission, or spread of diseases.[99]

Lastly, the 21st Century Cures Act creates a fast track review of definitive medicine if such a drug meets three criteria: (1) it is a regenerative therapy as defined by the Act, (2) it is "intended to treat, modify, reverse, or cure a serious life-threatening disease or condition," and (3) preliminary evidence, done through clinical trials, shows that the drug has potential to address unmet medical needs regarding said disease or condition.[100]

2. *Stem-Cell Treatment Approval*

By 2017, the only clinical pathway in the U.S. able to permit the use of stem cell research was the costly $1.2 billion route that allows for a new drug to be approved.[101] The big issue with this route is that since stem cells are not patentable, because they come from the human body, pharmaceutical companies are not interested in investing in the research.[102] If a pharmaceutical company were to bring a product to market, they essentially would not be able to exclusively own the product since no patent would be granted, therefore, getting funding is intrinsically difficult when it comes to bringing a new stem cell product to market.[103]

A regulatory path outside of clinical trials is as an investigational new drug (IND), which costs $700,000 for the application process alone.[104] By reason of these limited pathways, some scientists believe that the FDA's overreach into the regenerative medicine research area is stunting potential growth in an important frontier of science and medicine.[105]

"Thousands of stem cell trials have been completed or are ongoing," investigating "new combinations of stem cell products" for a range of diseases and conditions, which promises great progress to the world of regenerative medicine.[106] However, despite this progress, the FDA has only approved one stem cell product, hematopoietic.[107] Hematopoietic stem cells are blood-forming stem cells taken from cord blood and used to reconstitute a patient's blood and immune system after harsh treatments, such as radiation

99. *Id.*

100. Hope, *supra* note 94, at 264.

101. RIORDAN, *supra* note 30, at 231.

102. *Id.* at 232.

103. *See id.*

104. *Id.*

105. *See id.* at 233.

106. Sarah Duranske, *Reforming Regenerative Medicine Regulation*, 34 GA. ST. U. L. REV. 631, 636 (2018).

107. *Id.*

or chemotherapy.[108] Even though the only FDA-approved stem cell therapy is for diseases of the hematopoietic system, other stem cell therapies are being marketed through direct-to-consumer advertising.[109] For example, in 2021, 295 stem cell clinics located in the U.S. provided therapies without adequately disclosing the risk, efficacy, or regulatory approval status.[110] It follows that the FDA's attention to safety and efficiency during the drug application process is effectively slowing down the process of getting safe therapies to consumers, which allows clinical studies that have not proven their safety to monopolize the field.[111]

3. *The International Society for Stem Cell Research*

While not federal legislation, the International Society for Stem Cell Research (ISSCR) is considered the voice of the stem cell research community internationally and provides ethical and medical standards for researchers to follow when working with embryonic stem cells.[112] The ISSCR guidelines from 2016 prohibited research from being conducted on embryos fourteen days post-cultivation.[113] Most countries also follow some range of a fourteen day limit for using an embryo.[114] In May 2021, however, the ISSCR announced that it no longer endorses the international standard limiting embryonic research to fourteen days after fertilization.[115] Now the ISSCR leaves it up to the public, including national academies of science, academic societies, funders, and regulators to engage in scientific, societal, and ethical conversations to decide whether the fourteen day limit should be extended to projects depending on research objectives.[116]

---

108. *Id.*

109. Leah Nadel, Comment, *The Future of Stem Cell Therapy Regulation Under the FDA's Comprehensive Regenerative Medicine Policy Framework Through a Public Health Lens*, 21 HOUS. J. HEALTH L. & POL'Y 223, 233 (2021).

110. *Id.*

111. *See id.*

112. *See* Françoise Baylis, *Stem Cell Research Community Drops 14-Day Limitation on Human Embryo Research*, DALHOUSIE UNIVERSITY NEWS (June 1, 2021) https://www.dal.ca/news/2021/06/01/stem-cell-research-community-drops-14-day-limit-on-human-embryo-.html#:~:text=stem%20cell%20research%20community%20drops%2014%E2%80%91day%20limit%20on%20human%20embryo%20research,-Fran%C3%A7oise%20Baylis%20%2D%20June&text=applications%20of%20this%20research%20include,of%20embryos%20beyond%2014%20days [https://perma.cc/657K-JKR9].

113. *Id.*

114. *Id.*

115. *Id.*

116. *Id.*

C. State Legislation

Without a coordinated effort regarding stem cell research regulation from the U.S. Federal Government, the states are left to regulate independently.[117] Each state must answer the principal question of whether to permit or prohibit embryonic stem cell research.[118]

As of 2015, twenty-five states had enacted some type of regulation that banned the sale or research of embryos, fetuses, or both.[119] The states who have developed highly restrictive policies surrounding stem cell research have statutes falling into two general categories: (1) laws aimed to discourage research involving abortions, and (2) laws aimed to preclude research surrounding pre-implantation embryos.[120] Even when some of the anti-abortion states are otherwise supportive of research, their laws could impede the studies of embryonic stem cells that do not necessarily deal directly with abortions.[121]

Some states have chosen to widely permit research, even permitting reproductive cloning, whereas others permit stem cell research more narrowly.[122] Still, a handful of states have heavily restricted policies surrounding the research.[123] The wide range of policies creates an unharmonized front to the scientific and medical world.[124]

1. *Differing State Approaches*

Not all states have legislated on the issue of embryonic stem cell research but those that have legislated provide a guideline to understand the polarized stances in the U.S. surrounding stem cells.[125] On the one hand, states including Arkansas, Louisiana, North Dakota, and South Dakota specifically prohibit most or all forms of embryonic stem cell research.[126] On the other hand, Iowa permits embryonic stem cell research but does not fund it.[127] California provides both a right to conduct embryonic stem cell research

117. Jiang, *supra* note 11, at 79.

118. *Id.*

119. Nefi D. Acosta & Sidney H. Golub, *The New Federalism: State Policies Regarding Embryonic Stem Cell Research*, 44 J.L. MED. & ETHICS 419, 430 (2016).

120. *Id.*

121. *Id.*

122. *See id.* at 430–31.

123. *Id.* at 430.

124. *Id.*

125. *See* Acosta & Golub, *supra* note 119, at 430–31.

126. Simson, *supra* note 13, at 534.

127. *Id.*

and funding.[128] Then there are states in the middle, like North Carolina and West Virginia, that have no law on the subject, and states, like Florida that are deadlocked on the issue.[129]

Louisiana has the most restrictive research guidelines out of all states, and defines an embryo not even implanted in a woman's uterus as a "juridical person."[130] In short, Louisiana prohibits the use or destruction of embryos for research purposes under any circumstances.[131] Like Louisiana, states including South Dakota and Minnesota have statutes with similar prohibitions if the use of the embryo subjects the embryo to a substantial risk of injury and or death.[132]

Conversely, states like New Hampshire and Pennsylvania have enacted statutes that find research and experimentation on embryonic stem cells legal.[133] The Pennsylvania General Assembly proposed two bills in 2003, the Stem Cell Research Act and the Stem Cell Research Authorization Act.[134] Both of these bills allow for the research of embryos that have been donated from those who have leftover embryos prior to in vitro fertilization procedures, so long as they have agreed to donate such embryos specifically for obtaining stem cells for research.[135]

In 2004, the governor of New Jersey included a $6.5 million grant to build a research institute dedicated to stem cell research in the state budget allocation plan.[136] This marked the first state in the U.S. to provide funding for stem cell research.[137] California is another state providing state funding for stem cell research and proposed a ballot initiative in 2004 to raise $3 billion over the span of ten years to fund stem cell research in the state.[138] With its ballot initiative (Prop 71) in 2004, California became the largest and most influential state venturing into the realm of stem cell research, and can be used as an example for other states and the U.S. federal legislation.[139]

128. *Id.* at 548.

129. *Id.* at 535.

130. Newhart, *supra* note 15, at 340.

131. *Id.*

132. *Id.* at 340-41.

133. *Id.* at 341–42.

134. *Id.* at 342.

135. *Id.*

136. Newhart, *supra* note 15, at 361.

137. *Id.*

138. *Id.*

139. Acosta & Golub, *supra* note 119, at 418.

2. *California Prop 71*

Prop 71 was originated by a group of wealthy and political Californians who were raising

children with type 1 diabetes.[140] Stem cells hold great promise for diabetes research and treatment, which provided a strong incentive for these Californians to create this ballot initiative.[141] Prop 71 was not only a bond proposal it also notably amended the California Constitution to "establish a right to conduct stem cell research which includes research involving adult stem cells, core blood stem cells, pluripotent stem cells, and/or progenitor cells."[142] In addition to the descriptive amendment, Prop 71 also amended the California Constitution to create a new state agency, known as the California Institute for Regenerative Medicine (CIRM), which controls the allocation of grants and loans for stem cell research.[143] The CIRM is also authorized to establish regulatory standards and create oversight bodies related to stem cell research.[144]

One aspect of Prop 71 that stands out from all other regulations of stem cell research is its governance, which is overseen by an Independent Citizens Oversight Committee (ICOC).[145] While political bodies hold the oversight powers in many other regulatory systems, oversight of CIRM is "firmly in the hands of scientists and patients."[146] Reflecting a deep distrust of political and governmental influence Prop 71 attempts to combat political pressures by leaving oversight up to those directly in the line of stem cell research.[147]

In applying for funding and allowance to research on a line of cells, states generally take one of two approaches.[148] One is the peer review process undertaken by states including California, Connecticut, Maryland, New York, and Illinois.[149] The other is allocations made directly to state institutions, which is the approach taken by New Jersey and Massachusetts.[150] Other than coastal geography, there are several similar characteristics of these permissive states—each houses large research universities and active biotechnology industries, which means that these states have the resources

140. *Id.* at 421.

141. *See id.*

142. *Id.* at 423.

143. *Id.* at 424.

144. *Id.*

145. Acosta & Golub, *supra* note 119, at 424.

146. *Id.*

147. *Id.*

148. *Id.* at 427.

149. *Id.*

150. *Id.*

for research, and can expect economic benefits from successful research and treatment.[151]

3. *Why a Lack of Uniformity Among the States Matters*

While states have the ability to create their own laws on stem cell research, this ability presents a downfall to the U.S. when it creates such a wide range of policies throughout the country.[152] This lack of uniformity will put some states higher on the totem pole, both medically and economically, while others lag behind.[153] For the country as a whole, having this large of a range of policies across the map could make the U.S. appear polarized and in disarray, thus creating a disadvantage for being competitive in the medical field.[154]

IV. ARGUMENTS FOR AND AGAINST PERMISSIVE STEM CELL REGULATION

A. Opponents

Those who oppose the legality of embryonic stem cell research and therapy stand firmly on the argument that research involving embryonic stem cells violates current law and policy because it goes against the duty to protect potential life.[155] In other words, using embryos to harvest stem cells for research purposes is immoral.[156] The stem cell debates largely center around the ethical issues of collecting and using stem cells, but this debate did not begin solely with embryonic cells.[157] The catalyst case for this debate regarding life-sustaining cells started with the U.S. Supreme Court case, *Roe v. Wade*.[158] In *Roe*, the U.S. Supreme Court held that the Constitution did not support the view that life begins at conception.[159] Under *Roe*, the unborn were not considered persons, and had no constitutional right to life.[160]

151. Acosta & Golub, *supra* note 119, at 427.

152. *See* Simson, *supra* note 13, at 535.

153. *Id.*

154. *Id.*

155. *See* Ogolla, *supra* note 19, at 92.

156. *Id.*

157. *Id.* at 96.

158. *Id.*

159. Newhart, *supra* note 15, at 336–37.

160. *Id.*; *contra* Dobbs v. Jackson Women's Health Org., 142 S.Ct. 2228, 2261 (2022) ("Our [majority] opinion is not based on any view about if and when prenatal life is entitled to any of the rights enjoyed after birth.").

Public opinion and policy still seem to conflict with the Court's holdings in *Roe*.[161] Generally, there are at least three distinct perspectives regarding the definition of life.[162] The first perspective is proudly held by the Roman Catholic Church, which has a "long-standing belief that life starts the second the sperm meets and combines with an egg."[163] The second is held by scientists whose view is that life begins on a wider spectrum, ranging from conception to birth, depending on interpretation and background.[164] The third is expressed by the Supreme Court, that a "person" does not exist at an embryonic stage.[165] While each perspective has its own merit, the law provides the ledge upon which embryonic stem cell research will be regulated.[166]

The Framers of the U.S. Constitution placed safeguards around scientific advancements because they understood how essential these advancements are to society.[167] Due to this understanding, the Framers added Article 1, Section 8, Clause 8 to the United States Constitution, which grants Congress the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[168] The goal of this clause was to promote the progress of science and to recognize the rights of authors and inventors for limited times regarding such progress.[169] While freedom of religion is also written into the Constitution, the Constitution does not permit religion to infiltrate into the science realm.[170] Furthermore, it is the states' job to enact specific laws for regulating and promoting science, not religious establishments.[171]

B. Proponents

Proponents of stem cell therapy argue that, from a legal perspective, embryos are not

161. *See generally* Hieu The Le & Joan Catherine Bohl, *The Intersection of Stem Cell Research, the Roman Catholic Church, United States Constitutional Law, and Public Policy*, 23:1 QUINNIPIAC HEALTH L.J. 31, 33 (2020).

162. *Id.* at 44.

163. *Id.*

164. *Id.*

165. *Id.*

166. *Id*. at 40.

167. Le & Bohl, *supra* note 161, at 40.

168. *Id.*

169. *Id.*

170. *Id.*

171. *Id.* at 40–41.

legal persons and are not entitled to protections afforded to persons.[172] Accordingly, proponents push that embryos should be considered property and treated as such under the law.[173] Proponents of stem cell research also push that by funding stem cell research in the U.S., the U.S. will remain competitive in the medical field and not fall behind other countries that are advancing through stem cell research.[174]

Supporters of embryonic stem cell research argue that the benefits and advances of stem cell research greatly outweigh the damages done by destroying embryos.[175] Specifically, stem cells could be used in testing pharmaceuticals and experimental treatments, ultimately providing safer alternatives to trials that normally would involve human subjects.[176] In addition, there are hundreds of thousands of embryos being preserved in fertility clinics that are never going to be transferred into a woman's uterus, meaning eventually they will be discarded.[177] The argument that follows is, why not allow for a more productive use of these discarded cells, such as stem cell research?[178]

Proponents recognize that the public perception of stem cells is that they all come from the unborn but that such perception is not necessarily true.[179] There are arguably morally acceptable forms of embryonic stem cell research outside of the misleading perception that the only way to harvest embryonic stem cells is morally indecent.[180] Embryonic stem cells can be obtained from embryonic germ cells, which are cells from miscarriages or spontaneous abortions (not elective abortions), umbilical cord stem cells, and placenta-derived stem cells.[181] When it comes to in vitro, most of the frozen embryos have no chance of even being born.[182] It could be said that using those frozen embryos for research, which has potential for good, is a much better fate for them than simply staying frozen until they are no longer viable.[183] The immorality argument regarding embryonic stem cells carries little weight when

172. Newhart, *supra* note 15, at 350.

173. *Id.* at 350–51.

174. *Id.* at 348–49.

175. *Id.* at 347.

176. *Id.* at 347–48.

177. *Id.* at 348.

178. Newhart, *supra* note 15, at 348.

179. *See* Le & Bohl, *supra* note 161, at 37.

180. *See id.*

181. *Id.*

182. Miller, *supra* note 17, at 163.

183. *Id.*

they are harvested from cells that are no longer being used for sustaining life.[184]

C. Case Law Regarding the Legal Status of an Embryo

Case law surrounding the legality of stem cell research using embryos is limited, however, there are a few cases that have addressed the issue.[185] Courts in the U.S. generally follow either a majority or minority view.[186] The majority view is that frozen embryos are the property of the progenitors, while the minority view holds that embryos are potential lives and thus the law should afford them special protection as it has with other forms of human life.[187]

A Tennessee case, *Davis v. Davis*, illustrates the minority view on embryos; the court held that embryos should be afforded special protection under the law.[188] In *Davis*, the court held the embryos were not considered "persons" or "property" but declared that embryos occupy an interim category that entitles them to special respect because they hold power to potentially form into human life.[189]

The majority view regarding embryos is illustrated by the New York Court of Appeals case *Kass v. Kass*, which held that embryos are more like property than persons, and are the property of the progenitors.[190] Other cases such as *Cahill v. Cahill* have extended the holding from *Kass* by treating frozen embryos as property.[191] In addition to state cases, federal cases such as *York v. Jones* have also held that embryos are to be treated as property in support of the majority view.[192]

Federal cases have also explored whether embryos have any legal rights, such as redress for injuries.[193] In *Doe v. Irvine Scientific Sales Co.*, the U.S. District Court for the Eastern District of Virginia held that since embryos are not entitled to the protections which are granted to persons, embryos are not entitled to bring claims for injury in tort.[194] Further, in *Satana v. Zilog*, the U.S. Court of Appeals for the Ninth Circuit held that a nonviable fetus did

184. *See id.*

185. Newhart, *supra* note 15, at 332.

186. *Id.*

187. *Id.*

188. *Id.*

189. Newhart, *supra* note 15, at 332 n.23.

190. *Id.* at 333.

191. *Id.* at 335.

192. *Id.* at 337–38.

193. *Id.* at 338.

194. *Id.*

not have the right to bring a wrongful death action.[195] Since embryos are earlier in the development process than nonviable fetuses, the argument follows that embryos would have no privilege to bring a wrongful death action.[196]

V. STEM CELL REGULATIONS IN OTHER REGIONS

A. The European Union and Its Member States

The European Union (E.U.) is considered to have a restricted legal framework in terms of

stem cell research regulation.[197] However, its member nations have various regulations worth considering.[198] Member nations do not have the power to define what an embryo is, but they do have the power to interpret what is a human embryo.[199] The case of *Evans v. United Kingdom* ruled that no uniform legal status exists for human embryos within the E.U., leaving member states to "doubt whether the organism is a human embryo."[200] The case of *Vo v. France* created the "margin of appreciation" principle for the E.U. that allows the member nations to interpret what a human embryo is based on different cultural, moral, and philosophical ideals and circumstances.[201]

The European Patent Convention (EPC) was directed to harmonize patent laws throughout the E.U.[202] An interesting element of the ECP is the Morality Clause, which asserts that even if an invention fulfills the requirements to obtain a patent, the patent may still be rejected for morality reasons.[203] Article 53(a) of the EPC states that patents will not be granted for biotechnology inventions that concern the uses of human embryos for industrial or commercial purposes.[204] Based on differing cultural and moral ideals, members nations have adopted different interpretations of Article 53(a).[205] Members states such as France, Italy, and the United Kingdom (U.K.) follow the wording of the EPC in their laws, while other states broaden the moral exclusion.[206]

195. Newhart, *supra* note 15, at 339.

196. *Id.* at 339–40.

197. *See* Jiang, *supra* note 11, at 57.

198. *Id.*

199. *Id.*

200. *Id.*

201. *Id.*

202. *Id.*

203. Jiang, *supra* note 11, at 58.

204. *Id.* at 58 n.20.

205. *Id.* at 61–62.

206. *Id.* at 62.

The U.K. has permissive regulation for embryonic stem cell research, however, their regulations are still moderate in comparison to other countries.[207] The U.K.'s regulatory system for stem cell research is considered by some as "one of the best in the world."[208] In 1990, the U.K. established a national Human Fertilization and Embryology Authority to grant licenses to researchers.[209] In order to obtain a license for research under this act, an applicant must demonstrate that (1) it is researching for the purpose of "promoting advances in the treatment of infertility. . . or developing [abnormality detection] methods for. . . embryos pre-implementation"; and (2) "the activity is 'necessary or desirable' to achieve one of the specified purposes."[210] The particular wording of the 1990 Act did not explicitly permit stem cell research and treatment but in 2001, the Parliament specified that a license could be granted for the purposes of "(a) increasing knowledge about the development of embryos[,] (b) increasing knowledge about serious disease, or (c) enabling any such knowledge to be applied in developing treatments for serious disease."[211] This specification was seen as a clear endorsement of stem cell research by the U.K.'s government.[212]

Specifically, Great Britain's policy on stem cell research is more permissible than most legislation found in the U.S.[213] Great Britain's policy includes restrictions much like the state of New Hampshire, such as a fourteen-day post-fertilization age limit for an embryo to be used for research purposes, and also requires informed consent for the use of an embryo.[214]

Germany, which is notoriously "conservative about genetic research," has passed an act that allows embryonic stem cell research.[215] Although it allows stem cell research, German law remains extremely restrictive.[216] The German Embryo Protection Act (ESchG) prohibits the cultivation of more than three embryos in order to protect human embryos, egg donation, and pre-implantation genetic diagnosis.[217] However, Germany does permit research on embryonic stem cells already harvested.[218] In addition to the regulation stated above, Germany also has extensive regulation regarding the

207. *See* Rewerski, *supra* note 8, at 418.

208. Jiang, *supra* note 11, at 62.

209. Simson, *supra* note 13, at 550.

210. *Id.*

211. *Id.*

212. *Id.*

213. Newhart, *supra* note 15, at 358.

214. *Id.* at 358–59.

215. Simson, *supra* note 13, at 536.

216. Jiang, *supra* note 11, at 71.

217. *Id.*

218. *Id.*

importation of human embryonic stem cells.[219] Under the Stem Cell Act (StZG), the basic principle stands that the importation and use of embryonic stem cells is prohibited unless the following licensing conditions are met: (1) the stem cells were extracted from surplus embryos via IVF before January 1, 2002; (2) the persons consented to the extraction of stem cells; (3) no remuneration or benefit of any kind was gained; and (4) no other regulations are violated.[220]

The Netherlands takes up the middle ground between permissiveness and prohibition for stem cell research as a result of political and commercial balancing.[221] The Netherlands, with their intermediate approach, forbids embryos to be created for research, however, it allows research to be done on surplus IVF embryos.[222] The potential issue with this intermediate approach is that the policies are "at risk of being ambiguous and internally inconsistent."[223]

1. *Japan*

Japan passed legislation in 2014 that simplified the clinical entry of cell-based products

for diseases and conditions so long as the product showed safety and efficacy.[224] This legislation allows a product or treatment to be provisionally approved with the ability to withdraw provisional approval at any time, thus allowing five years to amass enough clinical data for a proper efficacy review to be entertained.[225] At that point, the entity claiming the treatment would be able to petition for full approval by the Japanese regulatory authority.[226] This system of clinical entry takes away the need for the expensive phase III clinical trials required in the U.S., which keeps products out of clinical use until there is full approval by the U.S. regulatory authority.[227]

While Japan's simplified policies surrounding regenerative stem cell medicine boosted its ranking in the medical industry, patients may be paying the price.[228] Just five years after adopting these simplified regulations, over

219. *See id.* at 72.

220. *Id.*

221. *Id.* at 76–77.

222. Jiang, *supra* note 11, at 76.

223. *Id.* at 77.

224. RIORDAN, *supra* note 30, at 49, 233.

225. *Id.* at 49–50.

226. *Id.* at 49.

227. *Id.* at 50.

228. *See* David Cyranoski, *The Potent Effects of Japan's Stem-Cell Policies*, NATURE (Oct. 10, 2019), https://www.nature.com/articles/d41586-019-02847-3 [https://perma.cc/E8ST-8BAJ].

3,700 treatments were being offered at clinics across the country, making Japan a "focal point for the development of innovative therapies."[229] However, a large concern emerges that companies may take advantage of the meek regulatory paths to avoid any demanding testing of their treatment, which might lower the chance of getting patients *effective* treatments.[230]

2. *China*

China's policy is one of the least restrictive in the world, and China has Asia's most extensive stem cell research industry.[231] China allows embryonic stem cell research and the production of new stem cell lines, which leads to legal therapeutic cloning.[232] Scientists in China work under the Ethical Guiding Principles on Human Embryonic Stem Cell Research, promulgated in 2003.[233] While these principles act as guidelines for researchers, no legal or criminal ramifications exist for violations of these principles.[234] The Ethical Guiding Principles require each institution researching stem cells create an ethics committee, however, the prevalence of flexible ethical committees and philosophies may explain China's permissive policy regarding stem cells.[235]

3. *Australia*

In July 2019, the Therapeutic Goods Administration (TGA) in Australia implemented

new regulations in an attempt to lessen the potential harms of unproven stem cell treatments while still maintaining patient access to proven therapies.[236] These new regulations expanded the TGA's oversight of products and treatments derived from stem cells, requiring all non-hospital-based providers to comply with quality, efficacy, and safety requirements.[237] This means that any provider, even those obtaining cells for a patient's own use, could potentially face criminal penalties for providing unproven stem cell treatments.[238]

229. *Id.*

230. *See id.*

231. Rewerski, *supra* note 8, at 418, 422.

232. *Id.* at 422.

233. *Id.* at 422–23.

234. *Id.* at 423.

235. *Id.*

236. *Regulatory Crackdown on Unproven Stem Cell Treatments*, THE UNIV. OF MELBOURNE (Aug. 27, 2019), https://biomedicalsciences.unimelb.edu.au/news-and-events/archive-news/regulatory-crackdown-on-unproven-stem-cell-treatments [https://perma.cc/GB32-J29S].

237. *Id.*

238. *Id.*

VI. THE FUTURE OF STEM CELL RESEARCH IN THE U.S.

A. Medical Tourism

Medical tourism is the "act of going to another country to receive healthcare treatment."[239] Medical tourism is not a new concept, in fact, there is a long history and culture of

patients seeking and finding medical treatment in countries outside of their own.[240] In 2015 alone, around 1.25 million U.S. citizens sought medical treatment abroad.[241] This is not only common with patients but also with researchers and doctors who seek out countries with regulatory systems that provide them greater allowance to practice their specialties.[242]

There are several reasons why medical tourism exists, including cost, availability, and most important in this case, legality.[243] The U.S. healthcare system has become too expensive for the uninsured and the underinsured, which has encouraged U.S. citizens to seek treatment in other countries.[244] Further, extensive regulation and a lack of funding in the U.S. has turned patients to other countries for stem cell treatment.[245] Other countries are benefiting financially from stem cell tourism, unfortunately this does not come without costs to the patients.[246] In countries with more permissive standards than are present in the U.S., safety and effectiveness is a potential issue.[247] In order to combat the dangers of medical tourism, the U.S. should consider new regulation that allows for better availability and access to safe stem cell treatments domestically.[248]

B. How Much Regulation Should There Be

There are strong arguments, from an institutional standpoint, in favor of increasing the U.S. government's regulation and funding of stem cell research.[249] Too much regulation encourages research and treatment to occur overseas, possibly pushing scientists and doctors to other countries, and lessens the ability of terminally ill patients to access experimental drugs.[250] On

239. Gulinson, *supra* note 48, at 41.

240. *Id.*

241. *Id.* at 46.

242. *See id.* at 43–44.

243. *Id.* at 42.

244. *Id.*

245. Gulinson, *supra* note 48, at 42.

246. *Id.* at 42, 45.

247. *See id.* at 45–46.

248. *See id.* at 55–56.

249. Newhart, *supra* note 15, at 351.

250. *See* Nadel, *supra* note 109, at 225.

the other hand, too little regulation allows harmful products into the market, possibly opening the door for private companies to monopolize the field or even black-market operations overtaking the benefits of such research.[251] In providing national regulations, the U.S. government has the ability to make sure that embryonic stem cell research is not being abused.[252] Instead, by providing regulations the federal government could control the development of stem cell research and who, when, and how scientists can reap its benefit.[253]

C. What Could be Incorporated From Other Regulatory Systems in Forming a New System in the United States

In laboratory science, there is a saying that "not all experiments are successful, but all experiments teach."[254] In this case, the different state variations on stem cell policies and regulatory systems in other countries can teach the U.S. great lessons about what components are most desirable for a future national policy.[255]

From the various states that have created policies that function within considerable limits and oversight, the U.S. can see that research can be conducted even in areas complicated by varying religious and ethical concerns.[256] In permissive states, policymakers can allow research in these controversial areas with clearly established ethical guidelines.[257] For example, the states in favor of embryonic stem cell research have found that any reproductive cloning using embryonic stem cells is unacceptable, the buying and selling of embryos is unacceptable, and any donations of embryos are legal for research purposes so long as the donations are made with fully informed consent and rigorous procedures are followed.[258] The U.S. can also learn from the permissive states that the creation of an additional oversight group that directly monitors embryonic stem cell research to assess breaches and penalties could be a more immediate and effective method over the threat of criminal penalties.[259]

Like California and other states who have created a new administrative paradigm in support of stem cell research, the U.S. could place advisory

251. Newhart, *supra* note 15, at 351.

252. *Id.*

253. *See id.*

254. Acosta & Golub, *supra* note 119, at 433.

255. *Id.*

256. *Id.*

257. *Id.*

258. *Id.*

259. *Id.* at 434.

power into the hands of qualified individuals.[260] Instead of the current federal model, where the political process and governmental agencies control the administration of research funds, the U.S. could create new administrative bodies made up of scientists and patient advocates.[261] This change would likely come with pushback that taking administration powers away from the government is "an abdication of responsibility by the political sector."[262] But there are also very obvious advantages that come along with a new administrative structure.[263] Most importantly, scientists and patients generally possess the medical and industry specific expertise that legislative bodies often lack.[264] As it stands legislative bodies are politically pressured to make decisions that they are far removed from, while scientists and patients are on the frontlines.[265]

Outside of the U.S., other countries provide various guides when it comes to a national stem cell research policies. The U.S. could grant conditional approval of stem cell products after their safety has been demonstrated, much like the regulation used in Japan.[266] Like Japan, the U.S. could simplify the clinical entry program to allow easier entry of cell-based products used to advance medical research.[267] Using a model like Japan's could save anywhere from two to five years in approving stem cell products, and save tens of millions of dollars in medical research by allowing provisional approval of treatments.[268] However, this kind of legislation would not come without its challenges regarding ineffective treatments and safety issues, however, implementing other ethical and medical guidelines could lessen these challenges.[269]

Like California and Great Britain, the U.S. could create a centralized agency, whether it is run by the legislature or by scientists and patients, which make grants and loans to researchers and monitors all activities related to stem cell research.[270] A centralized agency would provide a number of benefits, including "encouraging cooperation, advocat[ing] for a common cause, allowing for effective monitoring, and could ensure that different sorts

260. Acosta & Golub, *supra* note 119, at 434.

261. *Id.*

262. *See id.*

263. *Id.*

264. *Id.*

265. *Id.*

266. *See* RIORDAN, *supra* note 30, at 49–50.

267. *See id.*

268. *Id.* at 50.

269. *See* Cyranoski, *supra* note 228.

270. Simson, *supra* note 13, at 552.

of projects are pursued in a way that avoids too much overlap."[271] Additionally, a centralized agency could ensure that funds are spread across the nation and implement greater adherence to certain ethical and medical standards.[272] Lastly, a centralized agency would provide a combined front rather than the current polarized state system currently in place.[273]

Like the U.K., the U.S. could create a federal licensing program.[274] A licensing program would promote cohesion and order in the current American system, and allow for the government to regulate the who, when, and how of stem cell research.[275] Unsurprisingly, a licensing program could create time delays in getting products to market, and would require extensive research to weigh the benefits and costs of creating such a licensing structure.[276]

Additionally, in order to promote the ethical standards discussed above, the U.S. could prohibit compensation for stem cell donations, and place a focus on informed consent.[277] Like the state prohibitions on compensation for selling and donating embryos in Massachusetts and California, the U.S. could create a nation-wide compensation prohibition.[278] The U.S. could implement the policy that "donation should not be coerced or executed out of self-interest, [r]ather, the donation should be voluntary and incentive-free."[279] Further, a regulation regarding informed consent could strengthen the above policy.[280] This regulation is increasingly important because if individuals are not adequately informed about the decision whether or not to donate embryos, then they would consequently be deprived of their "autonomous right to choose."[281]

VII. CONCLUSION

There are a variety of routes that the U.S. could take in creating a new legislation scheme regarding stem cell research. By comparing the successes and failures of regulations in domestic states and abroad, a system that functions harmoniously in the U.S. can be pieced together. In focusing on prohibiting compensation for stem cell donations, informed consent from donors,

271. *Id.*

272. *Id.*

273. *See id.* at 535, 552.

274. *Id.* at 555.

275. *Id.*

276. Simson, *supra* note 13, at 555.

277. *Id.* at 554.

278. *Id.*

279. *Id.*

280. *See id.*

281. *Id.*

and a federal licensing program the U.S. could regulate the use of stem cell research in ways that increase safety and efficacy.[282] While the available routes the U.S. can choose to address the legality of stem cell research vary, one thing is certain, the U.S. government and medical field need a coherent national stem cell research policy to remain competitive in medicine and disease treatment, to decrease the need for medical tourism, and to provide effective and safe options for its citizens.[283]

282. *See* Simson, *supra* note 13, at 552–58.

283. *See* Newhart, *supra* note 15, at 360–61; *see* Gulinson, *supra* note, at 56.