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The Flaws of Stem Cell Legislation: Sherley, Brüstle, and Future Policy Challenges Posed by Induced Pluripotent Stem Cells

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The Flaws of Stem Cell Legislation: *Sherley, Brüstle*, and Future Policy Challenges Posed by Induced Pluripotent Stem Cells

Nicholas J. Diamond, JD, MBE*

ABSTRACT

In this article, I first contextualize the origins of disagreement over the nature and extent of human embryonic stem cell (hESC) research regulation. By analyzing two key pieces of hESC legislation as considered in two landmark court decisions—one from the United States and one from the European Union—I argue that current stem cell policies are deeply flawed. After surfacing the flaws of these policies, I examine novel challenges for policymakers posed by the newest advancement in stem cell science, induced pluripotent stem cells. In view of these novel challenges, I contend that current policies, which are hESC-focused and deeply flawed, will require substantial revision so as to not unnecessarily encumber the ever-growing therapeutic promise of stem cell research.

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There is no twilight zone beyond the boundaries of a rigorously defined community of moral persons where we may act irrespective of normative rules and unscrupulously tamper with things. If, on the other hand, the interpretation of morally saturated legal terms like “human right” and “human dignity” tends to be counterintuitively construed in too broad a sense, they will not only lose their power to provide clear conceptual distinctions, but also their critical potential.¹

I. INTRODUCTION

Most discussions of stem cell research begin on a historical note. I shall not differ in this regard. I do not, however, begin with mention of the derivation of the first stable human embryonic stem cell (hESC) line, which dates to 1998, to note mere historical fact.² Rather, I make mention of it here, in an article that is concerned with nuanced legislative flaws and an emerging branch of stem cell science theretofore unheard of in 1998, for the benefit of a contextual point that is noticeably absent in the literature. We now seem to take for granted the heightened presence of complex science in the policymaking and judicial realms.³ In our era of emerging issues in, *inter alia*, genetic testing, gene therapy, and neuroscience, stem cells can seem rather ordinary.

But, in 1998, such a discovery was far from ordinary, not because it captured some ineffable wonderment at the possibilities of science—though it arguably did—but because it had a distinctly human component. Notwithstanding the marvel at

1. JÜRGEN HABERMAS, THE FUTURE OF HUMAN NATURE 36 (William Rehg et al. trans., 2003).

2. See James A. Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 SCI. 1145, 1145 (1998); see also Michael J. Shambloott et al., *Derivation of Pluripotent Stem Cells from Cultured Human Primordial Germ Cells*, 95 PROC. NAT'L ACAD. SCI. U.S. AM. 13,726, 13,726 (1998). The derivation of the first stable hESC line occurred concurrently by two labs, one under the leadership of James Thomson at the University of Wisconsin and the other under the leadership of John Gearhart at Johns Hopkins. These two citations denote the publication of their respective findings. Notable to the issue of federal funding for hESC research, to which I will devote substantial discussion, Thomson and his team made this discovery in a privately funded laboratory, created to keep their research separate from other publicly funded research at the University of Wisconsin. RONALD M. GREEN, BABIES BY DESIGN: THE ETHICS OF GENETIC CHOICE 206 (2007).

3. See generally William G. Childs, *The Overlapping Magisteria of Law and Science: When Litigation and Science Collide*, 85 NEB. L. REV. 643 (2007) (discussing science in the courts); Daniel Gervais, *The Regulation of Inchoate Technologies*, 47 HOUS. L. REV. 665 (2010) (discussing regulatory challenges posed by new and rapidly developing technologies).

the cloning of Dolly in 1996, she was, after all, a sheep, which is to say that scientists at the University of Edinburgh had not cloned a human being.⁴ Yet, for hESC research, its therapeutic promise was immediately broadcasted.⁵ Lauded as holding the promise of treating Parkinson's disease, heart disease, spinal cord injuries, diabetes, and amyotrophic lateral sclerosis (ALS), amongst a growing list of devastating medical conditions, it was at the time easy to feel that hESC research could do something for *us* in a way that biotechnology had theretofore been unable to do.⁶

I stress the novelty and significance of this discovery to suggest that much of the trouble that besets stem cell policies, which will constitute the focus of this article, originates in relation to this 'ethic of healing.'⁷ Thorny, persistent questions agitate our ethic of healing. What is the moral status of the human embryo? If, as most agree, human embryos ought to be accorded at least some measure of respect, under what circumstances, if any, may they be destroyed?⁸ May legislatures or judiciaries properly comment on these moral inquiries? More pointedly, may a particular stance on morality vis-à-vis stem cell research be codified? Should morally controversial science receive federal funding? Should such science enjoy patent protection? Our ethic of healing is not unbounded. The flaws of

4. Gina Kolata, *Scientist Reports First Cloning Ever of Adult Mammal*, N.Y. TIMES, Feb. 23, 1997, at A1.

5. Daisy A. Robinton & George Q. Daley, *The Promise of Induced Pluripotent Stem Cells in Research and Therapy*, 48 NATURE 295, 302–03 (2012).

6. *Id.*

7. The phrase 'ethic of healing' originates in Banchoff. See THOMAS BANCHOFF, EMBRYO POLITICS: ETHICS AND POLICY IN ATLANTIC DEMOCRACIES 128–38 (2011). Banchoff discusses how the foci of the scientific and bioethical community through the mid-1990s had been improved *in vitro* (IVF) technologies and accumulating greater knowledge of genetics and congenital disease. *Id.* at 130. The emergence of embryo research, however, turned the focus to developing stem cell therapies, as motivated by “[a]n appeal to solidarity with the sick.” *Id.* Banchoff defines the ethic of healing as referring to “the argument that healing potential necessitate[s] research . . . and that research that destroy[s] embryos [i]s compatible with respect for them.” *Id.* at 132. This shift within the bioethical community, therefore, was one of affording central focus to the “alleviation of suffering more than infertility-related issues . . .” *Id.*

8. See, e.g., Janet L. Dolginet et al., *Attitudes About Human Embryos, Embryonic Stem Cell Research, and Related Matters*, 37 HOFSTRA L. REV. 319, app. II.A (2008); KATHY L. HUDSON ET AL., VALUES IN CONFLICT: PUBLIC ATTITUDES ON EMBRYONIC STEM CELL RESEARCH 5 (2005), available at <http://www.dnapolicy.org/images/reportpdfs/2005ValuesInConflict.pdf>.

stem cell legislation originate, more specifically, in the tension between our ethic of healing and the bounds imposed by moral inquiry.

For all its heady progress, hESC research has been beset by many difficulties over the past twenty-five years.⁹ To be sure, some of these difficulties can be attributed to the many complexities inherent in the science itself.¹⁰ Others, however, can be attributed to the ramifications of governmental restrictions on the nature and funding of hESC research, particularly in the United States.¹¹ As I will demonstrate, these restrictions exhibit at their core the moral uncertainty that pushes against, and thereby reigns in the bounds of, our ethic of healing. For biotechnology, hESC research is the first, and arguably most complex, instance in which science policy has had the unpropitious task of obliging our ethic of healing while balancing an inseparably pluralistic gamut of moral opinion.

In 2007, the landscape of stem cell research radically changed when multiple laboratories reported the establishment of human induced pluripotent stem cells (iPSCs).¹² Despite some differences, iPSCs and hESCs are in fact very similar.¹³ As Yamanaka states, “If anything, we should perhaps be wondering why iPSCs and ESCs are in fact so similar despite their different origins and generation methods.”¹⁴ For many, however, these very differences offer the hope of obviating two chief difficulties that hESC research has as yet been unable to surmount, namely, intrinsic therapeutic limitations and politically and ethically complicated origins.¹⁵ While some contend that iPSCs will eventually render hESCs insignificant,¹⁶ at present

9. John A. Robertson, *Embryo Stem Cell Research: Ten Years of Controversy*, 38 J.L. MED. & ETHICS 191, 194–96 (2010).

10. Robinton & Daley, *supra* note 5, at 295–96 (2012).

11. *Id.*

12. Kazutoshi Takahashi et al., *Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors*, 131 CELL 861, 861 (2007); Junying Yu et al., *Induced Pluripotent Stem Cells Derived from Human Somatic Cells*, 318 SCI. 1917, 1917 (2007).

13. Shinya Yamanaka, *Induced Pluripotent Stem Cells: Past, Present, and Future*, 10 CELL STEM CELL 678, 681 (2012).

14. *Id.*

15. Douglas Sipp, *Gold Standards in the Diamond Age: The Commodification of Pluripotency*, 5 CELL STEM CELL 360, 360 (2009).

16. David G. Zacharias et al., *The Science and Ethics of Induced Pluripotency: What Will Become of Embryonic Stem Cells?*, 86 MAYO CLINIC PROC. 634, 638 (2011). Thomson has expressed that, if research advances enough such that there is no discernible difference between hESCs and iPSCs, then

hESCs remain integral fixtures in the research landscape as the “gold standard.”¹⁷ In view of the unstable history of hESC policy,¹⁸ as well as the rapid pace at which stem cell science advances,¹⁹ iPSCs present a significant, but more to the point, novel, challenge in coming years.

I will assess the current state of stem cell policies through analysis of two recent court decisions and the policies upon which both are based. My intent is to show that this legislation is deeply flawed. The first case, *Sherley v. Sebelius*, was decided by the D.C. Circuit in 2012.²⁰ The second case, *Brüstle v. Greenpeace*, decided in 2011, comes from the Court of Justice of the European Union (ECJ).²¹ I focus on these particular decisions for two reasons. First, they accent the dissimilar central issues in stem cell policies between the United States and the European Union. *Sherley* turns on the recurrent issue of federal funding for stem cell research in the U.S., which has to date varied, oftentimes significantly, across three presidential administrations.²² *Brüstle* highlights the difficulties inherent in promoting harmonization of biotechnological patents across EU nation states that are themselves culturally and socially distinct.²³ Second, as I will consider in some depth, the policies underlying these two cases demonstrate the influence of moral opinion on stem cell legislation.

Critical though such an analysis is, the revelation that

hESCs will “turn out to be a historical anomaly.” David Cyranoski, *Stem Cells: 5 Things to Know Before Jumping on the iPS Bandwagon*, 452 NATURE 406, 408 (2008).

17. See Sipp, *supra* note 15, at 360 (“The commodification of pluripotency by the arrival of iPSCs has not entirely diluted the value of the ESC, which is still generally held to be the ‘gold standard’ by which all pluripotency should be judged”); Zacharias et al., *supra* note 16, at 638 (“The general consensus among hES and iPS researchers alike is that ES cells are needed for the time being.”).

18. Robertson, *supra* note 9, at 194–96.

19. See *Timeline: A Brief History of Stem Cell Research*, SCI. PROGRESS, <http://scienceprogress.org/2009/01/timeline-a-brief-history-of-stem-cell-research> (last updated May 2012).

20. *Sherley v. Sebelius* (Sherley VI), 689 F.3d 776, 776 (D.C. Cir. 2012), *petition for cert. filed*, (U.S. Oct. 10, 2012) (No. 12-454).

21. Case C-34/10, *Brüstle v. Greenpeace e.V.*, 2011 EUR-Lex CELEX LEXIS 2599 (Oct. 18, 2011).

22. *Sherley v. Sebelius* (Sherley I), 686 F. Supp. 2d 1, 5–7 (D.D.C. 2009). See also Robertson, *supra* note 9, at 194–96.

23. *Brüstle*, 2011 EUR-Lex CELEX LEXIS 2599, ¶ 55–56.

stem cell policies are deeply flawed might be unsurprising to some. I can find no example in the literature that unequivocally extols the virtues of current stem cell policies. This is not insignificant, chiefly because current policies will soon need to adapt to the results of the rapid pace at which stem cell science progresses. In the final section of this article, I will argue that the unsupported current policies have yet another flaw, namely, an inability to account for novel challenges posed by iPSCs. By considering fundamental differences between hESCs and iPSCs, largely with regard to their distinct origins and moral complexities, I conclude that current policies must adapt to the changing science that they regulate, should the full therapeutic potential of stem cell research ever be realized.

II. A BRIEF INTERLUDE: THE SCIENCE OF STEM CELLS

This article presumes a basic familiarity with the science of stem cells. In the interest of this presumption, I will offer a rudimentary exposition on fundamental terms and distinctions in the science of stem cells. What follows does not purport to be an exhaustive overview, but rather constitutes a sufficient minimum for understanding of the policy and legal dimensions of the science discussed herein.

At present, the scope of stem cell research includes three different types of stem cells: adult stem cells (ASCs), hESCs, and iPSCs.²⁴ Research on ASCs is the oldest of the three, dating to the 1950s.²⁵ ASCs are undifferentiated cells found in adult tissues and organs in the body amongst already differentiated cells.²⁶ ASCs are multipotent, which means that they can be specialized into but a few different cell types.²⁷ As such, the utility of ASCs for research and therapeutic purposes is greatly limited.²⁸ For researchers using ASCs, the area of the body from which the ASCs were harvested limits the utility of the

24. Layla Cummings, Note, *Sherley v. Sebelius: A Call to Congress to Explicitly Support Medical Research on Human Embryonic Stem Cells*, 12 N.C. J.L. & TECH. 77, 79 (2010), available at http://www.ncjolt.org/sites/default/files/Cummings_v12OE_77_96.pdf.

25. *Id.* at 80.

26. Ryan P. O'Quinn, Note, *Sherley v. Sebelius: Stem Cells and the Uneasy Interplay Between the Federal Bench and the Lab Bench*, 2011 DUKE L. & TECH. REV. 002, ¶ 7 (2011), available at <http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1216&context=dltr>.

27. Cummings, *supra* note 24, at 80.

28. *Id.*

cell.²⁹ For instance, neural stem cells in the brain can replace neurons in the nervous system, but neural stem cells are unable to become heart, liver, or lung cells, to mention just a few.³⁰ In contrast to hESCs, ASCs are considered uncontroversial because harvesting them does not require the use and subsequent destruction of human embryos.³¹

hESCs are found in the embryonic layer of week-old human embryos.³² Unlike ASCs, which have limited utility, hESCs are pluripotent, which means that they can divide into nearly any type of cell in the human body, but do not have the capacity to develop into an independent, fully functional organism, e.g., a human being.³³ In contrast to ASCs, which are harvested with the informed consent of adult donors,³⁴ hESCs are harvested from human embryos—in most cases, surplus preimplantation embryos from *in vitro* fertilization (IVF) procedures—which have been donated for research purposes with the informed consent of both parents.³⁵ The process of harvesting hESCs from a donated embryo necessitates the destruction of the embryo.³⁶ Opinion as to the moral status of the human embryo differs widely.³⁷ Because human embryos are necessarily destroyed during the harvesting of hESCs, such research is considered morally and politically controversial.³⁸ While the full therapeutic potential of hESCs has not yet been fully realized, promising research results exist in animal studies of Parkinson's disease, spinal injury, type 1 diabetes, and cardiovascular disease.³⁹

iPSCs are the result of genetically reprogramming ASCs to

29. *Id.*

30. Amanda Warren-Jones, *Realising New Health Technologies: Problems of Regulating Human Stem Cells in the USA*, 20 *MED. L. REV.* 540, 545 (2012).

31. Cummings, *supra* note 24, at 80.

32. Ryan Fujikawa, Note, *Federal Funding of Human Embryonic Stem Cell Research: An Institutional Examination*, 78 *S. CAL. L. REV.* 1075, 1078 (2005).

33. *Id.* at 1078; *see also* Cummings, *supra* note 24, at 79–80; Warren-Jones, *supra* note 30, at 7.

34. Cummings, *supra* note 24, at 80.

35. ROBERT P. GEORGE & CHRISTOPHER TOLLEFSEN, *EMBRYO: A DEFENSE OF HUMAN LIFE* 8–11 (2011).

36. O'Quinn, *supra* note 26, ¶ 6.

37. HUDSON ET AL., *supra* note 8, at 8.

38. *Id.*

39. Zacharias et al., *supra* note 16, at 635.

behave like hESCs, which is to say that they have the utility of pluripotency.⁴⁰ Being that ASCs are more abundant than hESCs, iPSCs stand to make pluripotency theoretically limitless.⁴¹ Notwithstanding this potential spike in the availability of pluripotency, current research suggests that iPSCs and hESCs will complement one another, rather than having iPSCs negate the need for hESCs, which had been hypothesized in early iPSC research publications.⁴² At minimum, the ability to alter the fate of ASCs through reprogramming has changed researchers' views on the stability of cellular identity, thereby spurring new directions in research possibilities.⁴³ iPSC technology, however, has not yet been perfected.⁴⁴ Ultimately, researchers hope that encouraging advancements made in recent years augur well the chance that iPSCs will eventually offer the therapeutic benefits that hESCs have been slow to provide.⁴⁵

III. THE FLAWS OF *SHERLEY V. SEBELIUS* AND THE DICKKEY-WICKER AMENDMENT

In this section, I first consider the history of *Sherley v. Sebelius*. *Sherley* has an uncommonly complex case history, totaling six separate and important instantiations in the federal courts. Owing to this complexity, I will trace its case history in detail, emphasizing those points along the way that bear heavily on the overall trajectory of its march through the courts. Af-

40. O'Quinn, *supra* note 26, ¶ 7.

41. Sipp, *supra* note 15, at 360.

42. Robinton & Daley, *supra* note 5, at 295, 300; *see also* Owen C.B. Hughes et al., *United States Regulation of Stem Cell Research: Recasting Government's Role and Questions to be Resolved*, 37 HOFSTRA L. REV. 383, 419 (2008) ("[I]n the short run many scientists believe that work with hESCs must continue, if not only to validate the value of iPSCs . . .").

43. Robinton & Daley, *supra* note 5, at 295.

44. Zacharias et al., *supra* note 16, at 637.

45. *Id.* Examples of iPSC research promise have been coming rapidly. *See, e.g.*, David Cyranoski, *Rudimentary Liver Grown in Vitro*, NATURE NEWS (Jun. 21, 2012), <http://www.nature.com/news/rudimentary-liver-grown-in-vitro-1.10848> (evincing developments towards growing a human liver *in vitro*); David Cyranoski, *Biologists Grow Human-Eye Precursor from Stem Cells*, NATURE NEWS (Jun. 15, 2012), <http://www.nature.com/news/biologists-grow-human-eye-precursor-from-stem-cells-1.10835> (relating the growing of the precursor of a human eye in the laboratory); Ewem Callaway, *Alzheimer's 'in a Dish' Shows Promise*, NATURE NEWS (Jan. 25, 2012), <http://www.nature.com/news/alzheimer-s-in-a-dish-shows-promise-1.9889> (in relation to Alzheimer's research).

fording sufficient background, I will then turn to the Dickey-Wicker Amendment,⁴⁶ the legislation underlying the action brought in *Sherley*. After considering its prohibitions, I will put forth a multi-part argument as to why Dickey-Wicker is inherently flawed.

A. THE CASE HISTORY OF *SHERLEY V. SEBELIUS*⁴⁷

1. *Sherley I*

Sherley originated in U.S. District Court for the District of Columbia in August of 2009, when a group of plaintiffs, including Drs. James Sherley and Theresa Deisher, two scientists who performed ASC research, sought to enjoin implementation of new hESC research guidelines⁴⁸ promulgated by the National Institutes of Health (NIH).⁴⁹ Plaintiffs alleged, *inter alia*, that by allowing the NIH to fund hESC research, they would suffer irreparable harm because the new guidelines would increase competition for limited federal research funds, thereby impeding their ability to compete for funding.⁵⁰ The Government filed a motion to dismiss, on which the court looked favorably.⁵¹ Ruling that none of the plaintiffs had standing, the court dismissed the suit for lack of subject matter jurisdiction.⁵² With regard to Drs. Sherley and Deisher, the court held that standing was not present because, contrary to their allegations, the so-called “competitor standing” doctrine⁵³ was inapplica-

46. Balanced Budget Downpayment Act, Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (1996).

47. For clarity, I designate each instantiation of *Sherley* with a Roman numeral—e.g., *Sherley I*, *Sherley II*, and so forth.

48. Nat'l Inst. of Health, Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170, 32,173 (July 7, 2009). These guidelines were the result of an executive order from President Obama to remove President Bush's limitations on hESC research. See *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells*, Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 11, 2009).

49. *Sherley v. Sebelius* (Sherley I), 686 F. Supp. 2d 1, 3–4 (D.D.C. 2009).

50. *Id.* at 4. *But see* O'Quinn, *supra* note 26, ¶ 37 (“In truth, the Guidelines . . . would have presented little threat to grant applications submitted by Sherley because they had already been rejected through peer review.”).

51. *Sherley I*, 686 F. Supp. 2d at 5–7.

52. *Id.*

53. See *Hardin v. Ky. Util. Co.*, 390 U.S. 1, 6 (1968) (“[W]hen the particular statutory provision [or regulation] invoked . . . reflect[s] a legislative purpose to protect a competitive interest, the injured competitor has stand-

ble.⁵⁴ Being that Drs. Sherley and Deisher were applicants for research grants, as opposed to competitors in an economic market, the court found that an increase in competition for funding does not equate to other applicants suffering harm.⁵⁵

2. *Sherley II*

An appeal to the U.S. Court of Appeals for the District of Columbia Circuit followed, challenging only the adjudication that Drs. Sherley and Deisher lacked standing.⁵⁶ The D.C. Circuit adopted a differing approach to the competitor standing doctrine, disagreeing that it applied only to participants in a strictly regulated economic market.⁵⁷ The court found no difference in the applicability of the doctrine in the instance of competition for a governmental benefit, especially where the government has taken steps to benefit certain parties in opposition to the economic interests of others vying for the same funding.⁵⁸ Accordingly, *Sherley* was reversed and remanded back to the District Court.⁵⁹

3. *Sherley III*

The return of *Sherley* to the District Court proved to be significant for stem cell research.⁶⁰ *Sherley III* contains the first substantial discussion of the Dickey-Wicker Amendment,⁶¹ a rider to the Balanced Budget Downpayment Act of 1996, by the courts.⁶² Although I will return to a more substantive discussion of Dickey-Wicker later, at this juncture it is advantageous to briefly note its central prohibition. Dickey-Wicker provides, in pertinent part, that “[n]one of the funds made available by [the appropriation] may be used for . . . research in which a

ing . . .”).

54. *Sherley I*, 686 F. Supp. 2d at 6.

55. *Id.* at 7.

56. *Sherley v. Sebelius* (*Sherley II*), 610 F.3d 69, 70 (D.C. Cir. 2010).

57. *Id.* at 72.

58. *Id.*

59. *Id.* at 75.

60. *Sherley v. Sebelius* (*Sherley III*), 704 F. Supp. 2d 63 (D.D.C. 2010).

61. Balanced Budget Downpayment Act, Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (1996).

62. *Sherley III*, 704 F. Supp. 2d at 67–73. Dickey-Wicker has been included in every appropriations bill for Health and Human Services since 1996 absent substantive change. See Omnibus Appropriations Act, 2009, Pub. L. No. 111-8, § 509(a)(2), 123 Stat. 524, 803 (2009).

human embryo or embryos are destroyed”⁶³ Being that the D.C. Circuit had found Drs. Sherley and Deisher to have standing, the District Court was now charged with evaluating whether the grant of a preliminary injunction would be proper.⁶⁴

In order to reach the merits of whether a preliminary injunction would be proper, the court had to ascertain if, as the Government maintained, Dickey-Wicker is ambiguous.⁶⁵ The court focused on whether the use of ‘research’ in Dickey-Wicker was ambiguous.⁶⁶ The Government contended that, because ‘research’ is employed ambiguously in Dickey-Wicker, its interpretation should be granted *Chevron*⁶⁷ deference.⁶⁸ *Chevron* deference occurs as a two-step process, whereby the court first considers whether Congress has “directly spoken to the precise question at issue,” and, if it has done so, then the court must “give effect to the unambiguously expressed intent of Congress.”⁶⁹ However, if the “statute is silent or ambiguous with respect to the specific issue,” Congress would defer to the NIH’s interpretation, assuming that it is “based on a permissible construction of the statute.”⁷⁰

Owing to President Obama’s Executive Order removing Bush-era limitations on federal funding of ESC research,⁷¹ the NIH promulgated guidelines that speak to an interpretation of ‘research.’⁷² These guidelines allowed “funding of research using hESCs derived from human embryos created using [IVF] for reproductive purposes and no longer needed for these pur-

63. Balanced Budget Downpayment Act § 128, 110 Stat. at 34.

64. *Sherley III*, 704 F. Supp. 2d at 65–66.

65. *Id.* at 70.

66. *Id.*

67. *See Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

68. *Sherley III*, 704 F. Supp. 2d at 70.

69. *Chevron*, 467 U.S. at 842–43.

70. *Id.*

71. Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, Exec. Order No. 13,505, 74 Fed. Reg. 10,667, 10,667 (Mar. 11, 2009) (“[The NIH] may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.”).

72. Nat’l Inst. of Health, Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170, 32,170 (July 7, 2009) (finalizing April 23, 2009 draft guidelines).

poses.”⁷³ Of particular relevance to *Sherley*, these guidelines distinguished “between the derivation of stem cell from an embryo that results in the embryo’s destruction, for which federal funding is prohibited, and research involving hESCs that does not involve an embryo nor result in an embryo’s destruction, for which federal funding is permitted.”⁷⁴ The NIH conceived ‘research’ in a limited sense, arguing to the court that the language in Dickey-Wicker suggested an interpretation “of research as ‘a piece of research,’” which, it would follow, buttresses such a distinction.⁷⁵

The court, however, found no such ambiguity in Dickey-Wicker. The court read Dickey-Wicker as evincing the “unambiguous intent of Congress to enact a broad prohibition of funding research in which a human embryo is destroyed.”⁷⁶ Such a prohibition, the court reasoned, “encompasses *all* ‘research in which’ an embryo is destroyed,” contrariwise to the NIH’s reading of the prohibition as applying only to a ‘piece of research’ in which an embryo is destroyed.⁷⁷ The court held that, absent ambiguity, Congress had spoken directly to the issue, and this necessitated under *Chevron* that it give effect to Congress’s intent.⁷⁸ Accordingly, on August 23, 2010, Chief Judge Lamberth, rather notoriously, granted the preliminary injunction, thereby bringing all federal funding for hESC research to a halt.⁷⁹ This moratorium lasted just over two weeks, after an emergency appeal by the government resulted in the D.C. Circuit issuing an administrative stay on September 9, 2010.⁸⁰

73. *Id.* at 32,171.

74. *Id.* at 32,173.

75. *Sherley III*, 704 F. Supp. 2d 63, 70 (D.D.C. 2010).

76. *Id.* at 70–71.

77. *Id.* at 71 (emphasis in original).

78. *Id.*

79. *Id.* at 73 (“[I]t is in the public interest to enjoin defendants from implementing the Guidelines because the Guidelines allow federal funding of ESC research, which involves the destruction of embryos.”). See O’Quinn, *supra* note 26, ¶ 23 (“Outcry and controversy in the aftermath of Chief Judge Lamberth’s order was substantial and immediate.”). Of particular note, criticism from the legal academy argued that Chief Judge Lamberth’s grant of the injunction was in error as a matter of law. See, e.g., *id.* ¶¶ 23–31; Hank Greely, *Stem Cell Madness—Judge Lamberth’s Opinion and Order Enjoining HESC Research*, STANFORD L. & BIOSCIENCES BLOG (Aug. 31, 2010), <http://blogs.law.stanford.edu/lawandbiosciences/2010/08/31/stem-cell-madness-judge-lamberths-opinion-and-order-enjoining-hesc-research/>.

80. *Sherley v. Sebelius*, Civ. A. No. 10-5287 (D.C. Cir. Sept. 9, 2010) (order granting administrative stay).

4. *Sherley IV*

In *Sherley IV*, the D.C. Circuit now had to decide whether the preliminary injunction issued by Judge Lamberth was proper.⁸¹ Notably, *Sherley IV* contains the first instance in which a court recognized the curious timing of the passage of Dickey-Wicker, a point to which I will later return.⁸² Specifically, the D.C. Circuit noted that the “historical record suggests the Congress passed [Dickey-Wicker] chiefly to preclude President Clinton from acting upon an NIH report recommending federal funding for research using embryos that had been created for the purpose of in vitro fertilization.”⁸³ As the court rightly concluded, Dickey-Wicker would only become relevant to hESCs two years later, with the derivation of the first stable hESC line in 1998.⁸⁴

As to the merits in *Sherley IV*, the court disagreed with Chief Judge Lamberth’s interpretation of the language in Dickey-Wicker as evincing, in accord with Drs. Sherley and Deisher’s position, a broad reading of ‘research.’⁸⁵ Instead, the court reasoned that the “definition of research is flexible enough to describe either a discrete project or an extended process, but this flexibility only reinforces our conclusion that the text is ambiguous.”⁸⁶ The first step of *Chevron*, accordingly, was in favor of the NIH.⁸⁷ With respect to step two of *Chevron*, the court again sided with the NIH, concluding that its interpretation of Dickey-Wicker was reasonable “[b]ecause the Congress wrote with particularity and in the present tense—the statute says ‘in which’ and ‘are’ rather than ‘for which’ and ‘were.’”⁸⁸ Consequently, the court vacated the preliminary injunction.⁸⁹

Judge Henderson dissented from the decision, advancing a position in accord with Chief Judge Lamberth, which would stop at step one in the *Chevron* analysis of Dickey-Wicker.⁹⁰ Judge Henderson’s reasoning warrants close scrutiny because

81. *Sherley v. Sebelius (Sherley IV)*, 644 F.3d 388, 392 (D.C. Cir. 2011).

82. *See infra* Part II.B.2.

83. *Sherley IV*, 644 F.3d at 390.

84. *Id.* at 391.

85. *Id.* at 394.

86. *Id.*

87. *See id.* (dismissing arguments to the contrary of the NIH position).

88. *Id.* at 396.

89. *Id.* at 399.

90. *Id.* at 399–400 (Henderson, J., dissenting).

it highlights critical worries as to how various courts have examined the fundamental issue in *Sherley*, namely, how should the language of Dickey-Wicker be interpreted?⁹¹ Judge Henderson focused on the timing of Dickey-Wicker—enacted two years prior to the derivation of the first stable hESC line—as indicative of a broad reading of ‘research.’⁹² Judge Henderson reasoned that “[t]he Congress, recognizing its scant knowledge about the feasibility/scope of hESC research, chose broad language with the plain intent to make the ban as complete as possible.”⁹³ Furthermore, she argued that the majority had “strain[ed] mightily” to find the requisite ambiguity in the wording of Dickey-Wicker to proceed past step one of *Chevron*.⁹⁴

Judge Henderson, moreover, rightly points out the flawed reliance of the majority on the bare fact that Congress has enacted Dickey-Wicker unchanged every year since 1996.⁹⁵ The judge explained that “[w]here the law is plain,” Congressional reenactment “does not constitute an adoption of a previous administrative construction.”⁹⁶ Much as is the case with the majority’s analysis of this issue, her reasoning is incomplete. This issue is governed by the reenactment-acquiescence doctrine, first recognized in *National Lead Company v. United States*, under which subsequent reenactments “amount[] to an implied legislative recognition and approval of the executive construction of the statute” because “Congress is presumed to have legislated with knowledge of such an established usage of an executive department of the government.”⁹⁷ The majority in *Sherley* cited an instantiation of this principle from *Barnhart v. Walton* as support for the adoption of NIH’s interpretation of Dickey-Wicker.⁹⁸

As Judge Henderson adduces in her dissent, this doctrine is questionably applied by the majority, due to the plain mean-

91. See *id.* at 399 (“The majority opinion has taken a straightforward case of statutory construction and produced a result that would make Rube Goldberg tip his hat.”).

92. See *id.* at 401.

93. *Id.*

94. *Id.* at 402.

95. *Id.* at 404.

96. *Id.* (quoting *Brown v. Gardner*, 513 U.S. 115, 121 (1994)).

97. *Nat’l Lead Co. v. United States*, 252 U.S. 140, 146 (1920) (internal citations omitted).

98. *Sherley IV*, 644 F.3d at 396 (citing *Barnhart v. Walton*, 535 U.S. 212, 220 (2002)).

ing of the language in Dickey-Wicker.⁹⁹ Yet Judge Henderson commits the same mistake as the majority, namely, “mis-appl[ying] precedent by not searching for an affirmative congressional intent to acquiesce.”¹⁰⁰ *Barnhart* employed legislative history in its determination of the nature of the congressional intent to which the doctrine would acquiesce.¹⁰¹ Both the majority in *Sherley IV* and Judge Henderson in her dissent fail to further investigate precisely the nature of the congressional intent behind Dickey-Wicker.¹⁰² In this sense, the court has uncritically assumed the applicability of the doctrine without carrying out the full implications of the precedents upon which it relies.¹⁰³ Moreover, this deficiency is particularly troublesome because of Dickey-Wicker’s status as a rider amendment, where “shortcomings in the congressional procedures used to enact [policy riders render them] especially indeterminate expressions of congressional intent.”¹⁰⁴

5. *Sherley V*

With the preliminary injunction vacated, *Sherley* was once again before Chief Judge Lamberth in the U.S. District Court for the District of Columbia.¹⁰⁵ The parties sought a ruling on cross-motions for summary judgment, and largely rehashed previous arguments while differing as to their opinions of the effect of the D.C. Circuit’s decision vacating the preliminary injunction.¹⁰⁶ Chief Judge Lamberth’s opinion is comprehensive, yet at its core it is an unmistakably reluctant acquiescence to the D.C. Circuit’s prior decision. As Chief Judge Lamberth states: “While it may be true that by following the Court of Appeals’ conclusion as to the ambiguity of ‘research,’ this Court has become a grudging partner in a bout of ‘linguistic jujitsu’ [quoting *Sherley IV*], such is life for an antepenultimate

99. *Id.* at 404 (Henderson, J., dissenting).

100. Recent Cases, *Civil Law—Federal Funding of Human Embryonic Stem Cell Research—D.C. Circuit Vacates District Court’s Preliminary Injunction of Federal Funding for Research Using Human Embryonic Stem Cells.—Sherley v. Sebelius*, 644 F.3d 388 (D.C. Cir. 2011), 125 Harv. L. Rev. 626, 629 (2011).

101. *Barnhart v. Walton*, 535 U.S. 212, 220 (2002).

102. Recent Cases, *supra* note 100, at 629–31.

103. *Id.*

104. *Id.* at 629, 631.

105. *Sherley v. Sebelius (Sherley V)*, 776 F. Supp. 2d 1 (D.D.C. 2011).

106. *See id.* at 4, 10–11.

court.”¹⁰⁷

Ultimately, Drs. Sherley and Deisher failed to offer any new information or reasoning that would give Chief Judge Lamberth cause to depart from the D.C. Circuit’s holding in regards to the meaning of “research” in *Dickey-Wicker*.¹⁰⁸

6. *Sherley VI* and Future Concerns

Chief Judge Lamberth’s decision was appealed¹⁰⁹ and oral arguments were heard on April 23, 2012.¹¹⁰ On August 24, 2012, the court issued a ruling in favor of the NIH and a petition for a writ of certiorari has been filed in the U.S. Supreme Court.¹¹¹ For the moment, federal funding for hESC may continue.¹¹² Of particular note in the decision, Judge Brown offers this concluding reflection in her concurrence, which serves to frame many of the issues that I wish to raise with *Dickey-Wicker*: “Given the weighty interests at stake in this encounter between science and ethics, relying on an increasingly Delphic, decade-old single paragraph rider on an appropriations bill hardly seems adequate.”¹¹³

Regardless of whether *Sherley* receives its final word in the D.C. Circuit or the U.S. Supreme Court, the larger issue that *Sherley*’s tortured march through the courts underscores is the extent to which it is appropriate for courts to impact how the research community functions.¹¹⁴ This is a thorny issue, but

107. *Id.* at 15 (quoting *Sherley IV*, 644 F.3d 388, 398–99 (D.C. Cir. 2011) (Henderson, J., dissenting)).

108. *Id.*

109. *Sherley v. Sebelius* (*Sherley VI*), 689 F.3d 776, 776 (D.C. Cir. 2012).

110. Meredith Wadman, *Stem-cell Arguments Heard in US Appeals Court*, NATURE NEWS BLOG (April 23, 2012), <http://blogs.nature.com/news/2012/04/stem-cell-arguments-heard-in-us-appeals-court.html>.

111. *Sherley v. Sebelius* (*Sherley VI*), 689 F.3d 776, 776 (D.C. Cir. 2012), *petition for cert. filed*, (U.S. Oct. 10, 2012) (No. 12-454).

112. *But see* Cohen et al., *Sherley v Sebelius and the Future of Stem Cell Research*, 308 JAMA 2087, 2087 (2012) (“It is uncertain whether the legal discord over the federal funding of hESC research is over. The plaintiffs have sought review of the case by the US Supreme Court, a prospect contingent on the votes of 4 justices. If the Supreme Court should grant review of the case, the federal funding of hESC research would, once again, be placed in legal limbo. Moreover, a decision overruling the Court of Appeals would bar any future administration from funding hESC research.”).

113. *Sherley VI*, 689 F.3d at 790.

114. *See* O’Quinn, *supra* note 26, ¶ 33 (“Perhaps the only outcome worse than a judgment against the NIH Guidelines altogether is exactly what has transpired—placing the scientific community in a chaotic state of limbo.”).

one of increasing import as the prevalence of biotechnologies continues to grow.¹¹⁵

O'Quinn argues that the judiciary should not play any role in arbitrating funding issues, leaving such determinations to already-existing mechanisms in the research community, such as Internal Review Boards and the peer review process.¹¹⁶ Although his posited solution would suit the research community's objectives well, it neglects to account for the role of the judiciary in a case like *Sherley*, where the court is asked to evaluate whether, given the nature of the underlying law, to grant a preliminary injunction. A preliminary injunction is an "extraordinary remedy" necessitating that a high burden be carried by the moving party; a fact of which courts, including those that reviewed *Sherley*, are well aware.¹¹⁷ In short, a preliminary injunction is not granted lightly. While it is worrisome that, as in *Sherley*, the grant of a preliminary injunction can have a staggering effect on an entire research community, spotlighting the nature of a preliminary injunction in the case of stem cell research misses the more salient issue. As I will turn to in the subsequent section, the root worry rests with the law upon which the courts had to base their decision: the Dickey-Wicker Amendment.

B. THE FLAWS OF THE DICKEY-WICKER AMENDMENT

I will now consider Dickey-Wicker in more detail, offering criticism in the sub-sections to follow. As a rider, Dickey-Wicker occupied scant space in the Balanced Budget Downpayment Act of 1996.¹¹⁸ Dickey-Wicker provided that:

- (a) None of the funds made available in this Act may be used for—
 - (1) the creation of a human embryo or embryos

115. Cf. Cummings, *supra* note 24, at 77–78 (detailing the significance of stem cell research in developing progressive new treatments for many medical conditions); Fujikawa, *supra* note 32, at 1079 ("Stem cells command attention in the national debate because of their immense potential for advancing medical treatment.").

116. See O'Quinn, *supra* note 26, ¶¶ 35–39.

117. See, e.g., *Sherley v. Sebelius* (Sherley IV), 644 F.3d 388, 392 (D.C. Cir. 2011) (quoting *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008)); *Sherley v. Sebelius* (Sherley III), 704 F. Supp. 2d 63, 69 (D.D.C. 2010) (quoting *Cobell v. Norton*, 391 F.3d 251, 258 (D.C. Cir. 2004)).

118. The amendment consists of thirteen lines of text within this twenty-three-page law. See Balanced Budget Downpayment Act, Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (1996).

for research purposes; or

(2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

(b) For purposes of this section, the term “human embryo or embryos” includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.¹¹⁹

The prohibition in section (a)(1) has received uniform interpretation by three presidential administrations,¹²⁰ beginning with the Clinton Administration, which prohibited federal funding for research in which human embryos are created expressly for research purposes only.¹²¹ Although section (a)(2) seems straightforward enough, the case history of *Sherley* demonstrates that interpretations of “research” as used therein vary widely.

1. Appropriations Riders and Stem Cell Legislation

Apart from concern for the meaning of ‘research’ in section (a)(2), which occupied the court in *Sherley*, the first cause for worry about Dickey-Wicker stems from its status as an appropriations rider. One of the few scholars to examine *prima facie* worries over the use of appropriations riders as means of affecting substantive policies,¹²² Neal Devins strongly argues that appropriations riders are not conducive to developing sound policies, and claims that they skirt House and Senate rules aimed at ensuring deliberate and systematic policymaking decisions.¹²³ Moreover, he notes that the use of the appropriations

119. Omnibus Appropriations Act, 2009, Pub. L. No. 111-8, § 509, 123 Stat. 524, 803 (2009).

120. See, e.g., Address to the Nation on Stem Cell Research, 2 PUB. PAPERS 953–56 (Aug. 9, 2001) (calling the practice of creating embryos solely for research “deeply troubling”); Nat’l Inst. Of Health, Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170, 32,174 (July 7, 2009) (NIH Guidelines issued under the Obama Administration containing requirements to ensure embryos were not produced exclusively for research).

121. See Fujikawa, *supra* note 32, at 1082.

122. See *id.* at 1083 (describing the operation of the Dickey Amendment as a rider restricting federal funding).

123. Neal E. Devins, *Regulation of Government Agencies Through Limitation Riders*, 1987 DUKE L.J. 456, 457–58. Cf. Cummings, *supra* note 24, at 83

process to accomplish substantive objectives precludes application of appropriate committee expertise in crafting the legislation.¹²⁴ As importantly, Devins likewise cites resultant difficulties for other branches of the federal government, such as the judiciary, who are charged with interpreting these riders.¹²⁵

Applying these concerns to Dickey-Wicker, the problem with using an appropriations rider to govern federal funding for hESC research requires little explanation. Owing to the complexity of the issues operative in hESC research, leaving the determination of federal funding to committees with suitable expertise would be more appropriate. Similarly, allowing these federal funding policies to develop under deliberate and systematic congressional committee review would afford the surest means by which to avoid resultant interpretive difficulties in other branches of the federal government. As *Sherley* demonstrates, the materialization of such interpretive difficulties is a very real phenomenon, not just in the judiciary, but likewise in the Executive Branch.¹²⁶

In light of these difficulties, coupled with the therapeutic significance of hESC research efforts, Layla Cummings argues that comprehensive stem cell research legislation should be passed, in order to make Congress's intentions in this area transparent.¹²⁷ For Cummings, such legislation would "preferably . . . codify President Obama's executive order and open the door to a transparent set of rules that will regulate future hESC research."¹²⁸ She goes on to note that just such a bill, the Stem Cell Research Advancement Act, was introduced in the

(noting that appropriations riders do not pass through the same congressional review process as do other substantive pieces of legislation aimed at directly banning agency action).

124. Devins, *supra* note 123, at 458.

125. *See id.* ("Because most appropriations are restricted to a specific time period . . . the purposes for which they are enacted may vary with changed circumstances. . . . On the other hand, Congress may reenact a rider several times to establish its view as to how an authorizations statute should be interpreted. Court interpretations of limitation riders as amendments to previously enacted legislation, therefore, are inherently unreliable; they may be accurate one day, inaccurate the next, and irrelevant at the end of the fiscal year.").

126. The Executive Branch, through the NIH, consistently argued that the language of the Dickey Amendment was ambiguous in the *Sherley* cases. *See supra* Part II.A.

127. Cummings, *supra* note 24, at 93–95.

128. *Id.* at 93.

House of Representatives in 2009 and, in 2010, a companion bill bearing the same title was introduced in the Senate.¹²⁹ A similar bill was once again proposed in the House of Representatives in 2011.¹³⁰

Passing such a bill has proven difficult but, if successful, would theoretically alleviate many of the worries associated with having a rider control the issue.¹³¹ The position taken by Cummings, which advocates for such legislation to adopt a particular stance,¹³² misses the fundamental purpose of passing comprehensive stem cell legislation. Rather, the rationale for such legislation is to imbue an otherwise muddled issue with much needed clarity, a purpose that would be served regardless of the particular nature of the policies. This is, admittedly, a difficult point to conceive. However, read in light of later discussion in this paper on future policy challenges posed by iPSCs demonstrating that current policies are poorly equipped to address the changing science, it will become clear that the *prima facie* challenge for stem cell policies is not to sort out which stance is more advisable than others; rather, the challenge is to satisfy the bare requirement of accounting for the very science they seek to regulate.

2. Chronological Worries

The second cause for worry in Dickey-Wicker derives from the timing of its drafting and promulgation. Presently, regulatory and normative issues in hESC research are reasonably well defined.¹³³ During the period in which Dickey-Wicker arose, however, this was far from the case.¹³⁴ This fact can be witnessed in two regards. The promulgation of Dickey-Wicker occurred during a period in which biotechnological concerns

129. *Id.*

130. Stem Cell Research Advancement Act, H.R. 2376, 112th Cong. § 1 (2011).

131. A check of the THOMAS database indicates that none of the proposed legislation has made it out of committee for consideration by the full Senate or House. *See, e.g., Bill Summary and Status—H.R.2376, 112th Congress, LIBR.CONGRESS—THOMAS*, <http://thomas.loc.gov/home/Thomas.php> (use search function for H.R. 2376).

132. Cummings, *supra* note 24, at 93.

133. *See, e.g.,* Shannon McGuire, *Embryonic Stem Cells: Marrow of the Dickey Matter*, 11 J. HIGH TECH L. 160, 175 (2010) (describing the roles of the FDA and NIH in regulating hESC research).

134. *See id.* at 177 (explaining that at the time of Dickey-Wicker, “the concept of therapeutic stem cell research had not yet been developed”).

were focused on cloning, IVF, and somatic cell nuclear transfer (SCNT).¹³⁵ These concerns derived largely from worries that resurfaced following the successful cloning of the first mammal, Dolly, a sheep, at the University of Edinburgh in 1996.¹³⁶ As Jonathan Moreno notes: “[s]ince cloning is one way to obtain embryonic stem cells . . . the first tidal wave of publicity about cloning and Dolly merged into the second about embryonic stem cells.”¹³⁷ The scientific backdrop at the time, therefore, had little, if any, concerted focus on emerging issues in stem cell research.

Curiously, because Dickey-Wicker originated in 1995, it predates the discovery of the science it regulates.¹³⁸ As mentioned above, the derivation of the first human embryonic stem cell line would not come until 1998. In this sense, the “authors [of Dickey-Wicker] . . . could not have foreseen the dawn of human ESC research.”¹³⁹ Moreno likewise cites this chronological anomaly, stating that when Dickey-Wicker was passed, “no one anticipated the question that would be raised by the creation of human embryonic stem cells only three years later[;] [n]amely, could the NIH fund studies of cells that came from . . . leftover embryos?”¹⁴⁰ Particularly in the instance of a rapidly changing science like hESC research, it makes little sense to allow Dickey-Wicker to speak to the issue of federal funding when its origins predate the very science it regulates.¹⁴¹

3. Ambiguous Language

The third cause for worry turns on the varied interpretations of what precisely Dickey-Wicker prohibits. This fact is amply witnessed in the case history of *Sherley*. Following the

135. *Id.* at 177.

136. JONATHAN D. MORENO, *THE BODY POLITIC: THE BATTLE OVER SCIENCE IN AMERICA* 104–05 (2011).

137. *Id.* at 107.

138. Stem cells were successfully isolated in 1998, two years after the Dickey Amendment’s passage. McGuire, *supra* note 133, at 177.

139. I. Glenn Cohen & Eli Y. Adashi, *Human Embryonic Stem-Cell Research under Siege—Battle Won but Not the War*, 364 *NEW ENG. J. MED.* e48(1), e48(1) (2011), available at <http://www.nejm.org/doi/pdf/10.1056/NEJMp1105088>.

140. MORENO, *supra* note 136, at 104.

141. McGuire, *supra* note 133, at 177 (“To apply a regulatory law that was enacted before the research protocol was even discovered is not practical nor is it favorable for scientific research and advancement.”).

derivation of the first stable hESC lines in 1998, early proponents of hESC research argued that the purview of Dickey-Wicker did not apply to these new discoveries insofar as federal funds were not used to create these cell lines.¹⁴² In order to ensure compliance with Dickey-Wicker, Harold Varmus, then-chair of the NIH, sought the guidance of Harriet Rabb, then-General Counsel for the Department of Health and Human Services, as to the new hESC discovery.¹⁴³ Rabb asserted that federal funds could not be used to harvest hESCs from an embryo, but they could be used to support subsequent research on those cells.¹⁴⁴ Rabb based this opinion on her view that the statutory definition of “human embryo” did not include hESCs because hESCs are not organisms that, when implanted in the uterus, are capable of becoming a human being.¹⁴⁵ In accord with Rabb’s opinion, the NIH released guidelines that permitted federal funding for research on stem cells that were derived from human embryos using private funds.¹⁴⁶

Change came swiftly, however, after George W. Bush took office in 2001. President Bush put forth a new stem cell research policy, restricting federal funding to existing stem cell lines.¹⁴⁷ This policy superceded the previous NIH guidelines as of November 2001.¹⁴⁸ The Bush policy was repealed in 2009, at the request of President Obama, by the promulgation of updated NIH guidelines.¹⁴⁹ Amidst all of these changes, Rabb’s opinion remained the prevailing governmental interpretation of Dickey-Wicker.¹⁵⁰ However, as the procedural history of *Sherley* demonstrates, this interpretation has been incisively challenged, with judicial interpretations varying between different federal courts in the District of Columbia. This history *in toto* evinces a lack of clarity as to the precise scope and nature of the prohibitions in Dickey-Wicker.

142. Hughes, et al., *supra* note 42, at 407.

143. Fujikawa, *supra* note 32, at 1085–86.

144. *Id.* at 1086.

145. Cohen & Adashi, *supra* note 139, at e48(1).

146. Nat’l Insts. of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976, 51,979 (Aug. 25, 2000).

147. Address to the Nation on Stem Cell Research, *supra* note 120, at 955.

148. Nat’l Insts. of Health Guidelines for Research Using Human Pluripotent Stem Cells, 66 Fed. Reg. 57,107 (Nov. 14, 2001).

149. Nat’l Insts. of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170 (2009).

150. Cohen & Adashi, *supra* note 139, at e48(1).

C. DICKEY-WICKER AND THE MORAL DEBATE

The moral debate surrounding stem cell research confounds efforts to imbue Dickey-Wicker, and stem cell policy in general, with clarity. In the political realm, President Bush brought the moral debate to the fore in 2001, just prior to his significant changes to Clinton-era stem cell research policy.¹⁵¹ In an evening address to the nation, President Bush expressed that hESC research “raises profound ethical questions” because the derivation of hESCs necessitates the destruction of the embryo, thereby “destroy[ing] its potential for life.”¹⁵² This conservative moral stance on stem cell research was reflected in his changes to the Clinton-era policy; specifically, by allowing federal funding for hESCs only for stem cells derived from embryos that had already been destroyed and where, in his words, “the life and death decision ha[d] already been made.”¹⁵³ President Bush had waded into a thorny philosopher’s debate, the contours of which would not start to become well defined until a few years later.¹⁵⁴

In lifting Bush-era stem cell research restrictions, President Obama employed none of the moral language or reasoning of his predecessor. The purpose of lifting Bush-era restrictions, President Obama stated, was “to enhance the contribution of America’s scientists to important new discoveries and new therapies for the benefit of humankind.”¹⁵⁵ Other language in

151. *But see* Hughes et al., *supra* note 42, at 411, 413–15 (arguing that the “normative debate storm clouds over stem cell research” first appeared in the context of President Clinton’s reaction to the announcement in 1997 of the first mammal—Dolly, the sheep—produced through SCNT).

152. Address to the Nation on Stem Cell Research, *supra* note 120, at 956.

153. *Id.* at 955.

154. The debate over the moral status of the human embryo, which bears on the determination of what is considered permissible research on such an embryo, is a rich dialogue well beyond the scope of this article. *Compare* GEORGE & TOLLEFSEN, *supra* note 35, at 202 (claiming that human embryos are human beings with personhood rights), *with* Michael J. Sandel, *Embryo Ethics: The Moral Logic of Stem-Cell Research*, 351 NEW ENG. J. MED. 207, 208 (2004) (challenging the concept that embryos have the same rights as persons), Paul R. McHugh, *Zygote and ‘Clonote’: The Ethical Use of Embryonic Stem Cells*, 351 NEW ENG. J. MED. 209, 210 (2004) (arguing that IVF should strictly be used to produce viable infants, while SCNT should be used only to produce biological matter), *and* Gene H. Outka, *The Ethics of Human Stem Cell Research*, 12 KENNEDY INST. ETHICS J. 175, 206–207 (2002) (proposing that research on excess embryos not created for research is permissible).

155. Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 11, 2009).

his Executive Order emphasized that the hESC research must be “responsible” and “scientifically worthy.”¹⁵⁶ Subsequent NIH draft guidelines, promulgated to implement the changes ordered by President Obama, echoed this language, adding that such research must be “ethically responsible.”¹⁵⁷ This language, which feels almost boilerplate, is distinct from the moral tenor of hESC research opinions expressed by President Bush. In fact, within the academic debate over the moral status of the human embryo, concerted efforts have been made to structure the arguments around what science reveals about the early development of the human embryo.¹⁵⁸

In view of the history of the debate over federal funding of stem cell research, it is likely that moral worries will remain a part of the dialogue. Allowing moral discourse to permeate the dialogue is not in itself problematic. In fact, bioethics has much to offer public policy, not least in facilitating efforts to sort the oft-uncertain implications of new scientific developments. However, the extent to which moral worries control stem cell policy development needs to be constrained. In accord with President Obama’s approach to hESC research funding, effort should be made to curtail the prior impact of normative concerns on the development of new research funding policy. Dickey-Wicker, to be sure, does not offer the best means by which to accomplish such an agenda, owing to the fact that it originally arose in relation to concerns disparate from those that hESCs underscore.¹⁵⁹ Therefore, even if one wanted hESC research policy to reflect a particular moral stance, Dickey-Wicker would be poorly equipped to fulfill this role.

More crucially, I want to suggest that, owing to the discordant viewpoints that bear on the moral debate over the status of the human embryo, we should be hesitant to root the funding debate in normative matters at all. For those sympa-

156. *Id.*

157. Draft Nat’l Inst. of Health Guidelines for Human Stem Cell Research Notice, 74 Fed. Reg. 18,578 (proposed Apr. 23, 2009).

158. See, e.g., GEORGE & TOLLEFSEN, *supra* note 35, at 27–56. William Saletan, who engaged in a fruitful debate with George and Tollefsen in a series of articles, has noted the difficulties of couching the debate in science, particularly for those who, like George and Tollefsen, take a conservative stance on the status of the human embryo. See William Saletan, *Little Children*, N.Y. TIMES BOOK REV., Feb. 10, 2008, at 24 (“[George and Tollefsen’s] argument is brave but risky. Shifting the pro-life case from religion to science puts it at the mercy of scientific discovery, with all the attendant surprises.”).

159. See *supra* Part II.B.2.

thetic to Rawlsian political liberalism, this is likely a palatable claim. For John Rawls, it is reasonable for people in modern democratic societies to disagree about moral questions.¹⁶⁰ As he states: “[I]t is not to be expected that conscientious persons with full powers of reason, even after free discussion, will all arrive at the same conclusion.”¹⁶¹ In view of this, Rawls argues that, when debating justice, we should argue from a “political conception of the person,” which stands apart from our own moral convictions.¹⁶²

Rawlsian moral neutrality finds kinship, to some degree, in Habermas. To be sure, Habermas and Rawls disagree on many things in the domain of political philosophy, yet their shared conception in this regard is striking. Habermas asserts that

Rawls draws the proper conclusion: that the “just society” ought to leave it to individuals to choose how it is that they want to “spend the time they have for living.” It guarantees to each an equal freedom to develop an ethical self-understanding, so as to realize a personal conception of the “good life” according to one’s own abilities and choices.¹⁶³

If we are to take seriously the relevance of moral neutrality as applied to the funding debate—and I contend that we should—then it has salient ramifications for the design of policies like Dickey-Wicker.

Arguing against moral neutrality in Rawls and Habermas, Michael Sandel asserts that, in the instance of stem cell research, “the case for permitting embryonic stem cell research cannot be made without taking a stand on the moral and religious controversy about when personhood begins.”¹⁶⁴ According to Sandel, the argument for permitting hESC research “presupposes an answer to that controversy—namely that the pre-implantation embryo destroyed in the course of embryonic stem cell research is not yet a human being.”¹⁶⁵ If Sandel is right, then my appeal to moral neutrality in political liberalism is mistaken.

In point of fact, I agree with Sandel’s argument. In prom-

160. JOHN RAWLS, *POLITICAL LIBERALISM* 58 (expanded ed. 1993).

161. *Id.*

162. *Id.* at 29–31.

163. HABERMAS, *supra* note 1, at 2.

164. MICHAEL J. SANDEL, *JUSTICE: WHAT’S THE RIGHT THING TO DO?* 252 (2009).

165. *Id.* at 252–53.

ulgating a policy allowing a science that is inextricably bound up with a moral issue, we necessarily adopt the moral stance reflected in the particular side of the debate on which the policy falls. So far as I can tell, this is not a contentious point. In fact, Sandel rightly acknowledges that hESC research is perhaps a “special case,”¹⁶⁶ which is to say that his point cannot likely be generalized to other parts of the law. The purview of Sandel’s argument, however, differs critically from mine. My assertion concerns the *funding* debate, whereas his point speaks to the foundational issue of whether hESC research is to be permitted in the first place.¹⁶⁷ My argument properly distinguishes between this foundational issue, on which I would agree with Sandel, and the funding debate.

Dickey-Wicker, with which my contention is concerned, controls the funding debate, not the issue of whether hESC research should be allowed. I appeal to moral neutrality in the context of the funding debate because any discussion of whether hESC is morally permissible has no place in a debate concerned only with whether federal funding should or should not be allocated. In general, the contours of the hESC debate have been poorly defined, which results in the conflation of two distinct issues: whether hESC research should be allowed in the first place; and, granting that it should, whether it should receive federal funding. I do not suggest that we abandon all discussion of whether the federal government should or should not fund a morally controversial science. This critical issue, which has received little attention, is not the province of this article.

The history of Dickey-Wicker reveals that, when we argue over whether hESC should receive federal funding, we are more often than not actually arguing over whether hESC should be allowed at all.¹⁶⁸ That these separate issues have been conflated in debating the merits of Dickey-Wicker is telling, not merely in the sense that it further demonstrates the weaknesses of Dickey-Wicker, but also in the sense that it highlights how poorly the contours of the stem cell debate are understood in the political realm. Dickey-Wicker, ultimately, seeks to do indirectly what cannot be done directly. That is to say, if moral sentiment dictates that hESC is wrong, and an outright prohibi-

166. *Id.* at 253.

167. *See id.* at 252–53.

168. *See, e.g., id.* (claiming that the “legal question” of whether to allow such research hinges on the underlying moral dilemma).

tion is not viable, cutting off federal funding constituting nearly all funding for hESC research is the next best alternative. The perils of this approach should be quite clear by now. To take seriously our ethic of healing, our policies must, at bottom, exhibit sufficient awareness of the issues at stake.

IV. *BRÜSTLE V. GREENPEACE* AND THE FLAWS OF STEM CELL PATENT REGULATION IN THE EUROPEAN UNION

In this section, I first consider the history of *Brüstle v. Greenpeace*.¹⁶⁹ I then afford careful attention to its tripartite holding,¹⁷⁰ after which I consider the potential ramifications of the decision for biotechnological patents and stem cell research in the EU. This discussion will motivate an analysis of Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, the underlying piece of legislation in *Brüstle*.¹⁷¹ I will argue that the Directive exhibits certain flaws, some of which are akin to those in *Dickey-Wicker*, whereas others are unique to the Directive and its purported aim to unify biotechnological patents across EU Member States.

A. A HISTORY OF *BRÜSTLE*

Oliver Brüstle, Director of the Institute of Reconstructive Neurobiology at the University of Bonn, held a German patent, filed in 1997, relating to isolated and purified neural precursor cells, processes for their production from hESCs, and the subsequent use of neural precursor cells for the treatment of neural defects.¹⁷² Brüstle alleged that the transplantation of brain cells into the nervous system held the promise of treating many neurological diseases, including Parkinson's, for which the first clinical applications had been developed.¹⁷³ The process, however, required the transplantation of immature precursor cells from the human embryo, which accounted for the "significant

169. Case C-34/10, *Brüstle v. Greenpeace e.V.*, 2011 EUR-Lex CELEX LEXIS 2599 (Oct. 18, 2011).

170. *See id.* ¶ 53.

171. Directive 98/44, of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 1, 13 (EC) [hereinafter Directive].

172. *Brüstle*, 2011 EUR-Lex CELEX LEXIS 2599, ¶ 15.

173. *Id.* ¶16.

ethical questions” it raised.¹⁷⁴ The activist group Greenpeace challenged Brüstle’s patent in the Bundespatentgericht, Germany’s Federal Patent Court, which ruled that the patent was invalid.¹⁷⁵

Brüstle appealed the ruling to the Bundesgerichtshof, Germany’s Federal Court of Justice, which referred the case to the ECJ for guidance on three issues.¹⁷⁶ First, the Bundesgerichtshof requested guidance as to the meaning of “human embryos” in Article 6(2)(c) of the Directive.¹⁷⁷ Second, the Bundesgerichtshof requested guidance as to the expression “uses of human embryos for industrial or commercial purposes” in the same section, and specifically asked whether it also covers the use of human embryos for purposes of scientific research.¹⁷⁸ Third, the Bundesgerichtshof requested guidance as to whether a patent that does not directly claim use of human embryos, but either relies on a product whose production necessitates the prior destruction of human embryos or concerns a process for which such a product is needed as base material, is unpatentable.¹⁷⁹ I consider each of these referred questions in succession below.

1. The First Referred Question

With regards to the first question, the ECJ announced a basic principle in EU law that, where no express reference is made to the law of a particular, member state for the purpose of determining its meaning and scope, it must be given an “independent and uniform interpretation” throughout the EU.¹⁸⁰ Accordingly, the ECJ reasoned that, because the Directive neither defines ‘human embryo’ nor makes explicit reference to national laws that might elucidate such a definition, it must designate an “autonomous concept” of EU law with uniform interpretation across member states.¹⁸¹ This conclusion, the

174. *Id.* ¶¶17–18.

175. *Id.* ¶ 19.

176. *Id.* ¶¶ 19, 23.

177. *Id.* ¶ 23; *see also* Directive, *supra* note 171, at 18 art. 6(2)(c) (“[T]he following, in particular, shall be considered unpatentable: . . . (c) uses of human embryos for industrial or commercial purposes.”).

178. Case C-34/10, *Brüstle v. Greenpeace e.V.*, 2011 EUR-Lex CELEX LEXIS 2599 (Oct. 18, 2011).

179. *Id.*

180. *Id.* ¶ 25.

181. *Id.* ¶ 26.

ECJ notes, is in accord with the preamble to the Directive, which expresses the intent to harmonize legislation in this area in an effort to encourage trade and industrial research amongst member states.¹⁸²

This reasoning is obvious enough, yet it has troubling implications. Oddly, the ECJ speculates that, but for a uniform definition, researchers would be tempted to seek patents in those member states that have narrow conceptions of human dignity and, therefore, would be the most liberal in terms of patentability.¹⁸³ Hence, the ECJ seems to acknowledge that different definitions of human dignity exist amongst member states. However, it prioritizes the need for uniformity over these possible differences, based on reference to, *inter alia*, the intent behind the Directive as explicated in the preamble.¹⁸⁴ The ECJ supports this prioritization by noting that it is “not called upon . . . to broach questions of a medical or ethical nature, but must restrict itself to a legal interpretation of the relevant provisions of the Directive” because the “definition of human embryo is a very sensitive social issue in many Member States, marked by their multiple traditions and value systems.”¹⁸⁵ In terms of legal reasoning, this conclusion is not objectionable. However, a point to which I will later return, the fact that the Directive supports this prioritization is worrisome on a policymaking level.¹⁸⁶

Having announced the need for an “autonomous concept,”¹⁸⁷ the ECJ noted that, where definition of a specific term is absent, consideration of its possible meaning must look to the context in which it is employed.¹⁸⁸ In view of this consideration, the ECJ concluded that the context and aim of the Directive evinces the legislative intent “to exclude any possibility of patentability where respect for human dignity could thereby be

182. *Id.* at ¶ 27; *see also* Directive, *supra* note 171, at 13 pmb1. 3 (“Whereas effective and harmonised protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology . . .”).

183. *Brüstle*, 2011 EUR-Lex CELEX LEXIS 2599, ¶ 28.

184. Directive, *supra* note 171, at 13 pmb1. 3.

185. *Brüstle*, 2011 EUR-Lex CELEX LEXIS 2599, ¶ 30.

186. *See infra* Part IV.B.2.

187. *Brüstle*, 2011 EUR-Lex CELEX LEXIS 2599, ¶ 26.

188. *See id.* ¶ 31.

affected.”¹⁸⁹ Accordingly, ‘human embryo’ “must be understood in a wide sense.”¹⁹⁰ Adopting a broad construal, therefore, the ECJ held that ‘human embryo’ includes “any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis.”¹⁹¹

The ECJ left the issue of whether, in light of its recommendations, a stem cell obtained from a human embryo at the blastocyst stage constitutes a ‘human embryo’ under the Directive for the Bundesgerichtshof to determine.¹⁹² Nickas argues that the ECJ’s decision not to reach a conclusion on this issue undermines efforts to afford ‘human embryo’ a uniform meaning across the EU.¹⁹³ Particularly, “by sidestepping the issue, [the ECJ] has impeded, rather than promoted, harmonization of EU patent laws.”¹⁹⁴ In fact, as the argument goes, the referral is a foregone conclusion because isolation of stem cells from human blastocysts necessitates destruction of the embryos, which the ECJ has already stated are excluded from patentability.¹⁹⁵ This argument, however, seems to assuage its own worries. While the ECJ seems to have undercut its efforts towards uniformity with the referral, the very nature of its guidance provides the obvious conclusion to the referred question. In this sense, it does provide the desired uniformity, albeit in an indirect manner. Crucially, the force of *Brüstle* is that the scope of its patentability prohibition answers all questions raised by science where an embryo is destroyed.

2. The Second Referred Question

The ECJ noted that the Directive is intended to regulate

189. *Id.* ¶ 34.

190. *Id.*

191. *Id.* ¶¶ 37–38. As to the latter two inclusions, the ECJ noted that, even though these organisms have not been the object of fertilization, the effect of the technique used to obtain them indicates that they are capable of beginning the process of development of a “human being” in the same manner as an embryo created by fertilization. *Id.* at ¶ 36.

192. *Id.* ¶¶ 37–38.

193. Mark Nickas, *Discordant Harmonization: Did the European Court of Justice Interpret the Biotechnology Directive’s Exclusions to Patentability Too Broadly in Brüstle v. Greenpeace?* 17–18 (2012) (unpublished manuscript) (on file with author), available at http://works.bepress.com/mark_nickas/2.

194. *Id.* at 18.

195. *See id.* at 19.

the patentability of biotechnological inventions, rather than the use of human embryos in scientific research.¹⁹⁶ Restricting itself to the issue of patentability, the ECJ determined that “clearly the grant of a patent implies, in principle, its industrial or commercial application.”¹⁹⁷ Therefore, even though the aim of scientific research differs from industrial and commercial purposes, “the use of human embryos for the purpose of research which constitutes the subject-matter of a patent application cannot be separated from the patent itself”¹⁹⁸ Of note, however, is that the ECJ excluded from this category inventions for therapeutic or diagnostic purposes that are applied for the benefit of the human embryo itself.¹⁹⁹

3. The Third Referred Question

The reasoning that the ECJ employed in considering the first referred question would control its adjudication of the third referred question. Even if a patent does not mention the use of human embryos, the ECJ reasoned, where the implementation of the invention requires the destruction of human embryos, it must also be unpatentable.²⁰⁰ As the ECJ stated:

The fact that destruction may occur at a stage long before the implementation of the invention, as in the case of the production of embryonic stem cells from a lineage of stem cells the mere production of which implied the destruction of human embryos is, in that regard, irrelevant.²⁰¹

Collectively, therefore, the ECJ held that inventions are excluded from patentability where they “require . . . the prior destruction of human embryos or their use as base material.”²⁰² As the ECJ stated, this conclusion is necessary, to some degree, because without such exclusion, skillful drafting of patent applications could circumvent non-patentability.²⁰³

4. Ramifications of the Decision

At present, because the decision is relatively recent, the

196. *Brüstle*, 2011 EUR-Lex CELEX LEXIS 2599, ¶¶ 39–40.

197. *Id.* ¶ 41.

198. *Id.* ¶ 43.

199. *See id.* ¶ 46.

200. *See id.* ¶ 49.

201. *Id.*

202. *Id.* ¶ 52.

203. *See id.* ¶ 50.

full ramifications of its prohibitions are not yet concretely known. Yet, because the ECJ is the highest court in the EU, meaning that its decisions are not appealable and are binding upon all member states, *Brüstle* is considered immensely significant for stem cell researchers.²⁰⁴ Initially, criticism of the decision focused on the negative affect it was likely to have on research funding. Researchers contend that, without patent protection for their developments, it will be difficult to secure funding.²⁰⁵ Without the ability to secure funding, many researchers worry, efforts to develop viable hESC therapies will be stifled.²⁰⁶

Many, however, believe that *Brüstle* will have only limited ramifications. Chiefly, patents for stem cell technologies developed by EU researchers can still be applied for abroad.²⁰⁷ A possible downside to the ability to patent abroad, some have argued, is a potential “brain drain” in the EU in favor of more “biotech-friendly” countries.²⁰⁸ Importantly, *Brüstle* does not foreclose the ability to patent technologies related to hESC research, such as mechanisms and devices for delivering cells.²⁰⁹

The exclusions from patentability in the third referred question have a troubling upshot. By extending the exclusion from patentability to any invention that relies on the destruction of human embryos at a prior stage, the prohibition in *Brüstle* also seems to include inventions based on established cell lines.²¹⁰ While established cell lines are not mentioned as

204. Alexander Denoon, *Brüstle v. Greenpeace: Implications for Stem Cell Research*, 7 REGEN. MED. 85, 86 (2011).

205. See Nuala Moran, *European Court Bans Embryonic Stem Cell Patents*, 29 NATURE BIOTECH. 1057, 1057 (2011). See also David Holmes, *Sound and Fury after Stem Cell Ruling*, 378 LANCET 1617, 1617 (2011) (“[T]he CJEU ruling would ‘make it less likely that companies in Europe will invest in the research to develop treatments to use embryonic stem cells for treatment of human diseases.’”).

206. Moran, *supra* note 205, at 1057.

207. Holmes, *supra* note 205, at 1617; Charlotte Harrison, *EU Bans Embryonic Stem Cell Patents but Decision May Have Limited Implications*, 10 NATURE 892, 893 (2011). But see Moran, *supra* note 205, at 1058 (noting that some patents might not be applied for because, if EU researchers patent abroad, they will have to disclose information that could otherwise be kept as a trade secret in Europe).

208. Enrico Bonadio, *Stem Cells Industry and Beyond: What is the Aftermath of Brüstle?* 1 EUR. J. RISK REG. 93, 94 (2012).

209. Harrison, *supra* note 207, at 893; Moran, *supra* note 205, at 1059.

210. Berthold Rutz, *From Bench to Market: Life Science Patents in Europe*, 7 BIOTECHNOL. J. 171, 174 (2012).

such in the ECJ opinion, this conclusion finds support in the wide prohibition expressed in the ruling on this referred question.²¹¹ This concern, furthermore, raises the question of what will become of current patents that rely, at some prior stage, on the destruction of human embryos, perhaps from established cell lines. A strong reading of *Brüstle* would cast doubt on the enforceability of such patents post-*Brüstle*, which is to say that the retroactive reach of the decision remains uncertain.²¹²

B. PRACTICAL AND MORAL CONCERNS IN THE DIRECTIVE

1. Chronological Worries

The Directive, adopted in 1998 after over a decade of drafting, was an effort to harmonize biotechnology patent laws amongst the EU Member States.²¹³ It had economic motives, aiming to foster progress in the EU biotechnology industry by imbuing a fragmented patent law system with uniformity and clarity.²¹⁴ Much like Dickey-Wicker, the chronology of the drafting process suggests that the Directive could not possibly have anticipated salient changes in hESC research that occurred in 1998, even though it would come to regulate this area vis-à-vis patentability. While discussing Dickey-Wicker, I noted that dominant bioethical concerns at that time turned on the possibility of human cloning, in light of the first successful cloning of a mammal. Against the backdrop of human cloning worries, the first direct reference to the human embryo in the drafting process of the Directive occurred in 1996, following rejection of its

211. See *Brüstle*, 2011 ECJ EUR-Lex CELEX LEXIS 2599, ¶ 49 (“[A]n invention must be regarded as unpatentable [. . .] where the implementation of the invention requires the destruction of human embryos. [. . .] The fact that destruction may occur at a stage long before the implementation of the invention, as in the case of the production of embryonic stem cells from a lineage of stem cells the mere production of which implied the destruction of human embryos is, in that regard, irrelevant.”).

212. See Moran, *supra* note 205, at 1059 (noting the argument that existing patents would be difficult to enforce because anyone copying them would just assert that the patent is not enforceable).

213. See Aurora Plomer et al., *Challenges to Human Embryonic Stem Cell Patents*, 2 CELL STEM CELL 13, 15 (2008); Gerard Porter, *The Drafting History of the European Biotechnology Directive*, in EMBRYONIC STEM CELL PATENTS: EUROPEAN LAW AND ETHICS 3, 7–10 (Aurora Plomer & Paul Torremans eds., 2009).

214. Porter, *supra* note 213, at 8.

first draft in 1995.²¹⁵ In fact, the Directive affords central import to human cloning worries, citing “processes for cloning human beings” as the first specific example of an unpatentable invention.²¹⁶

2. Imprecise Normative Language

The Directive employs normative language to structure its prohibitions, but it fails to provide sufficient guidance as to its precise meaning. This lack of clarity, as it can be imagined, begets interpretive difficulties. This fact can be witnessed in *Brüstle*, where the ECJ had to conjecture as to the meaning of normative terminology in the Directive.²¹⁷ While the decision of the ECJ in *Brüstle* is easy to criticize, there is a sense in which, given the poor design of the language in the Directive, the ECJ’s broad construal of the patentability prohibitions could not have been otherwise. By emphasizing the need for harmony across Member States, without affording sufficient underlying guidance, the Directive promotes the prioritization scheme expressed by the ECJ in its opinion, where an emphasis on harmonization hampers both normative and regulatory clarity.

Consider the way in which normative principles structure prohibitions in the Directive. The Directive stresses that one of its purposes is to exclude from patentability inventions whose “commercial exploitation offends against *ordre public* or morality.”²¹⁸ In an apparent effort to provide definitional clarity, the Directive states that “*ordre public* and morality correspond to ethical or moral principles recognised in a Member State.”²¹⁹ The Directive likewise notes that the list of inventions it explicitly excluded from patentability is not to be regarded as comprehensive, but serves as a guidepost under the umbrella principle that other processes that “offend against human dignity” are “obviously also excluded.”²²⁰ As an example of such exclu-

215. Porter, *supra* note 213, at 14, 18.

216. Directive, *supra* note 171, at 18 art. 6(2)(a).

217. See generally *Brüstle*, 2011 EUR-Lex CELEX LEXIS 2599, ¶ 30 (noting that “the definition of human embryo is a very sensitive social issue in many Member States, marked by their multiple traditions and value systems,” but asserting that the court sought only to interpret the language of the Directive, and not to “broach questions of a medical or ethical nature”).

218. Directive, *supra* note 171, at 16 pmbl. 37.

219. *Id.* at 16 pmbl. 39.

220. *Id.* at 16 pmbl. 38. See *id.* at 18–19 art. 6(2)(a)–(d) (“[T]he following, in particular, shall be considered unpatentable: (a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of hu-

sions, the Directive specifies “processes to produce chimeras from germ cells or totipotent cells of humans and animals.”²²¹

The Directive’s use of normative principles—particularly, “morality” and “human dignity”—admits of at least two arguments. First, as a foundational matter, we must ask whether the use of normative principles is appropriate in legislation like the Directive. If it is conceded that normative principles are in fact appropriate in this context, then we can turn to the second argument, which concerns how, and to what extent, guidance should be offered as to the meaning of these principles. In considering whether normative principles are ever appropriate in legislation like the Directive, it is crucial to bear the ultimate objective of the Directive in mind. The Directive has a pragmatic intent, seeking to promote harmonization of biotechnological patent protection across Member States.²²² We can, therefore, bracket dense concerns over the extent to which law and morality ought ever to intersect in the first place. If use of normative principles in the Directive best advances its pragmatic intent, then their inclusion would not be *prima facie* problematic.

For the Directive, however, use of normative principles necessarily undercuts its intent to promote harmonization. Considering first the use of the term “human dignity,” an inherently indeterminate moral concept, whether a particular conception of the term applies to the life of the human embryo depends on the specific moral and religious backgrounds of its bearer.²²³ EU legislation has the unpropitious charge of respecting the oftentimes widely divergent social, cultural, and religious backgrounds of its member states.²²⁴ Owing to diverse backgrounds, member states do not all conceive of human dig-

man beings; (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such process.”).

221. *Id.* at 16 pmb. 38.

222. *See, e.g., id.* at 13 pmb. 3–7.

223. *See* Aurora Plomer, *Human Dignity, Human Rights, and Article 6(1) of the EU Directive on Biotechnological Inventions*, in *EMBRYONIC STEM CELL PATENTS: EUROPEAN LAW AND ETHICS* 203, 219 (Aurora Plomer & Paul Torremans eds., 2009).

224. *See, e.g.,* Directive, *supra* note 171, at 16 pmb. 36–37 (noting that the Directive must stress the exclusion of patents that offend the *ordre public*, or normative policy values, of member states).

nity equally.²²⁵ This fact is witnessed in the diversity of moral and religious perspectives represented across member states' constitutions, laws, and regulations on bioethical issues such as IVF, embryo research, and abortion.²²⁶

The term "morality" in the Directive presents similar issues to those expressed in relation to "human dignity." Viens argues that use of the concept of morality within intellectual property law is generally problematic.²²⁷ In the specific context of biotechnological patents in the EU, the concept of morality has been historically troublesome, owing to multiple uncertain uses by the European Patent Office and its related institutions.²²⁸ Without a clear, uniform interpretation of morality in the context of EU biotechnological patents, no general framework exists to provide guidance as to which inventions do or do not offend against morality.²²⁹ Absent some shared conception of morality and human dignity across member states, it is unclear how the intent to promote harmonization is best served by relying on these normative principles.

Suppose, in the contrary, that member states in fact conceive these normative concepts equally or at least closely enough so as to not encumber harmonization efforts. Even so, the lack of definitional guidance in the Directive would beget difficulties. Specifically, the Directive does not offer sufficient

225. Plomer, *supra* note 223, at 219. See Janne Rothmar Herrmann, *The Brüstle Case: Has the European Court of Justice Overstepped Its Competency in Deciding the Status of the Embryo?* 7 (Mar. 21, 2012) (unpublished manuscript), available at <http://ssrn.com/abstract=2028307> ("Applying a common ethical standard within a community such as the European Union does . . . raise the question of how the respect for the Member States' different cultural and religious characteristics is maintained."); Ciara Staunton, *Brustle v Greenpeace, Embryonic Stem Cell Research and the European Court of Justice's New Found Morality*, 21 *Med. L. Rev.* (forthcoming Winter 2013) (manuscript at 9–10) available at <http://medlaw.oxfordjournals.org.ezp2.lib.umn.edu/content/early/2012/08/06/medlaw.fws026.full.pdf+html> ("It would have been preferable if the ECJ had left Member States to each determine whether the patenting of embryonic stem cell research is immoral based on its own moral standards. While such a decision would be at the expense of harmonisation, it would have more accurately reflected the differing policies in relation to embryonic stem cell research across Europe.").

226. Plomer, *supra* note 223, at 219.

227. A. M. Viens, *Morality Provisions in Law Concerning the Commercialization of Human Embryos and Stem Cells*, in *EMBRYONIC STEM CELL PATENTS: EUROPEAN LAW AND ETHICS* 85, 87 (Aurora Plomer & Paul Torrems eds., 2009).

228. *Id.*

229. *Id.* at 89.

explication of the normative concepts it employs. The use of undefined normative language, particularly with respect to the concept of human dignity, has been criticized in other biotechnological contexts; for example, Caulfield and Ogbogu note the suggestion that human dignity is often used as a mere slogan or as a “vague placeholder for a variety of imprecise fears about socially controversial science.”²³⁰ Along similar lines, Macklin opines that, without criteria to determine when human dignity has been violated, it “remains [a] hopelessly vague” concept.²³¹ Read in view of the rich and varied interpretations of normative principles across European member states, it would be a mistake to presume that such language admits a shared meaning.

There remains the issue of whether, even absent sufficient definitional clarity, a particular stance on morality can be inferred from the Directive as it stands. This is an important matter, not least because the existence of any particular moral stance will bear on efforts to promote biotechnological harmonization across Member States. The text of the Directive catalogues myriad unpatentable inventions,²³² to which I have previously referred. In doing so, the prohibitions in the Directive come to encompass a wide gamut of unpatentable inventions. For instance, processes for cloning human beings—whatever these may be—and processes for modifying the germline genetic identity of human beings, both of which are cited in the Directive as unpatentable,²³³ are quite different things.

The expansive scope of the prohibitions in the Directive suggests that the normative concepts employed therein can be read as evincing a conservative stance on morality in the biotechnological sphere. Put differently, the reach of its prohibitions includes many of the specific biotechnological areas that conservatives would consider morally questionable.²³⁴ This in-

230. Timothy Caulfield & Ubaka Ogbogu, *Stem Cell Research, Scientific Freedom and the Commodification Concern*, 13 EUR. MOLECULAR BIOLOGY ORG. 12, 12 (2011).

231. See Ruth Macklin, *Dignity Is a Useless Concept*, 327 BRIT. MED. J. 1419, 1420 (2003).

232. Directive, *supra* note 171, at 18–19 art. 6(2)(a)–(d).

233. See *id.* at 18 art. 6(2)(a)–(b).

234. Cf. REPUBLICAN NAT'L COMM., 2012 REPUBLICAN PLATFORM 41 (2012), available at <http://www.gop.com/wp-content/uploads/2012/08/2012GOPPlatform.pdf> (“We call for expanded support for the stem-cell research that now offers the greatest hope for many afflictions[—]with adult

terpretation finds support in the ECJ's wide construal of the term 'human embryo' in the Directive.²³⁵ That the Directive reflects a conservative moral stance on biotechnology is not itself problematic, at least not by virtue of it being conservative. It is, however, problematic that the Directive reflects *any* particular moral stance at all, whether conservative, progressive, or transhumanist. If the chief intent of the Directive is to promote biotechnological harmonization across member states, it must respect the varying social, cultural, and religious traditions, which bear on particular conceptions of morality, across member states. Insofar as the Directive embodies a singular approach to morality, it necessarily undercuts its efforts towards harmonization.

3. The "Commodification" Issue

Commodification refers broadly to "turning something that is not regarded as a commercial product into a product."²³⁶ Far from novel, commodification worries have factored prominently in ethical discussions of biotechnology for decades.²³⁷ I will refer to the use of commodification worries in the biotechnological context as the 'argument from commodification.' The trouble with this argument will be apparent from the start. In point of fact, the argument from commodification evades precise definition. In a broad sense, it opines that "certain moral . . . goods are diminished or corrupted if bought or sold."²³⁸

When applied in the context of biotechnological discussions, commodification worries are cast in terms of objectifying human beings or parts of the human body, which is thought to offend, *inter alia*, human dignity and the intrinsic moral worth one would usually accord to such things.²³⁹ The Directive attends to these worries, rendering inventions unpatentable

stem cells, umbilical cord blood, and cells reprogrammed into pluripotent stem cells-without the destruction of embryonic human life. We urge a ban on human cloning and on the creation of or experimentation on human embryos.").

235. *Brüstle*, 2011 EUR-Lex CELEX LEXIS 2599, ¶ 34; *see id.* ¶¶ 35–38.

236. Michele Garfinkel, *Stem Cells, Morals and the Courts*, 13 EUR. MOLECULAR BIOLOGY ORG. 2, 2 (2012).

237. *See generally* MORENO, *supra* note 136, at 121–42 (tracing the issue of commodification, in economic theory, to Marx's early writings, and how it has been recast in biotechnological arguments since early worries over human cloning).

238. MICHAEL J. SANDEL, WHAT MONEY CAN'T BUY: THE MORAL LIMITS OF MARKETS 111 (2012).

239. *See* Caulfield & Ogbogu, *supra* note 230, at 13.

“where their commercial exploitation would be contrary to *ordre public* or morality.”²⁴⁰ More specifically, it excludes from patentability “uses of human embryos for industrial or commercial purposes.”²⁴¹ In fact, Greenpeace framed its challenge to Oliver Brüstle’s patent so as to invoke commodification worries.²⁴²

In the biotechnological context, however, the argument from commodification is poorly defined. Caulfield and Ogbogu contend that the argument is “rarely more nuanced than the following: commodification is bad because it leads to commodification.”²⁴³ They opine that the vagueness with which the argument often proceeds “impedes and frustrates ethical reflection.”²⁴⁴ The Directive, to be sure, is not charged with guiding ethical reflection, yet the appeal to the argument from commodification in its provisions becomes problematic when engaged as grounds for patent prohibitions. As Viens notes, EU and national European advisory boards provide no formal definition of commodification in conjunction with its use.²⁴⁵

Viens criticizes the argument from commodification in the context of stem cell patents on the grounds that it does not respect differences between regulating patents themselves and commercial activities that might occur beyond the grant of biotechnology patents, but instead conflates the two.²⁴⁶ Granting a patent on stem cell related technologies implies “providing exclusive rights to the patent holder(s) to prohibit third parties from exploiting [them] for industrial or commercial purposes.”²⁴⁷ While patenting such technologies might entail commercial application, or the bestowal of some commercial value, it need not, which demonstrates that one should not make such a presumption when evaluating the morality of such a patent.²⁴⁸ In *Brüstle*, the ECJ failed to make this distinction, conflating worries over the commercialization of hESC patents with the

240. Directive, *supra* note 171, at 18 art. 6(1).

241. *Id.* at 18 art. 6(2)(c).

242. See Garfinkel, *supra* note 236, at 2.

243. Caulfield & Ogbogu, *supra* note 230, at 14.

244. *Id.*

245. Viens, *supra* note 227, at 99.

246. See *id.* at 102.

247. *Id.*

248. *Id.* at 101–02.

mere grant of the patents themselves.²⁴⁹

Viens' critique of the argument from commodification holds in the context of the Directive. The vague appeal to the argument from commodification in the Directive begets at least two worries. First, the Directive does not provide guidance with regard to why certain biotechnological inventions offend against commodification worries while others do not.²⁵⁰ In not providing such guidance, the Directive frustrates efforts to offer clear guidelines for courts, lawyers, and researchers charged with sorting out its applications. As a result, the aim of the Directive to promote biotechnological harmonization across Member States is once again stifled. Second, by appealing to the argument from commodification, the Directive demonstrates a troublesome fact about the nature of the appeal itself, namely, that the argument from commodification is often used for "its rhetorical weight and persuasive force,"²⁵¹ rather than for its sound logic. Few would disagree, for instance, that exploiting human embryos for commercial gain is morally objectionable. In this sense, the Directive charms our common moral intuitions without demonstrating why such moral pangs ought to be offended in the first place.

V. iPSCS AND FUTURE POLICY CHALLENGES

In this section, I begin by detailing critical differences between hESC and iPSC research. I then consider the extent to which current policies are able to account for these critical differences. In closing, I survey the potentially problematic aspects of iPSC research, with the intention of defining the trajectory that future iPSC policies should follow.

A. ACCOUNTING FOR CRITICAL DIFFERENCES

Thus far I have considered weaknesses in two key pieces of stem cell legislation, made apparent through their treatment by judicial bodies in the US and EU. At its core, Dickey-Wicker

249. See *Brüstle*, 2011 EUR-Lex CELEX LEXIS 2599, ¶¶ 41–43 (“[C]learly the grant of a patent implies, in principle, its industrial or commercial application.”). A similar critique of the ECJ’s decision argues that it incorrectly equated “for industrial or commercial purposes” with “[susceptible of] industrial application.” Nickas, *supra* note 193, at 20–21.

250. The argument from commodification has been generally criticized on similar grounds, namely, that it rarely explicates the scope of commodification. See, e.g., Viens, *supra* note 227, at 99 n.40.

251. See Caulfield & Ogbogu, *supra* note 230, at 14.

poses a fundamental, yet thorny, question, namely, may federal funds be allocated to hESC research, which by nature entails the destruction of human embryos?²⁵² As I have noted, this question has received manifold answers in the judiciary and by three Presidential Administrations.²⁵³ The Directive, conversely, has enjoyed a far less tumultuous history, yet the crux of its patent prohibition—namely, whether an invention that relies, either directly or at some moment in its development, on the destruction of human embryos, is patentable—plucks the very same moral strings.²⁵⁴ Different though the nature of their regulations is, both Dickey-Wicker and the Directive share the same concern over the morally contentious origins of hESC research.

Unlike hESC research, however, iPSC research does not necessitate the destruction of human embryos.²⁵⁵ As a result, iPSC research circumvents ethical worries *vis-à-vis* the moral status of the human embryo. Even George and Tollefsen, who have heavily criticized hESC research because, in their view, human embryos are human beings and thus deserve full moral respect, embrace the promise of iPSC research. As they state: “iPS cells clearly offer the possibility of a research program for regenerative medicine that does not require the destruction of human beings in their earliest developmental stages. *That* is a possibility to be embraced by all.”²⁵⁶ The importance of the ethically uncomplicated origins of iPSCs for current stem cell research policies cannot be overstated.

The prohibitions in Dickey-Wicker assume the destruction of human embryos—after all, hESC research, which is the sole focus of Dickey-Wicker, necessitates the destruction of human

252. See *supra* Part III.A.3.

253. See *supra* Part III.A.3–6.

254. See *supra* Part IV.A.

255. See Zacharias et al., *supra* note 16, at 637 (“Human embryos need never be destroyed to obtain iPSC cells, but their destruction is required to obtain hES cells.”). Zacharias et al. note that, in theory, iPSCs could be used to create human embryos. *Id.* However, as they stress, “iPS technology does not require or mandate the creation of human embryos.” *Id.* To guard against abuse of iPSC technology by “maverick” scientists willing to risk both career loss and legal action, they suggest “enact[ing] logical, universal policy with severe penalties to discourage potential misuse” *Id.* at 638. Paralleling IVF technologies, which are not forbidden merely because of their potential contribution to cloning efforts, they argue that iPSC technologies should not be hampered by theoretical abuses. *Id.*

256. GEORGE & TOLLEFSEN, *supra* note 35, at 222 (emphasis in original).

embryos.²⁵⁷ As I have noted, hESC research will still remain relevant, despite the emergence of iPSC research in recent years.²⁵⁸ With that said, Dickey-Wicker—and all of its attendant flaws—will remain applicable to hESC research. For iPSC research, however, Dickey-Wicker is irrelevant. It would not preclude the availability of federal funding for iPSC research because this research neither entails the creation of human embryos for research purposes nor constitutes research in which human embryos are destroyed. As I will demonstrate in the subsequent section, iPSC research has its own peculiar ethical concerns, none of which are triggered by the central prohibition in Dickey-Wicker.

For the Directive, the implications of the morally uncomplicated origins of iPSCs are less clear. As I considered above,²⁵⁹ in *Brüstle*, the ECJ interpreted the meaning of ‘human embryo’ in the Directive in a wide sense.²⁶⁰ Vrtovec and Scott argue that this broad interpretation, articulated with teleological language—“capable of commencing the process of development of a human being”²⁶¹—is potentially troublesome for future technologies like iPSCs.²⁶² By using teleological language, rather than common embryological parlance, they contend, the broad definition “ignores the actions taken in order to prove a cell can commence the process of human development.”²⁶³ The revelation that *Brüstle* rests on imprecise language should be unsurprising by this point. Vrtovec and Scott note that some early developments in iPSC research, such as the injection of murine iPSCs into tetraploid embryos, thereby producing viable mice and satisfying an *in vivo* test, would seem to fall within this teleological language.²⁶⁴ In short, they worry that teleological language in *Brüstle* “would seem to extend to new technologies designed to overcome the very ethical concerns [that the ECJ] is trying to avoid.”²⁶⁵

257. O’Quinn, *supra* note 26, ¶ 6.

258. *See supra* Part I.

259. *See supra* Part IV.A.1.

260. *See Brüstle*, 2011 EUR-Lex CELEX LEXIS 2599, ¶ 34.

261. *Id.* ¶ 36.

262. Katja Triller Vrtovec & Christopher Thomas Scott, *The European Court of Justice Ruling in Brüstle v. Greenpeace: The Impacts on Patenting of Human Induced Pluripotent Stem Cells in Europe*, 9 CELL STEM CELL 502, 502 (2011).

263. *Id.*

264. *Id.*

265. *Id.*

It is easy to see that reliance on unspecified and broad teleological language to define ‘human embryo’ could be problematic for iPSCs. In fact, debate already exists as to the measure of moral worth that ought to be accorded to iPSCs, due in some part to confusion over how early embryo development aligns with teleological language not unlike that in *Brüstle*.²⁶⁶ Despite the fact that iPSC research need not involve the destruction of human embryos, some have posited that iPSCs ought to be accorded equivalent moral status to hESCs.²⁶⁷ As Watt and Kobayashi argue, however, this position is spurious.²⁶⁸ Those arguing for equal moral status between hESCs and iPSCs aver that, because iPSCs appear to possess the same capacity as hESCs to reach early differentiation stages, where individuation first occurs, they are functionally equivalent and thus deserve the same moral status as hESCs.²⁶⁹ Watt and Kobayashi have a convincing counter to this position. They argue that the special moral status of hESCs is “in virtue of their having the potential to develop into adult human beings, not in virtue of their capacity to achieve any particular early stage of embryonic development.”²⁷⁰

Apart from these concerns, iPSCs present other novel difficulties for the Directive. I have noted above that the Directive, much like Dickey-Wicker, arose at a time in which policymakers could not have foreseen crucial hESC discoveries, let alone subsequent iPSC discoveries.²⁷¹ Unlike Dickey-Wicker, however, we have seen that the Directive structures its patent prohibitions in terms of the vaguely defined notion of human dignity, which accounted for interpretive difficulties for the ECJ in *Brüstle*.²⁷² For patentability issues in iPSC research, this normative language seems likely to engender similar difficulties. Although the ethically uncomplicated origins of iPSCs would

266. See, e.g., Julia C. Watt & Nao R. Kobayashi, *The Bioethics of Human Pluripotent Stem Cells: Will Induced Pluripotent Stem Cells End the Debate?* 2 OPEN STEM CELL J. 18, 21 (2010) (noting the argument that “[b]ecause human iPSC cells appear to possess the same capacities as human ES cells . . . they are thought to possess the same embryo-like developmental capacity,” and may therefore raise similar ethical concerns).

267. *Id.*

268. *Id.* at 21–22.

269. *Id.* at 21.

270. *Id.*

271. See *supra* Part IV.B.1.

272. See *supra* Part IV.B.2.

not seem to offend against human dignity as construed in the language of the Directive itself, in view of the ECJ's broad rendering of 'human embryo' and the ensuing difficulties, courts will be forced to grapple with potentially conflicting positions on the patentability of iPSC technologies.

B. ANCILLARY ETHICAL CONSIDERATIONS

If iPSC research has ethically uncomplicated origins, the question becomes: is there *anything* ethically problematic about iPSC research? As we have witnessed, the extent to which a type of stem cell research implicates ethically contentious issues bears a direct relation to the nature of its regulation. The general consensus among commentators seems to be that, despite their ethically uncomplicated origins, iPSCs likely engender other ethical concerns.²⁷³ These ethical concerns surrounding iPSC research require a shift in perspective, such that policymakers must now look to potential ethical complications associated with downstream uses for iPSCs, rather than to foundational concerns associated with the nature of iPSC research itself.

One area of growing concern for iPSC research turns on somatic cell donor consent requirements. Aalto-Setälä et al. propose significant changes to the somatic donor consent requirements that currently apply when researchers collect somatic cells in which to induce pluripotency.²⁷⁴ They point to potential future uses for iPSCs, such as in large-scale genome sequencing and human-animal chimerism, which carry special ethical considerations of which donors should be made aware.²⁷⁵ Similarly, Brown argues that “[d]ownstream users of products developed within a comparative pluripotency research program . . . have an interest in avoiding complicity in practices which they deem morally unacceptable.”²⁷⁶

Asking more of donor consent requirements in the instance of iPSC research does not seem misplaced, given that the theoretical use of iPSCs is manifold. Notwithstanding a valid con-

273. See, e.g., Sipp, *supra* note 15, at 361 (“[I]t is unlikely that iPSCs will be entirely free of ethical problems as they become more widely accessible.”).

274. See Katriina Aalto-Setälä et al., *Obtaining Consent for Future Research with Induced Pluripotent Cells: Opportunities and Challenges*, 7 PLOS BIOLOGY 204, 206–07 (2009).

275. *Id.* at 205.

276. Mark Brown, *No Ethical Bypass of Moral Status in Stem Cell Research*, BIOETHICS (forthcoming 2012) (manuscript at 6).

cern for the adequacy of informed consent for somatic cell donors, however, some of the particular sources of concern seem to stretch the association between what is likely and what is merely possible. For instance, while iPSCs could theoretically be used for human-animal chimerism purposes, it seems much more likely that initial uses for iPSCs will focus on advancing the therapeutic purposes that hESCs have been so slow to provide.

It is worth noting that not all downstream uses for iPSCs are ethically problematic. For instance, Holm notes that developments in iPSC research stand to lessen reliance on human egg donation.²⁷⁷ Given that somatic cells are the only cells required for iPSC derivation, a simple cheek swab will suffice, thus obviating the need to obtain human ova.²⁷⁸ Given the invasive nature of the egg donation process,²⁷⁹ lessening reliance on human ova is medically relevant. Moreover, by lessening reliance on human ova, ethical concerns about the potential exploitation and coercion of egg donors are also greatly reduced.²⁸⁰

That current hESC-focused policies cannot account for ethical concerns surrounding potential downstream uses for iPSCs should be unsurprising. Even the Directive, which explicitly excludes from patentability inventions related to, *inter alia*, cloning human beings and “processes for modifying the germ line genetic identity of human beings,”²⁸¹ does not account for the multitude of potential downstream uses for iPSCs that might be ethically problematic. To no small degree, the ability to fulfill the unrealized potential of hESC research will depend on the careful balancing of iPSC research policies. While it might well be easy to isolate those downstream uses about which most would feel some moral trepidation, the challenge becomes demarcating just how far regulatory prohibitions ought to extend, without needlessly stifling our ethic of healing.

277. Søren Holm, *Time to Reconsider Stem Cell Ethics—The Importance of Induced Pluripotent Cells*, 34 J. MED. ETHICS 63, 63 (2008), available at <http://jme.bmj.com/content/34/2/63.full.pdf+html>.

278. Watt & Kobayashi, *supra* note 266, at 22.

279. Holm, *supra* note 277, at 63.

280. *Id.*; Watt & Kobayashi, *supra* note 266, at 22.

281. Directive, *supra* note 171, at 18 art. 6(2).

C. THE UBIQUITOUS SPECTER OF COMMODIFICATION

The fact that iPSC research does not involve the destruction of human embryos would seem, at first blush, to negate the applicability of the argument from commodification. For, if iPSC research circumvents disagreement over the moral status of the human embryo, how can commodification worries like those expressed in the context of hESC research continue to obtain? As I noted in the previous section, however, downstream uses for iPSCs add a salient wrinkle to the less ethically complicated status of iPSCs.²⁸² If iPSCs successfully increase access to pluripotency, downstream research activities might accelerate. As Sipp opines: “[P]luripotency has not only become a commodity, it is becoming a disposable one.”²⁸³ Moreover, given rapid progress in iPSC research, coupled with low regulatory entry barriers, the likelihood is high that unforeseen new applications for iPSCs will emerge.²⁸⁴

The argument from commodification is inherently bound up with downstream uses because the scope of the argument is itself so broad. As Watt and Kobayashi observe, the argument from commodification is not premised on the “literal buying and selling of human parts,” but on “the erosion of respect for the inherent value and dignity of human life that results when people start to view the constituents of human life (including embryos, gametes, somatic cells, and genes) in instrumental terms.”²⁸⁵ On their view, iPSC research would encourage people to conceive iPSCs in terms of their instrumental value, namely, *vis-à-vis* their value to specific research objectives.²⁸⁶ Importantly, they conclude that, for similar reasons, iPSCs would not be immune from commodification worries in the context of patentability.²⁸⁷

Even if the argument from commodification persists, it is a quite different matter to say that it has a place in future policymaking. I have already demonstrated that the argument from commodification is deeply flawed and has only served to further complicate development of effective stem cell policies.²⁸⁸

282. See *supra* Part V.B.

283. Sipp, *supra* note 15, at 362.

284. *Id.* at 361.

285. Watt & Kobayashi, *supra* note 266, at 22.

286. See *id.*

287. See *id.*

288. See *supra* Part IV.B.3.

Policymakers must distinguish between regulating iPSC research itself and regulating downstream uses for iPSCs. While the latter might trigger commodification worries, the former need not. However, if future policies ignore this distinction, instead conflating iPSCs with ethically complicated downstream technologies, unnecessary restrictions might result. This concern is not unfounded. For instance, as I considered above, the Directive conflates commodification worries with the purpose for granting a patent, which results in improper limitations being placed on the patentability of hESC technologies.²⁸⁹ For iPSC research, allowing worries regarding downstream uses to dictate overall iPSC policy would impede efforts to realize the technology's full therapeutic potential.

VI. CONCLUSION

In this article, I have endeavored to surface the flaws of current stem cell policies. I have, moreover, stressed that these flaws run much deeper than one might suspect, such that current policies are unfit to account for future challenges posed by iPSCs. In closing, I wish to stress a concern that emanates from the contextual points with which this article began. As the spectrum of biotechnological activities continues to widen, our ethic of healing will only further quarrel with the bounds imposed by moral inquiry. To conceive of the legislative difficulties that beset stem cell research as isolated and unique would be a hopelessly parochial characterization of the trajectory of modern biotechnological advancements.

None of this, however, is to suggest that moral inquiry should or should not reign in our ethic of healing. The ready willingness with which we intuit the worth of our ethic of healing seems equal to the ease with which our shared sense of moral concern motivates us to ask certain questions. The push and pull of moral inquiry against our ethic of healing, although sometimes difficult to justify, is ultimately necessary. As I have shown in the instance of stem cell research, the challenge for science policy is to exhibit a sound understanding of the underlying science, so as to properly define the moral inquiries that will necessarily be implicated in any regulatory schema. For advancements in stem cell research, as with any biotechnology, the extent to which our ethic of healing is to yield therapeutic

289. See *supra* Part IV.B.3.

benefits will ultimately be dependent on the maintenance of policies that do not carelessly appeal to broad or irrelevant ethical worries.