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Foreword: Biomedical Research and the Law- Embryonic Stem Cells, Clones, and Genes: Science, Law, Politics and Values

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BIOMEDICAL RESEARCH AND THE LAW— EMBRYONIC STEM CELLS, CLONES, AND GENES: SCIENCE, LAW, POLITICS, AND VALUES

FOREWORD

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The articles presented in this symposium issue developed from papers delivered at the second in a series of conferences at Hofstra University devoted to the study of “Biomedical Research and the Law.” The first conference, held in October 2006,¹ focused on conflicts occasioned by industry funding of biomedical research. The second conference, the subject of this issue, occurred in March 2008 and was dedicated to the study of “Embryonic Stem Cells, Clones, and Genes: Science, Law, Politics and Values.”² This conference provided a

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1. Papers delivered at the first conference in the series, “The Pharmaceutical Industry and Its Relationship with Government, Academia, Physicians, and Consumers,” are included in a symposium issue of the *Hofstra Law Review*. Symposium, *Biomedical Research and the Law—Selected Issues: The Pharmaceutical Industry and Its Relationship with Government, Academia, Physicians, and Consumers*, 35 HOFSTRA L. REV. 681 (2006). The symposium volume includes papers delivered at that conference.

2. We are grateful to Hofstra University, Hofstra Law School, the Hofstra Cultural Center, and the law firm of Garfunkel, Wild & Travis, P.C. for supporting and sponsoring the conference. We are especially appreciative to Natalie Datlof, Executive Director, and Athelene A. Collins, Senior Associate Director, both of the Hofstra Cultural Center. Their commitment to the project contributed significantly to its success. We appreciate the participation of North Shore-Long Island Jewish Health System in planning the conference. We thank Toni Aiello, Reference Librarian at Hofstra Law School, for generous and intelligent help in identifying research material, and we thank

productive context for debate among lawyers, physicians, scientists, theologians, philosophers, journalists, and others about a set of pressing questions facing American society. Among these were questions about how, if at all, to regulate research involving the destruction of embryos, about how best to fund such research, about the potential medical uses of human embryonic stem cells, and about the likely social consequences of research involving them. Participants in the conference debated the relationship between science and religion, and the significance to be assigned to each in research involving embryonic stem cells.

The papers presented at the second conference discussed the moral and political contexts of the intense debate regarding human embryonic stem cell ("hESC") research and developments in science that may diminish the intensity of the debate, or render it moot. Those matters are discussed in the four articles included in this symposium issue, and other related matters are expounded. These articles are significant not only in and of themselves, but also because, considered together, they animate the contours of a comprehensive debate about America as a culture. The debate between opponents and proponents of hESC research on moral grounds is sharply focused and fervent.

Pro-life adherents typically argue, on religious grounds, that the destruction of embryos is the destruction of human life.³ Other opponents of hESC research would limit or preclude the research because, they argue, it links commerce to "desperation" in the search for medical cures, or because it threatens to "redefin[e]" human nature.⁴ Still others urge caution regarding hESC research because, they suspect, absent more stringent regulation than now exists, securing ova for research may harm the women from whom the ova are obtained.⁵

Maggie Emma, J.D. candidate 2010, Hofstra Law School, and Fellow in the Institute for Health Law and Policy at Hofstra Law School, for research assistance.

3. Erin P. George, Comment, *The Stem Cell Debate: The Legal, Political and Ethical Issues Surrounding Federal Funding of Scientific Research on Human Embryos*, 12 ALB. L.J. SCI. & TECH. 747, 782-84 (2002); see also Paul Lauritzen, Dir., Applied Ethics Program, John Carroll Univ., Session 2: Stem Cell Research: Current Ethical Literature, Address Before the President's Council on Bioethics (July 24, 2003), available at <http://www.bioethics.gov/transcripts/july03/session2.html> (noting the fervency of the opposition to stem cell research by pro-life advocates).

4. See Lauritzen, *supra* note 3.

5. See *id.*

Proponents of increased support for hESC research appeal primarily to its medical promise:⁶ to the hope it prompts for the relief of suffering and pain and even for the cure of a wide variety of diseases.⁷

The debate about hESC research in the United States has also centered on federal funding.⁸ In August 2001, President George W. Bush precluded the use of federal funds for almost all research on embryonic stem cell lines.⁹ President Bush's 2001 "compromise" decision remained in effect until March 2009, when the executive policy was radically altered by a contravening Executive Order issued by President Barack Obama.¹⁰ On March 9, 2009, President Obama provided that "[t]he Secretary of Health and Human Services[,] . . . through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law."¹¹

More generally, the debate about hESCs may diminish in intensity and significance, or perhaps even be rendered moot, by ongoing experiments with a variety of stem cell types that may obviate the need for embryos in stem cell research. Research alternatives include the use of adult stem cells, as well as the use of induced pluripotent stem cells ("iPSCs")—pluripotent stem cells derived from adult skin cells.¹² Scientists hope that iPSCs may preclude the need for research on human

6. See, e.g., Michelle L. Anderson, Comment, *Are You My Mommy? A Call for Regulation of Embryo Donation*, 35 CAP. U. L. REV. 589, 620 (2006); George, *supra* note 3, at 770, 791-93 (describing the promise of stem cell research as "staggering").

7. Proponents also point to variations among major religions of the concept of the sanctity of the early human embryo. See, e.g., HOSSAM E. FADEL ET AL., ISLAMIC MED. ASS'N OF N. AM., STEM CELL RESEARCH: THE IMANA PERSPECTIVE 8-11, <http://www.imana.org/PDF%20Files/Stem%20Cell%20Position.pdf> (last visited Apr. 15, 2009).

8. George, *supra* note 3, at 782, 790-93; see also John A. Robertson, *Embryo Culture and the "Culture of Life": Constitutional Issues in the Embryonic Stem Cell Debate*, 2006 U. CHI. LEGAL F. 1, 2-3. Robertson suggests that funding restrictions, such as the one imposed by George W. Bush, limited stem cell research by "prevent[ing] the National Institutes of Health ("NIH") from playing its traditional role of supporting research that is too far upstream from marketable products to attract private investment." Robertson, *supra*, at 2.

9. Press Release, George W. Bush, Remarks on Stem Cell Research (Aug. 9, 2001), available at <http://georgewbush-whitehouse.archives.gov/news/releases/2001/08/20010809-2.html>. Bush provided that federal funds could be used only for hESC research on lines created before August 9, 2001, the date of his address. *Id.* He explained that research on pre-existing lines was permissible because "the life and death decision has been already made." *Id.*

10. Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009).

11. *Id.* The practical consequences of the words "to the extent permitted by law" are still not known. We are grateful to Professor Alan Jakimo for his insights on this issue.

12. See Gina Kolata, *Scientists Bypass Need for Embryo to Get Stem Cells*, N.Y. TIMES, Nov. 21, 2007, at A1.

embryos.¹³ However, others suggest that hESCs are likely to offer a safer treatment option than iPSCs.¹⁴ Thus, at present, many experts maintain that traditional embryonic stem cell research should be continued.¹⁵

Each of the articles in this symposium issue suggests an essential dimension of the scientific or socio-legal consequences of the debate regarding hESC research. One religious perspective, among several represented at the conference, is reflected in the article by Dr. Gerard Magill, who offers a Catholic argument based on the “development of doctrine” that would allow Catholics to support hESC research.¹⁶ Owen C.B. Hughes, Alan L. Jakimo, and Michael J. Malinowski, the authors of *United States Regulation of Stem Cell Research: Recasting Government’s Role and Questions to Be Resolved*, focus on conflicts between federal and state law about how to regulate stem cell research and stem cell medicine.¹⁷ These conflicts, they argue, have been a consequence of the inability of the NIH to take a leading regulatory role in this area of health science.¹⁸ Hughes, Jakimo, and Malinowski focus, in particular, on conflicts between the federal system for licensing patents and the system in California.¹⁹ Perhaps some of the conflicts outlined in their article can be resolved in light of President Obama’s March 9, 2009 Order that permits federal funding for “human embryonic stem cell research, to the extent permitted by law.”²⁰ Dr. Samuel Packer’s article, *Embryonic Stem Cells, Intellectual Property, and Patents: Ethical Concerns*, constructs a comprehensive ethical framework for furthering deliberation about the ethics of embryonic

13. *Id.*

14. Colin Nickerson, *Caution Urged in New Method for Stem Cells*, BOSTON GLOBE, Dec. 17, 2007, at A1.

15. George, *supra* note 3, at 796-98.

16. Gerard Magill, *Using Excess IVF Blastocysts for Embryonic Stem Cell Research: Developing Ethical Doctrine, Secular and Religious*, 37 HOFSTRA L. REV. 447, 453-54 (2009).

17. See generally 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 (2009) (comparing federal intellectual property law with the Californian model for stem cell research regulation and encouragement).

18. See *id.* at 403-19.

19. *Id.* at 423-45. The authors note that a number of other states have programs for funding stem cell research. However, they have focused on California because its funding program is “the most ambitious state effort to fill a science funding vacuum created through federal government law and policy.” *Id.* at 385.

20. Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009). As noted above, the extent to which such resolution is possible depends on interpretations of the language “to the extent permitted by law” in the Executive Order. *Id.*

stem cell research and medicine.²¹ In developing that framework, Dr. Packer considers social values and beliefs as well as various perspectives about science, knowledge, and institutional responsibility, among other things.²² Professors Janet L. Dolgin, Catherine Fisher, and Terri Shapiro describe the results of a survey and a set of subsequent interviews they carried out in order to reveal and explain public attitudes toward hESC research.²³

The various moral and political perspectives regarding hESC research that informed the discussion at the March 2008 conference, *Embryonic Stem Cells, Clones, and Genes: Science, Law, Politics, and Values*, and the articles in this symposium issue intimate that the debate regarding hESC research is part of a comprehensive debate about the cultural parameters of the social order in the United States. More specifically, it is part of a widespread discourse about the role of law in facilitating the benefits afforded by biomedical research while mitigating detriments to our health, society, and personhood.

21. Samuel Packer, *Embryonic Stem Cells, Intellectual Property, and Patents: Ethical Concerns*, 37 HOFSTRA L. REV. 487, 514-15 (2009).

22. *Id.* at 490-93, 497-502.

23. See Janet L. Dolgin et al., *Attitudes About Human Embryos, Embryonic Stem Cell Research, and Related Matters*, 37 HOFSTRA L. REV. 319, 352 (2009) (summarizing the results of the survey questionnaire and interviews).
