

1999

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### Recommended Citation

Marden, Emily and Nelkin, Dorothy (1999) "Cloning: A Business Without Regulation," *Hofstra Law Review*: Vol. 27: Iss. 3, Article 8.  
Available at: <http://scholarlycommons.law.hofstra.edu/hlr/vol27/iss3/8>

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## CLONING: A BUSINESS WITHOUT REGULATION

*Emily Marden\** and *Dorothy Nelkin\*\**

### I. INTRODUCTION

Only two years after “Dolly,” the lamb cloned by Scottish embryologist Ian Wilmut, the first human embryo was cloned from a cell of an infertile woman.<sup>1</sup> The South Korean scientists who accomplished this feat stopped short of implanting the embryo in a woman.<sup>2</sup> However, discussion surrounding the event made clear that eager commercial interests are driving research in this area. “It is a business, not a science,” said Dr. Richard Rawlins, the Director of an in vitro fertilization laboratory.<sup>3</sup> Practitioners of assisted reproductive technology are confident that reproductive technology is not so much an art as a thriving business, whose future lies in cloning.<sup>4</sup>

Commercial interests are driving the race toward human cloning.<sup>5</sup> Cloning research, from the experiments that created Dolly to the creation of cloned mice, cows, and now a human embryo,<sup>6</sup> is taking place mainly in the private sector where it is virtually unregulated. In the

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1. See Michael Schuman et al., *Korean Experiment Fuels Cloning Debate: More Work Is Needed to Prove a Live Birth Is Possible*, WALL ST. J., Dec. 21, 1998, at B7; see also *A Human Embryo Is Cloned: Scientists in South Korea Said They Stopped Because of Legal and Ethical Concerns*, ORLANDO SENTINEL, Dec. 17, 1998, at A3.

2. See Schuman et al., *supra* note 1, at B7.

3. Gina Kolata, *Speed of Cloning Advances Surprises U.S. Ethics Panel*, N.Y. TIMES, Dec. 17, 1998, at A12.

4. See Tim Beardsley, *Cloning Hits the Big Time*, SCIENTIFIC AMERICAN, available at <<http://www.sciam.com/explorations/090297clone/beardsley.html>>.

5. See *id.*

6. See Alison Fitzgerald, *Down on the Pharm: Cow-Cloning Tale May Result in Human Drugs*, CHI. TRIB., Jan. 20, 1998, at 2; *South Koreans Claim They Cloned Cell of Human*, CHI. TRIB., Dec. 17, 1998, at 4; Rick Weiss, *Mouse May Have Been Cloned: Success Would Be First with Mammal Since Dolly the Sheep*, WASH. POST, June 27, 1998, at A12.

United States, the National Institutes of Health (“NIH”) are able to regulate government supported research through the funding process.<sup>7</sup> At the present time, however, neither legislation nor regulation significantly restricts private cloning ventures.<sup>8</sup> At the same time, the specter of human cloning raises widespread moral, religious, and social concerns.<sup>9</sup> By reviewing the pattern of privatization and the absence of government oversight, we suggest some problems with the regulatory vacuum.

## II. COMMERCIAL INTERESTS

The relationship of the Roslin Institute (“Institute”), a not-for-profit research center, to PPL Therapeutics, a private, publicly-traded research corporation, illustrates the manner in which cloning research has been privatized.<sup>10</sup> The Institute, where Dolly was cloned, was formed in 1986 as a government research institute called the Edinburgh Research Station of the Institute of Animal Physiology and Genetics Research.<sup>11</sup> In 1993, it was recognized as an independent Scottish charity, or non-profit, whose research mission remained the same as that of the government institute.<sup>12</sup> At the same time, the Institute spun out PPL Therapeutics as a private research organization where researchers could venture into areas outside the Institute’s central mission and would not be bound by government restraints.<sup>13</sup> In 1996, PPL Therapeutics went

7. See Jesse A. Goldner, *The Unending Saga of Legal Controls over Scientific Misconduct: A Clash of Cultures Needing Resolution*, 24 AM. J.L. & MED. 293, 295 (1998) (reporting that there are “two agencies [which] have principal responsibility for federal funding of scientific research: the National Institutes of Health (NIH) and the National Science Foundation (NSF)”); see also Robert A. Bohrer, *Biotechnology Business Strategy: A Lawyer’s Perspective*, 33 CAL. W. L. REV. 1, 13 (1996) (“Federal funding of research in molecular biology, biochemistry, and molecular genetics, primarily by the NIH, is unquestionably the driving force behind the growth of the biotechnology industry and United States’ preeminence in biotechnology.”).

8. See George J. Annas, *Human Cloning: A Choice or an Echo?*, 23 U. DAYTON L. REV. 247, 265-66 (1998).

9. See generally Courtney S. Campbell, *Resistance and Meaning: Religious Communities and Human Cloning*, 32 VAL. U. L. REV. 607 (1998) (analyzing religious and theological reflections on cloning); Elliott N. Dorff, *Human Cloning: A Jewish Perspective*, 8 S. CAL. INTERDISC. L.J. 117 (1998) (focusing on the many moral issues that develop in the area of cloning); John A. Robertson, *Liberty, Identity, and Human Cloning*, 76 TEX. L. REV. 1371 (1998) (discussing the fact that the cloning of a sheep was a turning point in the social and ethical debates on cloning); Thomas A. Shannon, *Human Cloning: Examining Religious and Ethical Issues*, 32 VAL. U. L. REV. 773 (1998) (discussing the recent achievements in cloning and the risks involved).

10. See GINA KOLATA, *CLONE: THE ROAD TO DOLLY, AND THE PATH AHEAD* 213-16 (1998).

11. See *id.* at 23; *Ethics and Morals Aside, Dolly Promises to be Financial Boon*, BIOTECHNOLOGY NEWSWATCH, June 16, 1997, at 3, 3-4 [hereinafter *Ethics and Morals Aside*].

12. See *Ethics and Morals Aside*, *supra* note 11, at 4.

13. See Majorie Miller, *Britain Urged to Legalize Cloning of Human Tissue*, L.A. TIMES,

public at an initial valuation of 100 million pounds.<sup>14</sup>

PPL Therapeutics funded Wilmut's work at the Roslin Institute in the interest of finding a way to produce genetically engineered animals capable of producing proteins in their milk.<sup>15</sup> Upon the creation of Dolly, the Institute immediately patented the process through which Dolly was created and gave an exclusive license to PPL Therapeutics.<sup>16</sup> In turn, PPL Therapeutics made agreements with three major multinational pharmaceutical enterprises interested in production of therapeutic proteins.<sup>17</sup> The patent gives them a monopoly over the cloning of animals using the technique of somatic cell nuclear transfer, a procedure that permits a specifically designed genome to be cloned in a waiting embryo cell, and then grown into a healthy adult animal.<sup>18</sup>

There are numerous privatized efforts to create life. For example, a small company in Wisconsin, ABS Global Inc., successfully cloned cows purely as a commercial venture.<sup>19</sup> With the birth of the first cloned calf in August 1997, Dr. Michael Bishop, the director of research and technology at ABS, stated his hope that this success would advance efforts to take the company public.<sup>20</sup> ABS Global then created "a new subsidiary, called Infigen, to 'commercialize applications of cloning technologies in the cattle breeding, pharmaceutical, nutraceutical and xenotransplantation fields.'"<sup>21</sup> ABS Global never purported to be pursu-

Dec. 9, 1998, at A1.

14. See *Ethics and Morals Aside*, *supra* note 11, at 3.

15. See *Roslin Institute: Nuclear Transfer Work Receives DTI Link Award*, BIOACCESS, Aug. 1, 1998, available in 1998 WL 10754969. Dr. Wilmut is currently seeking financial support to further his research toward cloning human embryos. See Robert Frank & Ralph T. King, Jr., *Creator of Dolly Seeks Partners to Clone Embryos*, WALL ST. J., Jan. 21, 1999, at B6.

16. See *Bioprocessing: Here's Bonnie—Polly and Molly Too*, APPLIED GENETIC NEWS, July 1, 1998, available in 1998 WL 9890746.

17. See *Cloning: Honolulu Cloning Technique to be Licensed to PPL by Probio to Clone Pigs, Then Other Farm Animals*, "THE BLUE SHEET," July 29, 1998, at 11, 11-12; *Creators of Cloned Sheep Dolly to Take on Mad Cow Disease*, TRANSPLANT NEWS, Oct. 30, 1998, available in 1998 WL 9525630; Steven Lipin, *British Firm with Piles of Patents Hustles for Licensees*, WALL ST. J., Nov. 9, 1998, at B1.

18. See Mike Pezzella, *Clone Patents Raise Fears About Human Duplicates*, BIOTECHNOLOGY NEWSWATCH, May 19, 1997, at 1, 1. Some critics suggest that the patent may ultimately cover some forms of human cloning as well, as the patent language does not expressly exclude human applications. See *id.*

19. See *Cloned Calf Could Mean More Beef*, CHI. TRIB., Aug. 7, 1997, at 1; see also Robert Langreth & Scott Kilman, *Calf Is Cloned by Wisconsin Cattle Breeder*, WALL ST. J., Aug. 7, 1997, at B6 (discussing the various commercial advantages of using cloning technology in the dairy industry).

20. See Gina Kolata, *10 Cloned Cows Soon to be Born, Company Reports, Duplicating a Lamb Experiment*, N.Y. TIMES, Aug., 8, 1997, at A10.

21. Beardsley, *supra* note 4. Numerous other private companies are working on cloning projects. See, e.g., *Genetic Engineering: Building to Order*, ECONOMIST, Mar. 1, 1997, at 81, 81

ing the advancement of science—in fact, none of its cloning work is published in scientific journals.<sup>22</sup> More recently, a California biotechnology company announced that an American businessman was underwriting a two year, \$2.3 million project to clone dogs.<sup>23</sup> The motivating aim of this research investment, which is to be undertaken with Texas A&M University, is to clone the businessman's eleven-year-old pet collie.<sup>24</sup>

The unbounded pursuit of cloning in the private sector is further illustrated by the actions of Dr. Richard Seed. In December 1997, following Wilmut's success with Dolly, Seed announced that he intended to clone human beings using Wilmut's technique.<sup>25</sup> Seed, a physicist with no technical experience in area, received financial commitments of \$800,000 for his project and is seeking more from venture capitalists.<sup>26</sup> With similar entrepreneurial zeal, a company called Valiant Ventures, Ltd. announced a service called "Clonaid" to provide assistance to would-be parents wanting to have a child cloned.<sup>27</sup> The price of this service starts at \$200,000.<sup>28</sup>

### III. THE REGULATORY VACUUM

At present there is no effective regulatory mechanism in place to monitor the pursuit or use of human cloning research. After the introduction of Dolly, President William J. Clinton announced a ban on federal funding for human cloning research.<sup>29</sup> Thus, the NIH cannot fund research in this area. In January 1997, Clinton took the additional step of asking the National Bioethics Advisory Commission ("NBAC") to

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(describing how transgenetic animals are "living test tubes" for scientists working with human diseases); Keith Schneider, *Cloning Brings Factory Precision to the Farm*, N.Y. TIMES, Feb. 17, 1988, at A1 (discussing three North American companies striving to market cloned animals).

22. See Kolata, *supra* note 20, at A10.

23. See Christopher Lee, *Texas A&M Joins Project to Clone Businessman's Dog*, DALLAS MORNING NEWS, Aug. 25, 1998, at 12A.

24. See *id.*

25. See Joyce Howard Price, *Cloning Touted as Infertility Solution: Biologist's Proposal Draws Threat of Ban*, WASH. TIMES, Dec. 11, 1997, at A9; Rick Weiss, *Scientist Plans to Clone Humans*, WASH. POST, Jan. 7, 1998, at A3.

26. See Wendy Cole, *Seed of Controversy*, TIME, Jan. 11, 1999, at 77, 77.

27. See August Gribbin, *Human Cloning Draws Nearer as Ethicists Seek to Draw Rules*, WASH. TIMES, Nov. 9, 1998, at A1.

28. See *Welcome to Clonaid* (visited Mar. 8, 1998) <<http://www.clonaid.com>>.

29. See Memorandum on the Prohibition on Federal Funding for Cloning of Human Beings, 33 WEEKLY COMP. PRES. DOC. 281, 281 (Mar. 10, 1997); see also Rick Weiss, *Clinton Forbids Funding of Human Clone Studies*, WASH. POST, Mar. 5, 1997, at A10 (reporting President Clinton's announcement of the ban on federal funding of human cloning research).

advise the federal government on what actions it should take to prevent the abuse of cloning.<sup>30</sup> After several months of consideration, the NBAC recommended a moratorium on the cloning of human beings for three to five years.<sup>31</sup> President Clinton, in turn, proposed a law that would prohibit cloning in both the public and the private sectors for this length of time.<sup>32</sup> The bill, however, languished in the House of Representatives.<sup>33</sup> Additional bills to ban cloning were introduced in eighteen states.<sup>34</sup> However, these bills were either defeated or languished in committee.<sup>35</sup>

In December 1998, the Food and Drug Administration ("FDA") announced its intent to fill the regulatory void.<sup>36</sup> The Director for Cellular and Gene Therapies, Philip Noguchi, stated that by using its current regulations related to tissue, the FDA would block attempts to clone a human being because of unacceptably high risks to human subjects.<sup>37</sup>

However, legal experts doubt that the FDA has either the authority or ability to undertake this task.<sup>38</sup> "There are serious questions about whether the FDA can make its claim to be able to regulate [human] cloning consistent with its [lack of] regulation of other reproductive

30. See Letter from President Clinton to Dr. Harold Shapiro, Chairman, National Bioethics Advisory Commission (Feb. 24, 1997), reprinted in 1 NATIONAL BIOETHICS ADVISORY COMM'N, CLONING HUMAN BEINGS: REPORT AND RECOMMENDATIONS OF THE NATIONAL BIOETHICS ADVISORY COMMISSION (1997).

31. For a discussion of the National Bioethics Advisory Commission's ("NBAC") report, see Emily Marden, *The Revolution Ignored: A Critique of Cloning Human Beings: Report and Recommendations of the National Bioethics Advisory Commission*, 6 N.Y.U. ENVTL. L.J. 674 (1998) (book review).

32. See Cloning Prohibition Act of 1997, H.R. DOC. NO. 105-97 § 5 (1997) (draft legislation).

33. See Caroline Daniel, *Conflicting Aims Leave Ban on Human Cloning in Limbo*, WASH. POST, July 26, 1998, at A8.

34. See Lori B. Andrews, *Is There a Right To Clone? Constitutional Challenges to Bans on Human Cloning*, 11 HARV. J.L. & TECH. 643, 645 n.13 (1998) (including bills introduced in Alabama, Connecticut, Delaware, Hawaii, Illinois, Kansas, Maryland, Minnesota, Mississippi, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, South Carolina, Tennessee, and Virginia).

35. See Daniel, *supra* note 33, at A8.

36. See Rick Weiss, *Human Clone Research Will Be Regulated*, WASH. POST, Jan. 20, 1998, at A1.

37. See Lisa Seachrist, *Potential in U.S. Equals 'Promise and Problem': Korean News on Cloning Points up Need for Rules*, BIOWORLD TODAY, Dec. 18, 1998, at 1; see also Dear Colleague Letter from Stuart Nightingale, M.D., Associate Commissioner, Food and Drug Administration (Oct. 26, 1998) (stating "that clinical research using cloning technology to create a human being is subject to FDA regulation").

38. See Elizabeth C. Price, *Does the FDA Have the Authority to Regulate Human Cloning?*, 11 HARV. J.L. & TECH. 619, 629-41 (1998) (questioning whether the Food and Drug Administration ("FDA") can assert jurisdiction over human cloning by regulating it as a drug, medical device, or biological product).

techniques,”” commented one intellectual property lawyer.<sup>39</sup> Most legal experts see human cloning as simply a new form of fertility treatment and note that the FDA is not permitted to regulate the practice of medicine.<sup>40</sup> Additionally, as Richard Merrill, professor at the University of Virginia School of Law points out, “[t]he FDA is not equipped, either by law or personnel, to grapple with some of the wider social issues involved”” such as the psychological impact of being born a clone.<sup>41</sup> Professor Merrill concludes that it is difficult to envisage the grounds for an FDA action.<sup>42</sup> The FDA’s Noguchi cedes this point: “We still do not have a very satisfactory way to weigh not only the science and the safety concerns, but to balance that against the ethics of a given situation.””<sup>43</sup>

Moreover, the FDA does not generally require prior approval for research on cells that are subject only to “minimal manipulation.””<sup>44</sup> Work is subject to FDA regulation if cells are deemed to be “more than minimally manipulated.””<sup>45</sup> An FDA official stated that cloning surpasses this “minimally manipulated” trigger.<sup>46</sup> However, legal experts point to an inconsistency in this position; other technologies, such as in vitro fertilization, involve significant manipulation of cells, but the FDA has not tried to regulate them.<sup>47</sup>

European countries more actively sought to control the practice. Nineteen European countries signed an accord banning human cloning.<sup>48</sup>

39. Daniel, *supra* note 33, at A8 (alteration in original).

40. See William L. Christopher, *Off-Label Drug Prescription: Filling the Regulatory Vacuum*, 48 FOOD & DRUG L.J. 247, 250-56 (1993) (detailing the judicial indication that the FDA’s oversight does not extend to regulation over the practice of medicine); see also *Misuse of Prescription Drugs, Hearings Before the Subcomm. on Human Resources and Intergovernmental Relations of the House Comm. on Gov’t Reform and Oversight* (1996), available at 1996 WL 10830744 (statement of Michael Friedman, Deputy Commissioner for Operations, FDA) (“The history of the [FD&C] Act indicates that Congress did not intend FDA to interfere with the practice of medicine.”); 142 CONG. REC. S12,024 (daily ed. Sept. 30, 1996) (statement of Senator Frist) (“While the FDA regulates medical devices and pharmaceuticals, it has no authority to regulate the general practice of medicine.”).

41. Daniel, *supra* note 33, at A8.

42. See *id.* (quoting Richard Merrill, a professor at the University of Virginia School of Law: “The FDA is not supposed to regulate the practice of medicine’ . . .”).

43. Seachrist, *supra* note 37, at 4.

44. See Daniel, *supra* note 33, at A8.

45. *Id.*

46. See *id.*

47. See *id.*

48. See *Research Oversight: FDA May Assert Its Authority to Regulate Human Cloning Technology Under Biologic Product Regs*, “THE BLUE SHEET,” Jan. 14, 1999, at 2, 3 [hereinafter *Research Oversight*] (reporting that on January 12, 1998, “19 European nations signed a Council of Europe protocol banning human cloning”).

In addition, in 1997, the United Nations Educational, Scientific and Cultural Organization's ("UNESCO") 186 member states adopted the "Universal Declaration on the Human Genome and Human Rights" that called for a ban on any practice "contrary to human dignity," including human cloning.<sup>49</sup> Europe's position meant that cloning research does not take place in any setting.

#### IV. PUBLIC RESPONSE

In contrast to the legislative apathy in the United States, American media and various religious organizations are outspoken. Critics place cloning in a context of other fears about genetic manipulation, and even in a context of more general concerns about science and its applications. Some journalists, for example, worry that the shortage of organs for transplantation could be resolved by cloning anencephalic babies (babies born without a brain but are otherwise normal), so that their organs could be harvested for patients in need.<sup>50</sup> They view cloning as an example of technology out of control.<sup>51</sup>

Theologian Rabbi Mosher Tendler, a professor of Jewish medical ethics at Yeshiva University in New York, warns that, "whenever man has shown mastery over man, it has always meant the enslavement of man."<sup>52</sup> Other theologians worry that the scientists who experimented with cloning were "playing God" and tampering with God's creation.<sup>53</sup> A *Time* magazine public opinion survey found that forty seven percent of the public wanted the government to regulate cloning of animals.<sup>54</sup>

The key issue shaping the public reaction is the commercial control of biotechnology and its implications for the commodification of the body. Dolly evoked cynical references, such as "test tube capitalists," and sardonic queries about a market for genetic "factory second" and

49. See UNITED NATIONS EDUCATIONAL, SCIENTIFIC AND CULTURAL ORGANIZATION, UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS (1997) (providing in Article 11 that "[p]ractices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted").

50. See *Human Fetuses Will Be Grown to Harvest Organs in 10 Years, Ethics Expert Warns*, CHARLESTON GAZETTE & DAILY MAIL, Oct. 20, 1998, at 2A; see also Joy Ufema, *Organs on Demand?*, NURSING, Aug. 1, 1998, at 30, 30 (discussing the attempts of some scientists to harvest organs from embryos as "distasteful").

51. See Oliver Morton, *First Dolly, Now Headless Tadpoles*, 278 SCI. 798, 798 (1997).

52. Gustav Neibuhr, *Suddenly, Religious Ethicists Face a Quandary on Cloning*, N.Y. TIMES, Mar. 1, 1997, at A1.

53. See *id.*

54. See Leon Jaroff, *Fixing the Genes*, TIME, Jan. 11, 1999, at 68, 68.



“irregulars,” and images of breeding factories.<sup>55</sup> Anthropologist Sarah Franklin refers to the patenting of Dolly as the creation of “breedwealth,” a new kind of genetic capital.<sup>56</sup> A clone becomes in effect a corporate entity—a manufactured being.<sup>57</sup> Philippe Vasseur, France’s former farm minister, worries of the specter of six-legged chickens when industry is allowed to clone animals.<sup>58</sup> Environmentalist Kirkpatrick Sale despairs that any reasoned regulation of cloning will be hijacked by the “cult of progress.”<sup>59</sup> Others express concern over who would “control or regulate the outcomes of [biotechnology] research in order to avoid unpredictable catastrophes.”<sup>60</sup>

A program on Genetics, Ethics and the Law at Case Western Reserve University ran a workshop called “Stopping Science” to examine controversial scientific advances including cloning.<sup>61</sup> Commenting on the fusion of human DNA with a cow embryo cell, David Magnus, director of Graduate Studies at the University of Pennsylvania’s Bioethics Center, stated that “[i]t’s an example of an issue that requires deep, careful thought. Instead, there was a race to get it done as fast as possible, because there were commercial benefits.”<sup>62</sup> Medical associations, with the notable exception of infertility societies, define human cloning as unacceptable.<sup>63</sup> They worry about risks from hidden mutations and about premature aging.<sup>64</sup> Too little is known, they claim, about the harmful consequences of the technology and about potential abuses that might result.<sup>65</sup>

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55. For a more moderate perspective on the technology that produced Dolly, see *Hello, Dolly*, *ECONOMIST*, Mar. 1, 1997, at 17.

56. See Sarah Franklin, *Dolly: A New Form of Transgenic Breedwealth*, 6 *ENVTL. VALUES* 427, 427-37 (1997).

57. See *id.*

58. See *Hello, Dolly*, *supra* note 55, at 17.

59. See Kirkpatrick Sale, *Ban Cloning? Not a Chance*, *N.Y. TIMES*, Mar. 7, 1997, at A35.

60. Joseph K. Chemplavil, Readers Report, *Hopes and Hazards of the Biotech Century*, *BUS. WK.*, Mar. 31, 1997, at 12, 12.

61. Workshop on Stopping Science, Case Western Reserve University, September 24-25, 1998.

62. James Walsh, *Brave New Farm*, *TIME*, Jan. 11, 1999, at 86, 87.

63. See Charlene Kalebic, *The Constitutional Question of Cloning Humans: Duplication or Procreation? An Examination of the Constitutional Right to Procreate*, 8 *S. CAL. INTERDISC. L.J.* 229, 278 (1998).

64. See Sharon Begley, *Little Lamb, Who Made Thee?*, *NEWSWEEK*, Mar. 10, 1997, at 53, 59.

65. See *id.* at 57; see also Charles Marwick, *Put Human Cloning on Hold, Say Bioethicists*, 278 *JAMA* 13 (1997) (discussing the ethical and medical concerns raised in the NBAC report).

## V. OPPOSITION TO REGULATION

As political and social pressures grew, scientists responded, defending the importance of the work. Media images are selling science short, they claim.<sup>66</sup> Scientists argue that calls for regulations and restrictions ignore the medical benefits that could follow from the cloning experiments and their potential contribution to the development of life saving treatments and the testing of new drugs.<sup>67</sup> "We are not interested in playing God," said James Geraghty, president of the biotechnology firm, Genzyme, but in "playing doctor."<sup>68</sup> According to scientists, mammalian cloning could help to generate tissue for organ transplantation and encourage transgenics experimentation. In addition, research using cloning could enhance scientific knowledge about cell differentiation. The politicians who sought a ban on cloning research, scientists said, were "'shooting from the hip."<sup>69</sup> Scientists compare the proposed bans to the efforts to stop Galileo and even claim constitutional rights to scientific inquiry.<sup>70</sup>

A leading association of biologists, the Federation of American Societies for Experimental Biology, approved a five-year moratorium on human cloning,<sup>71</sup> stating that while they were opposed to cloning a human being, the laboratory techniques involved in cloning are important research tools.<sup>72</sup> Such research, they said, may be valuable for treating many types of diseases.<sup>73</sup> At the same time, they worried that the bills introduced in Congress could hinder vital research.<sup>74</sup>

While scientists seek unobstructed research, industry interests warn of obstructing the free market.<sup>75</sup> At Congressional hearings on proposed legislation banning human cloning research, a Biotechnology Industry

66. See Declan Butler & Meredith Wadman, *Calls for Cloning Ban Sell Science Short*, 386 NATURE 8, 8 (1997).

67. See Gina Kolata, *Congress Is Cautioned Against Ban on Human-Cloning Work*, N.Y. TIMES, Mar. 13, 1997, at B11.

68. *Biotechnology and the Ethics of Cloning: How Far Should We Go?: Hearings Before the Subcomm. on Tech. of the House Comm. on Science*, 105th Cong. (1997) (testimony of James Geraghty, president and chief executive officer, Genzyme Transgenics Corp.).

69. Meredith Wadman, *Politicians Accused of 'Shooting From the Hip' on Human Cloning*, 386 NATURE 97, 97 (1997).

70. See Andrews, *supra* note 34, at 661.

71. See *Research Oversight*, *supra* note 48, at 2-3.

72. See *id.*

73. See *Capitol Hill: AAMC Opposes Legislative Action Banning Cloning in Letter to Senators as Cloture Vote Approaches*, "THE BLUE SHEET," Feb. 11, 1998, at 13, 13.

74. See *id.*

75. See Finlay Lewis, *Congress' Cloning Debate Worries Biotechs*, SAN DIEGO UNION-TRIB., Apr. 3, 1998, at A-29.

Organization (“BIO”) representative made it clear that the industry would oppose restrictions on economically productive research.<sup>76</sup> Carl Feldbaum of BIO warned that “[h]astily drafted legislation . . . could inadvertently ban legitimate research.”<sup>77</sup> Industry representatives also evoke the threat of international competition: If cloning is not done here it will be done elsewhere; America has to maintain its leadership in the world economy.

## VI. CONCLUSION: THE REGULATION GAP

American researchers are racing toward human cloning in private commercial enterprises with little regulatory scrutiny. While scientists and commercial interests promise that this is the path to knowledge and financial success, many sectors of the public remain doubtful. We have suggested a significant gap between public views and business perspectives on the value and viability of cloning. Such a gap can lead to public distrust and hostility towards the new technology. We wonder if this is truly the most productive way to move forward.

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76. See Meredith Wadman, *Backing for Anti-Cloning Bill Reopens Embryo Debate*, 388 NATURE 505, 505 (1997).

77. David Kestenbaum, *Cloning Plan Spawns Ethics Debate*, 279 SCI. 315, 315 (1998). But see David Holzman, *Combining Politics with Genetics*, CHEMISTRY & INDUS., Feb. 2, 1998, at 78, 78 (citing Feldbaum as stating that “[c]loning a human being poses major ethical and moral questions, as well as deeply troubling medical safety issues . . . . It is plainly inappropriate to apply this technique to human beings”).