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Deconstructing the Human Egg: The FDA's Regulation of Scientifically Created Babies

INTRODUCTION

In 1997, scientists cloned Dolly, the now famous Scottish Sheep;¹ since then, animal cloning techniques have proceeded at a rapid pace.² Dolly was a great technical achievement, presenting scientists with the possibility of human cloning. Then in 1998, scientists successfully cloned eight identical cow calves from a single cow,³ and several litters of mice.⁴ These mammalian clones thus raised questions regarding the ethics, morality and safety of human cloning.⁵ This morality questioning resulted in a ban on

1. Dolly was the first mammal cloned from the transfer of a somatic cell's DNA (the molecular basis of genes) into an enucleated egg cell. See Lori D. Andrews, *Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning*, 11 Harv. J.L. & Tech. 643, 644 (1998).

2. See Teruhiko Wakayama et al., *Full-term Development of Mice from Enucleated Oocytes Injected with Cumulus Cell Nuclei*, 394 Nature 369, 373 (1998) (stating that:

contrary to previous opinion, mammals can be reproducibly cloned from adult somatic cells. Furthermore, we believe that the success of these experiments in the mouse provides an amenable model with which to evaluate the molecular mechanisms that regulate the reprogramming of somatic cell genomes, genomic imprinting, embryonic genomic activation and cell differentiation).

3. See Jeffrey Kluger, *How to Clone a Herd*, Time, Dec. 21, 1998, at 63, available in 1998 WL 21378329 (explaining how two different types of cells were placed into cow ova (without genes) and out of ten implanted embryos, eight calves were born. However, no one knows how the Japanese scientists managed to produce eight calves out of ten embryos).

4. See Michael D. Lemonick, *Dolly Your History, by Making Dozens of Copies of a Mouse Scientists Take Cloning One Step Closer to the Assembly Line*, Time, Aug. 3, 1998, at 64, available in 1998 WL 14834988 (stating that it was believed that mice cloning would be more difficult than cloning humans because mice have been "long believed to be among the worst candidates for cloning because their egg cells are particularly delicate and their embryos develop so rapidly").

5. See National Bioethics Advisory Commission, *Cloning Human Beings: Report and Recommendations of the National Bioethics Advisory Commission*, at I (1997) [hereinafter NBAC Report].

federal funds for human cloning by President Clinton.⁶ Congress also attempted to quickly pass federal legislation under its spending or Commerce Clause authority.⁷ However, the executive and congressional bans on federal funding for human cloning do not inhibit the use of private research funds; adding to this problem, Congress has not passed legislation under its Commerce Clause authority that could prevent the dangers of privately funded research.⁸ In fact, in 1998, Richard Seed, a physicist, proposed to clone a human being with private funds as a way to aid infertile women.⁹

On January 20, 1998, in response to the potential physical risks to women and children, the Food and Drug Administration (FDA) announced its intentions to regulate human cloning under section 351 of the Public Health and Service Act (PHSA).¹⁰ Thus, using this already existing Act to regulate tissue and cell-based products, the FDA claimed that it could, in theory, regulate some instances of somatic cell cloning (human cloning).¹¹ The FDA proposal to regulate cell and tissue-based products was intended to: (1) prevent the use of contaminated tissue; (2) prevent mishandling that might contaminate the tissue; and (3) ensure clinical

6. *See id.*

7. *See* Jennifer Cannon & Michelle Haas, *The Human Cloning Prohibition Act: Did Congress Go Too Far?*, 35 *Harv. J. on Legis.* 637, 639 (1998) (citing 143 *Cong. Rec.* E607).

8. *See id.* at 645; Nicole Z. Dizon, *Chicago Physicist Wants Money From NASA for Cloning* (last modified Nov. 18, 1998) <<http://www.dailyregister.com/archive1998/cloning111898.html>> (noting Richard Seed's claim that he and his wife have volunteered as test models for human cloning. He will continue to attempt cloning even if the federal government interferes because the federal government cannot regulate test experiments performed with the use of private funds. His wife would carry an embryo that would be created by combining the nucleus of one of his cells with a donor egg).

9. *See* Rick Weiss, *Scientist Plans to Clone Humans*, *Wash. Post*, Jan. 7, 1998, at A3, available in 1998 WL 2460652 (describing Seed as "a brilliant man . . . a little crazy . . . and if anyone can make [human cloning] happen it would be someone like Richard Seed").

10. *See* Rick Weiss, *Human Clone Research Will be Regulated*, *Wash. Post*, Jan. 20, 1998, at A1, available in 1998 WL 2462936.

11. Somatic cells are cells of the embryo, fetus, child, or adult, having two sets of chromosomes; a germ cell, in contrast, has one set of chromosomes. NBAC Report, *supra* note 5, at 1 n.2. This type of cloning is the most controversial because it involves "the creation of genetic replicas of existing or previously existing children or adults." *See* N.Y. Task Force on Life and the Law, *Assisted Reproductive Technologies* 391 (1998) [hereinafter N.Y. Task Force].

safety for tissue that is more than minimally manipulated.¹² As outlined above, the proposal could cover human cloning because the cloning procedure involves cells that are more than minimally manipulated.¹³ Thus, according to the FDA, human cloning is a form of cellular or genetic therapy that requires prior approval by the FDA reviewers; any attempts lacking FDA approval would therefore violate the law.¹⁴ Under an approved proposal, anyone who desires to legally attempt human cloning must first file a formal application with the FDA and then undergo a lengthy review.¹⁵ The million dollar question is who will attempt to clone a human being and why. This Comment assumes that human cloning could someday be considered an assisted reproductive technology because the technology will inevitably become a valid treatment for infertile couples.¹⁶

Many people, including infertility specialists, question the FDA's decision to regulate human cloning since the FDA failed to regulate assisted reproductive technology (ART), such as in vitro fertilization (IVF) or intracytoplasmic sperm injections (ICSI), when they were first developed.¹⁷ However, some people believe that the states should regulate human cloning. This is supported

12. See Food and Drug Administration, Proposed Approach to Regulation of Cellular and Tissue-Based Products 6 (1997) [hereinafter FDA Proposal].

13. See Weiss, *supra* note 10, at A1; see also Sheryl Gay Stolberg, *F.D.A. Stand on Cloning Raises Even More Questions*, N.Y. Times, Jan. 21, 1998, at A15, available in 1998 WL 5394533 (noting that in February of 1997, the FDA issued a new guidance proposal governing cells and tissue products. Under this proposal the FDA claims it has the authority to regulate cell or gene therapies that involve "more than minimal manipulation" (MTMM) of human cells or tissue. Mr. Feldbaum, the acting commissioner of the FDA, argued that "cloning, which involves taking genetic material from one cell and inserting it into another, meets the 'more than minimal manipulation standard'").

14. See Weiss, *supra* note 10, at A1; see also Stolberg, *supra* note 13, at A15 (quoting an unknown agent of the FDA as stating "[w]e regard this as a gene therapy or a cell therapy or both, and these therapies are subject to FDA requirements that cover clinical trials").

15. See Stolberg, *supra* note 13, at A15 (stating that because the FDA claims human cloning involves more than minimum manipulation of cells, then "any scientist who wants to create a genetic replica of a person will have to submit an 'investigational new drug application,' the same request that drug companies must submit when they want to test a new medicine").

16. According to John Robertson, a professor of law and co-chair of the American Society for Reproductive Medicine (ASRM) Ethics Committee, human cloning may soon become a valid treatment for infertile couples. See John A. Robertson, *Liberty, Identity, and Human Cloning*, 76 Tex. L. Rev. 1371, 1373 (1998).

17. See Andrews, *supra* note 1, at 658 n.102.

by evidence that some states have banned human cloning prior to the FDA's proposed regulation.¹⁸ These proponents of states' rights argue that the only federal regulation of assisted reproductive techniques is a federal law requiring the monitoring of assisted reproduction clinics using IVF.¹⁹ The FDA's delay has caused inconsistency among the states' human cloning regulations and confusion as to whether the FDA has authority to regulate cloning.

This Comment examines: (1) the FDA's regulatory authority over human cloning provided by section 351 of the Public Health and Service Acts (PHSA), (2) the FDA's current inability to effectively utilize that authority due to its own narrow proposal and (3) the urgent need for the FDA to maximize its regulatory authority. Part I of this Comment defines cloning and explains the cloning procedure. This Part also considers the harm posed to women undergoing and children created by the cloning procedure. Part II examines the reasons supporting regulation of human cloning. This Part describes the past problems caused by the lack of uniform assisted reproductive regulations. Part III explores the need for uniform regulation to replace outdated and meaningless state and congressional legislation.

For the FDA to regulate human cloning, a cloned embryo must be considered a biological product under section 351 of the PHSA.²⁰ Thus, Part IV explores the FDA's authority to regulate human cloning, as dictated in section 351 of the PHSA's definition of "biological products."²¹ The definition of "biological products" includes a more than minimally manipulated egg cell used for treating infertility, thus providing the support for FDA regulation.

18. See *id.* at 658 (citing Michigan and California as states that currently prohibit cloning); NBAC Report, *supra* note 5, at 89.

19. See NBAC Report, *supra* note 5, at 88 (noting that 42 U.S.C.A. § 263a-1, the Fertility Clinic Success Rate and Certification Act, "covers all laboratories and treatments that involve manipulation of human eggs and embryos, and requires that rates of success at achieving pregnancies be reported to the Department of Health and Human Services (DHHS) for publication in a consumer guide"). This statute only extends to the monitoring of ART; it does not require FDA approval before a procedure can be used.

20. See Elizabeth C. Price, *Does the FDA Have Authority to Regulate Human Cloning?*, 11 Harv. J.L. & Tech. 619, 624-25, 638-39 (1998); Andrews, *supra* note 1, at 658.

21. See Public Health Service Act, 42 U.S.C. § 262(a) (1997).

Specifically, this part demonstrates how banning federal funds will not deter human cloning.²²

This Comment concludes that the FDA has the authority to regulate human cloning. However, the FDA undermines and restricts its authority through its own cell and tissue based proposal. The proposal could cover human cloning because the cloning procedure involves cells that are more than minimally manipulated. However, the proposal's primary concern with reproductive tissue is to stop the spread of communicable diseases rather than to ensure clinical safety of more than minimally manipulated reproductive tissue.²³ The FDA does not believe that there is a large risk of harm from reproductive tissue failure to women.²⁴ "Failure of reproductive tissue generally does not have life-threatening or systemic adverse effects except for fertility per se."²⁵ Although unstated in its proposal, the FDA implies that if the reproductive transplant fails, the tissue is naturally rejected by the woman's body with limited harm, in the form of a miscarriage; and not organ failure which could lead to death. Therefore, the proposal covers only cells and tissues that come from a donor, however, it does not require regulation of cells and tissue removed from the same person or from that person's sexual partner. The FDA's concern with only donated reproductive tissue is a catastrophic oversight in the FDA's proposed regulation of cloning. This oversight provides a loophole that could lead to misuse of cloning as an assisted reproductive technique. The FDA needs to revise its current tissue and cell based-products proposal to address all forms of cloning procedures, including reproductive tissues and cells from a sexual partner or oneself, and the products of these cells and tissues (embryos/children).

I. HUMAN CLONING AND ITS POSSIBLE HARM

As aforementioned, scientists have successfully used the somatic cell cloning procedure on other mammals. However, this procedure, if attempted on a human embryo, could cause unexpected side effects.

22. See Dizon, *supra* note 8.

23. See FDA Proposal, *supra* note 12, at 6.

24. See *id.* at 20.

25. *Id.*

A. *What is Human Cloning?*

The scientists at the Roslin Institute in Scotland used somatic cell cloning to create Dolly from an adult sheep.²⁶ In theory, this same procedure could be used to clone a human child from a human adult.²⁷ Essentially, the somatic cell process requires the removal of an egg cell's DNA and the transfer of an adult cell's nucleus into the egg.²⁸ In other words, the DNA from the adult cell replaces the fusion of sperm and egg during regular sexual reproduction.²⁹ In the cloning procedure, scientists "depriv[e] the [reproductive] cells of the full amount of nutrient-laden serum that is naturally supplied and in effect cause[] the cells to remain in the beginning stages of the [reproductive] cell cycle."³⁰ This process prevents the adult DNA (DNA from a fully developed human) from replicating before the transfer into the egg cell is complete.³¹ Next, scientists introduce an electric charge to the egg cell.³² This charge fuses the adult DNA with the "unfertilized chromosome-extracted egg" (an egg without a nucleus).³³ The cloned egg cell be-

26. See Jason T. Corsover, *The Logical Next Step? An International Perspective on the Issues of Human Cloning and Genetic Technology*, 4 ILSA J. Int'l & Comp. L. 697, 706 (1998).

27. See Herbert Wray et al., *The World After Cloning*, U.S. News & World Rep., Mar. 10, 1997, at 59, available in 1997 WL 8331693 (describing how infertile couples could use cloning to create a child).

28. See Corsover, *supra* note 26, at 706. The following is a brief overview of the genetic process that drives a cell to differentiate. Inside a cell is a nucleus which contains genes composed of DNA. These genes tell the cell to produce proteins. See Neil A. Campbell, *Biology* 247 (3d ed. 1993). As an organism grows after fertilization, its cells develop, divide, differentiate and specialize by switching on and turning off certain genes inside their nuclei. See *id.* at 230. All somatic cells have the same genes in the nucleus; the type of genes activated depends on the type of cell. See *id.* at 234-35. The role of cell types (muscle, liver, and skin) depends on the specialized proteins. See *id.* at 316. With the right cellular environment and with the correct regulatory molecules, it should be possible to turn on or off genes in cells. See Davor Solter, *Dolly is a Clone—and no Longer Alone*, 394 *Nature* 315-16 (1998). It was once believed that if genes were turned off, it was permanent, but Dolly revealed the process was reversible. Michael J. McDaniel, *Regulation of Human Cloning: Implications for Biotechnological Advancement*, 32 *Val. U. L. Rev.* 543, 545-46 (1998). The manipulation seemed to enable the nucleus-free egg to reprogram the new nucleus. See *id.*

29. See Corsover, *supra* note 26, at 706 (citing Elizabeth Pennisi & Nigel Williams, *Will Dolly Send in the Clones*, *Science*, Mar. 7, 1997, at 1415).

30. *Id.*

31. See *id.*

32. See *id.*

33. *Id.*

gins the process of cellular division and differentiation, just as if it were a fertilized egg containing both male and female genetic materials.³⁴

To understand the potential threats of human cloning, one must realize that cloning is dramatically different from a normal assisted reproductive technology such as in-vitro fertilization (IVF). In IVF, sperm fertilizes a new egg cell, and after about two and one half days in a petri dish, the fertilized egg (embryo) is placed in the uterus.³⁵ IVF is the same as regular human conception, except in IVF, conception occurs outside of the human body.³⁶ Conversely, human cloning, unlike IVF and "traditional" sexual reproduction, is a complicated procedure with unknown risks and dangers, which scientists should not rush into clinical use.³⁷

B. *Risks of Human Cloning*

Human cloning raises some potentially dangerous health issues. Specifically, this difficult procedure can deform the DNA and the egg by subjecting them to unnatural treatment. First, an enormous number of miscarriages would occur through the cloning procedure.³⁸ The accepted data demonstrates that cloning a human has a "high likelihood of failure and a consequent high rate of miscarriage, and . . . unknown risks of developmental abnormalities in the offspring."³⁹ Second, there is a distinct chance of deformed births. When the scientific team attempted to create Dolly, many of the sheep were born with deformities and died quickly thereaf-

34. See Michael Broyde, *Cloning People: A Jewish Law Analysis of the Issues*, 30 Conn. L. Rev. 503, 510 (1998).

35. See N.Y. Task Force, *supra* note 11, at 57 (noting that at this time, the embryo has only made four to eight cellular divisions and then the embryo is transferred into the uterus of the woman, via a long sterile tube connected to a syringe on one end. The procedure requires no anesthesia for the patient. Overall, the stress on the embryo is minimal).

36. See *id.* at 51 (noting that IVF "refers to the union of sperm and egg in a laboratory dish, literally 'in glass' rather than inside the body").

37. In 1998, Richard Seed, a physicist, proposed to clone a human being. See Weiss, *supra* note 9.

38. See Andrews, *supra* note 1, at 652 (citing Dr. Wilmut, the scientist who is responsible for Dolly, when he stated that "with people, the possibility of 276 failures, many of which would involve miscarriages, sounds horrific and raises huge ethical barriers").

39. Bonnie Steinbock, *The NBAC Report on Cloning Human Beings*, 38 Jurimetrics J. 39, 40-41 (1997).

ter; Dolly was the first survivor out of 277 attempts.⁴⁰ The human cloning procedure would use differentiated human DNA (which already contain a full set of genes). As a result, this DNA may have acquired genetic mutations and could produce deformities.⁴¹ An adult nucleus has already completed forty-five cell divisions, and may have accumulated genetic disease and mutations, which would be transferred upon implantation into an undifferentiated egg cell.⁴² Thus, when a cell's genes are reactivated to differentiate a new egg cell, many hidden risks exist.⁴³

Even if the adult DNA does not contain mutations before the procedure begins, it is still likely that the overall process of cloning will cause stress on the egg and create genetic deformities in the cloned child. In order to produce a clone, the nucleus of the egg cell is stressed through bio-chemical processes.⁴⁴ First, "using an electrical charge, the researchers . . . fuse[d] the donor cell with an unfertilized chromosome-extracted egg."⁴⁵ Second, "this new fused egg [is] now provided with a full complement of DNA from the original donor . . . and the egg [begins] to divide and develop."⁴⁶ Therefore, the added stress to a rapidly dividing cell during development creates a high potential for cellular deformity.⁴⁷

40. See Andrews, *supra* note 1, at 652 (citing Nick Thorpe, *Scientists Baffled by Oversized Sheep Clones*, Scotsman, July 28, 1997 at 1; Steven Connor, "Giant" Lambs Put Future of Cloning in Doubt, Sunday Times (London), July 27, 1997, at 5).

41. See *id.* at 650 (noting that many top geneticists believe that using aged cells to create a new life might not facilitate the average life span of most humans. In fact, cloning might create a new child that is as old as the adult DNA that differentiated the egg cell. Thus, if a thirty-year-old person's DNA was used to differentiate the egg cell, the resulting child would age at the same rate as the thirty-year-old person. This has lead one geneticist to state that "to avoid subjecting human clones to premature aging and the potential harms associated with aged cells" more animal testing must be done before cloning is used on humans).

42. See *id.* (noting that "[a]n adult cell which has already been differentiated contains a complete complement of genes, but only a small proportion are activated in order to do specialized task of that cell. Activating the slumbering genes may reveal hidden mutations").

43. See *id.*

44. See Corsover, *supra* note 26, at 707.

45. *Id.* (citing Pennisi & Williams, *supra* note 29, at 1415).

46. *Id.* (citing Clive Cookson, *FT Guide to: Cloning*, Fin. Times, Mar. 3, 1997, at 10).

47. See *id.* at 708.

Successful animal testing does not guarantee positive results for human cloning.⁴⁸ One variance lies in gene activation.⁴⁹ If DNA replication (gene activation) starts before the transfer of adult DNA into the undifferentiated egg, then there will be an excess of DNA. Thus, this excess DNA will likely cause chromosome damage.⁵⁰

Sheep genes are slow to activate⁵¹ in the nucleus during their first few hours of development.⁵² In humans, gene activation is faster than in sheep, but slower than gene activation in mice.⁵³ For example, mice genes activate at the two-cell stage (fast); human genes activate at the four-eight cell stage (slower); and, sheep genes activate at the eight-sixteen cell stage (slowest).⁵⁴ Some scientists believe that the newly cloned mice offer proof that scientists could successfully clone humans.⁵⁵ Mammals were believed to be more difficult to clone than humans because of the shorter gene activation times.⁵⁶ However, no animal has been cloned with the same gene activation time as a human.⁵⁷ Thus,

48. See Ricki Lewis, *Mammalian Cloning Milestone, Mice from Mice from Mice*, *The Scientist*, Aug. 17, 1998, at 1, 7 (stating that "cloning . . . sheep and mice are about as far apart as you can get among placental mammals") (citing Lee Silver explaining the cell stages).

49. See *id.*

50. See Robert Edwards, *Remarks at Chicago-Kent College of Law: Institute for Science, Law and Technology Changing Conceptions Conference "Creating the next generation: scientific developments"* (visited Oct. 17, 1999) <<http://www.kentlaw.edu/islt/cc/edwards.html>>.

51. A gene is a specific sequence in a DNA molecule that performs a specific function in the body, such as creation of the pigments and fibers of the body. In the cell, activated genes control the cell's performance of specific functions. See Helena Curtis, *Biology* 268 (5th ed. 1989).

52. See *id.*

53. See Lewis, *supra* note 48, at 7.

54. See *id.* The following is a brief explanation of how the meiotic divisions take place in humans:

Formation of the ovum begins with the growth of an oogonium into a primary oocyte. In the first meiotic division, this cell divides into a secondary oocyte and a polar body. The first meiotic division begins in the human female during the third month of fetal development and ends at ovulation, which may take place 50 years later. The second meiotic division, which produces the egg cell and a second polar body, does not take place until after the fertilizing sperm cell has penetrated the secondary oocyte.

Curtis, *supra* note 51, at 258.

55. See Lewis, *supra* note 48, at 7.

56. See *id.*

57. See *id.*

cloned mice offer no assurance that the cloning process will achieve the desired results for humans. Rather, uncertainty, fears of mutated human "clones" and unnecessary deaths loom over human cloning.

As for Dolly, a successfully cloned sheep, researchers have recently determined that she may be susceptible to premature aging and disease because her genetic source was taken from a six-year-old sheep.⁵⁸ All chromosomes are "capped" with tips called telomeres.⁵⁹ These "caps" regulate a cell's life span and prevent the genetic code from disassembling.⁶⁰ As part of the aging process, telomeres eventually break down and signal the cell to do the same, leading to the cell's destruction.⁶¹ Dolly, an animal model for cloning, has been found to have shorter telomeres than average for a sheep Dolly's age.⁶² These findings further illustrate that the cloning process should not be used on humans until scientists have a better understanding of the consequences.

The Director of the National Institute of Health (NIH), Harold Varmus, testified before Congress that animal cloning technology is currently inapplicable to human cloning research.⁶³ Technical questions exist, which can only be answered by continued animal research.⁶⁴ In fact, the recently cloned mice created more safety questions for researchers because scientists created the mice clones from different cells. By using cells from different parts of an adult body, with each cell possibly causing different ramifications in a cloned child's cellular development, scientists will encounter great difficulty when monitoring the cloning process.⁶⁵ The safety of surrogate mothers (who will be subjected to the imperfect cloning

58. See *Dolly's DNA Shows Signs of Decay: Using 6-Year-Old as Genetic Source Could Mean Earlier Death for Clone*, USA Today, May 27, 1999, at 2D, available in 1999 WL 6843925.

59. See *id.*

60. See *id.*

61. See *id.*

62. See *id.*

63. See Andrews, *supra* note 1, at 649 (citing Paul Recer, *Sheep Cloner Says Cloning People Inhumane—Senator Disagrees*, Associated Press Pol. Serv., Mar. 13, 1997, available in 1997 WL 2508493).

64. See *id.*

65. See Lewis, *supra* note 48, at 7 (noting that the scientists who cloned Dolly used a mammary gland cell's nucleus, while the scientists who cloned Cumulina, the mouse, used three types of cumulus cells (cumulus cells are a type of cells that surround an oocyte (a developing egg), but are not egg cells)).

ing procedures) is of great concern.⁶⁶ Women will be subjected to experimentation, unless continued animal research, as well as regulation of human cloning (by the FDA) are made mandatory for their safety.⁶⁷ The FDA should restrict cloning until this procedure is made as safe as possible for women and children.

II. THE NEED FOR REGULATION

The possibility of human cloning presents a need for regulation. When compared to IVF and other similar assisted reproductive techniques, the need for FDA regulation of cloning is apparent. Regulation is required due to: (1) the current business-oriented approach taken towards medicine; (2) doctors' tendencies in similar IVF situations to boost success rates;⁶⁸ (3) the lack of regulations for administrators of similar assisted reproductive programs;⁶⁹ (4) assisted reproduction doctors' failure to follow professional guidelines;⁷⁰ and (5) the lack of avenues for redress for those injured by negligently performed assisted reproductive practices.⁷¹ For these reasons, the FDA must take actions to regulate cloning.

A. *Modern Medicine Becomes a Business*

Many infertility practitioners are becoming more business-oriented than medically-oriented.⁷² This field of medicine (ART programs that someday might offer cloning) has become a billion-dollar annual business.⁷³ Doctors are choosing to provide whatever procedure the patient desires (so long as they can pay), rather than advance professional and ethical standards concerning

66. See Lori D. Andrews et al., *ART into Science: Regulation of Fertility Techniques*, 281 Science 651, 652 (1998).

67. See *id.*

68. See George J. Annas, *Human Cloning: A Choice or an Echo?*, 23 U. Dayton L. Rev. 248, 258 (1998) (noting that "bio-ethics communities have consistently underestimated the power of the market forces and commercialism to shape the demand for and uses of new reproductive technologies"); N.Y. Task Force, *supra* note 11, at 398.

69. See N.Y. Task Force, *supra* note 11, at 410 (stating that "there is no comprehensive federal regulation of assisted reproduction programs").

70. See Rick Weiss, *Fertility Innovation or Exploitation?*, Wash. Post, Feb. 9, 1998, at A1, available in 1998 WL 2466726.

71. See Andrews, *supra* note 66, at 651.

72. See Annas, *supra* note 68, at 258.

73. See *id.* at 258, 263-64.

infertility practices.⁷⁴ When considering new assisted reproductive techniques, such as IVF and human cloning, one can only hope that infertility doctors will ensure that the procedure is completely safe before using it on their patients. Unfortunately, this was not the case with IVF. Practitioners used the IVF procedure on women for years before using it on monkeys.⁷⁵ This has led some embryologists to ask, who were the research models?⁷⁶

If fertility doctors wish to attempt an innovative and unproven technique like human cloning, nothing would stop them except sporadic legislative bans.⁷⁷ In fact, the FDA's proposed cloning regulation would only act as a deterrent. Although the success rates and published statistics may dissuade potential patients, scientists/doctors who perform human cloning, like doctors performing IVF, may fail to inform them of low success rates.⁷⁸ Thus, patients will undertake the procedure regardless of the results.⁷⁹ One IVF provider has already suggested that "even though the cloning success rate is low (1 in 277 as in the Dolly experiment), this should not be a deterrent since all new reproductive technologies have low success rates."⁸⁰

74. *See id.*

75. *See Andrews, supra note 66, at 652 (citing D.P. Wolf & M.M. Quigley, Historical Background and Essentials for a Program in In Vitro Fertilization and Embryo Transfer, in Human In Vitro Fertilization and Embryo Transfer 3-4 (D.P. Wolf & M.M. Quigley eds. 1984)).*

76. *See id.* (footnotes omitted).

77. *See id.* at 651.

78. *See N.Y. Task Force, supra note 11, at 163 (citing National Advisory Board on Ethics in Reproduction, NABER Identifies Ethical Issues Raised by Increased Use of Micromanipulation Techniques, 1 NABER Report 5 (1995). ("The National Advisory Board on Ethics in Reproduction (NABER) has identified several ethical issues raised by the introduction of ICSI, including a rush to offer the technique based on its reported success despite the fact that it takes time to learn to perform it with any proficiency").*

79. *See id.* at 161 (citing L. Brown et al., *Our Miracle Called Louise: A Parent's Story* (1979) (quoting a client of an ART saying "I don't remember Mr. Steptoe saying his methods of producing babies had ever worked and I certainly didn't ask. I just assumed that hundreds of children had already been born through being conceived outside their mother's wombs").

80. *See Andrews, supra note 66, at 651 (citing P. Kendall & W. Neikirk, Cloning Breakthrough a Large Step on Much Longer Road, Chi. Trib., Feb. 25, 1997, at A1). See also Jean Macchiaroli Eggen, The "Orwellian Nightmare" Reconsidered: A Proposed Regulatory Framework for the Advanced Reproductive Technologies, 25 Ga. L. Rev. 625, 634 (1991) (discussing the IVF procedure).*

Even today, the success rates of IVF, gamete intrafallopian transfer (GIFT)⁸¹ and zygote intrafallopian transfer (ZIFT),⁸² range from 22.3% to 27.7%: not much higher since their discovery over 10 years ago (slightly above 20%).⁸³ When the Center for Disease Control (CDC) published this statistical data from 281 assisted reproductive programs in 1995, many fertility doctors told patients not to believe the statistics.⁸⁴ The CDC success rates were reported without a system of verification and the statistics may not take into account clinics that handle tougher cases.⁸⁵ These "statistics are self-reported. No one systematically audits clinics to make sure they are telling the truth."⁸⁶ Thus even these statistics will not prevent human cloning if the doctors wish to experiment on their patients.

In fact, some fertility doctors have been accused of attempting risky procedures to boost success rates.⁸⁷ Fertility clinics may even deflate originally reported success rates of particular assisted reproductive techniques when they want to improve the appearance of the new technique or introduce a new technique to their patients.⁸⁸ At some point, fertility doctors may raise their success

81. GIFT is a procedure that removes eggs from the ovary, combines them with sperm, and uses a laparoscope to place the unfertilized eggs and sperm into the fallopian tubes through surgery. See N.Y. Task Force, *supra* note 11, at 60.

82. ZIFT is a procedure in which eggs are collected from an ovary and fertilized in the lab and uses a laparoscope to place the zygote (fertilized egg) into the fallopian tubes through surgery. See *id.* at 62-63.

83. See Center for Disease Control and Prevention et al., *1995 Assisted Reproductive Technology Success Rates* (visited Oct. 20, 1999) <<http://www.cdc.gov/nccphp/drh/arts/fig7.htm>>.

84. See Catherine Winter, *The Fertility Race: Medical Specialty or Baby Industry* (visited Oct. 20, 1999) <<http://www.msnbc.com/news/140296.asp?cp1=1>>.

85. See N.Y. Task Force, *supra* note 11, at 399 (citing P.A.L. Lancaster, *Registers of In-Vitro Fertilization and Assisted Conception*, 11 *Human Reprod.* 89, 93 (1996)) (noting that some ART programs have patient selection criteria used to enhance a program's reported success rates).

86. See Winter, *supra* note 84.

87. See *id.* at 398 (citing F. Olivennes & R. Fryman, "The A.R.T. of Embroidery," 11 *Human Reprod.* 697, 697-99 (1996)). The N.Y. Task Force quoted one commentator stating that "it is almost always possible to achieve impressive success rates in this manner: 'All centres have known some marvelous series where for a couple of weeks, or even months, one pregnancy follows another and for such a period the success rate per oocyte retrieval amounts to 60%.'" *Id.* (quoting R. Schoysman, *Plea for Realism and Honesty in Results of Infertility Treatment*, 11 *Human Reprod.* 696 (1996)).

88. See *id.* at 398-99 (noting one example where a "practitioner widely reported pregnancy rates of 32 percent using standard IVF in couples with male

rate through human cloning, but for now this procedure is far too risky when compared with current assisted reproductive techniques. It is due to this high risk factor that regulation is necessary.

B. *Similar Assisted Reproductive Programs Lack Regulations*

Many medical professors are outraged by the lack of regulations in the fertility field. Brooks A. Keel, an obstetrics and gynecology professor said, "[a] fertility doctor can literally set up a laboratory in his garage and have his son or daughter who might have a bachelor's degree to run it, and it would be perfectly legal, . . . and [a] woman gets more regulatory oversight when she gets tattoo than when she gets IVF."⁸⁹ Larger fertility centers follow federal standards more often than smaller clinics, which are cutting corners to break into the field.⁹⁰ Although regulation is needed, doctors claim, "it would be unusual and inappropriate to impose federal regulation on a specific branch of medicine," especially reproductive technology, which has not previously been regulated.⁹¹ Unfortunately, too often this branch of medicine has rushed risky procedures into practice because of the strong desire to have successful results.

Researchers may be justified in treating terminally ill patients with risky, innovative procedures because these patients expect to die from their illness regardless of treatment. However, researchers are not justified in the risks taken with human cloning because these patients are not being treated for a life threatening illness.⁹²

factor infertility; when the same practitioner began to use intracytoplasmic sperm injection (ICSI), the pregnancy rate with standard IVF for couples with male factor problems were said to be less than 5 percent").

89. Weiss, *supra* note 70, at A1 (quoting Brooks A. Keel). "We have in many respects far better protection for hamsters than for human fertility patients . . ." *Id.* (quoting R. Alta Charo).

90. *See id.* *See also* Annas, *supra* note 68, at 258 (stating that medicine has become a business and advertising creates incentives to supply the demanded service. If a person has the money, she can find a willing seller).

91. Weiss, *supra* note 70, at A1. This contradicts Sauer's earlier point that "[w]e don't really have a public policy for fertility patients in this country. I wish we did." *Id.* Sauer would rather have the American Society for Reproductive Medicine (ASRM) regulate this field. *See id.* Many fertility clinics do not follow the ASRM standards and if the ASRM tried to regulate cloning, it is likely that fertility clinics will not follow its regulations of cloning. *See infra* pp. 280-81.

92. *See* NBAC Report, *supra* note 5, at 64. The ASRM Commission believes that without further animal testing, standard practice in the biomedical and

All reproductive doctors and researchers are not created equal. Many unqualified medical personnel will inevitably attempt to clone their patients.⁹³ Richard Seed is a good example. Seed, who does not have a medical degree, intends to clone himself by placing his wife at risk with this premature procedure.⁹⁴

In addition to unqualified doctors, concern exists regarding the facilities where doctors perform assisted reproductive procedures. Presently, the facilities offering IVF procedures range "from large university medical complexes to a single doctors office and the professional qualifications of those offering the procedure are equally disparate," because no regulatory body controls clinical IVF.⁹⁵ Due to the unidentified risks and dangers associated with human cloning, society must take a stand and prevent the same doctors who perform IVF in "offices" resembling car garages from attempting to clone a human being.⁹⁶

C. *The Failure of Assisted Reproduction Doctors to Follow Professional Guidelines*

A large number of the reproductive clinics that use IVF and other assisted reproductive techniques, fail to follow professional guidelines.⁹⁷ The possible addition of cloning compounds this problem. The American Society for Reproductive Medicine (ASRM), which sets clinical guidelines, strongly opposes human

clinical fields would never tolerate doctors performing this procedure on humans. *See id.*

93. *See Annas, supra* note 68, at 265 (stating that:

[i]f it is true that market values have been *de facto* incorporated into professional medical values (and are often indistinguishable), then professional ethics and practice standards provide no public protection . . . [w]e must then turn to governmental regulation to "manage" medicine's market competition in research related to new reproductive technologies, as well as clinical practice itself).

94. *See Dizon, supra* note 8.

95. *See Jennifer Gunning & Veronica English, Human In Vitro Fertilization 168-69 (1993)* (stating that there "is no regulatory body for clinical IVF though guidelines, setting out minimal standards and making recommendations for certain procedures, have been issued").

96. *See supra* note 89.

97. The ASRM has published guidelines for the number of eggs that may be safely implanted into a woman during procedures such as IVF. *See N.Y. Task Force, supra* note 11, at 154.

cloning on ethical grounds.⁹⁸ However, many clinics do not follow the ASRM guidelines.⁹⁹ For example, the ASRM issued professional practice guidelines dictating the number of transferable embryos per IVF procedure. Although the guidelines recommend that doctors transfer an average of three embryos per IVF procedure, on average, doctors are transferring four.¹⁰⁰ Any increase in that number exponentially increases the risk to the mother and offspring.¹⁰¹

Despite ASRM recommendations, practitioners still offer and therefore risk a patient's health through treatments that create multiple births. In fact today, many patients request that practitioners implant more embryos.¹⁰² Reproductive doctors fail to follow the guidelines because the more implants they use, the greater the success rates for the procedure.¹⁰³ Although the American Medical Association (AMA) strongly opposes money back guarantees, many fertility clinics still make such offers because every child born is another dollar made.¹⁰⁴ One fertility specialist claims, "you get a baby, or your money back."¹⁰⁵ Monetary goals illustrate why the reproductive doctors do not follow standards dic-

98. See Annas, *supra* note 68, at 265 (stating that cloning was the first reproductive technique that the ASRM has opposed. It is unusual for the ASRM to oppose a reproductive technique. If any good can come from a reproductive technique, the ASRM believes that it should not be outlawed).

99. See *id.*

100. See N.Y. Task Force, *supra* note 11, at 154 (noting that "published reports suggest that this particular guideline is not being observed closely"). In 1994, over half of the ART programs in New York State did not meet the ASRM's standards. See *id.* The reports revealed high amounts of triplets, four of seventeen programs resulting quadruplets, and three of the programs having five or more children. See *id.*

101. See *id.* "Multiple gestations involve significant risks. One in ten infants from multiple gestations dies before reaching twelve months of age and survivors are far more likely than singletons to suffer complications leading to lifelong disability." See *id.* at 151 (citing J.A. Martin et al., *Triplet Births: Trends and Outcomes, 1971-1994*, in 21 no. 55 *Vital Health Statistics 10* (Hyattsville, MA: National Center for Health Statistics, 1997)).

102. See *id.* at 153. Practitioners argue that limiting embryos transferred per cycle would lower the per-cycle chance of pregnancy, something that many infertile people could not pay for. See *id.*

103. See *id.* at 171 (calling for practitioners to eliminate the likelihood of multiple births, even if the other options reduce the possibility of a woman becoming pregnant).

104. See *id.* at 426 (noting that money back guarantees may cause fertility clinics to take risks in order to increase the likelihood of pregnancy).

105. Winter, *supra* note 84.

tating maximum numbers of implants. Fundamentally, it would be bad for business.

D. *No Redress for Injuries Caused by Reproductive Practices*

In addition to placing patients at risk, human cloning offers no redress for patients injuries. Cloning, like existing assisted reproductive techniques, is not covered by health insurance.¹⁰⁶ Other medical services and insurance providers require proof of efficacy before reimbursing the patient for the procedure.¹⁰⁷ Medical malpractice litigation, which serves as a quality control for other health care, does not work as well in the assisted reproductive field.¹⁰⁸ Because of the high failure rate, the patient usually never knows whether the failure was caused by negligence.¹⁰⁹ Even though a child may hold an independent right to sue for injuries caused by premature use of a risky technology,¹¹⁰ the courts are reluctant to find doctors negligent for trying risky procedures.¹¹¹

The FDA must regulate risky assisted reproductive procedures such as human cloning, because of doctors' business-like approach to infertility ethics and the intentionally unsafe methods sponsored by privately funded scientists. Thus, the FDA needs to promulgate a uniform standard for innovative assisted reproductive techniques involving more than minimum manipulation of cells or tissue. If the FDA continues to ignore the real dangers associated

106. See Andrews, *supra* note 66, at 651.

107. See *id.*

108. See N.Y. Task Force, *supra* note 11, at 102-03.

109. See Andrews, *supra* note 66, at 651 (stating that "[r]isk to the children may not be discernible for many years, which may be past the period of time a statute of limitations on a legal suit has run").

110. See N.Y. Task Force, *supra* note 11, at 103 (citing Procanik v. Cillo, 478 A.2d 722 (N.J. 1984); Harbeson v. Parke-Davis, 656 P.2d 483 (Wash. 1983); Turpin v. Sortini, 643 P.2d 954 (Cal. 1982)).

111. See Andrews, *supra* note 66, at 651. (noting that some "courts have been reluctant to impose liability on medical providers and laboratories for children born with birth defects where the child would not have been born if the negligent act had been avoided"). Some courts have not recognized a wrongful birth cause of action, because the courts have not found doctors to be the cause of genetic disorders. See Liddington v. Burns, 916 F. Supp. 1140 (W.D. Okla. 1996); see also Atlanta Obstetrics & Gynecology Group v. Abelson, 398 S.E.2d 557 (Ga. 1990); Wilson v. Kuenzi, 751 S.W.2d 741 (Mo. 1988); Azzolino v. Dingfelder, 337 S.E.2d 528 (N.C. 1985). As a result, the courts are actually backing doctors who use risky procedures instead of finding them liable for the resulting birth defects.

with the cloning process, inevitably tragic mistakes will occur and many innocent people will be hurt.

III. REGULATIONS CURRENTLY COVERING HUMAN CLONING

Scientists could begin experimenting with human cloning in the near future because of loopholes created by inconsistent state and federal cloning bills. When it comes to policing themselves, many fertility doctors and clinics fail to follow or enact guidelines meant to protect the health and safety of their patients. The FDA proposed cloning regulation would protect most United States citizens from this very risky, experimental procedure. By examining the problems with existing and proposed federal cloning regulations, as well as existing state cloning regulations, this section concludes that the state regulations, although a step in the right direction, are inadequate to protect the public. Thus, it is imperative that the FDA create uniform regulation for human cloning to remedy the existing discrepancies.

A. *Federal Regulations are Inadequate to Protect Against Human Cloning*

Congress had already banned federal funds for human embryo research, as opposed to human cloning, prior to the birth of Dolly.¹¹² However, the restriction on federal funds for embryo research will not stop privately funded institutions from cloning humans.¹¹³ Existing federal laws banning human cloning research have also failed to assure that cloning will not take place in the private sector. In an effort to eliminate embryo research, Congress banned Fiscal Year 1996 and 1997 funds appropriated to the Departments of Labor, Education and Health and Human Services.¹¹⁴ Congress' overall intent was to eliminate all federal funding for research to perfect methods for cloning humans.¹¹⁵

112. See Steven Benowitz, *Embryo Research Editorial Sparking Renewed Debate*, *The Scientist*, June 24, 1996, at 6 (citing how in December 1994, Congress would allocate no federal funding to create human embryos exclusively for research purposes).

113. See Andrews, *supra* note 1, at 670 (noting that federal regulation "based on the federal spending power is insufficient to reach research in the private sector").

114. See NBAC Report, *supra* note 5, at 89 (citing P.L. 104-91, 104-208).

115. See *id.*

Still, these restrictions prohibit only federally funded research. Even if the human embryo research ban extended to a cloned embryo created for implantation, privately funded universities, institutions or scientists could still attempt human cloning, albeit, without federal funds.¹¹⁶ Thus, presently there is limited federal oversight of privately funded scientists like Richard Seed, who are willing to attempt human cloning, regardless of whether public funding is available.¹¹⁷

As aforementioned in Part II, denying federal funds to reproductive clinics may have actually jeopardized the safety of clinic patients. Congress does not require fertility clinics to follow federal regulations if they do not receive federal funds. Human cloning could become another assisted reproductive technique, such as IVF, which receives no federal funding.¹¹⁸ The federally regulated institutional review boards (IRBs),¹¹⁹ which govern all risky research performed on human subjects, such as cloning, are only present at institutions receiving federal funding.¹²⁰ Thus, since fertility clinics do not receive federal funding, IRBs cannot review their innovative procedures. In fact, one rarely finds an institutional review board in the fertility field.¹²¹

Many of Congress' proposed bills to ban human cloning restrict federal funding, but allow cloning to occur in the private sector. For example, Congressman Vernon H. Ehlers' proposed bill

116. *See id.*

117. *See* Dizon, *supra* note 8 (discussing Richard Seed's willingness to use private funds to attempt cloning. Such action would thwart any federal government interference because the federal government cannot regulate test experiments performed by private funds).

118. *See* Gunning & English, *supra* note 95, at 167 (stating that "[t]here has been an effective moratorium on Federal funding for embryo research since 1975 when the Department of Health Education and Welfare (now Department of Health and Human Services, DHHS) published regulations for the protection of human subjects of research").

119. IRBs ensure that (1) human subjects are not exposed to harmful experiments and (2) have given consent. *See* NBAC Report, *supra* note 5, at 88 (citing 45 C.F.R. § 46 (1997)).

120. *See id.*

121. *See* Andrews, *supra* note 66, at 651.

[W]here the Board so establishes a class of applications or proposals which must be submitted, no application or proposal within the class may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

45 C.F.R. 46.204(c).

H.R. 922,¹²² which prohibited federal funds to conduct or support any project of research, including the use of human somatic cell nuclear transfer technology to produce an embryo.¹²³ Congressional bill, S. 1602, would prohibit human cloning by invoking Congress' Commerce Clause authority.¹²⁴ However, it should be noted that the Supreme Court, in *United States v. Lopez*,¹²⁵ limited Congress' Commerce Clause authority to commercial areas of interstate commerce.¹²⁶ Whether medical procedures, such as human cloning, could be considered a commercial activity is still debatable.¹²⁷ Cloning is an activity that includes "personnel and patients from a national market," and therefore should be considered a commercial activity that Congress could regulate under the Commerce Clause.¹²⁸ Thus, while Congress considers whether or not to regulate human cloning, the FDA must protect the public from the unknown risks.

Some commentators suggest that Congress should rely on the FDA to regulate human cloning until it is considered safe for humans. Such action would require the FDA to draft regulation on cells and tissues that "clearly delineates acceptable and unacceptable areas of research."¹²⁹ These commentators believe that in the rush to ban human cloning due to the large public protest against the procedure, Congress was not concerned about the long-term

122. See H.R. 922, 105th Cong. (1997). Representative Ehlers has introduced another human cloning bill, H.R. 923, which would make it unlawful for anyone (privately or publicly funded) to clone a human. See H.R. 923, 105th Cong. (1997). These bills have not been passed.

123. See Heidi Forster & Emily Ramsey, *Legal Response to the Potential Cloning of Human Beings*, 32 Val. U. L. Rev. 433, 440 (1998) (citing 143 Cong. Rec. H6714 (Aug. 1, 1997) (noting that the Committee on Science has altered the bill to allow non-human cloning to proceed)).

124. See S. 1602, 105th Cong. (1998) (Section b of the proposed act states: "[i]t shall be unlawful for any person or other legal entity, public or private" to clone human beings) (emphasis added).

125. 514 U.S. 549 (1995).

126. See Andrews, *supra* note 1, at 674-75 (citing *United States v. Lopez*, 514 U.S. 549, 551 (1995)); Cannon & Haas, *supra* note 7, at 641. For an in-depth discussion of Congress' Commerce authority see Andrews, *supra* note 1, at 674-75.

127. See Andrews, *supra* note 1, at 675.

128. *Id.*

129. See Cannon & Haas, *supra* note 7, at 641 (noting that "[t]he fact that Food and Drug Administration ("FDA") has claimed jurisdiction over human cloning and has promised to prevent any attempt to clone a human being makes the need to enact legislation less urgent").

ramifications of these proposed bills on scientific research.¹³⁰ Whether Congress will regulate human cloning remains to be seen. Evidently, Congress must be extremely careful when creating bills to regulate human cloning.

Proposed federal bills¹³¹ banning human cloning are similar in that they ban the cloning process to create a baby, but then diverge into separate regulatory schemes. They differ in their respective definitions of cloning, sunset clauses (time limit for the cloning ban) and in their permission to use cloned embryos for research purposes. Dozens of medical organizations, biotechnology companies and distinguished scientists oppose Congressional bill S. 1601¹³² because it bans baby making, cloning human embryos and research on cloned embryos.¹³³ This bill upsets scientists because Congress has never before banned scientific or medical research.¹³⁴ Scientists prefer bill S, 1602,¹³⁵ which would forbid them from im-

130. See *id.* at 636-38.

131. See S. 1611, 105th Cong. (1998), also labeled as S. 1602, 105th Cong. (1998); S. 1601, 105th Cong. (1998), also labeled as S. 1599, 105th Cong. (1998); H.R. 3133, 105th Cong. (1998); S. 1574, 105th Cong. (1998); H.R. 923, 105th Cong. (1997); H.R. 922, 105th Cong. (1997); S. 368, 105th Cong. (1997).

132. See S. 1601, 105th Cong. (1998). The proposed act provides as follows:
Chapter 16—Cloning, Sec. 301: Prohibition on Cloning.

(a) In General—It shall be unlawful for any person or entity, *public or private*, in or affecting interstate commerce, to use human somatic cell nuclear transfer technology.

(b) . . .

(c) . . .

(d) Definition—The term 'human somatic cell nuclear transfer technology' means taking the nuclear material of a human somatic cell and incorporating it into an oocyte from which the nucleus has been removed or rendered inert and producing an embryo (including a preimplantation embryo).

133. See J.P. Kassirer & N.A. Rosenthal, *Should Human Cloning Research be off Limits?*, 338 *New Eng. J. Med.* 905, 905 (1998); see also Cannon & Haas, *supra* note 7, at 642-43 (noting that pro-life groups such as National Right to Life Committee and the Christian Coalition, believe that human life begins when the egg is fertilized. The groups oppose the bill because it fails to ban all research on the fertilized egg. Some members of Congress believe the ban is overly broad, thus regulating too many areas of research).

134. See Kassirer & Rosenthal, *supra* note 133, at 905 (arguing that both the House and Senate bills would stop all cloning experiments with human cells).

135. See S. 1602, 105th Cong. (1998). The proposed act provides the following:

(b) Prohibitions—It shall be unlawful for any person or other legal entity, public or private—

(1) to implant or attempt to implant the product of somatic cell nuclear transfer into a woman's uterus; . . .

planting an embryo into a woman's uterus using human cloning procedures, but could permit research into cloning technologies to clone molecules, cells and tissues.¹³⁶

B. *Existing State Laws are Unable to Prohibit all Possible Attempts at Human Cloning*

Traditionally, states regulate medical procedures.¹³⁷ Thus, some argue that federal agencies should not regulate reproductive techniques such as human cloning.¹³⁸ However, the issue of human cloning is larger than states' rights. The FDA has, on occasion, intervened in states' rights to regulate medical procedures.¹³⁹ This is because the FDA has the knowledge and ability to test these advanced medical procedures.¹⁴⁰ The FDA is superior compared to the states in determining the safety of human cloning.

Although existing cloning bills vary from state-to-state, it still remains to be seen whether states will have comprehensive bills to regulate human cloning. Laws regulating research and/or experimentation on embryos, fetuses or unborn children must include comprehensive language encompassing early stage embryos, such as would be used in cloning a human.¹⁴¹ Today, only ten states use

(c) Protected Research and Practice—Nothing in this section shall be construed to restrict areas of biomedical and agricultural research or practice not expressly prohibited in this section, including research or practices that involve the use of—

- (1) somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues;
- (2) mitochondrial, cytoplasmic or gene therapy; . . .

136. See Kassirer & Rosenthal, *supra* note 133, at 905.

137. See Andrews, *supra* note 1, at 669.

138. See generally Cannon & Haas, *supra* note 7 (discussing the ethical dilemmas associated with the regulation of human cloning).

139. See Arthur L. Caplan, *Why the Rush to Ban Cloning*, N.Y. Times, Jan. 28, 1998, at A25, available in 1998 WL 5395773. The FDA has recently created the Recombinant DNA Advisory Committee (RAC), an advisory body that will determine the safety of gene therapy before it is used on humans. See Susan M. Wolf, *Human Cloning: The Trouble with a Ban* (visited Oct. 27, 1998) <http://www.law.umn.edu/alumninews/spring98/human_cloning.htm>.

140. See generally FDA Proposal, *supra* note 12. This guideline proposal regulates technical manipulation of cells and genes.

141. See Andrews, *supra* note 1, at 658 n.107; See Fla. Stat. § 390.011(5) (1997); La. Rev. Stat. Ann. § 9:121-:122 (West 1991); Me. Rev. Stat. Ann. tit. 22, § 1593 (West 1992); Mass. Gen. Laws Ann. ch. 112, § 12J (West 1996); Mich. Comp. Laws Ann. § 333.2685-.2692 (West 1992); Minn. Stat. § 145.421-.422 (1994); N.D. Cent. Code § 14-02.2-01 to 14-02.2-02 (1991); N.H. Rev. Stat. Ann. § 168-B:15

such language in their laws. Some state laws regulating embryo management could restrict even privately funded attempts at human cloning, if cloning is considered to be a form of fertilization.¹⁴²

In addition to state laws regulating research on embryos and assisted reproductive techniques, as of December 7, 1999, nineteen states introduced bills to ban human cloning.¹⁴³ Alabama, California, Illinois, New Jersey, New York, North Carolina, Oregon, and West Virginia have introduced bills banning the cloning of an entire individual regardless of the funding source.¹⁴⁴ Other states have bills that specifically ban any research using cloned cells or tissue (California and Florida); ban the use of governmental funds for cloning an entire individual (Missouri and Maryland); or may unintentionally ban beneficial research using cloned human tissue or cells not intended for the creation of a child (South Carolina and New York).¹⁴⁵ Alabama proposed a bill banning governmental funds for research involving cloned cells or tissue. Additionally, Alabama proposed another bill that would ban cloning an entire individual with or without federal or state funding.¹⁴⁶ Thus, the inconsistency among state human cloning bills reinforces the need for FDA regulation.

(1994); Pa. Cons. Stat. Ann. § 3216 (West Supp. 1998); R.I. Gen. Laws § 11-54-1 (1994).

142. See NBAC Report, *supra* note 5, at 89.

143. See S.B. 68, 1998 Reg. Sess. (Ala. 1998), S.B. 8, 1998 Reg. Sess. (Ala. 1998); H.B. 5475, 1998 Reg. Sess. Gen. Assembly (Conn. 1998); S.B. 241, 139th Gen. Assembly, 2d Sess. (Del. 1998); H.B. 3206, 19th Leg. (Haw. 1998); S.B. 1243, 90th Gen. Assembly, 1997-98 Reg. Sess. (Ill. 1998); S.B. 825, 1999 Reg. Sess. (La. 1999); H.B. 2235, 90th Gen. Assembly, 1997-98 Reg. Sess. (Md. 1998); H.J.R. 11, 1998 Reg. Sess. (Md. 1998); S.B. 2423, 80th Reg. Sess. (Md. 1998); H.B. 2730, 80th Reg. Sess. (Minn. 1998); H.B. 996, 1998 Reg. Sess. (Miss. 1998); H.B. 1658, 155th Sess., 2d Year (N.H. 1998); A.B. 329, 208th Leg. (N.J. 1998); A.B. 2849, 207th Leg. (N.J. 1997); S.B. 5993, 221st Leg. Sess. (N.Y. 1998); A.B. 9183, 221st Leg. Sess. (N.Y. 1998); S.B. 2877, 220th Leg. Sess. (N.Y. 1997); H.B. 675, 122d Gen. Assembly, 1997-98 Reg. Sess. (Ohio 1998); S.B. 218, 122d Gen. Assembly, 1997-98 Reg. Sess. (Ohio 1998); H.B. 2128, 182d Gen. Assembly, 1997-98 Reg. Sess. (Pa. 1998); H.B. 7123, 1997-98 Leg. Sess. (R.I. 1998); H.B. 3617, 112th Gen. Assembly Sess. (S.C. 1997); S.B. 2295, 100th Gen. Assembly (Tenn. 1998); H.B. 2281, 100th Gen. Assembly (Tenn. 1998); H.B. 2198, 100th Gen. Assembly (Tenn. 1998); S.B. 2208, 100th Gen. Assembly (Tenn. 1998); H.B. 752, 1998 Sess. (Va. 1998).

144. See NBAC Report, *supra* note 5, at 104. The states banning all cloning attempts, regardless of the funding source, are Alabama, Illinois, New Jersey and New York. See Andrews, *supra* note 1, at 660 n.121.

145. See NBAC Report, *supra* note 5, at 104.

146. See *id.*

Also, technology is advancing faster than state legislation in the area of reproductive technologies. Recent technological advances with animal embryo research may make much of the legislation obsolete.¹⁴⁷ For example, researchers have placed DNA from primates into cows' eggs that developed into early embryos.¹⁴⁸ If the same technique can produce normal human embryos, then laws prohibiting the transfer of the nucleus into only a human egg actually provide a legal loophole for doctors using donor cow eggs.¹⁴⁹ Essentially, doctors would be able to transfer the human nucleus into the cow's egg and then implant the cow's egg into a human. FDA regulation would provide much-needed, up-to-date legislation of reproductive technology (notwithstanding inevitable technological advances).

FDA should also regulate human cloning because state legislators suffer from a bane ignorance of human cloning. This ignorance produces proposed state bills with significant drafting weaknesses. Five of these bills prohibit the cloning of a "genetically identical person."¹⁵⁰ Statutes that prohibit the cloning of a genetically identical person would not apply to human cloning, since the clone would not be exactly identical to its donor.¹⁵¹ The cloned child's DNA would be differentiated differently from the clone's donor DNA, because of variations in the conditions of the mother's uterus and mother's mitochondrial DNA present inside her egg cells.¹⁵²

While these state bills and regulations are a step in the right direction, they are poor substitutes for a uniform federal law regulating cloning. The state regulations have too many hidden weaknesses; thus, as an agency experienced in medical procedures, the FDA should use its authority to create a uniform regulation for human cloning. The next section considers in detail why both the federal and state regulations, presently in place, are insufficient.

147. See Andrews, *supra* note 1, at 660-61.

148. See *id.*

149. See *id.* at n.122 (revealing Illinois, Kansas, New York, South Carolina, and Tennessee as the five states and describing how the current technique uses a donated egg that carries mitochondrial DNA from the enucleated egg; thus the clone will not be genetically identical to the original individual).

150. *Id.*

151. See *id.*

152. See *id.*

C. Existing Agencies are Insufficient to Regulate Human Cloning

One federal agency, the Department of Health and Human Services (DHHS), which usually protects embryos and pregnant women from risky, new research, lacks the authority to regulate cloning.¹⁵³ The DHHS requires that researchers receive informed consent from pregnant women, the approval of institutional review boards and perform prior studies on animals to show that their research poses only minimal risk to the fetus.¹⁵⁴ However, the

153. See Jonathan F.X. O'Brien, *Cinderella's Dilemma: Does the In Vitro Statute Fit? Cloning and Science in French and American Law*, 6 Tul. J. Int'l & Comp. L. 525, 536 (1998) (citing 45 C.F.R. §§ 46.201-46.211 (1996)) (arguing that before Dolly, the only way the federal government could dissuade scientists from performing research on embryos was by restricting funding). 45 C.F.R. § 46.201 (Applicability) states: (a) The regulations in this subpart are applicable to all Department of Human Health and Human Services grants and contracts supporting research, development, and related activities involving: (1) the fetus, (2) pregnant women, and (3) human *in vitro* fertilization. 45 C.F.R. § 46.201 (1997).

154. See O'Brien, *supra* note 153, at 536 (citing 45 C.F.R. §§ 46.201-46.211 (1996)). 45 C.F.R. § 46.207 (Activities Directed Toward Pregnant Women as Subjects) states:

(a) No pregnant woman may be involved as a subject in an activity covered by this subpart unless:

- (1) The purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to meet such needs, or
- (2) the risk to the fetus is minimal.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus

45 C.F.R. § 46.205 (Additional duties of the Institutional Review Boards in Connection with Activities Involving Fetuses, Pregnant Women, or Human In Vitro Fertilization) states:

(a) In addition to the responsibilities prescribed for Institutional Review Boards under Subpart A of this part

- (2) Determine that adequate consideration has been given to the manner in which potential subjects will be selected, and adequate provisions has been made by the applicant or offeror for monitoring the actual informed consent process

(3) Carry out such other responsibilities as may be assigned by the Secretary.

45 C.F.R. § 46.206 (General Limitations) states:

(a) No activity to which this subpart is applicable may be undertaken unless:

- (1) Appropriate studies on animals and nonpregnant individuals have been completed;
- (2) Except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is

DHHS's enabling statute fails to grant the DHHS the authority to regulate cloning because the statute protects against embryo manipulation only after the embryo is a viable fetus.¹⁵⁵ Cloning a human involves the manipulation of cells before the embryo is created; the cells are not manipulated again.¹⁵⁶ The DHHS does not protect an embryo until it is considered a viable fetus (fourteen days after conception); at that point, the risks to the human clone have already occurred. Thus a cloned embryo may continue to be manipulated until implantation in the uterus because only then is it considered a viable fetus.¹⁵⁷ Therefore, the FDA must protect embryos from the hazards of cloning because the DHHS lacks the authority to do so.

If the FDA fails to regulate human cloning, then the United States must rely on a hodgepodge of state human cloning laws as the primary means for regulating clinical applications of the technology. The proposed state bills on human cloning reveal tremendous differences, with many of these states still awaiting FDA or Congressional action for guidance and uniformity.

IV. FDA'S AUTHORITY TO REGULATE HUMAN CLONING

The FDA has the authority to regulate human cloning under section 351 of the Public Health and Service Act.¹⁵⁸ However, to fully comprehend how the FDA can regulate human cloning, one must understand the history of the FDA's authority to regulate bi-

minimal and, in all cases, is the least possible risk for achieving the objectives of the activity.

155. See O'Brien, *supra* note 153, at 536 (citing 45 C.F.R. § 46.201(a) (1996)).

156. See *id.* (citing 45 C.F.R. § 46.209 (1996)). 45 C.F.R. § 46.209(c) (Activities directed towards fetuses *ex utero*, including nonviable fetuses, as subjects) states "[i]n the event the fetus *ex utero* is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other subparts of this part." 45 C.F.R. § 46.209 (1997). The fertilized egg cell (embryo) is not considered a viable fetus until fourteen days after fertilization; thus an egg manipulated and fertilized via cloning would not be considered a fetus before being put into the uterus. See O'Brien, *supra* note 153, at 536 n.86.

157. See *id.*

158. If a person were to attempt cloning a human being in violation of section 351 of the Public Health and Service Act, that person could be punished by a \$500 fine and up to one year imprisonment. See 42 U.S.C. § 262(f) (1997). If cloning is considered "an imminent or substantial hazard to the public health . . .," the person could also be charged with a civil penalty of up to a \$100,000 per day. 42 U.S.C. § 262(d)(2)(B) (1997).

ological products. Over the years, Congress has given the FDA increasing authority to regulate public health. In 1972, Congress gave the FDA the job of regulating biological products under section 351, which covers health concerns, including the control of communicable diseases.¹⁵⁹

To regulate human cloning under section 351 of the Public Health and Services Act, the FDA must meet a two-part test. The FDA must prove that human cloning falls: (1) within the definition of a biological product and (2) under its proposed regulations of cell and tissue-based products.¹⁶⁰ Human cloning falls under the definition of a biological product because the cells and tissues are "manipulated extensively [and] combined with non-tissue components . . . other than their normal functions."¹⁶¹ Recently, the FDA announced that it had classified human cloning as a form of cellular genetic therapy that fits within the FDA's cellular and tissue-based products proposal; therefore the FDA considers a cloned embryo a biological product.¹⁶²

A. *Human Cloning as a Biological Product*

At first glance, the FDA may appear to lack the authority to regulate biological products in the area of reproductive technologies, such as human cloning. For many years, the FDA failed to regulate reproductive tissue (semen and ova) as biological products because at that time the states regulated reproduction.¹⁶³ However, in 1997, the FDA demonstrated its ability to revise its authority over biological products. In order to protect public health, the FDA began regulating human tissue banks.¹⁶⁴ This rationale sets forth that "broad agency discretion is consistent with the FDA's responsibility to protect the public health," courts generally allow the FDA great discretion to interpret statutory language gov-

159. See Kevin L. Ropp, *Just What is a Biologic, Anyway?*, FDA Consumer, Apr. 1, 1993, at 27, 30.

160. See FDA Proposal, *supra* note 12, at 6.

161. *Id.*

162. See Weiss, *supra* note 10, at A1.

163. See Martha A. Wells, *Overview of FDA Regulation of Human Cellular and Tissue-Based Products*, 52 Food & Drug L.J. 401, 402 (1997).

164. See Marc. O. Williams, *The Regulation of Human Tissue in the United States: A Regulatory and Legislative Analysis*, 52 Food & Drug L.J. 409, 411-12 (1997) (stating that the FDA regulates organs such as hearts and livers under the PHS Act, because organs are *analogous products* to blood and blood products).

erning the classification of products.¹⁶⁵ Since the courts give the FDA this discretion, the FDA has the authority to include the genetically manipulated reproductive tissue used in human cloning within its definition of biological products.¹⁶⁶

In 1902, the original federal definition of biological products included only vaccines and blood products.¹⁶⁷ However, today's definition of a biological product has two broad components: "(1) it must be a 'virus, therapeutic serum . . . or analogous product' and (2) it must be 'applicable to the prevention, treatment, or cure of diseases or injuries to man.'"¹⁶⁸ Still, the egg cell (human embryo), duplicated through the cloning procedure, is an "analogous product" as stated in the above-mentioned definition. The next subsection addresses the reasons why cloning is an analogous product to those products specifically listed as biological products in section 351 of the PHSA.

For the FDA to regulate human cloning, the embryo manipulated during the cloning procedure must be considered a biological product as defined in section 351 of the Public Health and Service Act (PHSA).¹⁶⁹ According to Michael Beatrice, of the FDA's Center for Biologics Evaluation and Research, "[y]ou have to look at the source [of a product] and the *intended use*, to determine if a product is a biological product" suitable for treatment of a disease.¹⁷⁰ When looking at the creation of an embryo through the process of human cloning, the source of the original embryo is a human prod-

165. Jennifer Kulynych, *Blood as a Biological "Drug": Scientific, Legal, and Policy Issues in the Regulation of Placental and Umbilical Cord Stem Cell Transplantation*, 32 U. Rich. L. Rev. 407, 418 (1998).

166. See Andrews, *supra* note 1, at 657-58.

167. See Jodi K. Fredrickson, *Umbilical Cord Blood Stem Cells: My Body Makes Them, But Do I Get to Keep Them? Analysis of the FDA Proposed Regulations and the Impact on Individual Constitutional Property Rights*, 14 J. Cont. Health L. & Pol'y 477, 482-83 (1998) (citing William R. Pendergast, *Biological Drugs, in Food and Drug Law 306-08* (Richard M. Cooper ed. 1991)). In 1902, the Virus-Toxin Law brought biological products under federal regulatory control. See Ropp, *supra* note 159, at 27.

168. Price, *supra* note 20, at 639 (quoting the Public Health and Service Act, 42 U.S.C. § 262(a) (1997)).

169. Biological products include "any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, or derivative, allergenic product, or analogous product or arsphenamine or its derivative (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man." Public Health and Service Act, 42 U.S.C. § 262(i) (1998).

170. Ropp, *supra* note 159, at 28 (emphasis added).

uct. However, in order to clone a child, that embryo must be more than minimally manipulated. Thus, the creation of an embryo, through the process of human cloning, falls into the biological product category.¹⁷¹ A human embryo is not considered to be a "product" because an embryo is not typically "something produced."¹⁷² Congress could not have anticipated such biological innovations to create an all-inclusive definition of biological products.¹⁷³ As such, the definition can include human cloning as a modern day biological product.

1. *Human Cloning, an Analogous Product*

The human egg cell, when genetically manipulated and manufactured in a laboratory through a cloning procedure, is an "analogous product" to a live, whole cell vaccine under the PHSA because the cloned embryo passes the first prong of the biological product test.¹⁷⁴ A cloned embryo, like a live vaccine originates from a living entity and lives after manipulation.¹⁷⁵

Professor Elizabeth Price challenges the FDA's authority to regulate cloning under section 351 of the Public Health and Service Act based on the distinction between a biological entity and a biological component. Price argues that the genetically manipulated egg cell develops into "a complete biological entity onto itself" as the embryo.¹⁷⁶ She is under the belief that a human embryo could never be analogous to a laboratory-created vaccine because a vaccine is just a biological component and not "a complete biological entity onto itself."¹⁷⁷ However, her analysis ignores the fact that "whole cell vaccines and microorganisms" may similarly be considered "a complete biological entity onto itself."¹⁷⁸

171. See FDA Proposal, *supra* note 12, at 7.

172. Ropp, *supra* note 159, at 29-30.

173. See *id.*

174. A bacterial cell is a prokaryotic cell which reproduces by dividing in half through a process called binary fission. See Campbell, *supra* note 28, at 222. "Live bacterial vaccines include the orally administered live, attenuated *S.typhi* strain Ty21a vaccine for typhoid; the bacille Calmette-Guérin (BCG) vaccine for tuberculosis, which consists of an attenuated strain of *Myco-bacterium bovis*; and an attenuated tularemia vaccine." Patrick R. Murray et al., *Medical Microbiology* 130-31 (3d ed. 1998).

175. See Stolberg, *supra* note 13.

176. Price, *supra* note 20, at 639.

177. *Id.*

178. *Id.*

The FDA regulated whole cell vaccines and microorganisms in the past; they were more than mere "biological components," they were the whole "biological entity."¹⁷⁹ Many vaccines have used a whole cell to carry out a biological function when in use.¹⁸⁰ A whole cell vaccine, such as a live bacterial vaccine, is a living, self-sustaining cell that has the ability to reproduce itself.¹⁸¹ Like a cell vaccine, a scientifically developed human egg has the same reproductive capabilities.

Genetically developed human egg cells are analogous to cell vaccines. Cloning is a creation of a human embryo that would otherwise not occur in nature. Unlike other assisted reproductive techniques, such as IVF and intracytoplasmic sperm injections (ICSI)¹⁸² that require the egg and sperm cell's genetic material to go through meiosis,¹⁸³ cloning eliminates this stage.¹⁸⁴ Meiosis is a very important stage of human development because during meiosis, the female and male's DNA are crossed over each other and a mixing of genes occurs.¹⁸⁵ The crossing over of genes is nature's way of ensuring genetic variation in every generation.¹⁸⁶ Eliminating meiosis from human reproduction creates a human without nature's genetic swap. Thus, the cloned embryo, like a whole cell

179. "This category comprises products derived from living materials—humans, plants, animals, or microorganisms—when such products are used in the treatment or prevention of disease." Kulynych, *supra* note 165, at 421 (citing statement by Michael Beatrice of the FDA's Center for Biologics Evaluation and Research (CBER), in Kevin L. Ropp, *Just What is a Biologic, Anyway?*, FDA Consumer, Apr. 1, 1993, at 27). In 1902 when Congress created the definition of biologics, "the word *virus* could refer to what are now recognized as a variety of disease-causing microorganisms, including viruses, bacteria and protozoa." Ropp, *supra* note 159, at 28 (emphasis added).

180. *Hurly v. Lederle Lab.*, 651 F. Supp. 993, 995-96 (E.D. Tex. 1986) (noting that the FDA regulated whole cell vaccines under the PHSA).

181. See Murray, *supra* note 174.

182. Scientists use intracytoplasmic sperm injections to inject sperm into the egg cell. See N.Y. Task Force, *supra* note 11, at 64. This procedure still requires the egg's genetic material and sperm's genetic material to go through meiosis and the process of crossing over, which allows for a mixing of both cell's genes.

183. Meiosis is a crucial part of development that contains numerous steps. This section will cover only a few pertinent steps. During Meiosis both the female's and male's chromosomes combine to form a nuclei, and segregation, crossing over, and reassortment of the genes occurs. See Curtis, *supra* note 51, at 249.

184. See Corsover, *supra* note 26, at 706-07.

185. See Curtis, *supra* note 51, at 984.

186. See *id.*

vaccine, is a biological product, created from human egg cell manipulation.

The genetically manipulated human egg cell is an analogous product to those products listed in the PHSA definition of biological products. Thus, the FDA could regulate a genetically manipulated embryo as an "analogous product"¹⁸⁷ of a whole cell vaccine, which would fall within section 351 of the PHSA. However, the FDA must also demonstrate that human cloning may represent a treatment for the disease of infertility.

2. Cloning's Application to Disease Prevention

Human cloning must also be "applicable to the prevention, treatment, or cure of diseases or injuries to man."¹⁸⁸ Thus, the first issue to address is whether human infertility is indeed, a disease. Until recently, courts have split on whether infertility should be viewed as a malfunction or illness of the human body.¹⁸⁹ The United States Supreme Court put an end to this split in *Bragdon v. Abbott*¹⁹⁰ viewing infertility as a disease or a disorder of the human body.¹⁹¹ Thus, one could view human cloning as a possible treatment and a cure for the disease of infertility.

187. The courts will likely allow regulation of cloning as an "analogous product" because they have given the FDA great deference in the past to determine what it considers to be an "analogous product" of a virus, serum, toxin, or antitoxin. *United States v. Calise*, 217 F. Supp. 705, 708-09 (S.D.N.Y. 1962) (holding that: if defendants were true in their claim that blood cannot be 'propagated' or 'manufactured and prepared' except in the body of a person, and that therefore blood cannot be one of the products to which Congress intended the licensing statute to apply, then nothing which is ultimately derived from nature would ever be capable of subsequently being 'manufactured and prepared'. The word 'manufactured' as employed in this statute obviously was intended to include 'processing' within its signification).

188. 42 U.S.C. § 262(h)(1) (1998).

189. Compare *Erickson v. Board of Governors*, 911 F. Supp 316 (N.D. Ill. 1995), and *Pacourek v. Inland Steel Co.*, 916 F. Supp. 797 (N.D. Ill. 1996) (holding that infertility is a disability because it is a major physical impairment that substantially limits life activities), with *Zatarain v. WSDU-Television, Inc.*, 79 F.3d 1143 (5th Cir. 1996), and *Krauel v. Iowa Methodist Med. Ctr.*, 95 F.3d 674 (8th Cir. 1996) (holding that reproduction is not a major life activity).

190. 524 U.S. 624 (1998).

191. See *id.* at 637-39 (holding that HIV's inhibiting affect over reproduction is a disability because reproduction is a "major life activity" and infertility obviously "substantially limits" this activity); see also *Egert v. Connecticut Gen. Life Ins. Co.*, 900 F.2d 1032, 1038 (7th Cir. 1990) (holding that artificial insemination and IVF are treatments for infertility despite the fact that such therapies do not correct the underlying problem). The ADA defines a "physical or mental impairment" as a

The second issue to address is whether human cloning will actually prevent, treat or cure this disease. In several cases, insurance companies have argued that assisted reproductive techniques, such as IVF and artificial insemination, do not treat infertility because the procedures do not cure the underlying disease.¹⁹² In *Egert v. Connecticut General Life Insurance Co.*,¹⁹³ the insurance company stated that it would cover treatments for blocked fallopian tubes but not IVF.¹⁹⁴ The Seventh Circuit held that the insurance company would have to pay for the IVF treatments because infertility is an illness and IVF is a viable treatment.¹⁹⁵ Human cloning will treat this disease because it enables infertile people to have children, through the use of a genetically manipulated embryo (a biological product). Thus, the cloned embryo is a biological product, which will treat the disease of infertility.

Some scholars doubt the value of cloning as a treatment for a disease. In particular, Professor Elizabeth Price discounts the "treatment" merit of cloning.¹⁹⁶ The flaw in Price's argument is the way in which she frames the question of disease. Instead of considering whether infertility is a disease, she asks whether pregnancy is a disease.¹⁹⁷ While cloning is not a treatment for pregnancy, it may be a possible treatment for infertility. Had Price framed the disease at issue as infertility, she would have reached the conclusion that cloning is a viable treatment.

As aforementioned, the embryo used in cloning is a biological product. Since it is a biological product and it will effectively treat the disease of infertility, the FDA has jurisdiction to regulate cloning through its regulations of biological products under section 351 of the PHSA.

condition affecting one or more of a number of listed "body systems" with a specific reference to the reproductive system. 29 CFR Part 1630.2(h)(1) (1995). The American Society for Reproductive Medicine defines infertility as a *disease* that exists when a couple has tried to conceive for 12 months, without the use of contraceptives. See American Society for Reproductive Medicine, *Guidelines for the Provision of Infertility Services* (visited Oct. 2, 1999) <<http://www.asrm.com>>.

192. See *Witcraft v. Sunstand Health and Disability Group Benefit Plan*, 420 N.W.2d 785 (Iowa 1988); *Egert*, 900 F.2d at 1038.

193. 900 F.2d 1032, 1038 (7th Cir. 1990).

194. See *id.*

195. See *id.*

196. See Price, *supra* note 20, at 640.

197. See *id.*

B. *Does the FDA's Cellular and Tissue-Based Proposal Cover Human Cloning?*

In February 1997, the FDA published its first guidance document to propose new regulations for human cellular and tissue-based products.¹⁹⁸ The FDA has never had a formal regulatory program for human cellular and tissue-based products; instead it has regulated these products on a case-by-case basis.¹⁹⁹ Through its proposal to regulate cell and tissue-based products the FDA intended to: 1) prevent the use of contaminated tissue; 2) prevent mishandling that might cause contamination of the tissue; and 3) ensure clinical safety for tissue that is more than minimally manipulated.²⁰⁰ The FDA determined that it would regulate tissues based on degree of risk, source, use and the necessity for FDA review.²⁰¹

As noted above, the FDA believes human cloning is a form of cell/gene therapy, which involves the manipulation of human tissue, thus requiring FDA approval. The FDA determined that the kind of manipulation involved in human cloning presents "serious health and safety issues" for the fetus and the mother.²⁰² To understand why the FDA believes human cloning falls within its regulatory authority, one must understand the FDA's proposed regulations of cellular and tissue-based products. The FDA's proposed guidance document explains the regulation of human tissue and covers reproductive tissues that are minimally manipulated and used for their normal functions.²⁰³ In determining whether human cellular tissue based products fall within its proposal the FDA considers: 1) whether donor or non-donor tissue is required for cloning procedures and 2) whether the procedure requires more

198. See FDA Proposal, *supra* note 12.

199. See Wells, *supra* note 163, at 405. "[T]he term 'human cellular and tissue-based products' encompasses an array of medical products derived from the human body and used for replacement, reproductive, or therapeutic purposes Semen, ova, and embryos are transferred for reproductive purposes." Establishment Registration and Listing for Manufactures of Human Cellular and Tissue-Based Products, 63 Fed. Reg. 26,744 (1998).

200. See FDA Proposal, *supra* note 12, at 6.

201. See Establishment Registration and Listing for Manufactures of Human Cellular and Tissue-Based Products, 63 Fed. Reg. 26,745 (1998).

202. Price, *supra* note 20, at 619 (quoting Rick Weiss, *Human Clone Research Will Be Regulated*, Wash. Post, Jan. 20, 1998, at A1, available in 1998 WL 2462936).

203. See FDA Proposal, *supra* note 12, at 6.

than minimal manipulation of cells and tissue.²⁰⁴ However, the proposal's distinction between non-donor and donor tissue creates a loophole that defeats one of the original intentions of the proposal.

1. *Human Cloning Within FDA Regulation of Donor Tissue (Allogeneic Tissue versus Autologous Tissue)*

Human cloning carries the risk of transmitting communicable disease because cellular or tissue-based products are used.²⁰⁵ The FDA believes that the transfer of reproductive tissue poses limited harm to the recipient, therefore the FDA is only concerned with reproductive tissue when it comes from a donor.²⁰⁶ The FDA believes that the level of public health concern for semen, eggs and embryos depends on whether they are obtained from a sexually intimate partner of the transplant/insemination recipient or from donors that might spread communicable diseases.²⁰⁷ The FDA only recommends that autologous stem cells²⁰⁸ or cells taken from intimate sexual partners be screened before clinical use.²⁰⁹ In general, the transfer of reproductive tissues such as semen and eggs, obtained from the recipient's partner or the same person poses less risk to the recipient's health. Tissue rejections among recipients having prior exposure to each other and to the risk of disease from that partner poses a lesser degree of danger to the recipient.²¹⁰

Therefore, in the guidance document, only allogeneic²¹¹ living somatic cells which have been manipulated would require screening before clinical use.²¹² A person may use tissue that has undergone more than minimal manipulation if the tissue is autologous

204. *See id.* at 7.

205. *See id.* at 12.

206. *See* Establishment Registration and Listing for Manufactures of Human Cellular and Tissue-Based Products, 63 Fed. Reg. 26,750 (1998).

207. *See* Establishment Registration and Listing for Manufactures of Human Cellular and Tissue-Based Products, 63 Fed. Reg. 26,745 (1998).

208. Autologous stem cells are cells or tissues used in the same person from whom they were obtained. *See* FDA Proposal, *supra* note 12, at 29.

209. *See id.* at Table I.

210. *See* Establishment Registration and Listing for Manufactures of Human Cellular and Tissue-Based Products, 63 Fed. Reg. 26,750 (1998).

211. Allogeneic cells are cells or tissue used in a different person from whom they were obtained. *See* FDA Proposal, *supra* note 12, at 29. The term Allogeneic cells does not include reproductive cells and tissues from sexually intimate partners of the intended recipient. *See id.* at 12.

212. *See id.* at Table I.

reproductive tissue or tissue from an intimate sexual partner, without filing an investigational new drug application (IND).²¹³ This distinction (within the FDA's proposal) fails to give the FDA sufficient authority to regulate cloning because the FDA would not regulate such reproductive tissue even if the tissue has been more than minimally manipulated.²¹⁴ The proposal would only allow the FDA to regulate cloning in situations where an infertile woman needs a donor egg cell, or where a female is not willing to use her own DNA and needs DNA from a donor.²¹⁵ FDA authority is invalid in situations similar to that of Richard Seed, where a couple does not require the help of donated reproductive tissue.²¹⁶ If the FDA does not change this distinction, human cloning could still occur even with FDA regulation under its cell and tissue proposal.

Next, one must define the FDA's standard of manipulation to determine if *donor* tissue used in cloning is more than minimally manipulated and falls under the FDA proposal's regulatory requirements.

2. *Standards of Manipulation*

The FDA should regulate donor cells and tissue used in human cloning, which unlike IVF and ICSI, requires more than minimal manipulation of cells and tissue.²¹⁷ The more than minimal manipulation standard is of great significance to the FDA because it differentiates human tissue experiments that do and do not require prior approval.²¹⁸ The definition of manipulation is a measure of the extent to which the biological characteristics of a

213. See *id.* This filing process, if applied to human cloning attempts, would require researchers to prove to the FDA's satisfaction that their proposed experiments do not pose unreasonable risk of harm to human subjects. See Price, *supra* note 20, at 620-21 (stating that this process is identical to the IND application that drug companies must file when they want to conduct human trials to test new medicines. Both of these therapies use IND's applications, the same as described for any investigational biological product in 21 C.F.R. 312.23).

214. See Price, *supra* note 20, at 620.

215. See Andrews, *supra* note 1, at 658 (citing FDA, Proposed Approach to Regulation of Cellular and Tissue-Based Products 6, 9 (1997)).

216. See Dizon, *supra* note 8.

217. See NBAC Report, *supra* note 5, at 32.

218. See Establishment Registration and Listing for Manufactures of Human Cellular and Tissue-Based Products, 63 Fed. Reg. at 26,748 (1998).

tissue have been changed.²¹⁹ Therefore, minimal manipulation is when the processing does not alter the original relevant characteristics of the cell or tissue.²²⁰ Examples of minimal manipulation include the cutting, grinding, shaping, separating, cryopreservation,²²¹ and freezing of cells and tissues.²²² More than minimal manipulation is "when the processing alters the biological characteristics (and potentially the functional integrity) of those cells or tissue, or when adequate information does not exist to determine whether the processing will alter the biological characteristics of the cell or tissue."²²³ Examples of more than minimal manipulation include "cell expansion, encapsulation, activation, or genetic modification."²²⁴ Also, the FDA might consider a minimal tissue product to be more than minimally manipulated if it is used by a large number of patients or is very risky and harmful.²²⁵

The process of human cloning, which requires more than minimal manipulation, would involve the transfer of a cell nucleus from an adult cell into a denucleated egg (an egg without a nucleus).²²⁶ Human cloning is not just the process of separating adult stem cells²²⁷ from mature tissue, which the FDA considers to be minimal manipulation.²²⁸ Instead, human cloning is the genetic modification of the cell because the nucleus of the cell, which contains the genetic material, is removed. The cell's genetic material differ-

219. See Mary Pendergast, *FDA Outlines Possible Regulatory Scheme for Engineered Tissue Products* (visited Oct. 29, 1999) <<http://www.info@ptei.org/brochure/government/FDAReg.html>>.

220. See Establishment Registration and Listing for Manufactures of Human Cellular and Tissue-Based Products, 63 Fed. Reg. at 26,748 (1998).

221. Cryopreservation is a freezing process used on embryos, cells, tissues and organs. See N.Y. Task Force, *supra* note 11, at 81.

222. See Establishment Registration and Listing for Manufactures of Human Cellular and Tissue-Based Products, 63 Fed. Reg. 26,748 (1998); FDA Proposal, *supra* note 12, at 16-17.

223. FDA Proposal, *supra* note 12, at 17.

224. Establishment Registration and Listing for Manufactures of Human Cellular and Tissue-Based Products, 63 Fed. Reg. 26,748 (1998); see FDA Proposal, *supra* note 12, at 16-17.

225. See Pendergast, *supra* note 219.

226. See NBAC Report, *supra* note 5, at 1. The denucleated egg cell is an egg cell that has its nucleus removed. "Examples of more-than-minimal manipulation include encapsulation, activation, [and] genetic modification." FDA Proposal, *supra* note 12, at 17.

227. Adult stem cells are any cells other than reproductive cells.

228. See Establishment Registration and Listing for Manufactures of Human Cellular and Tissue-Based Products, 63 Fed. Reg. 26,748 (1998).

entiate the cell during cellular growth; replacing this genetic material during human cloning alters the outcome of the cell after differentiation.²²⁹ The egg cell now has the parental cell's nucleus; this nucleus triggers the transformation of the egg into an embryo.²³⁰ Thus, human cloning is a genetic modification of the cell that requires more than minimal manipulation.

IVF, as compared to cloning, does not fall under the FDA standard of more than minimal manipulation. Therefore, the FDA cannot regulate IVF under this proposal. There are six major procedures during IVF: (1) ovarian stimulation; (2) egg collection; (3) fertilization and embryo culture; (4) embryo transfer; (5) pregnancy; and, (6) delivery.²³¹ The second, third and fourth procedures of IVF involve a needle puncture to remove the eggs, placing the eggs and sperm in a petri dish which leads to fertilization, and finally implanting the egg into the uterus through a catheter.²³² In IVF procedures, no genetic manipulation occurs because sperm fertilizes the egg and normal meiosis occurs. In human cloning, however, the egg's nucleus is removed and replaced with another nucleus, thereby changing the genetic make-up of the egg cell and causing the egg to differentiate differently.

Human cloning also differs from intracytoplasmic sperm injection (ICSI), known as micromanipulation.²³³ ICSI is another new infertility technique that was used before it was proven safe for children.²³⁴ ICSI, as noted above, allows doctors to inject the sperm directly into the egg cell with minimal manipulation of the egg's coating.²³⁵ But, the chromosomes of the egg and sperm cells still undergo meiosis, which the cloning procedures eliminated.

229. See Andrews, *supra*, note 1, at 650.

230. See *id.*

231. See N.Y. Task Force, *supra* note 11, at 52.

232. See *id.* at 52-58; Nicole L. Cucci, *Constitutional Implications of In Vitro Fertilization Procedures*, 72 St. John's L. Rev. 417, 421 (1998).

233. Micromanipulation is a procedure in which a single sperm is injected directly into an egg. See N.Y. Task Force, *supra* note 11, at 64.

234. See *id.* at 65 (citing J.J. Kurinczuk & C. Bower, "Birth Defects in Infants Conceived by Sperm Injection: An Alternative Interpretation," 315 Brit. Med. J. 1260 (1997)). Some studies indicated that children born after ICSI are twice as likely to have major congenital abnormalities and 50% more likely to have a minor defect as compared to "natural births." *Id.*

235. See *id.* at 65 (stating that in this procedure, the egg cell is exposed to enzymes, heat, intense light and chemicals, but these exposures have not been proven to cause genetic abnormalities) (citations omitted).

This procedure only requires the injection of sperm into the nucleus of the egg cell, which allows for meiosis to occur and causes no genetic modification. Thus, ICSI does not involve more than minimum manipulation, so the FDA has not been able to regulate this procedure.²³⁶ Although some people believe that the FDA should not regulate cloning if it cannot regulate ICSI,²³⁷ cloning involves much more manipulation of the egg cell than does ICSI, therefore requiring a different standard of regulation.

Since cloning should be considered an "analogous product" of a whole cell vaccine and is intended for the treatment of infertility, the FDA has the authority to regulate it under section 351 of the PHSA. The FDA, however, cannot fully regulate human cloning because it has not included autologous tissue and reproductive tissue from sexually intimate partners in the proposal.²³⁸ Unless the

236. In her law journal article, Lori Andrews asked why the FDA did not regulate ICSI, "in which DNA (in the form of sperm) is being injected into women's eggs?" Andrews, *supra* note 1, at 658 n.102. The answer is that, unlike in the cloning procedure, the DNA injected into the egg cell in ICSI has not already differentiated a cell. ICSI uses sperm DNA; the sperm's and egg's DNA go through normal sexual reproduction stages of meiosis and crossover. With human cloning, the DNA is from an adult cell; this DNA does not go through meiosis when it is put into an enucleated egg. Rather, the DNA differentiates the egg without ever changing its genetic makeup. Therefore, ICSI does not involve more than minimum manipulation of cells and tissues as occurs during cloning.

237. *See id.*

238. If used to regulate cloning, the FDA's current proposal could fall to constitutional claims of Due Process because the FDA has failed to narrowly tailor its proposal to ban all possible forms of human cloning. The possible benefits of human cloning for infertile people raises constitutional issues of whether the FDA has the authority to regulate a medical procedure possibly used for the treatment of infertility. The Supreme Court established that the agencies' regulations involving privacy and reproductive rights must pass "strict judicial scrutiny" to ensure that they do not violate the Fourteenth Amendment. *Carey v. Population Serv. Int'l*, 431 U.S. 678, 688 (1977). Thus, any agency regulating reproductive methods must satisfy a two-prong strict scrutiny test in order to pass Constitutional muster. First, the agency's regulations must serve a compelling interest and, second, the regulation must be narrowly tailored to further that interest. *See id.*

The FDA's regulations on human cloning do not pass the strict scrutiny standard. Even though the regulations serve a compelling interest of protecting people from a risky medical procedure, the regulations are not narrowly tailored according to the criteria established in *Carey v. Population Serv. Int'l*. *See id.* The Court declared that in order to be narrowly tailored to achieve its interests, a ban must: (i.) be necessary, and (ii.) be geared to achieve its goal. *See id.* at 695-96. As it stands now, the FDA's current proposal to regulation cloning is not narrowly tailored, because of the distinction between autologous tissue, intimate sexual partner tissue and allogeneic tissue. The FDA's proposal would only allow the agency

FDA redefines its proposal of cellular and tissue-based products, human cloning, with its potential health risks, will likely occur in the private sector.

C. *Possible Solutions to the Lack of Authority*

Although one of the FDA's objectives, along with stopping the spread of communicable diseases, is to ensure the clinical safety and effectiveness of more than minimally manipulated tissue, the FDA proposal allows for a high probability of children being born with human cloning-caused deformities.²³⁹ For the FDA to completely regulate human cloning, it would have to drop the autologous and intimate/sexual partners characterization of its guidance proposal for genes and human tissue.²⁴⁰ This distinction stems from the FDA's mistaken conclusion that reproductive tissue transfer does not pose a significant risk to the health of recipients, especially when the tissue is from that person or an intimate sexual partner.²⁴¹ The FDA may be correct in its belief that "the failure of a reproductive-tissue product will generally cause lesser health risks to the individual than the failure of other systemic products."²⁴² However, the manipulated DNA of a cloned embryo may have some risk of carrying genetic mutations, which could cause the child to have deformities. As noted in Part I of this Comment, an adult nucleus has already completed forty-five cell divisions, and may have accumulated genetic disease and mutations, which would be transferred upon implantation into an undifferen-

to ban human cloning from occurring in cases where donor tissue is necessary. See Andrews, *supra* note 1, at 658 (citing Guidance Table I). The FDA's regulations "do not require prior approval if a patient's cells are being used for his or her own reproductive purposes." *Id.* Given its ability to regulate human cloning through this proposal, the FDA could stop some couples (when the woman is infertile) from using donated eggs in cloning. The proposal, however, would not allow the FDA to restrict fertile couples and fertile individual women from using their own eggs in cloning. Thus, the FDA must eliminate this distinction between autologous tissue and intimate sexual partner to equally regulate human cloning and not violate the Due Process Clause of the Fourteenth Amendment.

239. See FDA Proposal, *supra* note 12, at 6.

240. See *id.* at 20. Under the FDA's regulatory requirements, the autologous cells and tissues (i.e. cells from the same person) would not be subject to any regulatory requirements.

241. See Establishment Registration and Listing for Manufactures of Human Cellular and Tissue-Based Products, 63 Fed. Reg. 26,750 (1998).

242. *Id.*

tiated egg cell.²⁴³ The FDA should be concerned, not only about the health of the reproductive-tissue recipient, but also with the health of the children born through the cloning process.

If the FDA is truly concerned about "ensuring that clinical safety and effectiveness is demonstrated for tissues that are highly processed," then it should regulate a cloned embryo as a biological product that could quite possibly cause great harm to the person created from the procedure. The reproductive method of human cloning has a high chance of producing genetic deformities because the procedure creates an embryo from adult DNA that nature never meant to differentiate an egg cell.²⁴⁴ However, because the FDA will not test more than minimally manipulated autologous tissue to ensure safety and effectiveness, children with severe genetic deformities could be born via cloning.²⁴⁵

Obviously, all expecting parents fear giving birth to a child with a genetic deformity. Many people have tests done, such as amniocentesis, to determine whether deformities exist in their unborn children.²⁴⁶ So, why would the FDA permit a procedure that is likely to cause many genetic deformities in children? The answer seems to be that the risk for the recipient of reproductive tissue is minimal when autologous tissue is used. However, this illustrates how the FDA overlooks the fact that human cloning could be as damaging to children as any disease.²⁴⁷ The FDA must not ignore this fact because in doing so, they are guaranteeing that many parents may face their worst nightmare, a child with a genetic deformity. Both parents and child will now have to face a lifetime of hardships (physically, emotionally, and financially)

243. See Andrews, *supra* note 1, at 650 (noting that "[a]ctivating the slumbering genes may reveal hidden mutations").

244. See Annas, *supra* note 68, at 254 (stating that "[c]loning has nothing inherently to do either with infertile couples or natural twins because women would be able to replicate themselves without male involvement . . . [a]sexual cloning by nuclear substitution represents such a discontinuity in the way humans reproduce").

245. See Establishment Registration and Listing for Manufactures of Human Cellular and Tissue-Based Products, 63 Fed. Reg. 26,750 (1998).

246. This procedure makes it possible for prenatal detection of Down's syndrome and many other genetic deformities present in the fetus. See Curtis, *supra* note 51, at 387.

247. See *supra* note 58, at 2D (noting that, by trying to create new life from old cells, clones "may be susceptible to premature aging and disease").

which not only *could* have been prevented, but *should* have been prevented.

Assuming *arguendo* that the FDA were to drop the distinction between donor and non-donor tissue, then fertility clinics offering human cloning would have to file an investigational new drug application (IND) with the FDA, followed by a lengthy review.²⁴⁸ This filing process, if applied to human cloning attempts, would require researchers to prove to the FDA's satisfaction that their proposed experiment does not pose unreasonable risk of harm to human subjects.²⁴⁹ The FDA can ask questions such as: "Have you established animal models?; Can you improve the odds?; Have you looked at safer alternatives?"²⁵⁰ Thus, the FDA's regulation would help protect public health and safety and cause potential human cloning researchers to contemplate their actions before placing human beings in danger.

V. CONCLUSION

Human cloning presents potential health risks to people undergoing this procedure. Until this cloning procedure is perfected, men, women and children will be subjects of a dangerous experiment, unless (1) scientists conduct animal research and (2) FDA regulation continues. While the FDA has the authority to regulate human cloning, the FDA's present regulations will not achieve the agency's goals. With the rapid progress of modern science, human cloning will inevitably occur in the near future. However, under the FDA's proposal as it stands today, a cloned child can be made without the FDA's consent, unless the FDA moves away from their misconceived belief that reproductive tissue cannot harm humans. Thus, it must drop the autologous and intimate/sexual partners characterization of its guidance proposal for human cells and tissue. Although the FDA's current regulations cannot completely regulate against human cloning, the FDA does have the basis for more strict regulation and, most importantly, the duty to preserve the health and safety of our country's people.

B. Jason Erb

248. See Price, *supra* note, 20, at 620-21.

249. See *id.*

250. Weiss, *supra* note 10, at A1.

