

DOES THE FDA HAVE AUTHORITY TO REGULATE HUMAN CLONING?

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I. INTRODUCTION

The Food and Drug Administration ("FDA") recently announced that it has statutory authority to regulate human cloning.¹ Proclaiming that human cloning raises "serious health and safety issues," Acting Commissioner Michael Friedman has made it clear that the Agency will take legal action against anyone who attempts to clone a human being without obtaining prior approval from the FDA.² Although the FDA has not specified which provision of current law grants it such authority, a letter to Senator Kennedy, dated February 10, 1998, from the FDA Deputy Commissioner for External Affairs hinted as follows:

FDA already has jurisdiction over such [human cloning] experiments and is prepared to exercise that jurisdiction. While FDA's authority does not address the larger question of whether or not creating a human being using cloning technology should be altogether prohibited, this authority will ensure that such experimentation does not proceed until basic questions about safety are answered.

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1 See Rick Weiss, *Human Clone Research Will Be Regulated*, WASH. POST, Jan. 20, 1998, at A1 (quoting Acting FDA Commissioner Michael Friedman as asserting that "[t]hrough the Food, Drug and Cosmetic Act we do have the authority to regulate human cloning, and we are prepared to assert that authority"); see also *FDA is Prepared to Block Unapproved Cloning Efforts*, N.Y. TIMES, Jan. 20, 1998, at A12 (quoting Acting Commissioner Friedman as stating that "[w]e're not only able to move, we're prepared to move" against any individual who attempts to clone a human being without FDA approval) [hereinafter *FDA is Prepared*].

2 See Weiss, *supra* note 1, at A1; see also *FDA is Prepared*, *supra* note 1, at A12 (reporting that Acting Commissioner Friedman stated that "we're more interested in the 277 failures [involved in cloning Dolly the sheep] than in the success").

Creating a human being using cloning technology is subject to FDA regulation under the Public Health Service Act and the Federal Food, Drug and Cosmetic Act. Under these statutes and implementing regulations, clinical research on the creation of a human being using cloning technology may proceed only when an investigational new drug application (IND) is in effect.

In the case of attempts to create a human being using cloning technology, there are major unresolved safety questions. Until those questions are appropriately addressed, the Agency would not permit any such investigation to proceed.³

Thus, although the FDA has not yet cited any specific statutes, there are only three possible bases for its assertion of jurisdiction over human cloning: (1) classification as a "drug" under section 201(g) of the Federal Food, Drug, and Cosmetic Act ("FDCA");⁴ (2) classification as a medical "device" under Section 201(h) of the FDCA;⁵ or, perhaps most likely, (3) classification as a "biological product" under Section 351(a) of the Public Health Service Act ("PHSA").⁶

If human cloning fell within any of these three statutory provisions (or some combination thereof),⁷ the FDA would have authority to require premarket approval and/or licensing based upon reasonable, clinical assurance of safety and efficacy.⁸ More specifically, human cloning would be subjected to the rigorous investigational new drug ("IND") approval process,⁹ which requires, *inter alia*, detailed clinical

3. 144 CONG. REC. S561 (daily ed. Feb. 10, 1998) (letter from Sharon Smith Holston, the FDA Deputy Commissioner for External Affairs) [hereinafter FDA Letter].

4. 21 U.S.C. § 321(g)(1) (1994); see also *id.* at § 321(p) (defining "new drug").

5. 21 U.S.C. § 321(h) (1994).

6. 42 U.S.C. § 262(a) (1994).

7. See 21 U.S.C. § 353(g)(1) (1994) (allowing for regulation of so-called "combination products").

8. See 21 U.S.C. § 355 (1994) (setting forth the safety and efficacy standards for new drugs); 21 U.S.C. § 360-c(a)(1)(C) (1994) (stating that a class III medical device must obtain premarket approval "to provide reasonable assurance of its safety and effectiveness"); 21 U.S.C. § 360-e (1994) (setting forth the premarket approval requirements of class III medical devices); 42 U.S.C. § 262(d) (1994) (stating that in order to obtain a biological product license, a manufacturer must demonstrate that the product meets standards of safety, purity, and potency); see also 21 C.F.R. § 600.3(p)-(s) (1997) (setting forth safety, purity, and potency standards for biological product licensure).

9. See 21 C.F.R. § 312.2(a) (1996) ("[T]his part applies to all clinical

protocols,¹⁰ safety reports,¹¹ extensive record keeping,¹² and continuing oversight by an Institutional Review Board ("IRB").¹³ Moreover, any product subject to the IND process may be placed on a "clinical hold" by the FDA,¹⁴ which means that the FDA may indefinitely delay or suspend a proposed clinical investigation if the FDA finds that "[h]uman subjects are or would be exposed to an unreasonable and significant risk of illness or injury."¹⁵

If the FDA's view of its current statutory authority is correct, a scientist who conducts human cloning research in the United States without obtaining or retaining the Agency's approval risks a wide array of criminal and/or civil sanctions.¹⁶ As the following analysis will show, the FDA's assertion of authority over human cloning appears to be legally unsupportable. Part I provides a brief background of the events leading to the FDA's assertion of authority. Part II discusses the possibility that cloning may be classified as a "drug" under the FDCA. Part III explores whether cloning may properly be considered a medical "device" under the FDCA. And finally, Part IV examines whether cloning may be a "biological product" under the PHSA.

investigations of products that are subject to section 505 [new drugs] or 507 [certification of antibiotics] of the Federal Food, Drug and Cosmetic Act or to the licensing provisions [i.e., biological products] of the Public Health Service Act . . . as amended . . ."; see also FDA Letter, *supra* note 3.

10. See 21 C.F.R. § 312.23(a)(6) (1996).

11. See 21 C.F.R. § 312.32.

12. See 21 C.F.R. §§ 312.57, 312.62, 312.64.

13. See 21 C.F.R. § 312.66.

14. 21 C.F.R. § 312.42.

15. *Id.* at § 312.42(b)(i). Even if the FDA initially approved an IND for human cloning, it could later terminate the IND based upon the same safety concerns. See *id.* § 312.44(b)(i).

16. See, e.g., 42 U.S.C. § 262(f) (1994) (establishing that a violation of section 351 of the Public Health Service Act is a misdemeanor punishable by a fine of up to \$500 and/or imprisonment of up to one year); 42 U.S.C. § 262(d)(2)(B) (providing for imposition of a civil penalty of up to \$100,000 per day for biological products determined by the Secretary to present "an imminent or substantial hazard to the public health . . ."; 21 U.S.C. § 303(a) (1994) (setting forth both misdemeanor and felony sanctions for violations of various provisions of the FDCA, including section 505, relating to new drugs); 21 U.S.C. § 333(f) (1994) (authorizing civil monetary penalties for most of the provisions of the FDCA which apply to medical devices).

II. BACKGROUND

In early 1997, a team of Scottish scientists announced that a fuzzy-faced lamb named "Dolly" had been born,¹⁷ the first mammalian offspring of the process of somatic cell nuclear transfer cloning.¹⁸ The cloning process that had been used to create Dolly was quickly condemned by ethicists,¹⁹ religious leaders,²⁰ and scientists²¹ (including

17. See Michael Specter & Gina Kolata, *A New Creation: The Path to Cloning*, N.Y. TIMES, Mar. 3, 1997, at A1.

18. Cloning by somatic cell nuclear transfer involves the removal of an egg's original nucleus (which contains the female's DNA) and the insertion of new genetic material (DNA) of a donor. See Nat'l Bioethics Advisory Comm'n, CLONING HUMAN BEINGS: REPORT AND RECOMMENDATIONS OF THE NAT'L BIOETHICS ADVISORY COMM'N 15-16 (1997) [hereinafter *NBAC REPORT*]. In 1981, two scientists, Dr. Peter Hoppe of the Jackson Laboratory in Bar Harbor, Maine, and Dr. Karl Illmensee of the University of Geneva, announced that they had successfully cloned mice (mammals) using somatic cell nuclear transplantation. See Philip J. Hilts, *Genetic Transfer in Mammals Succeeds*, WASH. POST, Jan. 5, 1981, at A1; *Scientific Feat: Test-Tube Mice*, U.S. NEWS & WORLD REP., Jan. 19, 1981, at 7. Other scientists, however, were unable to replicate these results, leading to an investigation for scientific fraud which proved inconclusive. See James McGrath & Davor Solter, *Inability of Mouse Blastomere Nuclei Transferred to Enucleated Zygotes to Support Development In Vitro*, 226 SCIENCE 1317, 1317-19 (1984); *Scientists Can't Replicate Clone Experiments*, UPI, June 3, 1983, available in LEXIS, News Library, Arcnws File. See generally Gino Del Guercio, *Science Centers Act to Protect Themselves from Research Fraud*, UPI, Sept. 26, 1983, available in LEXIS, News Library, Arcnws File.

Somatic cell nuclear transfer should be distinguished from blastomere separation which involves the splitting of embryonic cells to form identical twins, triplets, or an even greater number of duplicates. *NBAC REPORT*, *supra*, at 15. Cloning by embryo splitting is common amongst animal breeders and was successfully performed on human embryos in 1993. See Gina Kolata, *Scientist Clones Human Embryos, and Creates an Ethical Challenge*, N.Y. TIMES, Oct. 24, 1993, at A1; Rebecca Kolberg, *Human Embryo Cloning Reported*, 262 SCIENCE 652, 652-53 (1993).

19. See, e.g., George J. Annas, *Human Cloning: Should the United States Legislate Against It?*, 83 A.B.A.J. 80, 80 (1997) (stating that "[h]uman cloning should be banned because it would radically alter our very definition of ourselves by producing the world's first human with a single genetic parent").

20. See, e.g., *Hearing on the Ethics of Human Cloning Before the Subcomm. on Health & Pub. Safety of the Senate Labor Comm.*, 105th Cong., (1997) (statement of John M. Haas, President, Pope John Center for the Study of Ethics in Health Care) ("A federal ban against the attempted cloning of human beings would certainly be consonant with Catholic moral teaching. But it must be an honest ban. Human life must be protected from its very beginnings, as soon as there is interior, spontaneous growth."), available in 1997 WL 332077; *Human Cloning Termed "Adulterous" Under Islamic Law*, AAP NEWSFEED, Jan. 10, 1998, available in LEXIS, News Library, Curmws File (reporting that a panel of legal and medical experts in the United Arab Emirates declared human cloning to be adultery under Islamic law); *Religious Leaders Oppose Human*

the scientist who cloned Dolly)²² as immoral or unethical for application to the human race. Public opinion polls show that an overwhelming majority of Americans concur in the condemnation.²³ Sensing the political waters, President Clinton swiftly halted federal funding of human cloning research²⁴ and urged American scientists voluntarily to refrain from conducting human cloning research.²⁵ In June 1997, the National Bioethics Advisory Commission concluded that human cloning was "morally unacceptable" and recommended that a federal legislative ban be enacted.²⁶ In early 1998, when physicist Richard Seed announced his intention to clone a human being using private funding,²⁷

Cloning, UPI, Jan. 9, 1998, available in LEXIS, News Library, Curnws File (reporting that the Reverend Frank Pavone, a Catholic priest in New York, believes the Catholic church is opposed to human cloning); *UCC Opposes Human Cloning*, UPI, Jan. 9, 1998, available in LEXIS, News Library, Curnws File (reporting that the Reverend Ronald Cole-Turner of the United Church of Christ condemned human cloning as "outrageous").

21. See, e.g., *Banning Federal Funds for Human Cloning Research: Hearings Before the Subcomm. on Tech. of the House Comm. on Science*, 105th Cong. (1997) (statement of Arthur F. Haney, M.D., President-Elect, Am. Soc'y for Reproductive Medicine ("ASRM")) ("Let me say from the outset that ASRM finds unacceptable any attempt at cloning an existing human being. At this time, there is no clinical, scientific therapeutic or moral justification for it."), available in LEXIS, Legis Library, Cngtst File.

22. See *Cloning: Challenges for Public Policy: Hearing Before the Subcomm. on Pub. Health & Safety of the Senate Comm. on Labor*, 105th Cong., (1997) (statement of Dr. Ian Wilmut) ("My own position and that of all my colleagues at the Roslin Institute and PPL Therapeutics is that cloning of [a] human would be unethical"), available in 1997 WL 115159.

23. See Meredith Wadman, *Politicians Accused of "Shooting from the Hip" on Human Cloning*, 386 NATURE 97, 97 (1997) (revealing that an ABC News Nightline poll found 87% of respondents believed human cloning should be banned, and 82% believed cloning humans would be morally wrong).

24. Memorandum on the Prohibition on Federal Funding for Cloning of Human Beings, 33 WEEKLY COMP. PRES. DOC. 281 (Mar. 4, 1997). Although federal funding of human embryo research had been banned since December, 1994, President Clinton decided that because "these restrictions do not explicitly cover human embryos created for implantation and do not cover all Federal agencies," an order specifically prohibiting federal funding of human cloning research was needed. *Id.*

25. See Remarks Announcing the Prohibition on Federal Funding for Cloning Human Beings and an Exchange with Reporters, 33 WEEKLY COMP. PRES. DOC. 278 (Mar. 4, 1997).

26. NBAC REPORT, *supra* note 18, at 108-09; see also Gina Kolata, *Ethics Panel Recommends a Ban on Human Cloning*, N.Y. TIMES, June 8, 1997, at Y18.

27. *Human Cloning Within Two Years? Chicago Scientist Talks of "Becoming One With God,"* S.F. EXAMINER, Jan. 7, 1998, at A1, available in LEXIS, News Library, Curnws File. Seed told NPR, "God made man in his own image. God intended for man to become one with God Cloning and the reprogramming of DNA is the first serious step in becoming one with God." *Id.* Seed has reported that he intends to raise

politicians at all levels condemned him.²⁸ Secretary of Health and Human Services Donna Shalala proclaimed Seed a "mad scientist" who must be stopped.²⁹

Only two days after Secretary Shalala's comment about Seed, Carl Feldbaum, the President of the Biotechnology Industry Organization ("BIO"), sent the Secretary a letter, asserting that the FDA had the authority necessary under current law to stop scientists like Seed.³⁰ Specifically, Feldbaum asserted that the FDA could regulate human cloning as a biological product because:

BIO believes that the [sic] Dr. Seed's proposal to clone human beings using nuclear transfer technology is much more than minimal manipulation [of cells or tissues] as the original function of the egg cell is unmistakably altered by the removal of the parental haploid DNA and insertion of DNA from a somatic cell from another person. Thus, any such research along these lines should be subject to the IND regulations that require patient informed consent, review by an institutional review board (IRB) where the research is being conducted, and FDA review under 21 CFR Part 312 [the investigational new drug application regulations].³¹

\$2 million to begin a for-profit human cloning center to assist infertile couples in their quest to have a child. *See id.*

28. *See, e.g.*, 144 CONG. REC. S507 (daily ed. Feb. 9, 1998) (statement of Sen. Harkin) ("Is Mr. Seed irresponsible? I believe so, absolutely."); 144 CONG. REC. S318 (daily ed. Feb. 3, 1998) (statement of Sen. Bond) ("Recent reports that a Chicago[-]based scientist is prepared to move forward with human cloning experimentation forces us to engage in an immediate debate on how far out on the moral cliff we are willing to let science proceed before we as a Nation insist on some meaningful constraints."); 144 CONG. REC. E49 (daily ed. Jan. 28, 1998) (statement of Rep. Cliff Stearns) ("I, for one, do not think we can just sit idly by when there are people like Dr. Seed out there who look upon human life in much different terms than most Americans.").

29. *A Cloning Plan Leads to Vows to Outlaw It*, N.Y. TIMES, Jan. 12, 1998, at A15. Secretary Shalala's statements vowing to stop Dr. Seed were initially made on a CBS television show, *Face the Nation*, on January 11, 1998. *See U.S. Health Authorities to Regulate Human Cloning*, AGENCE FRANCE PRESSE, Jan. 20, 1998, available in LEXIS, News Library, Cumwv File.

30. Letter from Carl B. Feldman, President, Biotechnology Industry Organization to The Honorable Donna E. Shalala, Secretary, Department of Health & Human Services, (Jan. 13, 1998) (on file with the *Harvard Journal of Law & Technology*). Acting FDA Commissioner Michael Friedman was listed on the letter as receiving a copy. *See id.*

31. *Id.* The reference to the "minimal manipulation" standard referenced in the BIO

Four days after the receipt of Feldbaum's letter, Acting FDA Commissioner Michael Friedman announced that the Agency agreed with the BIO's conclusion that it had authority to require prior approval of any human cloning activity.³²

The BIO's desire to have the FDA regulate human cloning likely stems from the unattractiveness of the apparent alternative: having Congress enact a legislative ban. If Congress were to enact such a ban, the wording of the law could be sufficiently broad that other, more "legitimate" scientific research would be chilled. Indeed, the two primary Republican-sponsored bills currently under consideration by the Senate would make it "unlawful for any person or entity, public or private, in or affecting interstate commerce, to use human somatic cell nuclear transfer technology."³³ Human somatic cell nuclear transfer is then defined as "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 pre-implantation embryo)."³⁴

The broad language in the Republican bills would thus ban any use of somatic cell nuclear transfer, including potentially useful stem cell research into the replication of specific human organs, such as skin, corneas, kidneys, livers, and hearts.³⁵ Despite the chilling effect this

letter to Secretary Shalala derives from the FDA's recent guidance document entitled, "Proposed Approach to Regulation of Cellular and Tissue-Based Products." PROPOSED APPROACH TO REGULATION OF CELLULAR AND TISSUE-BASED PRODUCTS, V(B)(2)(b), Docket No. 97N-0068, Feb. 28, 1997 (last modified May 6, 1998) <www.fda.gov/cber/gdlns/CELLTISSUE.txt>. The document sets forth a multi-tiered approach to the regulation of cellular and tissue-based products, with the highest level of regulation, pre-market approval, being reserved for those "[c]ells and tissues that [are] manipulated extensively, combined with non-tissue components, or [are] used for other than their normal functions." *Id.* at 6. It should be noted, however, that this document is: (1) only a guidance document at this time; and, more importantly, (2) only applies to products which fall within the statutory definition of a biological product or medical device. The second point—whether human cloning involves a product within the statutory definition of a biological product or medical device—is discussed extensively in Part IV, *infra*.

32. See Weiss, *supra* note 1, at A1.

33. See, e.g., S. 1601, 105th Cong., § 3(a) (1998); S. 1599, 105th Cong., § 3(a) (1998); cf. H.R. 923, 105th Cong., § 2 (1997) (stating that "[i]t shall be unlawful for any person to use a human somatic cell for the process of producing a human clone").

34. See S. 1601, *supra* note 33, at § 3(d).

35. See 144 CONG. REC. S425 (daily ed. Feb. 5, 1998) (1998) (statement of BIO, offered into record by Sen. Feinstein) ("The current bill [S. 1599] introduced by Senator Bond would, because it goes well beyond the issue of human cloning, imperil promising biomedical research, including research to generate stem cells."); 144 CONG. REC. S427

language could have on potentially useful research, right-to-life groups, such as the American Life League³⁶ and the National Right to Life Coalition,³⁷ support the language as is, believing that any use of human somatic cell nuclear transfer creates an embryo which is entitled to be born.³⁸

The breadth of the language of the Republican bills may ultimately spell their demise. In early February 1998, Senate Majority Leader Trent Lott bypassed the normal committee process in order to bring the Republican anti-cloning bills to a floor vote.³⁹ Democratic Senators Feinstein and Kennedy successfully led a filibuster, thereby preventing the vote from taking place.⁴⁰ The filibuster was successful primarily due to the lobbying efforts of numerous scientific and patient advocacy groups, which were able to create a doubt about how the Republican bills would affect research into the replication of specific cells and tissues to cure various diseases.⁴¹

(daily ed. Feb 5, 1998) (statement of the ASRM, offered into record by Sen. Feinstein) ("The ASRM is very concerned that in the rush to make human cloning illegal, Congress will inadvertently outlaw very serious and promising medical research that may uncover cures to some of the most deadly diseases.").

36. See American Life League, *Alert: Ban Human Cloning* (last modified Mar. 31, 1998) <www.all.org/resource/980129.html> [hereinafter *ALL Alert*] (urging American Life League members to support the Bond bill (S. 1601) and oppose the Kennedy-Feinstein bill, which is described as a "fake cloning ban" because it "would require that the baby be killed and not implanted").

37. See *National Right to Life Response to Cloning Recommendations* (last modified June 9, 1997) <www.nrlc.org/release970609.html>. NRLC President Wanda Franz, Ph.D. stated, "with time and nourishment, human embryos grow to be adult humans. They do not grow to be guinea pigs and should not be treated as guinea pigs and subsequently killed." See *id.*; see also *Morning Edition* (NPR radio broadcast, Feb. 10, 1998) (stating that the National Right to Life "Coalition" supports the Bond bill).

38. See Edwin Chen, *Human Cloning Ban Runs Into Wall of Science*, L.A. TIMES, Feb. 11, 1998, at A1.

39. See Lizette Alvarez, *Senate, 54-42, Rejects Republican Bill to Ban Human Cloning*, N.Y. TIMES, Feb. 12, 1998, at A20; Chris Black, *Senate Vote Effectively Kills GOP Bill to Ban Human Cloning*, BOSTON GLOBE, Feb. 12, 1998, at A3.

40. Black, *supra* note 39, at A3; see also *For the Record*, WASH. POST, Feb. 19, 1998, at V4.

41. A letter dated Feb. 2, 1998 and signed by over fifty scientific and patient advocacy groups, including the AIDS Action Council, the American Diabetes Association, the American Heart Association, the American Society for Reproductive Medicine, the Cystic Fibrosis Foundation, and the National Association for Biomedical Research warned Senators as follows:

Poorly crafted legislation to ban the cloning of human beings may put at risk biomedical research, such as the use of cloning techniques on human cells, genes and tissues, which is vital to finding the cures to the diseases and ailments which our

In contrast to the Republican bills, the Democratic alternatives, sponsored by Senators Kennedy and Feinstein,⁴² would make it unlawful only to "implant or attempt to implant the product of somatic cell nuclear transfer into a woman's uterus."⁴³ In addition, the Feinstein-Kennedy bills contain an explicit provision permitting the use of somatic cell nuclear transfer technology to clone "molecules, DNA, cells, and tissues."⁴⁴ While these Democratic bills may satisfy the concerns of the scientific community,⁴⁵ they are unacceptable to right-to-life groups, which have dubbed them "clone-and-kill" bills.⁴⁶

Crafting legislative language which would simultaneously satisfy both the right-to-life groups and the scientific community will be a difficult, if not impossible, task. On the one hand, the right-to-life groups desire legislative language which would explicitly recognize the right of an embryo to be born.⁴⁷ On the other hand, the scientific community desires language which would permit scientists to conduct research on early-stage embryos which could potentially be programmed to develop into specific organs or tissues rather than a whole human being.⁴⁸ Given the emotional nature of this debate and its wide-ranging implications, scientific organizations such as the BIO understandably

organizations champion.

... We believe there are two distinct issues here, cloning of a human being and the healing which comes from biomedical research. Congress must be sure that any legislation which it considers does no harm to biomedical research which can heal those with deadly and debilitating diseases.

144 CONG. REC. S570 (daily ed. Feb. 3, 1998); see also Chen, *supra* note 38, at A1.

42. See S. 1602, 105th Cong., (1998); S. 1611, 105th Cong., (1998).

43. S. 1611 at § 4(b)(1). Interestingly, by employing the phrase "into a woman's uterus" the Feinstein-Kennedy bills may inadvertently permit the implantation of human clones into an artificial embryo.

44. *Id.* at § 4(c)(1).

45. See 144 CONG. REC. S425-28 (daily ed. Feb. 5, 1998) (reprinting letters from various scientific organizations expressing concern about the Republican bills and preference for the Democratic bills).

46. See *ALL Alert*, *supra* note 36.

47. See Letter from the National Right to Life Committee to members of the U.S. Senate (Feb. 5, 1998), available at <www.nrlc.org/news/NRL2.98/clone.html>. The NRLC stated, "[i]f the life of any human being is begun through the process of somatic cell nuclear transfer — wisely or unwisely, legally or illegally — then that human being must be recognized as a human being. Thus, NRLC is strongly opposed to the Kennedy-Feinstein proposal" (Emphasis in original.)

48. See 144 CONG. REC. S425 (daily ed. Feb. 5, 1998) (statement of BIO regarding the Bond bill, offered into record by Sen. Feinstein); see also Madeleine Nash, *The Case for Cloning*, *TIME*, Feb. 9, 1998, at 81.

may prefer the potentially less political (and hence, easier) route of having the FDA simply assert jurisdiction.

While having the FDA assert jurisdiction over cloning may take the pressure off Congress to find a middle ground between these ideological extremes, it is unlikely to cause these ideological differences to evaporate. Indeed, right-to-life groups are likely to prefer having the cloning issue debated and decided by the political branch, not only because they may be able to leverage greater support there, but because of the unnerving implications of acknowledging FDA jurisdiction. Specifically, if the FDA has jurisdiction to regulate human cloning, what does this say about human cloning? Would it imply that an embryo produced via cloning is a "product" or "article" subject to governmental regulation? If so, would allowing governmental regulation over human embryos demean the value or meaning of human life? Although the right-to-life groups have been silent since the FDA announced its intention to regulate human cloning, at least one influential member of Congress, House Majority Leader Richard Armey, has publicly expressed opposition to the FDA's assertion of jurisdiction. Congressman Armey stated that, "human cloning cannot be equated to manufacturing drugs. Human embryos, however they are created, are human beings. To assert that we need only regulate the practice of human cloning as if it is a drug, and not the process of creating life, is morally obtuse."⁴⁹

Because questions concerning these deeper implications of FDA jurisdiction are inevitable, one must wonder why the FDA would want to throw itself into the middle of a seemingly unwinnable debate. One answer may be that the FDA wanted to find an expeditious way to stop scientists like Dr. Richard Seed⁵⁰ and discovered — perhaps to its own surprise — that it had the authority it needed without the passage of

49. *Press Release: Armey Makes Comments on FDA Decision to Regulate Cloning*, Jan. 20, 1998, available in LEXIS, News Library, Cumwv File; see also 144 CONG. REC. S432 (daily ed. Feb. 5, 1998) (statement by Sen. Gregg that cloning should "not [be] left to a regulatory environment such as the FDA for a determination, because it is a matter of dramatic import to our culture and to our scientific community").

50. No one besides Dr. Seed has yet stepped forward to announce an intention to attempt cloning of human beings by somatic cell nuclear transfer. In February 1998, a South African physician was briefly rumored in the foreign press to have been preparing to clone humans, but he quickly went public to deny such reports. See *Reports on S. African Cloning are Bogus*, XINHUA NEWS AGENCY, Feb. 16, 1998, available in LEXIS, News Library, Cumwv File; *South African Doctor Denies Preparing to Clone Humans*, AGENCE FRANCE PRESSE, Feb. 16, 1998, available in LEXIS, News Library, Cumwv File. Of course, any cloning attempts on foreign shores would be beyond the jurisdiction of the FDA.

special legislation. Another possible answer may be that the FDA saw the human cloning issue as a way to expand upon its jurisdiction, something that governmental agencies are almost always hungry to do. As former FDA Commissioner Frank Young once put it, "dogs bark, cows moo and regulators regulate."⁵¹ Asserting jurisdiction over human cloning not only expands the Agency's power, but it does so in a way unfettered by new legislative language, which would likely carry with it new regulatory headaches or other undesirable side effects, such as a chilling effect on scientific research.⁵² A final, more cynical explanation of the FDA's sudden zeal to regulate human cloning may be that Acting Commissioner Friedman desires to become Commissioner Friedman.⁵³ Since it is clear that the White House, the scientific community, and the American public wants to stop Dr. Seed or anyone like him from cloning a human being, the FDA's assertion of jurisdiction appears to be a win-win position. Whatever the FDA's motivation, however, the ultimate question is: Does the FDA have the authority to do what they say they can do — that is, regulate human cloning? As the following analysis shows, it appears that they do not.

III. MAY HUMAN CLONING BE REGULATED AS A "DRUG"?

The relevant provisions of section 201(g)(1) of the Federal Food, Drug and Cosmetic Act ("FDCA") define the term "drug" as including:

51. See Henry I. Miller, *The FDA's Fear of the Future*, N.Y. TIMES, May 20, 1995, at A23.

52. Indeed, this was a recurring theme during the debate on cloture of the Republican anti-cloning bills. During the Democratic filibuster, several senators stated that because the FDA has asserted jurisdiction over human cloning, there was no need to rush poorly crafted legislation through Congress. See 144 CONG. REC. S606 (daily ed. Feb. 11, 1998) (statement of Sen. Durbin) ("It is also not clear as to why we are rushing to consider this bill given that the FDA has already announced that it has authority over this area."); 144 CONG. REC. S561 (daily ed. Feb. 10, 1998) (statement of Sen. Kennedy) ("It should also be clear to everyone that there is absolutely no need to act tomorrow to prevent the cloning of a human being. . . . [T]he FDA, which has jurisdiction over this area, has made it clear that it has both the authority and intention to prevent any human cloning until further research is done."); 144 CONG. REC. S431 (daily ed. Feb. 10, 1998) (statement of Sen. Feinstein) ("Why does this [cloning ban] have to be done in 48 hours? The FDA says it will prevent human cloning.")

53. See Marlene Cimon, *Strong Medicine Sought Atop FDA: Clinton Weighs Kessler Deputy as Nominee*, L.A. TIMES, Jan. 22, 1998, at A5 (reporting that the medical device industry prefers to keep Dr. Friedman as head of the Agency).

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals⁵⁴

As an initial matter, it is important to note that both of these definitions are limited to "articles." Thus, if the FDA wishes to assert jurisdiction over human cloning under the drug definition of the FDCA, it must first identify the requisite "article" to regulate. Although the term "article" is not defined in the FDCA itself, the ordinary meaning of the word is "a member of a class of things; *esp.* a piece of goods."⁵⁵

The only conceivable item which may be considered an "article" in the human cloning context is the embryo itself. It is highly unlikely, however, that a court would find that an embryo could properly be considered an "article" within the meaning of the FDCA. If it were, all human embryos would be subject to prior approval and/or licensure by the FDA, whether created by passion or the petri dish.⁵⁶ Thus, if a court were to conclude that an embryo is an "article" under the FDCA, it would, by necessary implication, give the FDA authority to pre-approve the formation of all human life. Such an absurd construction of the term "article" is in keeping neither with common sense nor legislative intent. The legislative history relating to the FDCA nowhere intimates an intent on the part of Congress to regulate the formation of human life. And given the social importance of the issue, congressional silence should strongly caution against implying an intent to regulate a right as fundamental as procreative liberty.⁵⁷ Moreover, the FDA's historical

54. 21 U.S.C. § 321(g)(1) (1994).

55. WEBSTER'S NEW COLLEGIATE DICTIONARY 63 (1981) (emphasis in original).

56. The FDA does not, of course, currently claim jurisdiction over sexual intercourse, in vitro fertilization, artificial insemination, or any other form of procreation.

57. The right of procreation is a fundamental right protected by the Constitution. See *Griswold v. Connecticut*, 381 U.S. 479 (1965); *Skinner v. Oklahoma*, 316 U.S. 535, 541 (1942) (describing procreation as "one of the basic civil rights of man"); see also *Planned Parenthood v. Casey*, 505 U.S. 833 (1992); *Roe v. Wade*, 410 U.S. 113 (1973); *Eisenstadt v. Baird*, 405 U.S. 438 (1972). Any law which would infringe upon the fundamental right of procreation would therefore be strictly scrutinized by the courts. Moreover, any law which gave the FDA authority to regulate procreation may be beyond the congressional commerce power. U.S. CONST. art. I, § 8, cl. 3; see also *United States v. Lopez*, 514 U.S. 549 (1995) (holding the Gun Free School Zones Act beyond the

failure to assert jurisdiction over embryos created in other ways — such as through in vitro fertilization — strongly implies that the Agency itself never believed it had jurisdiction over such matters.⁵⁸

Even assuming, arguendo, that a court were to find that Congress intended to include a human embryo as an “article” under the FDCA, it is clear that generally the embryo is neither (1) “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease”⁵⁹ nor (2) “intended to affect the structure or function of the body of man or other animals.”⁶⁰

With regard to the “disease” definition of a drug, it is conceivable that the “article” created by human cloning— i.e., the embryo— could be used in the diagnosis, cure, mitigation or prevention of disease. Specifically, if cloning were conducted using human cells, the resulting embryo—the “article”—could theoretically be manipulated in such a way that it would cease its normal development and instead develop into a specific organ or tissue — say, a heart — which would then be implanted into an individual who needed it.⁶¹

Under this scenario, the article (embryo) would be “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” within the meaning of section 201(g)(1)(B) of the FDCA and would be properly classified as a drug. Under this view, however, the FDA’s jurisdiction over cloning would be limited to human cloning that is conducted for the purpose of creating tissues or organs, not pregnancy.

congressional commerce power).

58. Indeed, in the late 1980s, Congress held a series of hearings focusing on the relatively low success rates of infertility clinics. See, e.g., *Consumer Protection Issues Involving In Vitro Fertilization Clinics, Hearing Before the Subcomm. on Regulation, Business Opportunities & Energy of the House Comm. on Small Business*, 101st Cong. (1989); *Consumer Protection Issues Involving In Vitro Fertilization Clinics, Hearing Before the Subcomm. on Regulation & Business Opportunities of the House Comm. on Small Business*, 100th Cong., 2d Sess. (1988). These hearings ultimately led to the passage of a federal law requiring fertility clinics to publicize their success rates using a standardized methodology. Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, 106 Stat. 3146 (codified at 42 U.S.C. §§ 263a(1)–(7)). Interestingly, it was never once suggested during these hearings that the FDA had existing authority to regulate fertility clinics or the process of in vitro fertilization itself. In fact, the federal agency responsible for implementing the Act is the Centers for Disease Control and Prevention (“CDC”), not the FDA. See 42 U.S.C. § 263(a)(1) (1994).

59. 21 U.S.C. § 321(g)(1)(B) (1994).

60. *Id.* § 321(g)(1)(C).

61. See Joan Stephenson, *Threatened Bans on Human Cloning Research Could Hamper Advances*, 270 JAMA 1022, 1023; Madeleine Nash, *The Case for Cloning*, TIME, Feb. 9, 1998, at 81.

In other words, if one accepts that an embryo is an "article" within the meaning of the FDCA, cloning could conceivably be classified as a "drug," subject to pre-market approval when it is intended to create organs or tissues that cure or treat disease. However, if cloning were conducted with the intention of creating a baby, it would fall outside the drug definition in section 201(g)(1)(B).

This is so because it is clear that courts do not consider pregnancy to be a "disease."⁶² Thus, if cloning were conducted with the intention of creating a pregnancy, it would not be an article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." As the district court in the famous *Ova II* case stated, "[t]he condition of pregnancy, as such, is a normal physiological function of all mammals and cannot be considered a disease of itself. Pregnancy is an execution of an inherent bodily function and implies no ailment, illness, or disease."⁶³ Thus, any procedure which is intended to "diagnose, cure, mitigate[e], treat[], or prevent[]" pregnancy is not a "drug" within the meaning of section 201(g)(1)(B).⁶⁴

Even assuming arguendo that the FDA considers pregnancy brought about via asexual procreation (i.e., cloning) to be distinguishable from pregnancy brought about by sexual procreation and hence, a "disease" within the meaning of the FDCA, the process of human cloning does not attempt to diagnose, cure, mitigate, treat or prevent this "disease." Indeed, cloning — as a form of procreation — attempts to *create* the "disease," *not* diagnose, cure, mitigate, treat or prevent it.

With regard to the second relevant definition of a "drug" found in subsection (C), it is also clear that human cloning is not an "article[] . . . intended to affect the structure or function of the body of man." Any *in vitro* manipulation of human cells falls outside the definition of "drug" under subsection (C).⁶⁵ "Drugs" under the Act only include articles which are inserted into, injected in, ingested by, or applied to the body.⁶⁶ Thus, if the FDA considers human cloning to be a "drug" under subsection (C), its conclusion would necessarily hinge upon the *in vivo* process of inserting the embryo into the mother's womb, not upon any *in vitro* manipulation of the cells.

That being so, the FDA's thesis would be that inserting an embryo into a womb is the introduction of an "article[] . . . intended to affect the

62. United States v. An Article of Drug — *Ova II*, 414 F. Supp. 660, 664 (D.N.J. 1975), *aff'd mem.*, 535 F.2d 1248 (3d Cir. 1976).

63. *Id.*

64. *Id.*

65. *Id.* at 665.

66. *Id.*

structure or function of the body of man." This argument must fail for several reasons. First, the primary intended function of an embryo is not to "affect the structure or function of the body of man," but to be born. In other words, one does not insert an embryo into a womb with the primary intention of affecting the structure or function of the body of the mother, but rather with the primary intention of giving the embryo an appropriate environment in which to thrive. Second, even if the primary intention of inserting an embryo into the mother's womb were to affect the structure or function of the mother's body, this would necessarily mean that any embryo would be a "drug" under subsection (C). Thus, embryos implanted due to other forms of procreation such as sexual intercourse, artificial insemination, or in vitro fertilization would also be "drugs" subject to premarket approval. Finally, if one were to apply the subsection (C) definition of "drug" to human cloning, the logical result would be that the insertion of an embryo into a living womb would be classified as a "drug," whereas the insertion of an embryo into an *artificial* womb⁶⁷ would not, since the latter could not be said to "affect the structure or function" of the body of man (there being no "body of man" involved).

Thus, if this argument is to be taken seriously, the FDA must necessarily concede its inability to regulate human cloning (or any other form of procreation) which is not dependent upon the use of a human womb. The application of artificial insemination, in vitro fertilization, or cloning, followed by insertion of the embryo into an artificial womb, would fall outside the subsection (C) definition. It is unlikely that Congress intended to enact a statute that grants the FDA authority to regulate the growth of an embryo *inside* a human womb, yet grants it no authority to regulate the growth of an embryo *outside* a human womb.

IV. MAY HUMAN CLONING BE REGULATED AS A "MEDICAL DEVICE"?

The relevant portions of section 201(h) of the FDCA define a medical device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory" that is:

67. Artificial wombs are not yet feasible for any animals, but a team of Japanese researchers has succeeded in sustaining goat fetuses outside the womb in an "extrauterine fetal incubation" ("EUF") device for up to three weeks. *Artificial Womb Can Sustain Goat Fetus for Up to 3 Weeks*, CHI. TRIB., July 20, 1997, at C8; Perri Klass, *The Artificial Womb is Born*, N.Y. TIMES, Sept. 29, 1996, at 117.

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. . . .⁶⁸

The medical device definitions, like the drug definitions, hinge upon the preliminary identification of a relevant "article." As discussed above in the context of the drug definition of the FDCA, classifying a human embryo as an "article" subject to FDA regulation would require a finding that Congress intended the Agency to have authority to regulate *all* forms of procreation, an intent most courts would be loathe to find.

Nonetheless, assuming a court would be willing to entertain the notion that an embryo is an "article," the chief difference between the use of the term "article" in the drug definition and the use of the term "article" in the medical device definition is that the latter contains many elaborate illustrations to guide a court in divining congressional intent. Specifically, subsection (h)(2) defines a medical device as an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article," bolstering the proposition that an embryo was not intended to be an "article" within the meaning of the Act. This laundry list of the types of "articles" covered by the medical device definition strongly suggests that the category was intended to be restricted to items of a tangible commercial nature.

Of course, an argument can be made that a human embryo falls within the term "implant" within the medical device definition. In order for the embryo-implant to be classified as a medical device, however, it would have to be either: (1) "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease"⁶⁹ or (2) "intended to affect the structure or any function of the body" through non-chemical means.⁷⁰

68. 21 U.S.C. § 321(h) (1994).

69. 21 U.S.C. § 321(h)(2).

70. *Id.* § 321(h)(3).

The first relevant medical device definition — the so-called “disease” definition — is identical to the disease definition of “drug” under section 201(g)(1)(B), with the notable addition of the phrase, “or other conditions.” This phrase, combined with the term “in vitro reagent” in section 201(h), was added by Congress as part of the 1976 Medical Device Amendments, and was specifically intended to give the FDA authority to regulate pregnancy test kits such as the ones that were at issue in the *Ova II* case.⁷¹ Thus, in vitro reagents intended to diagnose “conditions” such as pregnancy are now considered “medical devices” under section 201(h)(2).⁷²

Although pregnancy is now clearly a “condition” within the meaning of subsection (h)(2), an embryo-implant clearly would not be intended for “use in the diagnosis of” the condition of pregnancy. An embryo, after all, does not “diagnose” a pregnancy, but creates it. Thus, in order to fall within the disease definition of medical devices, the embryo implant must be intended for use in the “cure, mitigation, treatment, or prevention of disease, in man or other animals.”⁷³ As with the earlier discussion of the disease definition of “drug,” it is conceivable that if one accepts that an embryo implant is an “article,” an embryo created by cloning could be properly classified as a medical device if it were intended for use in the cure, mitigation, treatment, or prevention of disease. Such an embryo-implant could, in fact, be so intended if it were developed for the purpose of being programmed to develop into a specific organ or tissue rather than a whole human being.

Thus, an embryo-implant intended for use in the treatment or mitigation of disease may well be classified as a medical device. But what of embryos that are not so intended? What of the embryo that is implanted with the intention of carrying it to term? As the earlier discussion of the disease definition of drugs shows, an embryo that is intended to be carried to term would fall outside the disease definition because: (1) pregnancy is not a disease within the meaning of the FDCA; and (2) even if pregnancy were considered a disease under the Act, the embryo-implant would not be intended to cure, mitigate, treat or prevent the disease, but rather to create it. The somewhat odd result, therefore, would be that human embryos created by cloning in order to create life-saving tissues or organs would properly be classified as drugs or medical devices (and hence subject to premarket approval by the FDA), whereas human embryos created by cloning in order to create a child would not.

71. See 44 Fed. Reg. 10,133 (1979).

72. *Id.*

73. 21 U.S.C. § 321(h)(2).

Given that many (if not most) opponents of human cloning would appear to object primarily to the latter use of human cloning rather than the former,⁷⁴ the current statute would appear to provide little solace.

Finally, even if human cloning is properly classified as a medical device when used to create tissues or organs in the treatment or mitigation of disease in man or animals, the FDA may not have authority to regulate scientific research short of such direct use. In *United States v. Undetermined Quantities of Article of Device*,⁷⁵ the district court was asked to determine whether various tape recordings touting self-hypnosis as beneficial for ailments such as insomnia, acne, high blood pressure, and hair loss, fell within the definition of a medical device. Although the court ultimately found that the tapes in question were medical devices, it drew a clear distinction between the tapes themselves and the ideas contained within the tapes:

There is no doubt that a tape recording is an implement, apparatus, or contrivance. However, a distinction must be made in this case between the tapes themselves, and the ideas that are contained in the tapes. Congress did not intend to regulate an article or device, the sole function of which is to serve as a means of communicating health related ideas or information. Had Congress such an intent it would have expressly included books, the quintessential

74. The House Committee on Science expressed this widespread sentiment as follows:

The Committee [on Science] believes that attempting to clone a human being is unacceptably dangerous to the child and morally and ethically unacceptable to our society. This appears to reflect a national, if not a worldwide, consensus on the issue. The Committee, however, recognizes the complexity of legislating a prohibition . . . that does not adversely impact other scientifically important forms of research. . . . [T]he Committee seeks to preserve federal funding for genetic research and animal cloning technologies that could substantially improve our quality of life and provide us with life-saving cures for diseases.

HUMAN CLONING RESEARCH PROHIBITION ACT, H.R. REP. NO. 105-239, at 9 (1997); see also 144 CONG. REC. S436 (Feb. 5, 1998) ("The legislation that Senator Feinstein and I have introduced makes it illegal to implant a human embryo using this technique in a woman's womb. Without that, no baby, no human being can be created by current cloning technology. This is what Dr. Seed says he is going to do. This is what most ethicists oppose. This is what the American people want banned — and our legislation will do it").

75. Med. Devices Rep. (CCH) ¶15,055 (W.D. Mich. 1982).

communication device, in the definition of "medical device." It did not do so. . . .

By no stretch of language can an idea or a mental process be considered an instrument, apparatus, implement, machine, contrivance, implant, or in vitro reagent, or similar or related article. . . .

The "liberal interpretation" to be accorded the [Federal Food, Drug and Cosmetic] Act must yield somewhat when it comes into conflict with First Amendment freedoms. . . . Since ideas, beliefs, and mental processes do not come within the statutory definition [of a medical device] they are outside the jurisdiction of the FDA.⁷⁶

There likewise may be no doubt that a human embryo manipulated to grow into a liver instead of a whole human being is an "article" within the meaning of the medical device disease definition. However, there may be, as the *Undetermined Quantities* court pointed out, a distinction between the use of the embryo-article to treat or mitigate disease in man or animals and the basic ideas or research which bring about the development of the embryo-article but which is not actually used in the treatment or mitigation of disease in a man or an animal.

Viewed in this light, the actual use of the embryo-article is crucial; if the actual use is for scientific research, the "sole function of which is to serve as a means of communicating health related ideas or information[.]"⁷⁷ it would not be a medical device. On the other hand, if the embryo-article is actually used to treat or cure a disease in a man or animal, it would be a medical device.

This "use" distinction may appear to be splitting hairs. But in fact, the use distinction is important because, as the *Undetermined Quantities* court recognized, failure to acknowledge it may cause serious First Amendment difficulties.⁷⁸ Although courts have never been asked to determine if there is a right of "scientific inquiry" protected by the First Amendment, it would be preferable to construe the FDCA so as to avoid a possible constitutional difficulty⁷⁹ by applying it only to "applied"

76. *Id.*

77. *Id.*

78. *See id.*

79. *Hooper v. California*, 155 U.S. 648, 657 (1895) ("The elementary rule is that every reasonable construction must be resorted to in order to save a statute from unconstitutionality."); *see also* *Edward J. DeBartolo Corp. v. Florida Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1985).

research which may harm individuals or animals, leaving "pure" research unregulated.⁸⁰

The second relevant definition of a "medical device" is found in subsection (h)(3), and is identical to the "drug" definition in subsection (g)(1)(C) except for the addition of the phrase, "which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." The net effect of these additional words is simply to clarify that medical devices can affect the structure or function of the body, but unlike drugs, they do not achieve their primary purpose through chemical action or metabolism.

This difference in wording has no adverse effect upon the arguments made above with regard to the analogous drug definition. In other words, the medical device definition in (h)(3) suffers from the same deficiencies as the drug definition in (g)(1)(C) — namely, it necessarily assumes that: (1) an embryo is an "article," (2) which is primarily intended to affect the structure or function of the body. The only difference is that under the medical device definition, the intended effect is accomplished through mechanical rather than chemical or physiological means. As discussed above, premises (1) and (2) are invalid. And the additional requirement of achieving primary intended purpose through mechanical means makes medical device classification even more tenuous. An embryo — even if it is an "article" that, when implanted, is "intended" to affect the structure/function of the body — does not "achieve" its "primary intended purpose" through mechanical action. Indeed, to the extent that an embryo is an "article" which "affects the structure or function of the body," its affect is clearly physiological or chemical, not mechanical.

V. MAY HUMAN CLONING BE REGULATED AS A "BIOLOGICAL PRODUCT"?

Section 351 of the Public Health Service Act ("PHSA") defines a biological product as:

80. See IRA H. CARMEN, *CLONING & THE CONSTITUTION* 40-47 (1985) (concluding that "[c]onstitutional protection for new forms of scientific exploration and insight deserves no less deference than that which we ought to accord new forms of political protest").

any virus, therapeutic serum, toxin, antitoxin, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man⁸¹

The definition of a biological product thus has two 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 of man." The FDA has taken the position that any somatic cell therapy "product" which is applicable to the prevention, treatment, cure, diagnosis, or mitigation of disease or injuries is a combination drug/biological product which is subject to IND regulations.⁸² The relevant questions, therefore, are much the same as in the drug and medical device context: (1) is there an identifiable "product" involved in human cloning?; and (2) if so, is that product "applicable to the prevention, treatment or cure of diseases or injuries"?

With regard to the first question — whether there is a "product" involved in human cloning that is "analogous" to a virus, serum, toxin, et al. — it is (again) doubtful that Congress intended, by using the word "product," to include human embryos. A "product" is ordinarily defined as "something produced."⁸³ While the ordinary meaning of "product" is broad enough to include human embryos (since they could conceivably be viewed as "something produced" by the process of asexual procreation), is an embryo "analogous" to substances such as viruses, serums, vaccines, blood and toxins? While all of these substances are biologically based — as is an embryo — there does seem to be a significant difference between the items listed in section 351 and a human embryo. Specifically, the items listed in section 351 are mere components of a biological entity, whereas an embryo is, of course, a complete biological entity unto itself. In other words, it would be a fair construction to say that, in listing the items in section 351, Congress intended to limit the definition of biological products to those substances that were *sui generis* — i.e., biological components, not complete biological entities. Thus, blood, vaccines and toxins are biological products, but complete animals or humans — no matter how early in their development — are not. Moreover, as discussed with regard to the drug definition of the FDCA, it seems unlikely that Congress intended,

81. 42 U.S.C. § 262(a) (1994).

82. See 58 Fed. Reg. 53,248 (1993).

83. WEBSTER'S NINTH NEW COLLEGIATE DICTIONARY 938 (1988).

by its silence on the subject, to take the extraordinary measure of subjecting embryos to governmental regulation.

Moreover, even assuming *arguendo* that the first requirement is met (i.e., that a human embryo is a "product" which is "analogous" to the specified products such as serum, viruses and toxins), it is clear that the second requirement is not satisfied since the embryo is *not* applicable to the prevention, treatment, or cure of disease.⁸⁴

Although no courts have yet been asked to define the scope of the word "disease" as it is used in section 351 of the PHSA, it seems reasonable that they would follow the definition and reasoning of the court in *Ova II* and hold that pregnancy is not a "disease."⁸⁵ In other words, "disease" under the FDCA should mean the same thing as "disease" under the PHSA, and therefore any "product" that created the condition of "pregnancy" would not be considered "applicable to the prevention, treatment, or cure of diseases or injuries of man."

The *Ova II* definition of "disease" also comports with a plain language analysis, as *Webster's Dictionary* defines "disease" as "a condition of the living animal . . . or of one of its parts that impairs the performance of a vital function: SICKNESS, MALADY" or "a harmful development."⁸⁶ Thus, since the creation of life or a pregnancy is not a "condition . . . that impairs the performance of a vital function," nor a "sickness," "malady," or "harmful development," the process of human cloning would not be "applicable to the prevention, treatment, or cure of disease" within the meaning of the definition of a biological product. If "pregnancy" is not a disease, then a human embryo created by cloning that is implanted for the purpose of creating a pregnancy cannot be a biological product. And again, even assuming *arguendo* that pregnancy or the creation of life could be considered a "disease" or "injury" within the meaning of section 351, the process of human cloning would not be applicable to "preventing," "treating," or "curing" such disease or injury but rather would be applicable to *creating* it.

84. The definition of "biological product" under section 351 of the PHSA also encompasses "injuries" as well as "diseases." 42 U.S.C. § 262(a). Thus, if a product were applicable to the "prevention, treatment or cure" of an "injury," it would be a biological product. While there is no case law interpreting the word "injuries" under section 351, an "injury" is ordinarily defined as "an act that damages or hurts" or a "hurt, damage, or loss sustained." WEBSTER'S NINTH NEW COLLEGIATE DICTIONARY 623 (1988). Because a court would not likely consider pregnancy an "injury," any more than a "disease," see *United States v. An Article of Drug — Ova II*, 414 F. Supp. 660, 664 (D.N.J. 1975), *aff'd mem.*, 535 F.2d 1248 (3d Cir. 1976), this additional language should not affect the legal analysis.

85. See *Ova II*, 414 F. Supp. at 664.

86. WEBSTER'S NINTH NEW COLLEGIATE DICTIONARY 362 (1988).

As in the drug and medical device concepts, it is conceivable that a human embryo created by cloning could be applicable to the prevention, treatment, or cure of disease if it were programmed to develop into a specific tissue or organ destined for transplantation, rather than allowed to develop into a whole human being. Again, however, the result is that the statute would only give the FDA authority to regulate human cloning when it is used for such disease prevention or treatment purposes,⁸⁷ when used to produce babies. This, of course, is the exact opposite of what most people want.⁸⁷

VI. CONCLUSION

The FDA's belief that current statutes would permit it to regulate human cloning is legally insupportable. In order to stretch current law to grant the FDA such authority, a court would have to find both: (1) that Congress intended a human embryo to be considered an "article" or "product" within the meaning of the FDCA or PHSA; and (2) that human embryos created by cloning are intended or applicable to the diagnosis, cure, mitigation, treatment, or prevention of disease. While human embryos created by cloning may satisfy this second requirement if they are intended to be programmed to develop into specific organs or tissues (rather than babies), it is highly doubtful that the first requirement can be met. Even assuming, however, that human embryos are deemed "products" or "articles," the FDA would only have jurisdiction to regulate those human embryos that are intended to diagnose, cure, mitigate, treat or prevent disease — i.e., those human embryos that are programmed to develop into specific tissues or organs. The net result is that the FDA has statutory authority only to regulate human cloning activity that is aimed at disease prevention or cure, not human cloning aimed at producing children. Thus, the FDA would not have authority to stop scientists who, like Richard Seed, have expressed a desire to use cloning techniques to help infertile couples have children.⁸⁸ If the FDA wants the authority to regulate human cloning intended to produce children, a statutory amendment will be necessary.⁸⁹

87. See *supra* notes 35, 41 & 74.

88. See *Cloning Clinic Promoter Predicts a Big Demand*, N.Y. TIMES, Jan. 8, 1998, at A16.

89. I shall leave for future articles the question as to whether such a statute, if enacted, would be constitutional.

