Human Cloning: Is the Reach of FDA Authority Too Far a Stretch? †

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INTRODUCTION

On July 5, 1996, Dolly the sheep was born at the Roslin Institute in Scotland[1] and became the first offspring born as the result of the transfer of genetic material from a differentiated adult cell to an enucleated, unfertilized egg.[2] This somatic cell nuclear transfer technique[3] resulted in the first successful cloning of an adult mammal.[4] In essence, Dolly, possessing the genetic makeup of only one parent, became the delayed genetic twin of an adult sheep.[5] The idea that human cloning might now be possible ignited global debate regarding the moral, scientific, and medical ramifications of such a

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The contents of this Article represent the views of its author and are not intended to reflect the positions of the New Jersey State Board of Medical Examiners.

[1] *See* National Bioethics Advisory Comm'n, CLONING HUMAN BEINGS: REPORT AND RECOMMENDATIONS OF THE NAT'L BIOETHICS ADVISORY COMM'N 1 (1997) [hereinafter NBAC REPORT].

[2] *See* Ian Wilmut et al., *Viable Offspring Derived from Fetal and Adult Mammalian Cells*, NATURE, Feb. 27, 1997, at 810. The cell nucleus containing the genetic material was transferred to the enucleated egg from an adult sheep mammary gland cell. *See id.*

[3] *See* NBAC REPORT, *supra* note 1, at 1.

[4] *See* Kenton Abel, *Biotechnology and Medical Devices: State Legislation: 1997 California Legislative Service 688 (West) — Human Cloning*, 13 BERKELEY TECH. L.J. 465, 465 (1998).

[5] *See* NBAC REPORT, *supra* note 1, at 1.

prospect.[6]

Subsequent to the publication of the successful cloning of a sheep by researchers at the Roslin Institute, President Clinton implemented a ban on federal funding for human cloning experiments.[7] The President also charged the National Bioethics Advisory Commission (NBAC) with the task of analyzing the legal and ethical issues concerning human cloning and of reporting its recommendations within ninety days.[8] Shortly after Dolly's birth announcement, legislative proposals to ban human cloning were introduced at both the state[9] and federal levels.[10]

When momentum for such a ban seemed to lessen,[11] Chicago physicist Richard Seed announced at a December 1997 scientific symposium that he was ready, willing, and able to clone humans as soon as he procured the necessary funding.[12] Seed's proclamations

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[6] *See* Ian Wilmut, *Dolly's False Legacy*, TIME, Jan. 11, 1999, at 74.

[7] *See* NBAC REPORT, *supra* note 1, at 3; William J. Clinton, Speech Regarding the Prohibition on Federal Funding for Cloning of Human Beings, *in* 33 WEEKLY COMP. PRES. DOC. 281 (Mar. 4, 1997). Unlike the ban on federal funding of human embryo research instituted in December 1994, the prohibition of federal funding for human cloning research would apply to all federal agencies. *See id.*

[8] *See* NBAC REPORT, *supra* note 1, at 3.

[9] *See* Abel, *supra* note 4, at 466 n.7 (citing state bills S. 511, 1997 Leg., Reg. Sess. (Ala. 1997); A.B. 1082, 1997 Leg., Reg. Sess. (Ala. 1997); S.J.R. 14, 1997-98 Leg., 1st Sess. (Cal. 1997); S.C.R. 39, 1997-98 Leg., 1st Sess. (Cal. 1997); S. 1344, 1997-98 Leg., 1st Sess. (Cal. 1997) (enacted); A.B. 1251, 1997-98 Leg., 1st Sess. (Cal. 1997); H.B. 1237, 1997-98 Leg., 1st Sess. (Fla. 1997); H.B. 2235, 90th Leg., 1st Sess. (Ill. 1997); H.B. 1829, 90th Leg., 1st Sess. (Ill. 1997); S. 134, 118th Leg., 1st Sess. (Me. 1997); H.J.R. 28, 1997-98 Leg., 1st Sess. (Md. 1997); H.B. 4846, 89th Leg., 1st Sess. (Mich. 1997); H.B. 4962, 89th Leg., 1st Sess. (Mich. 1997); H.B. 824, 89th Leg., 1st Sess. (Mo. 1997); A.B. 2849, 207th Leg., Reg. Sess. (N.J. 1997); S. 2877, 220th Leg., Reg. Sess. (N.Y. 1997); A.B. 5383, 220th Leg., Reg., Sess. (N.Y. 1997); S. 782, 1997-98 Leg., 1st Sess. (N.C. 1997); S. 1017, 69th Leg., 1st Sess. (Or. 1997); H.B. 3617, 112th Leg., 1st Sess. (S.C. 1997); S. 410, 73rd Leg., 1st Sess. (W. Va. 1997)).

[10] *See id.* at 466 n.6 (citing federal bills S. 368, 105th Cong. (1997); H.R. 922, 105th Cong. (1997); H.R. 923, 105th Cong. (1997)). In addition, President Clinton suggested legislation that would ban all human cloning for a period of five years, exclusive of cell or tissue cloning and consistent with NBAC guidelines. *See* Joanne Silberner, *Seeding the Cloning Debate; Richard Seed; Capital Report*, THE HASTINGS CTR. REP., Mar. 13, 1998, at 5. The President's proposal, however, failed to progress for want of a legislative sponsor. *See id*

[11] *See* Gina Kolata, *On Cloning Humans, "Never" Turns Swiftly into "Why Not,"* N.Y. TIMES, Dec. 2, 1997, at A1.

[12] *See* Silberner, *supra* note 10, at 5. On January 6, 1998, Seed stated on National Public Radio: "We are going to have almost as much knowledge and almost as much power as God . . . . Cloning and the reprogramming of DNA is the first serious step in coming to one with God." *Id.* Because of the medical risks associated with human cloning, Seed later said that he decided to clone himself first. *See* Richard Saltus, *Would-Be Cloner Plans to Start with Himself*, BOSTON GLOBE, Sept. 6, 1998, at A6. Seed was also quoted as saying that "'clones would be 'fun' and would unleash a 'torrent of

rekindled the human cloning debate[13] and precipitated another round of legislative proposals to ban human cloning.[14] Such sentiment was not limited to the United States, and many nations

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research' . . . [and] would be the first step toward discovering immortality.'" *Id.* He predicted that his Chicago clinic would achieve success with human cloning within two and one-half years. *See id.*

[13] *See* Silberner, *supra* note 10, at 5; *see also* John A. Robertson, *Human Cloning and the Challenge of Regulation*, 339 NEW ENG. J. MED. 119, 121 (1998) (noting that profit-motivated entrepreneurs such as Seed are unlikely to have many customers until the safety of cloning is ensured); George J. Annas, *Why We Should Ban Cloning*, 339 NEW ENG. J. MED. 122, 125 (1998) (commenting on the increased public discussion and legislative activities following Seed's announcements); Mara Bovsun, *GOP Human Cloning Bill Bumped Off Fast Track by Senate Vote*, BIOTECH. NEWSWATCH, Feb. 16, 1998, at 1 (recognizing that "[t]he rush to get a cloning bill passed was spurred by . . . maverick scientist Richard Seed"); Kathleen Fackelmann, *Cloning Debate Erupts Anew: Bill Clinton Denounces a Plan Announced by Physicist Richard Seed to Open a Fertility Clinic for Human Cloning*, 153 SCI. NEWS, Jan. 24, 1998, at 59 (noting the FDA's assertion of regulatory authority over human cloning research); Deborah Josefson, *U.S. Scientist Plans Human Cloning Clinic*, 316 BRIT. MED. J. 167, 167 (1998) (discussing Seed's effect on the congressional timetable for cloning legislation and suggesting a causal relationship between Seed's actions and an emergency meeting of the NBAC). Following Seed's statements, White House Press Secretary Mike McCurry declared that Seed would be "irresponsible, unethical, and unprofessional" if he was to carry out his intentions. *Id.* Donna Shalala, Secretary of the Department of Health and Human Services (HHS), said "that the Food and Drug Administration has the authority to regulate human cloning in the meantime." *Id.* Richard Seed has stated that he would open a human cloning clinic in another country if such activities were banned in the United States, that he has already discussed this possibility with Mexican officials, and that he has already identified a team of doctors, laboratory researchers, and four infertile couples willing to proceed should he obtain the necessary funding. *See id.*

[14] *See* Abel, *supra* note 4, at 466 n.12 (citing federal legislative proposals S. 1574, 105th Cong. (1998); S. 1599, 105th Cong. (1998); S. 1601, 105th Cong. (1998); S. 1602, 105th Cong. (1998); S. 1611, 105th Cong. (1998); H.R. 3133, 105th Cong. (1998)). State legislatures have also debated similar issues. *See* Abel, *supra* note 4, at 466 n.13 (citing state bills S. 8, 1998 Leg., Reg. Sess. (Ala. 1998); S. 68, 1998 Leg., Reg. Sess. (Ala. 1998); S.J.R. 6, 1998 Leg., Reg. Sess. (Ala. 1998); H.B. 5475, 1998 Leg., Reg. Sess. (Conn. 1998); S. 241, 139th Leg., 2d Sess. (Del. 1998); H.B. 1508, 144th Leg., 2d Sess. (Ga. 1998); S. 1230, 90th Leg., 2d Sess. (Ill. 1998); S. 1243, 90th Leg., 2d Sess. (Ill. 1998); S. 411, 110th Leg., 2d Sess. (Ind. 1998); H.B. 3206, 19th Leg., 2d Sess. (Haw. 1998); H.B. 2846, 77th Leg., 2d Sess. (Kan. 1998); H.J.R. 11, 1998 Leg., Reg. Sess. (Md. 1998); S. 864, 89th Leg., 2d Sess. (Mich. 1998); H.B. 5475, 89th Leg., 2d Sess. (Mich. 1998); H.R. 197, 89th Leg., 2d Sess. (Mich. 1998); H.B. 198, 89th Leg., 2d Sess. (Mich. 1998); H.C.R. 80, 89th Leg., 2d Sess. (Mich. 1998); H.B. 2730, 80th Leg., 2d Sess. (Minn. 1998), S. 2423, 80th Leg., 2d Sess. (Minn. 1998); H.B. 996, 1998 Leg., Reg. Sess. (Miss. 1998); H.B. 1658, 155th Leg., 2d Sess. (N.H. 1998); A.B., 329, 208th Leg., Reg. Sess. (N.J. 1998); S. 5993, 221st Leg., Reg. Sess. (N.Y. 1998); A.B. 9116, 221st Leg., Reg. Sess. (N.Y. 1998); S. 218, 122d Leg., 2d Sess. (Ohio 1998); H.B. 675, 122d Leg., 2d Sess. (Ohio 1998); H.B. 2128, 182d Leg., 2d Sess. (Pa. 1998); H.B. 7123, 1997-98 Leg., 2d Sess. (R.I. 1998); S. 2208, 100th Leg., 2d Sess. (Tenn. 1998); S. 2295, 100th Leg., 2d Sess. (Tenn. 1998); H.B. 2198, 100th Leg., 2d Sess. (Tenn. 1998); H.B. 2281, 100th Leg., 2d Sess. (Tenn. 1998); A.B. 769, 93d Leg., 2d Sess. (Wis. 1998); H.B. 752, 1998 Leg., Reg. Sess. (Va. 1998)).

called for an international ban on human cloning projects.[15] Dr. Seed's declarations also touched off an assault against his movement by the medical community.[16] Carl B. Feldbaum, president of the Biotechnology Industry Organization (BIO), sought the assistance of Donna Shalala, Secretary of the Department of Health and Human Services (HHS), to support the assertion of FDA authority and jurisdiction over human cloning attempts.[17]

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[15] *See* Abel, *supra* note 4, at 467 nn.14-15. On January 12, 1998, French President Jacques Chirac called for a human cloning ban before a European conference of national ethics committees. *See id.* Nineteen out of forty nation members of the Council of Europe signed a treaty on January 12, 1998 to ban human cloning, and in so doing declared that human cloning is "contrary to human dignity and thus constitutes a misuse of biology and medicine." *Id.* Signatory nations included Denmark, Estonia, Finland, France, Greece, Ireland, Italy, Latvia, Luxembourg, Macedonia, Moldavia, Norway, Portugal, Romania, San Marino, Slovenia, Spain, Sweden, and Turkey. *See id.* England declined to sign the treaty, finding the it too strict, while Germany declined on the basis that it was too liberal. *See id.* Pope John Paul II likewise advocated a ban on human cloning. *See id.*

[16] *See Opposition Grows to Human Cloning on Bioethics Premise*, MED. INDUS. TODAY, Jan. 15, 1998.

[17] *See id.* The Biotechnology Industry Organization (BIO) also endorsed President Clinton's initiatives and the moratorium recommended by the NBAC. *See id.* Carl B. Feldbaum opined that the "'recognition and assertion of the FDA's regulatory power over human cloning will protect biomedical advances, and at the same time will give everybody some breathing room to debate this issue.'" *Id.* Feldbaum emphasized the experimental nature of cloning in correspondence to HHS by noting that there were 276 unsuccessful cloning attempts prior to the birth of Dolly. *See id.* The BIO posited that the FDA's authority to regulate biological products might very well encompass human cloning attempts. *See id.* An FDA source has been quoted as saying that "not only does the agency believe it has the authority to regulate attempts at human cloning, it is prepared to do so with a view toward protecting the public health." *See* Lisa Seachrist, *BIO Says Human Cloning Falls Under FDA's Purview*, BIOWORLD TODAY, Jan. 15, 1998. Feldbaum opined that the FDA has broad power to regulate biologic products under a regulatory framework for cellular and tissue-based products promulgated in February 1997. *See id.* Noting that this framework regulates tissue-based products based on the amount of cellular or tissue manipulation, Feldbaum postulated that somatic cell nuclear transfer cloning techniques involving more than minimal manipulation would fall within the FDA's regulatory authority and would require both investigational new drug (IND) applications and license review. *See id.* The BIO further asserted:

> The FDA not only regulates tissues and manipulated cells, but has the authority to regulate nucleic acid used in humans and regulates many of the medical devices that would be used to produce a human clone . . . . [T]he FDA is prepared to use tissue and biologics regulations to assert its authority to review any protocols that attempt to clone a human being.
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> In deciding whether to approve any cloning IND, the agency would seek to ensure that preclinical and animal data were sufficient to indicate the safety and efficacy of the procedure. The FDA could issue clinical holds on protocols, disqualify investigators who make attempts in spite of a clinical hold, or go to the courts to enjoin such individuals

On the heels of this public debate, and sparked in part by Richard Seed's public declarations of his intent to clone human beings, the FDA announced in January 1998 that it had statutory authority to regulate human cloning.[18] The FDA determined that "manipulated" cells and nucleic acids constitute biologic products, thus placing cloning technology under the agency's jurisdiction pursuant to its tissue-product regulations.[19] The agency asserted that any attempts at human cloning would necessitate the filing of an Investigational New Drug (IND) application.[20] The FDA also

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from cloning a human being.

Id. Feldbaum emphasized that neither the safety nor the efficacy of cloning technology has been established and concluded that a clinical hold should be placed on any IND application for human cloning. *See id.* For a discussion concerning FDA guidance documents and an FDA-proposed rule regarding regulation of cellular and tissue-based products as biological products, see *infra* notes 173-77 and accompanying text.

[18] *See* F.D.C. Reports, 60 "The Pink Sheet" No. 3, Jan. 19, 1998 at T&G1. The FDA maintained that violations of agency regulations would be judicially enforced under the Public Health Service Act, 42 U.S.C. § 212 (1994). *See id.* Lead Deputy Commissioner Michael Friedman, M.D. was quoted on National Public Radio's January 12, 1998 *Diane Rehm Show* as saying:

> "We believe we have jurisdiction over this, and before an investigational procedure can go forward, it needs our review and approval . . . . We all think that this is a technology that is enormously promising for animals, for plants and for other kinds of situations . . . . [W]e would not prohibit this activity, but we would ask for the scientific data that shows it is safe, that there is adequate expertise behind it, that the facilities are satisfactory [and] that the individuals involved have the proper experience and training . . . . [T]he general scientific community is very uncomfortable with the idea of moving forward right now. At least our agency certainly agrees with that, and the Secretary of HHS has said that."

Id. Friedman acknowledged that although exercise of FDA regulatory authority over cloning would enable the agency to "'put the brakes on cloning efforts, [it would also] create a regulatory pathway for potential future approval of the technology.'" F.D.C. Reports, 24 "The Gray Sheet" No. 3, Jan. 19, 1998 at I&W8; *see also* Rick Weiss, *Human Clone Research Will Be Regulated; FDA Asserts It Has Statutory Authority to Regulate Attempts at Human Cloning*, WASH. POST, Jan. 20, 1998, at A1 (quoting Lead Deputy Commissioner Friedman's assertions of FDA jurisdiction under the FFDCA and statements of agency resolve to assert regulatory authority over cloning). Freidman represented that "serious health and safety issues" for both the mother and fetus were implicated by the kinds of manipulations inherent in human cloning procedures. *See id.*

[19] *See* F.D.C. Reports 60, "The Pink Sheet" No. 3, Jan. 19, 1998 at T&G1. Philip D. Noguchi, Director of FDA's cellular and gene therapy division, announced that the agency has firmly decided that "more than minimal manipulation" of human cells is involved in human cloning and that this standard "is the dividing line between human tissue experiments that do and do not require prior approval from the FDA." Weiss, *supra* note 18, at A1; *see also infra* notes 165-69, 171-77 and accompanying text (discussing FDA regulation of cellular and tissue-based products).

[20] *See* Weiss, *supra* note 18, at A1. Prospective cloners would need to comply with

asserted, in an October 26, 1998 "Dear Colleague" letter, that the agency has regulatory jurisdiction "over clinical research using cloning technology to create a human being"[21] pursuant to the Public Health Service Act (PHSA)[22] and the Federal Food, Drug, and Cosmetic Act (FFDCA).[23] Interestingly, Richard Seed reported that he would now need to decide "whether to challenge the FDA's legal interpretation[s] or simply move his cloning effort out of the country."[24]

Considerable debate has since arisen as to whether the reach of FDA authority, which usually encompasses regulation of drugs and therapies for the treatment of disease, can be stretched to cover human cloning.[25] Three possible theories have been advanced to

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a formal IND application procedure similar to that required of drug companies when they seek to test new medicines. *See id.* The FDA would undertake a lengthy review and cloning researchers would need to convince the agency that the proposed protocols do not create an unreasonable risk of harm to human subjects. *See id.* Given the extremely high failure rate in animal cloning attempts, researchers would find it difficult to comply with agency mandates on safety and public hearings that might be required each time a human cloning proposal is evaluated. *See Cloning: FDA Will Regulate Procedures*, HEALTH LINE, Jan. 20, 1998.

[21] *See* Letter from Stuart L. Nightingale, M.D., Associate Commissioner, *Department of Health and Human Services* (Oct. 26, 1998) (on file with the *Seton Hall Law Review*). The agency asserted that under the FFDCA, the PHSA, and the FDA's implementing regulations, any human cloning researcher must submit an IND to the FDA before commencing such experimentation. *See id.* In addition, the FDA requires a research plan description, an authorization from a properly constituted and functioning Institutional Review Board (IRB), and informed consent from all human research subjects. *See id.* The FDA would not permit any such studies to proceed until all major unresolved safety questions have been answered. *See id.* The agency noted that "[t]the procedures and requirements governing the use of investigational new drugs, including those for the submission and review of IND[ ], are set forth in Title 21 of the Code of Federal Regulations (CFR), Part 312." *Id.* Compliance with IRB requirements is set forth in 21 C.F.R. Part 56. *See id.*

[22] 42 U.S.C. § 262 (a) (1994).

[23] 21 U.S.C. § 321 (a) (1994).

[24] *Feds: Cloning is Regulated, FDA Says Procedure Requires Approval*, NEWSDAY (New York), Jan. 21, 1998, at A20.

[25] *See* Sheryl Gay Stolberg, *F.D.A. Stand on Cloning Raises Even More Questions*, N.Y. TIMES, Jan. 21, 1998, at A14. "While agency officials insist they have jurisdiction, some experts in food and drug law — as well as [ ] Congressman [Ehlers] who proposes to ban the cloning of people — said they were not so certain." *Id.* Representative Vernon J. Ehlers, a Michigan Republican, opined that classifying cloning procedures as drugs would be a difficult argument to make. *See id.* By contrast, Acting Commissioner Michael Friedman has publicly agreed with the stance taken by the BIO that cloning falls under FDA authority to regulate biologics, although the agency has "yet to issue a formal policy statement on its justification to govern cloning experiments." *Id.* Former FDA lawyer Arthur Levine stated, "'[i]t is not uncommon, in this kind of sensitive area involving medical ethics, for the FDA to take a position through various informal statements, drafts, and meetings where they try to explore what the market will bear . . . . These are informal ways that FDA tests

justify FDA authority over human cloning: (1) designation of cloning materials as "biological products" pursuant to § 351(a) of the PHSA;[26] (2) designation of such products as "drugs" pursuant to § 201(g) of the FFDCA;[27] and (3) regulation of cloning procedures as "medical devices" under § 201(h) of the FFDCA.[28] Exercise of FDA regulatory authority over human cloning pursuant to any one of these statutory provisions would include premarket approval requirements and a need by the researcher to demonstrate the safety and efficacy of the cloning procedures.[29]

Without doubt, any attempts at human cloning would be

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the water.'" *Id.* Historically, biologics consisted of blood products and vaccines, but today are regulated under guidelines that include products composed of a living organism such as human cells or tissue that are "substantially altered, through 'more than minimal manipulation.'" *See id.* Although Levine suggested that an argument for FDA authority over cloning could be made, another lawyer with expertise in food and drug law believed that the biologics provisions were not applicable to cloning. *See id.* The manipulation of cells might not be considered therapeutic in function since the intent "is really to create a new human being." *Id.* (internal quotations omitted); *see also FDA Asserts Human Cloning Authority*, FACTS ON FILE WORLD NEWS DIG., Jan. 22, 1998, at 29 (reporting that Dr. Friedman stated that cloning required FDA approval under the FFDCA as a type of cellular genetic therapy).

[26] 42 U.S.C. § 262(a) (1994).

[27] 21 U.S.C. § 321(g)(1) (1994).

[28] 21 U.S.C. § 321(h) (1994); *see also* Elizabeth C. Price, *Does the FDA Have Authority to Regulate Human Cloning*, 11 HARV. J.L. & TECH. 619, 620 (1998); F.D.C. Reports, 60 "The Pink Sheet" No. 32, Aug. 10, 1998, at 3. The Pink Sheet notes that a questionnaire prepared by Republican members of the Senate Labor and Human Resources Committee in August 1998 and presented to FDA Commissioner nominee Jane Henney specifically asked "which section of the FD&C Act gives FDA authority, and whether it would apply its drug, device, or biologics rules." *Id.*

[29] *See* 42 U.S.C. § 262(a)(1)(A) (1998) (requiring biologics license for biological products introduced into interstate commerce); 42 U.S.C. § 262 (a)(2)(B) (1998) (setting forth the requirements of safety, purity, and potency for licensure of biological products); 21 C.F.R. § 600.3(p) (1997) (defining safety of biological products as "relative freedom from harmful effect to persons . . . when prudently administered, taking into consideration the character of the product . . . "); 21 C.F.R. § 600.3(r) & (s) (defining purity and potency of biological products, respectively); 21 U.S.C. § 321(p)(1) (1994) (defining the term "new drug" as any drug which is "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested . . ."); 21 U.S.C. § 355(a) (1994) (necessitating approval of a new drug application prior to introduction of any new drug into interstate commerce); 21 U.S.C. § 355(d) (setting forth the grounds for refusing or approving a new drug application and delineating the safety and efficacy requirements); 21 U.S.C. § 360(c)(a)(1)(c) (1994) (requiring premarket approval for class III medical devices to ensure safety and efficacy); *see also* Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products, 63 Fed. Reg. 26,744 (1998), 63 Fed. Reg. 68,212 (1998) (requiring premarket approval for cells and tissues that are processed extensively or have a system effect).

deemed experimental by the FDA and would thus require submission of an IND application by the clinical researcher, as well as institutional review board (IRB) oversight.[30] Given the high failure rates in sheep-cloning attempts, it is highly unlikely that the FDA presently would approve any IND application involving human cloning, and if empowered, would place a clinical hold on any such attempts.[31] The real question is whether the FDA has authority to regulate cloning in the first place. Part I of this Article provides a brief background of the science of cloning. Part II explores the ideological differences and ethical arguments inherent in the cloning debate. Part III outlines the most significant legislative responses to the human cloning controversy and notes the various levels of support for FDA authority over cloning by various constituencies. Finally, Part IV analyzes the legitimacy of FDA authority under the aforementioned regulatory schemes.

I. THE SCIENCE

The term "cloning" has been used differently in various research settings.[32] A strict scientific definition of cloning, however, describes the process of producing a "precise genetic copy of a molecule, cell, plant, animal, or human being."[33] Cloning technologies are not new

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[30] *See* Nightingale, *supra* note 21 (explaining the FDA's position, as circulated in a "Dear Colleague" letter, regarding the applicability of the IND application and IRB processes to human cloning); *see also* 21 C.F.R. § 312.2(a) (1999) (applying the IND application process to clinical investigations of new drugs subject to § 505 of the FFDCA and to the licensing of biological products under the PHSA); 21 C.F.R. § 312.22(a) (1996) (describing general principles of the IND submission); 21 C.F.R. § 312.23(a)(6) (delineating requirements for protocol description, including investigator qualifications); 21 C.F.R. § 312.32 (listing IND safety report requirements); 21 C.F.R. § 312.62 (detailing investigator record keeping and record retention requirements); 21 C.F.R. § 312.64 (describing investigator progress, safety, and final report requirements); 21 C.F.R. § 312.66 (ensuring IRB review); 21 C.F.R. § 312.42 (outlining the "clinical hold" process in situations determined to pose an "unreasonable and significant risk of illness or injury" to human subjects).

[31] *See* Seachrist, *supra* note 17 (postulating the FDA position regarding human cloning attempts).

[32] *See* NBAC REPORT, *supra* note 1, at 14.

[33] *Id.* Henry T. Greely has noted:

> The term "clone" dates to the beginning of the twentieth century when agricultural scientists adapted it from the Greek word "clon," meaning twig. The term was used to refer to the process of producing new copies of plants by cuttings rather than by seeds . . . .
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> The verb "to clone" has come to refer to the reproduction of a living organism or some of its parts without the mixing of genetic information caused by sexual reproduction. "Clones," the noun, are thus a set of organisms or parts of organisms that are identical genetically, and, in the case of specialized types of cells, are identical in

and have been used extensively in both horticulture and agriculture to maintain various plant varieties.[34] For example, regenerating an entire plant from a small cutting produces a genetically identical copy of the original plant.[35] Although some animals can, to some extent, regenerate certain organs, tissues, or limbs, vertebrates have lost the ability to generate another whole organism in an analogous fashion.[36] Production of genetically identical copies of organisms, however, does occur naturally in animals and humans in the form of identical twins.[37] The splitting of an early embryo (typically two to eight-cell stage) into halves results in genetically identical offspring derived from a single fertilized egg.[38]

At the molecular level, cloning of deoxyribonucleic acid (DNA) fragments containing genes has been ongoing for several decades.[39] The process of using bacteria to copy and amplify human DNA fragments and manufacture proteins coded from these fragments has been the foundation for recombinant DNA technology. This technology has led to the production of commercially available quantities of valuable medicines to treat human disease.[40]

Culturing somatic (i.e., body) cells in a laboratory is another form of cloning that results in a cell line genetically identical to the original cell. This cellular cloning technique has been used to test and produce new medicines.[41] In addition, primordial stem-cell therapy, based on cellular cloning techniques, has the potential to revolutionize health care.[42] Clinical trials are already being

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both what genes they have and what genes they are using.

Henry T. Greely, *Banning "Human Cloning": A Study in the Difficulties of Defining Science*, 8 S. CAL. INTERDISC. L.J. 131, 132-33 (1998).

[34] *See* NBAC REPORT, *supra* note 1, at 14.

[35] *See id.*

[36] *See id.*

[37] *See id.*

[38] *See id.*

[39] *See id.*

[40] *See* NBAC REPORT, *supra* note 1, at 14. Insulin used in the treatment of diabetes, erythropoietin used to treat anemia associated with end-stage renal disease, and tissue plasminogen activator used to dissolve coronary artery clots during the evolution of a heart attack are examples of clinically useful products of recombinant DNA technology. *See id.*

[41] *See id.* at 14-15. Cloning of somatic cells in this manner does not involve the use of egg or sperm cells, thus it precludes the cloning of an entire organism. *See id.*

[42] *See Prepared Testimony of Michael D. West, Ph.D., Founder and Chairman of Origin Therapeutics, Inc., South San Francisco, California, on Behalf of the Biotechnology Industry Organization (BIO) Before the House Committee on Commerce, Subcommittee on Health and Environment, Subject — Legislative Proposals Regarding Cloning of Human Beings*, FED. NEWS SERV., Feb. 12, 1998 [hereinafter *West*]. Primordial stem cells are different

conducted utilizing nonprimordial stem cells for therapeutic purposes such as cancer treatment.[43]

Attempts to clone genetically identical animals are typically classified as one of two separate methodologies: blastomere separation, or embryo splitting, and nuclear transplantation techniques.[44] Blastomere separation involves the splitting of an early embryo, allowing each split blastomere cell to develop into a separate organism.[45] These cells, considered totipotent, are capable of producing multiple genetically identical organisms when split.[46] This technique exhibits great potential in the area of cattle and livestock breeding.[47] Since 1993, embryo splitting has also been successfully performed with human embryos.[48]

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from other stem cells, which have differentiated into a specific cell line. *See id.* Because many tissues in the body do not contain stem cells, any injury to them is permanent and disabling. *See id.* "By way of contrast a primordial stem cell has the potential to become literally any cell in the body and therefore it offers a solution to many untreatable diseases and conditions." *Id.* Primordial stem-cell therapy has the potential to restore damaged cells in the body, including

> cardiac muscle cells to treat heart attack victims and degenerative heart disease; skin cells to treat burn victims; spinal cord neuron cells for treatment of spinal cord trauma and paralysis; neural cells for . . . neurodegenerative diseases; pancreas cells to treat diabetes; blood cells to treat cancer, anemia, and immunodeficiencies; neural cells to treat Parkinson's, Huntington's and Amyotrophic Lateral Sclerosis (ALS); cells for use in genetic therapy to treat 5,000 genetic diseases . . . blood vessel endothelial cells for treating artherosclerosis; liver cells . . . cartilage cells . . . bone cells . . . myoblast cells for the treatment of Muscular Dystrophy; respiratory epithelial cells for the treatment of Cystic Fibrosis and lung cancer; adrenal cortex cells . . . retinal pigment epithelial cells for age-related macular degeneration . . . .

Id. Various stem cells differentiate into a variety of cell types and are self-renewing. *See id.* Primordial stem cells are undifferentiated stem cells that are able to differentiate into many different types of cells and may "provide a means of manufacturing any human cell type in the industrial setting." *Id.* This technology may even resolve ethical issues related to the source of material for transplantation. *See id.* Primordial stem-cell research could possibly result in the development of "universal donor cells." *See id.* (internal quotations omitted).

[43] *See id.* For example, hematopoetic stem cells can be isolated from the blood of adults or children, cloned by cellular culturing techniques, and used to treat human disease, such as cancer. *See id.*

[44] *See* NBAC REPORT, *supra* note 1, at 15.

[45] *See id.*

[46] *See id.*

[47] *See id.*; *see also* Gina Kolata, *Japanese Scientists Clone a Cow, Making Eight Copies*, N.Y. TIMES, Dec. 9, 1998, at A8. Kolata observes that "one reason for cloning cattle would be to reproduce exact copies of animals that are superb producers of meat or milk." *Id.* The procedure the Japanese used to clone a cow involved transfer of somatic cell nuclear material into an enucleated egg. *See id.*

[48] *See* Gina Kolata, *Scientist Clones Human Embryos, and Creates an Ethical Challenge,*

Nuclear transplantation cloning is a more sophisticated cloning method and involves removing the haploid nucleus from an egg cell and replacing it with the diploid nucleus of a donor somatic cell.[49] Early experiments using this technique in frogs, mice, cattle, and rhesus monkeys were successful when embryonic cells served as the donor cell.[50] Dolly's birth, which resulted from the use of an adult cell nucleus donor, was astonishing proof that "cell differentiation and specialization are reversible" and that a fully differentiated adult cell nucleus could be reprogrammed to produce an entire, viable mammal.[51]

It also seems possible to pair somatic cell nuclear transfer techniques with primordial stem-cell research to produce

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N.Y. TIMES, Oct. 24, 1993, at A1.

[49] *See* NBAC REPORT, *supra* note 1, at 15. Somatic cells contain a diploid nucleus that contains two sets of genes, one set contributed by each parent. *See id.* Germ cells (i.e., egg or sperm cells) contain haploid nuclei, either maternal or paternal in gene composition. *See id.* A fertilized egg then acquires a full diploid complement of chromosomes with genetic contributions from both parents. *See id.* By contrast, nuclear transplantation cloning results in a single genetic parent. *See id.* "The result is an animal that is essentially an identical twin of the donor animal, although the cloned offspring has a small genetic contribution — the mitochondrial genome — from the animal providing the enucleated egg cell." Joan Stephenson, *Threatened Bans on Human Cloning Research Could Hamper Advances*, 277 JAMA 1023, 1023 (1997).

[50] *See* Stephenson, *supra* note 49, at 1023-25.

[51] NBAC REPORT, *supra* note 1, at 16; *see also* Stephenson, *supra* note 49, at 1025. Recognizing that all somatic cells within a given organism contain the same diploid DNA composition, Stephenson explains:

> [U]ntil Dolly, many researchers had speculated that cloning attempts using nuclei from nonembryonic cells might be doomed to failure, because they hypothesized that the developmental pathways from totipotent embryonic stem cells to differentiated liver, brain, or kidney cells were strictly 1-way. They believed that chemical and structural changes in the DNA presumed to take place during differentiation would prevent differentiated cells from switching on genes silent in those cells and switching off or muting the genes responsible for a differentiated cell's distinctive properties.

Id. The Roslin group used a new technique in which the nutrient content of the culture medium used to support the adult donor cells was reduced in order to induce the DNA to enter the quiescent G0 or G1 stages of the cell cycle. *See id.* This caused the DNA activity to more resemble that of germ cells. *See id.* An electric current was used to fuse the donor nucleus with the enucleated egg, creating a cell with its DNA apparently reprogrammed by substances in the egg's cytoplasm. *See id.* The fused cell behaved like a fertilized egg, started to divide, and then developed into an embryo that was subsequently implanted into the surrogate mother for gestation. *See id.* Apparently, the genome of differentiated cells is "malleable enough to permit formerly quiescent genes to be switched on and active genes to be switched off." *Id.* For a more detailed report on the scientific history leading up to the successful cloning of Dolly the sheep and various techniques used in somatic cell nuclear transfer, see NBAC REPORT, *supra* note 1, at 13-38.

"customized" stem cells reflecting the DNA of a particular patient.[52] A physician might want to generate primordial stem cells containing DNA identical to the recipient patient, thereby ensuring that the "therapy would be compatible with, and not be rejected by, the person for whom the therapy is created."[53] To accomplish this, researchers would use somatic cell nuclear transfer technology to "reprogram somatic cell nuclei to generate more undifferentiated primordial stem cells for that patient."[54]

There are many reasons to permit animal cloning research to continue.[55] Cloning technologies may be used to produce groups of genetically identical animals for research purposes, thus eliminating genetic differences that often lead to experimental variation.[56] Cloning research also has the potential to provide a means of expanding the number of livestock with desirable traits such as enhanced meat or milk production.[57] The use of nuclear transfer technology is also apt to bring about major advances in the production of transgenic livestock, resulting in a wide array of medical benefits for humans.[58] The value of molecular and cellular cloning techniques for the treatment of human disease has already been discussed. In addition, adult cell cloning techniques ultimately

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[52] *See West, supra* note 42. West remarked that the "process of using the patient's own cells is similar to current technologies that utilize a patient's own bone marrow, cleansing it of cancer, irradiating the remaining bone marrow in the patient . . . and then giving them a bone marrow transplant of their own bone marrow." *Id.* Some patients have a compatible sibling to serve as a marrow donor, obviating the need for this hazardous procedure, and very few have twins available for this purpose. *See id.*

[53] *Id.*

[54] *Id.*

[55] *See* NBAC REPORT, *supra* note 1, at 24.

[56] *See id.* at 24-25.

[57] *See id.* at 25.

[58] *See West, supra* note 42. Examples of the potential usefulness of transgenic animal initiatives include: (1) Animal models for testing: In order to decrease the time needed to develop human drug therapies, medicines can be tested on laboratory animals genetically manipulated to be susceptible to human diseases; (2) Organ transplantation: To greatly increase the supply of available organs for human transplantation and to minimize the risk that the genetically altered animal organ will be rejected by its recipient, human genes can be transferred into animals that are subsequently cloned for organ donation to human patients; and (3) Production of medicine in animal milk or eggs: Human genes can be transferred into dairy animal or commercial poultry cells that are subsequently used to clone animals capable of producing therapeutic human proteins in their milk or eggs. *See id.* For example, the milk of livestock can be modified through the use of nuclear transfer technology to contain substantial quantities of important therapeutic proteins, such as insulin for treatment of diabetes or factor VIII for hemophilia. *See* NBAC REPORT, *supra* note 1, at 26.

may be helpful in preventing the extinction of endangered species.[59] Furthermore, research on nuclear transfer cloning techniques used to generate targeted gene alterations in laboratory animals has proven invaluable in studying normal gene function and in developing accurate models of human genetic disease.[60] It is also anticipated that ongoing animal cloning research will further scientific knowledge on cell differentiation.[61] Finally, continued research on nuclear transfer procedures should find significant application in the field of assisted reproduction.[62]

Despite the myriad potential benefits of nuclear transfer cloning research in animals, this technology is not without risks and safety concerns, especially when applied to humans. One concern is for the safety of a surviving clone. Due to the accumulation of genetic mutations throughout life, the older the organism, the greater the predisposition to cancer.[63] Thus, a donor somatic cell used for cloning may contain the accumulated mutations acquired during years of cell division, which may possibly lead to a predisposition for cancer, premature aging, or immunological disease in the resulting clone.[64] In addition, the possibility that some instability in genetic

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[59] *See* Robert Winston, *The Promise of Cloning for Human Medicine: Not a Moral Threat but an Exciting Challenge*, 314 BRIT. MED. J. 913, 913 (1997). Are the fictions portrayed in Michael Crichton's *Jurassic Park* closer to reality than anyone now realizes? *See generally* MICHAEL CRICHTON, JURASSIC PARK (1990) (envisioning a grand-scale theme park, populated by previously extinct dinosaurs that were brought to life through advances in cloning technology).

[60] *See* NBAC REPORT, *supra* note 1, at 26-28.

[61] *See id.* at 28-29.

[62] *See id.* at 31.

[63] *See* Stephenson, *supra* note 49, at 1025; *see also* D.J. Galton et al., *Human Cloning: Safety Is the Issue*, NATURE MED., June 1998, at 664. The authors explain this enhanced risk of disease with the use of somatic cell nuclear transfer for reproduction:

> In sexual reproduction, the zygote receives a random assortment of alleles from each parent, and previous somatic mutations of one parent are paired with alleles of the other, thus diluting the load of somatic mutations from each parent. In contrast, when a zygote receives its entire genetic complement from a nucleus derived from an adult tissue, further accumulation of somatic mutations during development may lead to increased risks of genetic abnormalities, especially when previously inactive genes become de-repressed in differentiating embryonic tissues. It would be outrageous to handicap a child from birth with a multitude of somatic mutations from the adult nucleus used for transfer, particularly as there is no possibility of informed consent for the experiment.

Id.

[64] *See supra* note 63 and accompanying text (detailing the possible effect of accumulated genetic mutations in the development of disease in the cloned

imprinting may exist, particularly in cultured cells, could limit the efficiency of somatic cell nuclear transfer.[65] Researchers have learned "that disturbances in imprinting lead to growth abnormalities in mice and are associated with cancer and rare genetic conditions in children."[66] Other safety concerns would apply to human egg donors, recipients of cloned embryos for gestation, and the nonsurviving cloned embryos. The fact that only 1 live birth resulted from 29 implanted embryos, which in themselves resulted from 277 cellular attempts at cloning, attests to the unresolved safety issues applicable to human cloning.[67]

In addition to the Roslin Institute, various other institutions have attempted to clone animals. Researchers at the University of Massachusetts cloned two calves from the skin cells of cow fetuses.[68] Reproductive biologist Neal First of the University of Wisconsin, and

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offspring); *see also* NBAC REPORT, *supra* note 1, at 23 (describing the progressive shortening of the ends of the chromosomes, the telomeres, and other genetic changes observed with cellular aging).

[65] *See id.* Imprinting relates to "the fact that the genes inherited on the chromosomes from the father . . . and those from the mother . . . are not equivalent in their effects on the developing embryo . . . . [C]ertain genes are expressed only when inherited from the father or mother." *Id.*

[66] *Id.*

[67] *See* Wilmut, *supra* note 6, at 74 (reporting the scientific findings of the Roslin Institute's sheep-cloning experiments); *see also* Lori B. Andrews, *Human Cloning: Assessing the Ethical and Legal Quandaries*, CHRON. OF HIGHER EDUC., Feb. 13, 1998, at B4. Many in vitro fertilization clinics currently utilize a procedure called "intracytoplasmic sperm injection," in which a single sperm is injected into an egg. *See id.* This method could easily be adapted to clone humans. *See id.* Although fertility clinics in the United States are free to offer fertility treatments of their own choosing, they are not required to report when children resulting from reproductive technologies have birth defects. *See id.* Several studies have demonstrated that "children born after intracytoplasmic sperm injection . . . were twice as likely to have major congenital abnormalities as were children conceived naturally." *Id.* A report in the January 15, 1998 issue of the *New England Journal of Medicine* also reported a case in which embryos created through in vitro fertilization and implanted in a woman's uterus fused, creating a "chimera" possessing both male and female sex organs at birth. *See id.* (citing Lisa Strain et al., *A True Hermaphrodite Chimera Resulting from Embryo Amalgamation After In Vitro Fertilization*, 338 NEW ENG. J. MED. 166, 166 (1998)).

[68] *See* Carey Goldberg & Gina Kolata, *Scientists Announce Births of Cows Cloned in New Way*, N.Y. TIMES, Jan. 21, 1998, at A14. Doctors James Robl and Steven Stice successfully cloned two calves and subsequently announced that they viewed this achievement as a major step toward commercialization of the technology. *See id.* Both scientists work for Advanced Cell Technology, Inc., a biotechnology start-up company that already has a contract to produce a herd of genetically engineered cattle that can produce human serum albumin. *See id.* The company is also working on cloning pigs and plans to use cloned transgenic cows as donors for neural cells that can be used to treat human disease. *See id.* Although researchers do not know how to reprogram genetic material, an unfertilized egg is capable of this feat. *See id.*

Tanja Dominko of the Oregon Regional Primate Research Center inserted DNA from several species into enucleated cow eggs, and the eggs activated the DNA to produce a clone of the DNA donor.[69] University of Hawaii scientists cloned fifty mice from adult cells, nearly duplicating the process used at the Roslin Institute.[70] Japanese scientists reported in 1998 that "they . . . cloned eight calves from cells they gathered from a slaughterhouse, creating eight identical copies of a single cow."[71] Cloning of cows follows the cloning of a lamb and mice as the third such recorded milestone involving adult mammals, and the science behind these feats may prove "at least as efficient as in vitro fertilization."[72] With animal cloning research advancing at such a rapid pace, the focus on regulation of this technology is only apt to intensify.

II. ETHICAL CONSIDERATIONS

Apart from the safety concerns, human cloning raises a number of moral concerns, especially relating to the potential psychological harm to children.[73] Well-articulated arguments have stressed that the cloning of humans would be associated with a "diminished sense of individuality and personal autonomy" and would have a detrimental effect on the quality of family life and parenting.[74] Eugenic concerns and fears that human cloning would lead to the objectification or commodification of children are two additional ethical issues that need to be addressed.[75] Weighing against these arguments are

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[69] *See* Andrews, *supra* note 67, at B4. This discovery "raises the theoretical possibility that cow eggs could be used as a universal incubator for any adult mammal's cell" and that women could then possibly avoid the risks associated with egg donation. *Id.*

[70] *See Mice Clones Prove 'Dolly' was no Fluke*, MED. INDUST. TODAY, July 24, 1998. Ryuzo Yanagimachi and Teruhiko Wakayama announced that the process demonstrates that cloning can become routine and could perhaps also be used to grow vats of skin or other organs for transplantation. *See id.*; *see also* Gina Kolata, *A Tale of (Cloned) Mice and Men*, INT'L HERALD TRIB., July 25, 1998, at 4.

[71] *See* Kolata, *supra* note 47, at A8.

[72] *Id.*

[73] Dena S. Davis, *What's Wrong with Cloning?*, 38 JURIMETRICS J. 83, 83 (1997).

[74] *Id.*

[75] *See* NBAC REPORT, *supra* note 1, at 69-72. Regarding eugenics concerns, the NBAC Report goes on to say:

> [W]hat is at issue in eugenics is more than an individual act, it is a collective program. Individual acts may be undertaken for singular and often unknown or even unknowable reasons, whereas a eugenics program would propagate dogma about the sorts of people who are desirable and those who are dispensable. That is a path humanity has trodden before, to its everlasting shame. And it is a path to whose return the science of cloning should never be allowed to give even the

considerations of privacy, personal choice regarding procreation and child rearing, and the freedom of scientific inquiry.[76]

Cloning, if available as a means of reproduction, would most likely be pursued by couples who are unable to conceive a child because of infertility, or by couples who carry a high risk of inheritable genetic disease.[77] Cloning under these circumstances is morally less controversial and less likely to pose significant psychological harm to the child.[78] This is not to say, however, that cloning a parent in these situations would be without challenges. How would a wife, for example, react to a younger "copy" of her husband?[79] How would a parent react to living with a clone of himself

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slightest support.

Id. at 72.

[76] *See* Harold T. Shapiro, *Ethical and Policy Issues of Human Cloning*, SCIENCE, July 11, 1997, at 195. Constitutional principles that conflict with a ban on cloning include "the right of adults to have children and the right of scientists to investigate nature." Mark D. Eibert, *Clone Wars; Laws on Human Cloning*, REASON, June 1998, at 52. The United States Supreme Court has opined "that every American has a constitutional right to 'bear or beget' children . . . [including] the right of infertile people to use sophisticated medical technologies like in vitro fertilization." *Id.* Once human cloning is perfected, infertile couples could use any somatic cell to conceive children, thereby offering many couples the only possible avenue to assert their constitutional right to procreate. *See id.* Arguably, cloning bans would have the practical effect of forced sterilization. *See id.* Other commentators have asserted similar positions. *See generally* Lori B. Andrews, *Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning*, 11 HARV. J.L. & TECH. 643 (1998) (providing an in-depth analysis on the constitutional issues involved with cloning restrictions); Gina Kolata, *Human-Cloning Debate Growing Far Less Shrill, Opposition Remains, but Benefits Are Discussed*, DALLAS MORNING NEWS, Dec. 7, 1997, at A10. Kolata notes that "it is an American tradition to allow people the freedom to reproduce in any way they like." *Id.*; *see also infra* note 149 (discussing judicial decisions addressing the constitutionally protected right of procreation).

[77] *See* Robertson, *supra* note 13, at 119. Infertile couples suffering from gametic insufficiency might elect to clone one of themselves rather than to rely on an anonymous donation of sperm, egg, or embryo. *See id.* "[T]here is nothing inherently wrong in wishing to be biologically related to one's children, even when this goal cannot be achieved through sexual reproduction." *Id.* Couples at high risk of having children with genetic disease

> must now choose whether to risk the birth of an affected child, to undergo prenatal or preimplantation diagnosis and abortion or the discarding of embryos, to accept gamete donation, to seek adoption, or to remain childless. If cloning were available, however, some couples . . . might strongly prefer to clone one of themselves or another family member. Alternatively, if they already had a healthy child, they might choose to use cloning to create a later-born twin of that child.

Id; *see also* Kolata, *supra* note 76, at A10 (quoting Dr. Steen Willadsen, cloning pioneer and infertility expert from St. Barnabas Hospital, New Jersey, as stating, "cloning may be bad but telling people how they should reproduce is worse").

[78] *See* Davis, *supra* note 73, at 85.

[79] *See* Wilmut, *supra* note 6, at 74.

and what would that parent's understanding and expectations of his cloned offspring be?[80] How would a cloned child cope with a full awareness of his physical future?[81]

Other reproductive motives are significantly more controversial. For example, parents may seek to replace a child who died young,[82] or is terminally ill,[83] by using cells from the deceased or dying child to create a new embryo. Psychological problems may later manifest themselves in the child if the parents' motivations were founded on a mistaken belief of "the importance of genetics over environment."[84] Parental frustrations are likely when the child fails to live up to the expectations established by the deceased sibling.[85] The grieving parents in these circumstances may not seek a new baby, but rather the return of the deceased child.[86]

Another motivation for human cloning that is sure to generate ethical debate is the creation of clones for the purpose of donating organs or tissues to seriously ill family members.[87] Although there may be no reason to fear that such clones would be exploited to any greater degree than when existing offspring donate organs or tissues to their siblings, a level of discomfort arises when children are

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[80] *See id.*

[81] *See id.*

[82] *See* Davis, *supra* note 73, at 86.

[83] *See* Kolata, *supra* note 76, at A10.

[84] Davis, *supra* note 73, at 86.

[85] *See id.* Health care professionals should refuse to comply with the couple's wishes in these situations, especially if the couple is able to reproduce in other ways. *See id. But see* Kolata, *supra* note 11, at A1. Kolata acknowledges that in certain specialized situations, such as when grieving parents wish to reproduce a terminally ill child, scientists and infertility experts question whether it is worse to clone a parent or to procure an embryo "made-to-order" with donated sperm or egg, as is currently an option at fertility clinics. *See id.* A couple without eggs or sperm might want to contemplate cloning both wife and husband. *See id.*

[86] *See* Wilmut, *supra* note 6, at 74. The issue, however, becomes less clear when the lost child is very young because fewer expectations would be placed on the cloned replica. *See id.* The difficulty in crafting legislation banning the cloning of older children and adults while permitting the cloning of infants is self-evident. *See id.*

[87] *See* Davis, *supra* note 73, at 86. The NBAC Report describes a scenario in which the clinic is utilized for "spare parts" as follows:

> The parents of a terminally ill child are told that only a bone marrow transplant can save the child's life. With no other donor available, the parents attempt to clone a human being from the cells of the dying child. If successful, the new child will be a perfect match for bone marrow transplant, and can be used as a donor without significant risk or discomfort. The net result: two healthy children, loved by their parents, who happen to be identical twins of different ages.

Id.

intentionally created for purposes of donation, instead of being a desired end in and of themselves.[88]

Cloning also has been proposed as a method available to parents for the selection of particular physical characteristics in an effort to produce the "child of their dreams."[89] Attempts to clone a film star, athlete, or scientist, based on parental interests, ignore the fact that personality is not based solely on genetics.[90] Family conflict would likely arise if the cloned offspring did not live up to the lofty expectations of the parents.[91] Cloning with these intentions in mind "violates what philosopher Joel Feinberg calls 'the child's right to an open future,' because it violates the child's nascent autonomy and narrows the scope of her choices when she grows up."[92]

A further concern expressed when evaluating the ethical implications of cloning technology is that cloning leads to commodification — "treating persons . . . as . . . thing[s] that can be exchanged, bought, or sold in the marketplace."[93] Parents motivated to produce a specific child, and no other, may inadvertently impose this burden on their child, who subsequently is perceived as a consumer product.[94] On the other hand, parents who avail themselves of cloning technology simply because they want a child who is biologically related to one of them are no more likely to

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[88] *See id.* at 86-87. It may not be ethically problematic if a cloned child is created partially for the reason of organ or tissue donation because parents elect to bear children for a variety of reasons, including, for example, to preclude the first born from being an only child. *See id.* Eventually, it may be possible to obtain compatible organs or tissues for transplantation by "cloning the source DNA only to the point at which stem cells or other material might be obtained for transplantation, thus avoiding the need to bring a child into the world for the sake of obtaining tissue." Robertson, *supra* note 13, at 119.

[89] *See* Wilmut, *supra* note 6, at 74.

[90] *See id.*

[91] *See id.* "Every child should be wanted for itself, as an individual." *Id.* The need to consider the child's interest outweighs the rights of individuals to procreate in ways that they choose. *See id.* Wilmut specifically rejects this proposed cloning use. *See id.*

[92] Davis, *supra* note 73, at 87. It is true that parents often try to influence the life choices of their children; permitting child cloning to achieve these goals, however, elevates this concern to a new level. *See id.* The child's opportunity to pursue his own interests and options may thus be severely limited. *See id.* at 88.

[93] *Id.* (quoting NBAC REPORT, *supra* note 1, at 73) (internal quotations omitted).

[94] *See id.* at 88-89. Ethicists have opined that enabling parents to uncover major genetic disorders prenatally, with the option of abortion, may lead down a slippery slope to testing for minor physical abnormalities and eventually to allowing parents to select for specific desired characteristics, such as sex, intelligence, and physical attributes. *See id.* at 88.

commodify their child than are other parents.[95]

The widespread availability of human cloning techniques further expands the reproductive opportunities in nontraditional family settings. Single parents, or partners in a homosexual relationship, may elect self-cloning as a means to create an offspring who shares their genome.[96] Public debate on these issues would likely be significant and extensive.

The legal or social status of a child created through somatic cell nuclear transfer remains uncertain. Problems that theoretically could result include familial instability, ambiguity over parental roles, and self-identity problems for the child.[97] For example, would the cloned child be considered the sibling or the child of the parents, and what would the cloned child's status in relation to its "grandparents" be?[98] One can only imagine the added confusion when attempting to apply the various parentage acts to legal disputes involving cloned individuals.

Interestingly, religious perspectives regarding the morality of human cloning are not uniform.[99] Although religious convictions often provide a significant impetus to limit expansion in human knowledge, individual theological views on cloning vary.[100] As with the introduction of any new reproductive technology, the possibility of human cloning has catapulted the issues of procreative freedom and the right to life into the public forum.[101] In any event,

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[95] *See id.* at 89.

[96] *See* Wilmut, *supra* note 6, at 74.

[97] *See* NBAC REPORT, *supra* note 1, at 66.

[98] *See id.*

[99] *See* Shapiro, *supra* note 76, at 195. Shapiro, citing the NBAC Report, stated:

> Some religious thinkers argue that the use of . . . cloning to create a child would be intrinsically immoral and thus could never be morally justified. Other religious thinkers contend that human cloning to create a child could be morally justified under some circumstances but believe that it should be strictly regulated to prevent abuses.

Id.

[100] *See* Eibert, *supra* note 76, at 52. "Two leading rabbis and a Muslim scholar who testified before the National Bioethics Advisory Commission had no objection to the practice and even advanced religious arguments for cloning." *Id.* By contrast, politicians have proferred religious arguments against cloning in a bipartisan fashion, and a theologian representing the National Conference of Catholic Bishops announced to the President's Commission that "[c]loning exceeds the limits of the delegated dominions given to the human race." *Id.*

[101] *See, e.g.*, Robert J. White, *Human Cloning Research*, 388 NEW ENG. J. MED. 1170, 1170 (1998). White writes that "there are many of us who believe that a human being is formed at the time of conception . . . [and] the cloned embryo would be a human being entitled, in spite of its microscopic size, to the same rights and respect granted the fully formed child." *Id.*; *see also* Maurizio Soldini, Correspondence,

government restriction or prohibition on human cloning, based purely on religious grounds, would likely violate the Establishment Clause.[102]

Much concern has been expressed over the potential psychological risks faced by a cloned child created through somatic cell nuclear transfer procedures.[103] The "later-born twin" would be genetically identical to the original somatic cell donor, and therefore the donor and clone would be far more similar physically than would a natural parent and child.[104] These realities could "undermine human dignity by threatening the later child's sense of self and sense of autonomy."[105] Human personality, however, is derived from both genetic and environmental factors, and thus, analogous to the situation seen with naturally occurring twins, two clones would be expected to develop different personalities.[106] The argument may boil down to the question of whether cloned offspring would be better off having never been born at all.[107]

Finally, because certain applications of human cloning technology are likely to be injurious to the cloned offspring, cloning attempts should proceed only with extreme caution.[108] Some cloning scenarios may be morally and ethically justified, thus counseling against a total ban on human cloning.[109] The temporary ban on human cloning endeavors recommended by the NBAC appears well-founded and should provide breathing room for all interested and qualified parties to debate these issues and to establish reasonable guidelines for future use of human cloning technology.[110]

III. LEGISLATIVE RESPONSES TO HUMAN CLONING

Aside from the possibility of FDA authority over human cloning

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Human Cloning Research, 388 NEW ENG. J. MED. 1170, 1170 (1998) (asserting that, from the zygote stage, the embryo is a person, and, thus, experiments on human embryonic cells is immoral and human cloning should be permanently banned).

[102] *See* Eibert, *supra* note 76, at 52.

[103] *See* Andrews, *supra* note 67, at B4.

[104] *See* Wilmut, *supra* note 6, at 74.

[105] Andrews, *supra* note 67, at B4.

[106] *See* Wilmut, *supra* note 6, at 74. Genetics expert Dorothy Wertz believes "[t]he notion that cloning is an 'affront to human dignity' and individuality is based on the erroneous notion that clones would in fact be identical because of identical genes. 'We are not our genes' but subject to many environmental influences." Saltus, *supra* note 12, at A6.

[107] *See* Eibert, *supra* note 76, at 52.

[108] *See* Davis, *supra* note 73, at 89.

[109] *See id.*

[110] *See id.*

regulation, there is at present no federal legal mechanism that prohibits attempts to clone human beings despite widespread sentiment against the practice.[111] Although sponsors have introduced several congressional bills to ban human cloning, no such bill has been successfully enacted.[112] Presently, only two states, California and Michigan, have enacted legislation to ban human cloning.[113]

Republican bills in the United States Senate would ban the use of human somatic cell nuclear transfer procedures.[114] Individuals and entities convicted of violating any provision of the proposed act

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

[112] *See id.* Although it followed up on the recommendations of the NBAC Report, President Clinton's proposal, the Cloning Prohibition Act of 1997, found no support and died. *See id.* Several congressional proposals followed Richard Seed's stunning announcements of his intent to actually clone humans. *See id.* Senate bill 1599, 105th Cong. (1998) was initially sponsored by Senator Christopher S. Bond and was later introduced in its entirety as the Human Cloning Prohibition Act by Majority Leader Senator Trent Lott. *See* Greely, *supra* note 33, at 140 (discussing S. 1601, 105th Cong. (1998)). The Human Cloning Prohibition Act was introduced on February 3, 1998 by Senators Trent Lott (R-Miss.), Christopher Bond (R-Mo.), and Bill Frist (R-Tenn.). *See id.* This bill, which was supported by both the Christian Coalition and the National Right to Life Committee, would have banned both embryo and adult cloning. *See id.* However, bypassing the normal committee proceedings as an emergency measure, the bill failed, receiving only 42 of the required 60 votes to pass. *See id.* This was due in large part to lobbying by patient advocacy groups and the scientific community. *See id.* Senators Dianne Feinstein (D-Calif.) and Edward M. Kennedy (D-Mass.) introduced rival bills that would prohibit human cloning but allow research on the cloning of human embryos. *See id.* (citing S. 1602, 105th Cong. (1998) and S. 1611, 105th Cong. (1998)). No further action was taken on these bills after its referral to the Senate Labor and Human Resources Committee. *See id.* Although more acceptable to the scientific community, the Democratic bills met strong resistance from the right-to-life groups because the bills would prohibit any cloned embryos from being implanted, thereby necessitating their destruction. *See* Price, *supra* note 28, at 627. Vernon Ehlers (R-Mich.) is the only member of the House of Representatives to introduce anti-cloning bills. *See* Lisa Seachrist, *Armey Wants Cloning Bill on Floor by Memorial Day*, BIOWORLD TODAY, Apr. 29, 1998. These Democratic House bills, H.R. 922, 105th Cong. (1997) and H.R. 923, 105th Cong. (1997), would prohibit federal funding for human embryo cloning research and human cloning. *See id.* Representative Ehler's embryo cloning bills subsequently stalled in the House Commerce Committee. *See* Daniel, *supra* note 111, at A8.

[113] *See* Saltus, *supra* note 12, at A6.

[114] S. 1601, 105th Cong., § 301(d) (1998). A human somatic cell nuclear transfer is 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 preimplantation embryo)." *Id.* The bill specifically states, "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." *Id.* § 301(a).

would be subject to both civil and criminal penalties.[115] The blanket ban on somatic cell nuclear transfer for any purpose that these bills would impose ventures beyond the NBAC Report's recommendation to prohibit use of the procedure only for creating a human being.[116] The act would effectively eliminate all research involving human cloning, including potential beneficial applications,[117] such as stem-cell therapies.[118]

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[115] *See id.* § 301(c). Penalties are delineated in the act as follows:

> (1) In General – Any person or entity who is convicted of violating any provision of this section shall be fined according to the provisions of this title or sentenced to up to 10 years in prison, or both.
>
> (2) Civil Penalty – Any person or entity who is convicted of violating any provision of this section shall be subject to, in the case of a violation that involves the derivation of a pecuniary gain, a civil penalty of not more than an amount equal to the amount of the gross gain multiplied by 2.

Id. The bill could impose a ten-year prison sentence on anyone using this technology to produce an embryo, even if limited to the laboratory. *See* Eibert, *supra* note 76, at 52.

[116] *See* Silberner, *supra* note 10, at 5.

[117] *See* Eibert, *supra* note 76, at 52.

[118] *See West, supra* notes 42, 43 and accompanying text (discussing how stem-cell therapy applications could possibly revolutionize health care). It is clear that the Republican bills would criminalize "customized" stem-cell treatments and may very well also outlaw some noncustomized stem-cell research. *See id.* West testified: "[I]t would be tragic to ban research which is just beginning and holds such promise to relieve human suffering . . . . [W]e have every reason to believe that the research will provide novel and effective treatments for diseases where there is no current therapy available or current therapies are ineffective." *Id.* The bills prohibit research if it could possibly be related to creating a human by cloning, even if the research is not conducted for that purpose. *See id.* Greely notes that "an early embryonic cell might have daughter cells some of which would become germ cells and other somatic cells." Greely, *supra* note 33, at 140. Because the Bond/Lott bills do not define the term "somatic cell," and it is not clear at what stage in germ cell development these embryonic cells should be considered germ cells instead of somatic cells, the legislative prohibitions could be circumvented if these diploid embryonic cells are considered germ cells instead of somatic cells. *See id.* Alternatively, the ban may be applied to cases in which the cell nucleus used in primordial stem-cell research is the combination of the DNA of an egg and a sperm. *See West, supra* note 42. In this case, obviously not cloning, the transferred DNA is not identical to that of an existing human being (diploid somatic cells); the bill could then be interpreted to prohibit noncustomized primordial stem-cell research as well. *See id.* For the first time in our history, legislation proposes to ban technology, rather than outcome. *See id.* Considering the criminal penalties for violations, the ambiguities in the bill may indeed have a chilling effect on primordial stem-cell research. *See id.*; *see also* 144 CONG. REC. S425 (daily ed. Feb. 5, 1998) (statement of the BIO). The BIO stated that "the current bill 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." *Id.* Despite the potential chilling effect on biomedical research, right-to-life groups support the bills as written, believing that the cited technology creates an embryo that is entitled to life. *See* Price, *supra* note

The scientific community overwhelmingly believes that any legislative action should be limited to the cloning of human beings, should not include language that impedes important ongoing or potential new research, and should clearly recognize the distinction between the cloning of an entire human being and the healing potential that is derived from biomedical research.[119] Scientific organizations generally do not support the cloning of human beings, but do oppose overly broad legislation that goes beyond this narrow issue and threatens biomedical research that is vital to the discovery of cures for deadly and debilitating diseases.[120] Pro-life groups, on the other hand, support legislation such as that presented by Republicans in Senate Bill 1601 because these groups believe that human life begins with a fertilized egg, and that any cloning research resulting in a fertilized egg should be banned, regardless of any later intent to implant the egg and to carry a child to term.[121]

Democratic Senators Diane Feinstein of California and Edward Kennedy of Massachusetts have since proposed legislative alternatives to the Republican initiatives.[122] These Democratic bills would make it unlawful for any entity to "implant the product of somatic cell

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28, at 625-26.

[119] *See West, supra* note 42 (citing support for the BIO's position from more than 50 scientific, medical, and patient advocacy groups, as well as from 27 Nobel prize-winning researchers).

[120] *See id.*; *see also* 144 CONG. REC. S427 (daily ed. Feb. 5, 1998) (statement of the American Society for Reproductive Medicine (ASRM) offered into record by Senator 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." *Id.*

[121] *See* Jennifer Cannon & Michelle Haas, *The Human Cloning Prohibition Act: Did Congress Go Too Far?*, 35 HARV. J. ON LEGIS. 637, 642 (1998). By contrast, opponents of the Republican bill believe that life does not begin until after the fertilized egg is implanted in a viable uterus, and thus would permit research that generates fertilized eggs so long as they are not implanted. *See id.*; *see also Senate Vote Fails to Move Cloning Ban Through Congress*, MED. INDUS. TODAY, Feb. 12, 1998 (quoting Boston University Bioethicist George Annas as stating, "Anything related to embryos or abortions is a big problem for Congress"). Congress may also be deadlocked on the issue of cloning legislation "until Congress or the Court decides when life actually begins." *Id.*

[122] *See* S. 1602; S. 1611; *see also* Eibert, *supra* note 76, at 52. S. 1602 would ban human cloning for 10 years but allow limited laboratory experiments in this area so long as any resulting human embryos are destroyed early in development, not implanted in utero, and not allowed to be born. *See id.* A one-million dollar fine would be imposed for violations, along with confiscation of all real and personal property connected with the research. *See id.* These civil penalties would apply to prospective parents accessing this technology to procreate, as well as to the researchers involved. *See id.*

nuclear transfer into a woman's uterus."[123] This approach focuses on the banning of cloning technology for the purpose of cloning a human being, but allows the technology to be used for biomedical research.[124] In fact, the proposals contain an express biomedical research "savings clause" that allows the use of somatic cell nuclear transfer techniques to clone DNA, molecules, cells, and tissues.[125] The Democratic alternatives also contain a ten-year sunset provision requiring a reevaluation of the legislation and a subsequent recommendation of the NBAC concerning the advisability of a continued ban.[126] Although heavy civil fines would be imposed for violations of the Democratic legislation, unlike the Republican

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[123] *West, supra* note 42 (discussing S. 1602); The Prohibition of Cloning of Human Beings Act states, in pertinent part:

> (a) Definitions: . . . somatic cell nuclear transfer – the term "somatic cell nuclear transfer" means transferring the nucleus of a somatic cell of an existing or deceased human child or adult into an oocyte from which the nucleus or all chromosomes have been or will be removed or rendered inert.
>
> (b) Prohibitions: It shall be unlawful for any person or other legal entity, public or private . . . to implant or attempt to implant the product of somatic cell nuclear transfer into a woman's uterus . . . .

S. 1611. The bill defines the term "somatic cell" as a mature diploid cell. *See* Greely, *supra* note 33, at 141 (citing S. 1602 at 498(c)(a)(4) (1998)). Greely also discusses the theoretical loopholes emanating from the bill's reference to the terms "somatic cell," "mature," and "diploid," and in particular, the confusion possibly created when various congenital chromosomal aberrations are present. *See id.* at 141-42. Interestingly, human somatic cell nuclear transfer procedures using fetal or embryonic donors are not addressed in the proposed bill. *See id.* at 144-45. The Feinstein bill, supported by the ASRM, thus allows the continuation of some human cloning by infertility specialists, who see value in the transfer of an embryo nucleus to an enucleated egg with cytoplasm more capable of sustaining healthy embryonic development. *See id.* at 145. Other reproductive specialists use embryo splitting, a cloning procedure, to increase the number of embryos available for implantation. *See id.* Also, should science progress to the point of developing artificial wombs, the bill might then be circumvented because implantation would not be "into a woman's uterus." *See* Price, *supra* note 28, at 633. Japanese scientists have been able to maintain a viable extrauterine goat fetus for up to three weeks in an "extrauterine fetal incubation device." *See id.* (discussing *Artificial Womb Can Sustain Goat Fetus for up to 3 Weeks*, CHI. TRIB., July 20, 1997, at C8 and Perri Klass, *The Artificial Womb Is Born*, N.Y. TIMES, Sept. 29, 1996, at 117).

[124] *See West, supra* note 42.

[125] *See id.* S. 1611 provides, in relevant part:

> (c) Protected Research and Practices: Nothing in this section shall be construed to restrict areas of biomedical and agricultural research or practices 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 . . . .

S. 1611.

[126] *See id.* § 498C(d).

proposals, there would be no criminal penalties.[127] In addition, the Democratic bills include a clause, supported by the scientific community, that calls for preemption of inconsistent state laws.[128]

The Feinstein-Kennedy proposal may be acceptable to the scientific community because it does not create a chilling effect on crucial biomedical research and because it does not ban the use of somatic cell nuclear transfer technology that falls short of uterine implantation.[129] However, the bill will not satisfy the pro-life constituency, which favors the Republican legislative versions, because the bill does not protect embryos as human life.[130]

On March 5, 1997, Republican Representative Vernon Ehlers introduced two bills in the United States House of Representatives, which provide that no federal funds may be used to conduct or to support any "research that involves the use of a human somatic cell for the process of producing a human clone."[131] These proposals would also permanently outlaw cloning for the purposes of reproduction as well as any biomedical research leading to this goal.[132] Somatic cell nuclear transfer techniques would be banned even if these procedures are required for the generation of primordial stem cells used to treat human disease, notwithstanding the fact that there may be no intent to generate a human embryo for uterine implantation and gestation.[133] Although Ehler's bills would outlaw "customized" stem-cell research that utilizes somatic cell

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[127] *See id.* § 498C(e). The bill specifically states that "[a]ny person who intentionally violates the provisions of subsection (b) shall be fined the greater of $1,000,000 or 3 times the gross pecuniary gain or loss resulting from the violation." *Id.*

[128] *See West, supra* note 42. The NBAC supported state-law preemption to ensure comprehensive coverage of the issue, clarity, and interstate uniformity. *See id.* Well-drafted federal legislation would displace ongoing, variable, and sometimes ambiguous or poorly drafted state legislative efforts that may have an adverse impact on important biomedical research. *See id.*

[129] *See* Cannon & Haas, *supra* note 121, at 645; *see also* Price, *supra* note 28, at 627 (noting the opposition to the Democratic bills by the pro-life community, which has referred to the bills as "clone and kill" bills).

[130] *See* Cannon & Haas, *supra* note 121, at 645.

[131] NBAC REPORT, *supra* note 1, at F-24 (citing H.R. 922 and H.R. 923). As initially introduced, H.R. 923 carried a $5,000 civil penalty for violations of the Act. Considering the total research cost and financial incentives associated with successful cloning endeavors, however, these bills may provide little deterrence for such activity. *See id.*

[132] *See* Meredith Wadman, *Republicans Seek to Widen Cloning Ban*, NATURE, July 1998, at 6; *see also West, supra* note 42. Representative Ehler's bill, H.R. 922, would make the creation of "a zygote through the use of . . . somatic cell nuclear transfer" a crime carrying a ten-year prison sentence. *Id.*

[133] *See West, supra* note 42.

nuclear transfer technology, the bills would not ban stem-cell research that is not customized.[134]

On the state level, California enacted the California Cloning Act, effective January 1, 1998, thus becoming the first state to outlaw cloning.[135] Because the California legislation broadly describes cloning "as creating children by the transfer of nuclei from any type of cell to enucleated eggs," the legislation would also ban innovative new infertility treatments that are unrelated to cloning.[136] The California statute initially limits the ban on human cloning to five years.[137] Although dozens of other state legislatures have introduced their own versions of anti-cloning bills, Michigan is the only state thus far to follow California's lead by enacting such legislation.[138]

The current federal legislative stalemate over human cloning prohibitions exemplifies the virtually impossible task of devising statutory language acceptable to both the scientific community and

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[134] *See id.* West specifically states:

> The Ehlers/Science Committee bill does clearly imply that the DNA used in the somatic cell nuclear transfer be identical to that of an existing or previously existing human being, so the only type of primordial stem cell research funding it seeks to ban would be that which seeks to create "customized" primordial stem cells.

Id.; *see also supra* notes 52-54 and accompanying text (discussing application of "customized" primordial stem-cell technology).

[135] *See* Eibert, *supra* note 76, at 52.

[136] *Id.* These new infertility procedures transfer nuclei from older, dysfunctional eggs to younger and healthier enucleated eggs. *See id.* These eggs are then fertilized with the husband's sperm, ultimately resulting in a child with genetic contributions from both parents. *See id.* By contrast, cloning uses donor nuclei from differentiated, diploid, adult cells. *See id.*

[137] *See* Daniel, *supra* note 111, at A8. Recent technological advances may make the California bill obsolete. *See id.* Because the bill prohibits transferring a human donor nucleus into an enucleated human egg cell, the use of enucleated cow egg cells as incubators for human somatic cell nuclei would not be forbidden under California law. *See id.*; *see also* Andrews, *supra* note 67, at B4 and accompanying text (discussing cloning research using enucleated cow eggs as a "universal incubator" for the nuclei of other mammals). For a more detailed analysis of the California Cloning Act, see generally Abel, *supra* note 4.

[138] *See* Saltus, *supra* note 12, at A6. The Michigan ban encompasses the idea of a person grown from a single somatic cell when the new individual is genetically identical to its parent. *See* Greely, *supra* note 33, at 139. Language in the New Jersey-proposed legislation bans human cloning, which is defined as "the replication of a human individual by cultivating a cell with genetic material through the egg, embryo, fetal and newborn stages into a new human individual." A.B. 329, 208th Leg., Reg. Sess. (N.J. 1998); *see also* Greely, *supra* note 33, at 142-43 (discussing the inherent ambiguities created in the New Jersey bill through use of the terms "cultivating" and "replication of a human individual," and demonstrating how the language could apply to the traditional method of human reproduction).

the pro-life constituency.[139] The biotechnology industry, believing that the FDA has clear authority over human cloning attempts, asserts that there is no need to enact legislation in this area.[140] On the other hand, right-to-life organizations would likely prefer the issue to be debated publicly and resolved through the political process, which may allow these organizations to wield more influence.[141]

In February 1998, the FDA, based on safety and efficacy concerns, announced that it had authority to regulate human cloning under its biologics regulations, which deal primarily with human gene therapy and techniques that involve the "material manipulation of human cells that are then reinserted for medical purposes."[142] These regulations and their commentary do not discuss human reproduction, and the FDA had not previously claimed authority over other human reproductive technologies.[143] On October 26, 1998, in a "Dear Colleague" letter issued by Associate Commissioner Stuart L. Nightingale, M.D., the FDA reaffirmed its authority under the PHSA and FFDCA to regulate clinical cloning research for the creation of human beings.[144] According to Nightingale, any such attempts at human cloning would require submission of an IND application and IRB oversight.[145] Support for FDA regulatory authority over human

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[139] *See* Price, *supra* note 28, at 627.

[140] *See West*, *supra* note 42.

[141] *See* Price, *supra* note 28, at 628.

[142] Greely, *supra* note 33, at 151. Following both Richard Seed's daring assertions of his ability and intention to clone humans and DHHS Secretary Shalala's public response, the BIO sent Secretary Shalala a letter opining that the FDA had authority to regulate human cloning as a biological product. *See* Price, *supra* note 28, at 624. Four days after receiving the BIO's correspondence, acting FDA Commissioner Friedman announced the FDA's agreement with the BIO's position. *See id.* at 625. Although the FDA did not issue a formal statement on how it would regulate, Freidman stated that human cloning was a "kind of cellular genetic therapy" requiring FDA approval under the FFDCA. *FDA Asserts Human Cloning Authority*, *supra* note 25, at 29A2.

[143] *See* Greely, *supra* note 33, at 151.

[144] *See* Nightingale, *supra* note 21.

[145] *See id.* In general, the medical and scientific communities support FDA jurisdiction over human cloning. *See* Stolberg, *supra* note 25, at A14. The BIO and the Pharmaceutical Research and Manufacturers Association of America believe that the FDA, rather than Congress, is the proper forum for controlling human cloning and that the FDA has the scientific expertise to assess the procedure. *See id.*; *see also* Janet Firshein, *U.S. Medical Institutions Seek Voluntary Ban on Human Cloning*, LANCET, Feb. 14, 1998, at 508 (opposing legislative attempts to ban human cloning, the Association of American Medical Colleges supported FDA regulation of human cloning); *Senate Vote Fails to Move Cloning Ban Through Congress*, MED. INDUS. TODAY, Feb. 12, 1998 (noting the American Society of Reproductive Medicine position, which supports FDA assertion of jurisdiction over cloning); 144 CONG. REC. S. 606 (daily ed. Feb. 11, 1998) (statement of Senator Durbin espousing caution on

cloning is less certain outside of the scientific community.[146] Serious questions remain regarding whether the FDA does indeed possess the requisite jurisdiction to regulate the practice of human cloning.[147]

IV. BASIS FOR FDA AUTHORITY TO REGULATE HUMAN CLONING TECHNOLOGY

A. *Commerce Clause Analysis*

The FDA's assertion of jurisdiction over human cloning is sure to elicit various constitutional challenges, such as the violation of the freedom of scientific inquiry under the First Amendment[148] and the

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proceeding with legislative initiatives to ban cloning because the FDA asserted jurisdiction in this area). *But see National Bioethics Advisory Commission Members Suggest Regulation of Cloning Research Through Standing Body, Structure Could Be Modeled on NIH's RAC*, HEALTH NEWS DAILY, Mar. 18, 1997, at 5 (citing benefits of an FDA-like regulatory structure, similar to the NIH's Recombinant DNA Advisory Committee, to oversee research involving human cloning experiments).

[146] *See* Price, *supra* note 28, at 628. Right-to-life groups have been silent since the FDA's declaration of cloning jurisdiction. *See id.*; *see also Armey Rejects FDA Regulation of Human Cloning* (Jan. 20, 1998) (visited Jan. 7, 2000) <http://freedom.house.gov/library/technology/pr980120.asp> (homepage of the office of the House majority leader). In response to the FDA's assertion of authority over cloning, House Majority Leader Dick Armey responded: "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 a process of creating life, is morally obtuse." *Id.*; *see also* 144 CONG. REC. S432 (daily ed. Feb. 5, 1998) (statement of Senator Gregg opposing agency regulation of cloning, including the FDA, because of the cultural and scientific importance of this issue).

[147] *See* Caroline Daniel, *The Law's Lagging Behind Cloning, Research is Full Speed Ahead, but Bills to Curb It Languish*, NEWSDAY (New York), Aug. 4, 1998, at C3 (noting that the FDA has not invoked regulatory authority over other novel fertility treatments). Daniel also quotes University of Virginia Law School professor Richard Merrill as stating that "[t]he FDA is not supposed to regulate the practice of medicine." *Id.* Considering that the FDA does not regulate in vitro fertilization and other more aggressive fertility procedures (all of which involve manipulation of cells), the FDA may have difficulty justifying its assertion of authority over cloning technologies as involving more than minimal manipulation of cells. *See id.*; *see also* F.D.C. Reports, 60 "The Pink Sheet" No. 32, Aug. 10, 1998 at 3 (referencing an inquiry put to FDA Commissioner nominee Henney asking which section of the FFDCA conveys authority on the FDA to regulate cloning and whether drug, device, or biologics rules would apply).

[148] *See* NBAC REPORT, *supra* note 1, at F-6-7. "If the First Amendment [right to free speech] protects a marketplace of ideas, it seems likely that it would protect the generation of information that would be included in that marketplace." *Id.* at F-7. At least one federal district court, in dicta, has suggested that "scholars have a 'right . . . to do research and advance the state of man's knowledge.'" *Id.* (discussing Henley v. Wise, 303 F. Supp. 62 (N.D. Ind. 1969)). By contrast, other federal courts have not recognized a First Amendment right of scientific inquiry. *See id.* (discussing Margaret S. v. Edwards, 488 F. Supp. 181 (E.D. La. 1990); Margaret S. v. Treen, 597

violation of a couple's right of privacy or liberty interest in making procreative decisions.[149] A further constitutional challenge to FDA authority over cloning might be based on a lack of authority under the Commerce Clause.[150]

The Commerce Clause of the United States Constitution empowers Congress "to regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes."[151] The

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F. Supp. 636 (E.D. La. 1984), *aff'd sub nom.*, Margaret S. v. Edwards 794 F.2d 994 (5th Cir. 1986); Wynn v. Scott, 449 F. Supp. 1302 (1978), *aff'd sub nom.*, Wynn v. Carey, 599 F.2d 193 (7th Cir. 1979)). Although the Supreme Court has not decided this issue, there is general consensus that the research methods could be regulated for reasons of public health and safety. *See id.*; *see also* Andrews, *supra* note 76, at 661-64 (concluding that the freedom of scientific inquiry is not an absolute right and that the government could regulate cloning experimentation so long as the regulation was rational).

[149] *See* NBAC REPORT, *supra* note 1, at F-6-7. The right to decide whether to bear children is a constitutionally protected privacy right and liberty interest that insulates procreative choices from unnecessary governmental intrusion. *See id.* (discussing Planned Parenthood v. Casey, 505 U.S. 833 (1992); Eisenstadt v. Baird, 405 U.S. 438 (1972); Griswold v. Connecticut, 381 U.S. 379 (1965)). The right to make reproductive decisions includes the right to use reproductive technologies, such as in vitro fertilization and embryo donation. *See id.* (discussing Lifchez v. Hartigan, 735 F. Supp. 1361 (N.D. Ill. (1990), *aff'd sub nom.*, Scholberg v. Lifchez, 914 F.2d 260 (7th Cir. 1990)). Whether these constitutional protections would extend to human cloning attempts remains open to debate. *See id.* Research involving the cloning of cells and tissues not intended to create a child would not invoke these constitutional rights of privacy and liberty, and regulation of this research would be permissible as long as the government articulated a rational basis for the restrictions. *See id.* Even if constitutionally protected as a reproductive decision, attempts to clone a human being could still be regulated if the government asserts a compelling state interest and the regulation is narrowly tailored to further that interest. *See id.* at F-6. Considering the current state of technology, the unresolved ethical issues, and the potential physical as well as psychological harm to a child produced by cloning, the state should be able to meet this burden to ban the procedure. *See id.*; *see also* Andrews, *supra* note 76, at 664-69 (providing an in-depth analysis of whether a cloning ban would infringe on the constitutional right to make procreative decisions). For further analysis of whether a fundamental right to use cloning technologies exists, see generally Lawrence Wu, *Family Planning Through Human Cloning: Is There a Fundamental Right?*, 98 COLUM. L. REV. 1461 (1998) (arguing that married couples have a fundamental right to procreate using cloning technology). Cloning an entire human being whose genetic make up is known in advance may also constitute a form of "genetic bondage" that violates the Thirteenth Amendment's slavery prohibition. *See* Andrews, *supra* note 76, at 668. Cloning of individuals for the purpose of procuring organs or tissues for transplantation may also run afoul of the Thirteenth Amendment prohibition of involuntary servitude. *See id.* A more detailed analysis of these challenges, however, is beyond the scope of this Article.

[150] *See* NBAC REPORT, *supra* note 1, at F-5.

[151] U.S. CONST. art. I, § 8, cl. 3. Pursuant to the commerce power, Congress is permitted

(1) to regulate the use of the channels of interstate commerce, (2) to

FFDCA derives its authority from the Commerce Clause, and courts have subsequently sustained this exercise of constitutional power.[152] Generally, all doubts regarding Commerce Clause powers are resolved in favor of constitutional validity.[153] When regulating medical or scientific activities, Congress typically and expressly articulates this jurisdictional element within a statutory provision that states that the act at issue applies only to activities involving interstate commerce.[154] Human cloning clinics may well assert that their activities are conducted entirely intrastate and are therefore beyond the reach of FDA jurisdiction.[155] Congressional power over interstate commerce, however, is not limited to the "regulation of commerce among the states," but instead extends to those intrastate activities "which so affect interstate commerce . . . as to make regulation of them appropriate . . . [for] the exercise of the granted power of Congress to regulate interstate commerce."[156]

> regulate and protect the instrumentalities of interstate commerce, or persons and things in interstate commerce, even though the threat may come only from intrastate activities, and (3) to regulate those activities having a substantial relation to interstate commerce.

Anny Huang, *FDA Regulation of Genetic Testing: Institutional Reluctance and Public Guardianship*, 53 FOOD DRUG L.J. 555, 575 (1998) (citing United States v. Lopez, 514 U.S. 599, 558 (1995)).

[152] *See* Huang, *supra* note 151, at 575 n.142 (citing United States v. Sullivan, 322 U.S. 689 (1998); United States v. Funk, 412 F.2d 452 (8th Cir. 1969); Dean Rubber Mfg. Co. v. United States, 356 F.2d 161 (8th Cir. 1966)).

[153] *See* United States *ex rel.* Attorney General v. Delaware & Hudson Co., 213 U.S. 366, 408 (1909) (construing federal statutes to avoid conclusion of unconstitutionality).

[154] *See* Andrews, *supra* note 76, at 670.

[155] *See id.*; *see also* Abbot v. Bragdon, 912 F. Supp. 580 (D. Me. 1995), *aff'd*, 107 F.3d 934 (1st Cir. 1997).

[156] Andrews, *supra* note 76, at 670 (citing United States v. Darby, 312 U.S. 100, 118 (1941)); *see also Lopez*, 514 U.S. at 558 (recognizing congressional authority to "regulate those activities having a substantial relation to interstate commerce"). The "substantial relation" interpretation is probably the best basis for regulating cloning. *Cf.* Huang, *supra* note 151, at 575 (supporting this same proposition as it relates to genetic testing). Supreme Court precedent both supports and contravenes this position. *Compare* Wickard v. Filburn, 317 U.S. 111 (1942) (holding that the home consumption of wheat substantially affected the interstate economics of the wheat industry) *with Lopez*, 514 U.S. 549 (rejecting the claim that carrying firearms in school zones substantially affects interstate commerce and recognizing for the first time in 60 years that there are limits to Congress's power under the Commerce Clause). The facts of *Lopez* are distinguishable from the cloning scenario. *See* NBAC REPORT, *supra* note 1, at F-5. In *Lopez*, the congressional ban on the bearing of firearms within 1000 yards of a school was found not to be a proper exercise of commerce power because the activity "did not affect interstate commerce, interfered with a traditional state activity (education), and had already been addressed by state laws in most states." *Id.* In any cloning effort, equipment, supplies, personnel, patients, and funds are all likely to move in interstate commerce. *See id.* The statute and legislative history at

The federal government's authority to regulate interstate commerce has already been confirmed in cases in which medicine, supplies, surgical instruments, or customers move in interstate commerce.[157] Cloning facilities will likely acquire similar types of medical products from other states and will certainly attract patients from across state lines.[158] Even if the purchase of supplies and equipment from out-of-state vendors, the reimbursement for services from out-of-state sources, and the participation of providers in out-of-state conferences do not individually affect interstate commerce to a substantial degree, these commercial activities, when viewed in the aggregate, would affect interstate commerce to the requisite level, thus conferring congressional authority under the Commerce Clause.[159]

Health-care providers, including potential cloners, are subject to the commerce power entrusted to the federal legislature.[160] Congress can ultimately choose to exert direct control over or impose policy conditions upon health-care provider activity,[161] to ban the activity

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issue in *Lopez* also failed to address the Commerce Clause concerns, an oversight not evident in the FFDCA. *See id.*; *see generally* United States v. Calise, 217 F. Supp. 705 (S.D.N.Y. 1962) (finding that application of the mislabeling provisions of 42 U.S.C. § 262(b) are not restricted exclusively to products moving in interstate commerce); United States v. Sullivan, 332 U.S. 689 (1948) (holding that the language of § 301(k) of the FFDCA extended statutory coverage regarding adulteration and misbranding of articles that passed through interstate commerce to the moment that the articles were received by the ultimate consumer even though "such article is held for sale after shipment in interstate commerce").

[157] *See generally* Daniel v. Paul, 395 U.S. 298 (1969) (finding that a snack bar that served food to interstate travelers was subject to regulation under the Commerce Clause); Heart of Atlanta Motel, Inc. v. United States, 379 U.S. 241 (1964) (finding that a hotel that served interstate travelers was subject to regulation under the Commerce Clause). If cloning clinics treat out-of-state patients, regulation might also be sustained under the second prong of Commerce Clause jurisprudence, which is intended "to protect . . . persons . . . in interstate commerce, even though the threat may come only from intrastate activities." *Lopez*, 514 U.S. at 558. Another federal court, also utilizing a Commerce Clause analysis, has affirmed the constitutionality of the Freedom of Access to Clinic Entrances Act, 18 U.S.C. § 248 (1994), concluding that the rendering of reproductive health services substantially affects interstate commerce. *See* United States v. Wilson, 73 F.3d 675, 681-93 (7th Cir. 1995).

[158] *See* Andrews, *supra* note 76, at 673-74. Because there are only an estimated 10 laboratories in the world with the ability to replicate Roslin's sheep-cloning success, it is obvious that human cloning would entail interstate travel. *See id.* Cloning providers surely would travel interstate to share research findings and to attend educational seminars, and any cloned human beings would enjoy the right to interstate travel. *See id.* at 674.

[159] *See id.* at 672-73.

[160] *See id.* at 673.

[161] *See id.*

completely,[162] or to delegate regulatory authority to a federal agency under a relevant enabling statute. In any event, the scope of the Commerce Clause is unlikely to prevent Congress from delegating to the FDA, or other regulatory agencies, the authority to regulate cloning. The more important question will likely be one of statutory interpretation.

B. FDA Regulation of Cloning as Biological Products

Perhaps the strongest argument supporting FDA authority to regulate human cloning is that cloning may be regulated as a biological product introduced into interstate commerce.[163] "Biological product" is defined under this act as "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings."[164] Thus, in order

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[162] *See* NBAC REPORT, *supra* note 1, at F-5 (discussing Champion v. Marshal, 188 U.S. 321 (1903)).

[163] *See* 42 U.S.C. § 262 (1994). The FDA has already announced that manipulated cells and nucleic acids are biological products, that it can regulate cloning as a biological product, and that the technology can be regulated under the agency's tissue-products policy, which requires biological license approval for tissues undergoing significant manipulation. *See* F.D.C. Reports, 24 "The Gray Sheet" No. 3, Jan. 19, 1998; *see also* Seachrist, *supra* note 17 (citing an FDA source as stating that the agency is prepared to use the tissue and biologics regulations to assert authority over cloning, and noting that, in addition to regulating tissues and manipulated cells, the FDA has the authority to regulate both nucleic acid use in humans and the medical devices needed to clone humans); Eibert, *supra* note 76, at 52 (reporting FDA statements asserting regulatory jurisdiction over human cloning pursuant to the FDA's statutory authority over biological products (such as vaccines and blood products), and drugs). The BIO wrote to Donna Shalala, Secretary of the DHHS, to suggest that the FDA has broad authority to regulate cloning as biological products. *See* Stolberg, *supra* note 25, at A14. Historically, "biologics" referred to vaccines and blood products, but products such as human cells and tissues that are composed of living organisms are presently included in this category as well. *See id.*

[164] 42 U.S.C. § 262(i)(j) (1997). Section 262 specifically states:

> The Federal Food, Drug, and Cosmetic Act [21 U.S.C.S. § 301] applies to a biological product subject to regulation under this section, except that a product for which a license has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act [21 U.S.C.S. § 355].

Id. § 262 (j). The FDA regulations on biological products, promulgated pursuant to the PHSA, define biological products as "any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man." *See* 21 C.F.R. § 600.3 (1996). The regulation provides a brief description of these products as well as an interpretation of when a product is analogous to a virus, therapeutic serum, and toxin or antitoxin. *See id.* The

to satisfy the statutory definition and thereby confer authority on the FDA to regulate, the cloning procedure must involve an "analogous product" that is utilized to prevent, treat, or cure human disease.

The FDA includes within its definition of "human cellular and tissue-based products" a variety of "medical products derived from the human body and used for replacement, reproductive, or therapeutic purposes."[165] For example, semen, ova, and embryos used for reproductive purposes fall within this definition.[166] In the past, the FDA has regulated these cellular and tissue-based products on a case-by-case basis.[167] "Some tissues have been regulated as medical devices under section 201 of Federal Food, Drug, and Cosmetic Act[168] . . . [while] other products have been considered biological products under section 351 of the Public Health Service Act . . . and drugs under the [FFDCA]."[169] In addition, when the FDA has decided not to regulate these cellular and tissue-based products as medical devices or biological drugs, it has relied on § 361 of the PHSA to achieve its regulatory purpose; this section confers authority on the agency to prevent the spread of communicable diseases.[170] Interestingly, prior to issuing regulations concerning "human tissues intended for transplantation,"[171] the FDA asserted little or no regulatory authority over human cellular and tissue-based products.[172]

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regulation's language does not appear to apply to human cloning products any more than does the statutory language. *See id.* Also, the inclusion of the word "injuries" in the regulation would not apply to cloning products that would be used for procreation, rather than for treatment of an injury. *See id.*

[165] Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products, 63 Fed. Reg. 26,744 (1998) (proposed rule May 14, 1998). Various tissues have already been transplanted in order to treat human conditions, and new human cellular and tissue-based products are being developed to treat various human ailments such as diabetes, Parkinsonism, and viral infections. *See id.* The FDA's position is that any "product" of somatic cell therapy "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." Price, *supra* note 28, at 639 (discussing Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products, 58 Fed. Reg. 53,248 (1993)).

[166] *See* 63 Fed. Reg. 26,744 (1998).

[167] *See id.*

[168] *See id.* Dura mater, corneas, heart valve allographs, and umbilical vein graphs are examples of such regulated "medical devices." *See id.*

[169] *Id.* Gene therapy and somatic cell therapy products are considered to be biological drugs. *See id.*

[170] *See id.* at 26,745 (citing 42 U.S.C. § 264 (1998)). In 1993, the FDA exerted this statutory authority to require hepatitis and HIV testing of transplantation tissue. *See id.*

[171] 21 C.F.R. § 1270 (1999).

[172] *See* 63 Fed. Reg. at 26,745.

In February 1997, the FDA issued two guidance documents that replaced the current patchwork of regulatory policies with a comprehensive new system of regulation for human cellular and tissue-based products, and further concluded that the FFDCA and the PHSA provided sufficient authority to accomplish this.[173] In May 1998, the FDA published a proposed rule to regulate these products in a multi-tiered, risked-based fashion.[174] "Minimally processed tissues transplanted from one person to another for their normal structural functions would be subject to infectious disease screening and testing and to requirements for good handling procedures, but would not need FDA premarket review or marketing approval."[175] "Cells and tissues that are processed extensively, are combined with non-cellular or non-tissue components, are labeled or promoted for purposes other than their normal functions, or have a systemic effect," would be subject to the additional, and more stringent, requirement of premarket approval.[176] To date, these regulations have not been adopted.[177]

If the proposed regulations are adopted and found to be an appropriate exercise of FDA authority, human cloning products may fall within the category of the rule requiring premarket approval of cellular or tissue-based products that are more than minimally manipulated.[178] Notwithstanding this possibility, the more difficult

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[173] *See id.* at 26,744-46.

[174] *See id.*

[175] *Id.* at 26,745.

[176] *Id.*

[177] *See* 63 Fed. Reg. 68,212 (1998) (reopening the comment period for the proposed rule).

[178] *See* 63 Fed. Reg. at 26,746. The proposed rule states, in pertinent part:

> Human cellular and tissue-based products subject to regulation as biological drugs or devices are those that do not meet the criteria set out above for regulation under section 361 of the PHS Act. That is, they are: (1) More than minimally manipulated; (2) are promoted or labeled for a non-homologous use; (3) have been combined with or modified by the addition of a non-cellular or non-tissue component that is a drug or device; or (4) have a systemic effect (except in cases of autologous use, transplantation into a first degree blood relative, or reproductive use).

Id. "Minimal manipulation" for cells and nonstructural tissues is defined as "processing that does not alter the relevant biological characteristics and, thus potentially, the function or integrity of the cells or tissues." *Id.* at 26,748. The FDA defines "more than minimal manipulation" as processes that do not satisfy the definition of minimal manipulation. *See id.* Genetic modification is included as an example of manipulation not considered minimal. *See id.* Nuclear transfer technology used in cloning would entail more than minimal manipulation because the oocyte is altered by the removal of the original haploid DNA and replaced with

question is whether such cellular and tissue-based products are sufficiently analogous to other biological products delineated in the statute such that the FDA regulations could survive a judicial challenge. Human embryos produced by cloning technology, however, do not seem to "fit" within the same scientific or medical category as viruses, toxins, antitoxins, vaccines, serums, allergenic products, or blood products. The statutory background, legislative history, and resulting language of the FFDCA, the PHSA, and the Biologics Act[179] clearly demonstrate that Congress neither contemplated the potential ramifications of human cloning procedures nor drafted the statutory language broadly enough to encompass such a radically new technology.[180] Although embryos produced by cloning techniques and the other biologicals enumerated in the statute are all biologically based, there are significant differences between them.[181] For example, the products listed in § 351 of the Biologics Act are "components of a biological entity, whereas an embryo is . . . a complete biological entity onto itself."[182] It seems unlikely that a strict interpretation of the plain language of the statute itself would allow the FDA expansive

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the diploid DNA complement from a somatic cell of another individual. *See Opposition Grows to Human Cloning on Bioethics Premise*, *supra* note 16. "Cloning involves removing the genetic core, or nucleus, of an egg cell and injecting into that gutted cell the nucleus of another cell from the . . . person to be cloned." Daniel, *supra* note 147, at C3. This process results in a highly manipulated cell. *See id.* Gestation of implanted embryos created by somatic cell nuclear transfer techniques also would obviously produce a systemic effect in a human recipient; however, the regulatory language carves out an exception for cellular products used for reproductive purposes. *See* 63 Fed. Reg. at 26,746. The proposal defines "transfer" as "the placement of human reproductive cells or tissues into a human recipient." *Id.* at 26,750. The FDA decided that the term "reproductive use" was well understood and chose not to define it despite the controversy surrounding the use of cloning for human reproductive purposes. *See id.*

[179] 42 U.S.C. § 262 (1994).

[180] *See* PETER HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 660-719 (1991).

[181] *See* Price, *supra* note 28, at 639.

[182] *Id.* "[I]t would be a fair construction to limit the definition of biological products to those substances that were . . . biological components, not complete biological entities . . . . [I]t seems unlikely that Congress intended, by its silence on the subject, to take the extraordinary measure of subjecting embryos to governmental regulation." *Id.* The word "product" is defined as "something produced . . . by physical labor or intellectual effort . . . [or] a substance produced from one or more other substances as a result of chemical change." WEBSTER'S THIRD NEW INT'L DICTIONARY 1810 (1993). A product of human cloning technology would technically fit within this definition, but the modifier "analogous" in the statutory provision further emphasizes, *ejusdem generis*, that cloning products are not meant to be regulated along with the other biological products specified in the provision. *See* Price, *supra* note 28, at 639.

jurisdiction to regulate human cloning, even though the FDA has been inching toward this authority in the administrative arena through its biologicals and gene therapy rules.

In addition, the FDA itself fails to support its claim of cloning jurisdiction with any prior assertion of regulatory authority over either in vitro fertilization or other more aggressive fertility techniques that carry a high-risk profile.[183] Furthermore, the FDA regulations and commentary dealing with human gene therapy do not mention human reproduction despite the fact that, in February 1998, the FDA announced that these same regulations extended to human cloning.[184] The FDA has not generally claimed jurisdiction over human reproductive methods.[185] If human cloning is construed as a new variant of a treatment for infertility, the FDA may have an even weaker argument for regulatory authority because "[t]he FDA is not supposed to regulate the practice of medicine," a power traditionally entrusted to the states.[186]

If the courts do ultimately recognize that human cloning products are sufficiently analogous to viruses, serums, toxins, antitoxins, vaccines, blood products, and allergenic products such that they fall within the statutory envelope of regulatory consideration, the FDA first must demonstrate that these products are "applicable to the prevention, treatment, or cure of a disease or condition of human beings."[187] The resolution of this issue is unclear; however, it is probably more easily addressed than the "analogous

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[183] *See* Daniel, *supra* note 147, at C3. The FDA has not attempted to regulate in vitro fertilization (IVF) and other infertility techniques that also involve more than minimal manipulation of cells. *See id.* The FDA also has not tried to regulate intracytoplasmic sperm injection (ICSI) procedures, an invasive modification of IVF that carries a high-risk profile. *See id.* In fact, the process of a woman cloning herself may actually be safer than IVF because there is little risk of transmitting a communicable disease, such as AIDS, in this process. *See id.* "In the past, the FDA has largely ignored the fertility industry, making no effort to regulate in vitro fertilization . . . and other advanced reproductive technologies that have much in common with cloning techniques." Eibert, *supra* note 76, at 52.

[184] Greely, *supra* note 33, at 151. Gene therapy techniques involve "material manipulation of human cells that are then reinserted for medical purposes." *Id.*

[185] *See id.*

[186] Daniel, *supra* note 147, at C3 (quoting Richard Merrill, professor at the University of Virginia School of Law); *see also* United States v. Evers, 643 F.2d 1043 (5th Cir. 1981) (affirming judgment for defendant physician on grounds that he did not violate § 301(k) of the FFDCA regarding drug misbranding, and recognizing that a licensed physician can prescribe a lawful drug for a purpose not approved by the FDA), *aff'g* United States v. Evers, 453 F. Supp. 1141 (M.D. Ala. 1978) (declaring that Congress did not intend the FDA to interfere with the practice of medicine and the doctor-patient relationship).

[187] 42 U.S.C. § 262(i) (1990).

product" analysis, and more likely to be resolved in the FDA's favor. The issue then becomes whether human cloning products are utilized to treat or to cure a disease or condition of human beings.

If the statutory interpretation focuses on the use of cloning products to create a pregnancy, then assertion of regulatory jurisdiction would fail because pregnancy is not considered a disease, and although pregnancy arguably could be considered a human condition, such products are not applicable to the prevention, treatment, or cure of the "pregnancy."[188] Human cloning procedures would attempt to create a pregnancy — not to prevent, treat, or cure it.[189]

The FDA could proffer a compelling argument to establish that human cloning products would be used in many instances to treat another disease or human condition — infertility.[190] Under the

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[188] *See* United States v. Article of Drug (Ova II), 414 F. Supp. 660 (D.N.J. 1975), *aff'd mem.* 535 F.2d 1248 (3d Cir. 1976). In *Ova II*, a case involving regulation of pregnancy testing under the FFDCA, Judge Biunno explained:

> [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 . . . . A test for pregnancy, then, is not a test for the diagnosis of disease.

Id. at 664. The court did go on to differentiate between a normal pregnancy and an ailment or disease arising out of the pregnancy, such as a tubal pregnancy or toxemia of pregnancy. *See id.* The court noted, however, that these abnormal conditions, although related to the pregnancy, must be separately diagnosed. *See id.* In any event, the intent of human cloning procedures would be to create a normal pregnancy and not a disease or abnormal condition related to the pregnancy. Any attempt to use these circumstances to pull pregnancy within the statutory language of a disease clearly would be too far a stretch. *See* Price, *supra* note 28, at 632. Even assuming that pregnancy created by cloning is distinguishable from pregnancy created by sexual procreation and could be construed as a disease within the meaning of the statute, it is clear that cloning does not to prevent, treat, or cure the pregnancy or disease. *See id.* If anything, cloning would attempt to create "the disease," not prevent, treat, or cure it. *See id.* Although the courts have not yet defined the scope of the term "disease" within the context of section 351 of the PHSA, *Ova II* has done so in a case involving this interpretation under the FFDCA and has determined that pregnancy is not a disease. *See id.* at 640. If cloning technology was used to develop specific organs or tissues for transplantation, instead of being used for procreative purposes, it is conceivable that these procedures would be applicable to the prevention, treatment, or cure of disease and thereby could confer regulatory authority on the FDA for these limited purposes. *See id.* at 641.

[189] Human cloning procedures would be most analogous to fertility procedures. Prevention of pregnancy is clearly contraception, not cloning, and "curing" pregnancy could arguably encompass procedures to treat complications of pregnancy and possibly abortion, not cloning.

[190] *See* WEBSTER'S THIRD NEW INT'L DICTIONARY 648 (1993). The definition of "disease" includes "an impairment of the normal state of the living animal . . . or any of its components that interrupts or modifies the performance of the vital functions,

Americans with Disabilities Act (ADA),[191] courts have already considered infertility to be a physical condition affecting the reproductive system in the context of a disability determination.[192] Although "pregnancy" cannot be classified as a disease, and cloning products cannot be considered applicable to the prevention, treatment, or cure of pregnancy as a human condition, an implanted human embryo created by a cloning procedure could be classified as a biological product that is used to treat the disease or condition of infertility.

Although the issue of whether the FDA has power to regulate human cloning technology as biological products under the PHSA is unclear and has yet to be determined, it seems unlikely that a court would recognize such authority. The FDA's assertion that "analogous biological products" include cloning products would not stand up to judicial scrutiny because such a position would be inconsistent with the express statutory language and legislative history of the PHSA. Even though the FDA's biological regulations seemingly could be construed to include human cloning within their jurisdiction, it is not apparent that the PHSA enables the FDA to promulgate broad regulations that encompass human cloning products. Should Congress decide to confer this power upon the FDA, it could do so by simply amending the PHSA. This approach would undoubtedly have a greater chance of success than would the direct legislative initiatives previously discussed.

C. FDA Regulation of Cloning as a Drug

Section 201(g)(1) of the FFDCA defines the term "drug" as:

(A) *articles* recognized in the official United States

being a response to . . . inherent defects of the organism." *Id.* One medical dictionary defines disease as "morbus; illness; sickness; an interruption, cessation, or disorder of bodily functions, systems, or organs." *See* STEDMAN'S MED. DICTIONARY 444 (25th ed. 1990); *see also* Katskee v. Blue Cross/Blue Shield of Neb., 515 N.W.2d 645, 651 (1994) (determining what constitutes a disease or illness in the context of health insurance coverage). "Infertility" is defined as "the quality or state of being infertile," and "infertile" is defined as "not fertile or productive." WEBSTER'S, *supra*, at 1158. "Sterile" is used synonymously with "infertile" and is defined as "not having or not manifesting the power to produce offspring . . . stressing some defect or lack in the reproductive functions." *Id.* at 2238.

[191] 42 U.S.C. §§ 12,101-213 (1990).

[192] *See generally* Pacourek v. Inland Steel Co., 916 F. Supp. 797 (N.D. Ill. 1996). The *Pacourek* court held that infertility is a physiological disorder or condition that affects a major life activity (i.e., reproduction), that the reproductive system is a body system that can be impaired under the ADA, and concluded that because infertility substantially limits reproduction, an infertile employee was disabled under the ADA. *See id.* at 797, 800-04.

> Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement to any of them; and (B) *articles* intended for use in the *diagnosis, cure, mitigation, treatment or prevention of disease* in man . . . and (C) *articles* (other than food) intended *to affect the structure or any function of the body* of man . . . and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).[193]

Suffice it to say that human cloning products do not appear in the cited Pharmacopoeias or National Formulary and, thus cannot be regulated as drugs under § 201(g)(1)(A). Whether cloning products can be regulated as drugs under subsections (B) or (C), however, depends on whether such products can be considered "articles" and still remain consistent with the statutory scheme and legislative intent.[194]

The FFDCA itself provides no direct assistance in this regard because the statute does not further explain the term "article."[195] The plain dictionary definition of this word is "a material thing: item, object . . . [or] a thing of a particular class or kind as distinct from a thing of another class or kind."[196] This definition provides a logical, although not very helpful, starting point for further statutory interpretation.[197]

In the context of human cloning, to arguably remain applicable to the subsequent language of the drug definition, the "article" could only refer to the implanted product of a somatic cell nuclear transfer procedure.[198] Under this interpretation, conferring authority upon

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[193] 21 U.S.C. § 321(g)(1) (1994) (emphasis added).

[194] *See id.*; *see also* Price, *supra* note 28, at 630.

[195] *See id.* (noting absence of the definition of "article" in 21 U.S.C. § 321(a)).

[196] WEBSTER'S, *supra* note 190, at 123.

[197] *See infra* notes 243-45 and accompanying text (discussing Chevron v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984), and federal administrative agency construction of statutory provisions); *see also* MCI Telecomm. Corp. v. American Tel. & Tel. Co., 512 U.S. 218 (1994) (critiquing the use and limitations of dictionary definitions in statutory interpretations and finding that the relevant time for determining legislative intent of statutory language is the time that the controlling statute was enacted).

[198] *See* Price, *supra* note 28, at 630. Price argues that an embryo produced by cloning technology could not constitute an "article" within the meaning of the FFDCA. *See id.* By interpreting the statute to include human cloning products as articles and thereby granting the FDA power to regulate them as drugs, the FDA would be able to license cloned human embryos and require pre-procedure approval. *See id.* Price posits that this would empower the FDA to pre-approve the creation of human life, a scenario neither contemplated by Congress nor impliedly approved of by legislative silence on the issue. *See id.* That Congress has independently proposed several bills to limit or ban human cloning procedures would support this premise. *See supra* notes 111-47 and accompanying text

the FDA to license, pre-approve, or otherwise regulate human cloning products as drugs would raise significant constitutional questions as to whether the FDA's regulatory jurisdiction could permissibly include a fundamental procreative liberty.[199] These questions, however, would present themselves regardless of which avenue the FDA chose in regulating human cloning. To overcome this constitutional impediment to agency regulation, the FDA would likely argue the existence of a compelling state interest in the safety of the embryo and/or born-alive, cloned person.[200]

Another substantial challenge the FDA would need to address is the agency's "historical failure to assert jurisdiction over embryos created in other ways," including in vitro fertilization.[201] The FDA

(discussing legislative responses to human cloning).

[199] *See* Price, *supra* note 28, at 630.

[200] *See supra* note 149 and accompanying text (discussing constitutionally protected rights and liberties involving procreation and possible compelling governmental justifications to regulate in the human cloning context). A state may restrict abortions after fetal viability "as long as the law contains exceptions for pregnancies which endanger a woman's life or health." Planned Parenthood v. Casey, 505 U.S. 833, 846 (1992). *Casey* further held that "the [s]tate has legitimate interests from the onset of pregnancy in protecting the health of the woman and the life of the fetus that may become a child." *Id.* Considering the high failure rate of present-day cloning attempts, human cloning procedures could not conceivably be considered safe for the cloned embryo. *See supra* note 17 (discussing high failure rate of cloning attempts); *see also* Andrews, *supra* note 76, at 664-69 (discussing the constitutional issues revolving around procreative liberties and the regulation of human cloning); *supra* notes 63-67 and accompanying text (postulating physical and genetic dangers to the subsequently cloned individuals); *supra* notes 73-75, 79-81 and accompanying text (discussing potential psychological harm to cloned offspring). At present, the unknown physical dangers to successfully cloned individuals and the foreseeable psychological harms to them would likely be construed as compelling governmental interests to satisfy any constitutional concerns over restricting reproductive liberties. *See* NBAC REPORT, *supra* note 1, at F-6. By contrast, any statutory scheme infringing on fundamental procreative rights would be subject to strict scrutiny and could fall outside of Congress's commerce power. *See* Price, *supra* note 28, at 631. *But see* F.D.C. Reports, 60 "the Pink Sheet" No. 35, Aug. 31, 1998, at 5. The safety of the abortifacent RU-486 was not considered with respect to an unborn child carried by a woman taking the drug because the FDA is required by statute to ensure that drugs are safe and effective for their intended use. *See id.* Because the intended user of RU-486 is a pregnant woman seeking a termination of pregnancy, the safety and efficacy for the embryo need not be evaluated by the agency. *See id.*

[201] Price, *supra* note 28, at 630-31. Price stated that the FDA never believed it had regulatory authority over matters such as in vitro fertilization, artificial insemination, traditional sexual intercourse, or other methods of human reproduction. *See id.* Price cites several congressional hearings held in the 1980s that addressed the low success rates of fertility clinics, and that subsequently led to the Fertility Clinic Success Rate and Certification Act of 1992 (codified at 42 U.S.C. §§ 263 (a)(1)-(7)). *See id.* at 631. The Centers for Disease Control (CDC) became the federal agency responsible for the Act's implementation; the FDA was never mentioned during this

would be hard-pressed to justify a position asserting agency authority over human cloning when it has not previously expressed an interest in regulating other reproductive technologies that utilize similar techniques.

Furthermore, FDA efforts to regulate cloning and other reproductive techniques may exceed agency authority because such efforts could easily be construed as attempts to regulate the practice of medicine.[202] The line between in vitro fertilization regulation and the regulation of human cloning techniques, if the line exists at all, would be a blurred one regardless of how the FDA attempts to justify its authority over cloning.

Assuming that Congress intended to include human cloning products within the meaning of "articles" under the FFDCA (which is an arguably easier determination to reach than considering cloning products as "analogous products" under the PHSA), a reviewing court would then need to decide if these "cloning articles" were either "intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease," or "intended to affect the structure or

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process as having jurisdiction over fertility clinic procedures. *See id.*

[202] *See supra* note 186 (discussing the FDA's lack of authority to regulate the practice of medicine); *see also* HUTT & MERRILL, *supra* note 180, at 619-21 (discussing Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration: Notice of Proposed Rule Making, 37 Fed. Reg. 16,503 (1972)). In discussing the scope of § 505 of the FFDCA, the rule proposal sets out, in pertinent part:

> [T]he new drug provisions apply only at the moment of shipment in interstate commerce and not to action taken subsequent to shipment in interstate commerce .... The 1948 [Miller] amendment did not ... extend the reach of the new drug provisions of the Act ... to action taken after interstate shipment ....
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> ....
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> ... Once the new drug is in a local pharmacy after interstate shipment, the physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient, or may otherwise vary the conditions of use from those approved in the package insert, without informing or obtaining the approval of the Food and Drug Administration ....
>
> ... The physician is then responsible for making the final judgement as to which, if any, of the available drugs his patient will receive ....
>
> ... [T]he Act does not require a physician to file an investigational new drug plan before prescribing an approved drug for unapproved uses or to submit ... data concerning the therapeutic results and the adverse reactions ....

Id. at 619-20. Although the FDA did not take final action on the proposal, the agency considers the substance of the rule proposal as its established policy. *See id.* at 621 (citing "Use of Approved Drugs for Unlabelled Indications," 12 FDA DRUG BULL. 4 (Apr. 1982)).

function of the body."[203] The analysis of whether cloning products would be used in the "diagnosis, cure, mitigation, treatment, or prevention of disease"[204] closely parallels the previous discussion concerning analogous biological products "applicable to the prevention, treatment, or cure of a disease" under the PHSA.[205] Because the intended use of cloning products would be to create, and not to treat, diagnose, or prevent a pregnancy, and because pregnancy is not considered by the courts to be a disease,[206] then, ipso facto, the assertion of FDA jurisdiction over human cloning under this analysis would fail. In addition, unlike the biological products provisions of the PHSA, the FFDCA does not include "human conditions" within its targeted scope of regulatory authority,[207] thus any further argument for jurisdiction is defeated.

As under the biological products provisions of the PHSA, a better argument for FDA regulatory authority under the FFDCA would be that cloning products are articles intended for use in the treatment of infertility.[208] The same general analysis would apply in this context and could possibly permit a court, liberally interpreting congressional intent, to find the necessary statutory authority for FDA regulation of human cloning as a drug.

Regarding the issue of whether cloning products could be construed as drugs "intended to affect the structure or any function of the body,"[209] a court must first determine if the cloning articles would be "inserted in, injected in, ingested by or applied to the body."[210] The in vivo act by a physician of physically implanting the

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[203] Price, *supra* note 28, at 631 (quoting 21 U.S.C. § 321 (g)(1)(B) & (C)).

[204] 21 U.S.C. § 321 (g)(1)(B) (1994).

[205] 42 U.S.C. § 262(i) (1997).

[206] *See supra* note 188 (discussing *Ova II*, as well as the possible use of cloning techniques to develop tissues or organs (interpreted as products or articles) for transplantation, thereby possibly satisfying the statutory requirement of treating, curing, or mitigating disease).

[207] *Compare* 21 U.S.C. § 321(g)(1)(B) (1994) (containing the term "disease" in this FFDCA provision) *with* 42 U.S.C. § 262(i) (1997) (including the phrase "disease or condition of human beings" in this PHSA provision).

[208] *See supra* notes 190-92 (suggesting that infertility may be included within the definition of disease).

[209] 21 U.S.C. § 321(g)(1)(C) (1994).

[210] *Ova II*, 414 F. Supp. at 666 (D.N.J. 1975). "In the ordinary sense of the word 'drugs,' it would be rational to limit its meaning to items used or applied for diagnostic purposes to those employed 'in vivo' and not for those employed 'in vitro.'" *Id.* at 663. "The [ ] definition, articles intended to affect the structure or any function of the body is obviously not applicable to any article which is used 'in vitro' and in no way inserted in, injected in, ingested by, or applied to the body." *Id.* at 666. Although actual formation of the embryo by means of somatic nuclear cell transfer

embryo created by in vitro cloning technology into the uterus of a woman for gestation and subsequent birth would likely satisfy this requirement.[211]

The question then becomes whether implantation of the cloned embryo would be intended to "affect the structure and function of the body."[212] There is little dispute that pregnancy has such effects on the human body. Although the primary purpose of a cloning procedure would clearly be to bring the implanted embryo to term,[213] the cloning "article" or "drug" would also be implanted with the intent to affect the structure and function of the woman's body in order to allow such gestation to continue. The statute, however, does not specify that only one intended use of the article is permissible or that the purpose to be regulated must be the primary intended use. In this case, the article's intent to affect the structure and function of the body complements the primary purpose of allowing the cloned individual to be born. Acceptance of this line of reasoning could also mean that implanted embryos that were created through artificial insemination or through in vitro fertilization techniques would also be subject to FDA regulation as drugs that potentially require "premarketing" approval.[214] As previously stated, this is an area that the FDA has chosen not to regulate.[215]

Although the FDA could make several plausible arguments to justify its authority to regulate human cloning as a drug, it would have to overcome a series of statutory obstacles to achieve that jurisdiction. Furthermore, the FDA has not established its authority to regulate other reproductive technologies.[216] One leading expert on food and

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would occur in vitro, the end product of this procedure would be inserted or implanted into the woman for gestation, arguably, in many circumstances, to treat infertility and to affect the structure and function of the woman's body to allow her to carry the cloned individual to term.

[211] *See* STEDMAN'S MED. DICTIONARY 769-70 (25th ed. 1990). STEDMAN'S defines "implant" as "[t]o graft or insert . . . [to] transplant." *Id.* at 769. "Implantation" is defined as "[a]ttachment of the fertilized ovum (blastocyst) to the endometrium, and its subsequent embedding in the compact layer." *Id.* at 770.

[212] *See* Price, *supra* note 28, at 633.

[213] *See id.*

[214] *See id.*

[215] *See supra* note 201 and accompanying text (discussing the FDA's lack of regulatory history with human reproductive technologies).

[216] *See generally* Jay M. Zitter, Annotation, *What Is "Drug" Within Meaning of § 201(g)(1) of Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 321(g)(1))*, 127 A.L.R. FED. 141 (1998). In discussing the extensive case law relating to the regulation of drugs by the FDA, including drugs directed at the reproductive system, no cases involved the regulation of human reproductive technologies, cloning technologies, or infertility procedures. *See id.* Likewise, no cases deal with the regulation of

drug law has concluded that the FDA clearly does not possess the power to regulate the practice of medicine.[217] These additional obstacles to FDA regulation should prove insurmountable.

D. FDA Regulation of Cloning as a Medical Device

> Section 201(h) of the FFDCA defines the term "device" as:
> an instrument, apparatus, implement, machine, contrivance, *implant*, in vitro reagent, or other similar or related article, including any component, part or necessary, which is: (1) recognized in the official National Formulary, or the United States Pharmacopeia . . . (2) *intended for use* in the diagnosis of disease or conditions, or *in the cure, mitigation, treatment, or prevention of disease* in man . . . or (3) *intended to affect the structure or any function of the body* of man . . . and which does not achieve its *primary intended purposes* through chemical action within or on the body of man . . . and which is not dependent upon being metabolized for achievement of its primary intended purposes.[218]

As previously noted, human cloning products are not listed in the National Formulary or United States Pharmacopeia; thus, any analysis pursuant to this language may be quickly dismissed.

Upon further review of the statutory language, human cloning products would most closely be analogous to "implants" or "other similar or related articles."[219] The analysis of whether cloning products could be considered "articles" mirrors the reasoning employed when considering cloning products as drugs.[220] With regard to medical devices, however, the scope of the term "article" is narrowed considerably by use of the modifiers "similar or related," thereby compelling a more limited categorization of cloning products — "articles" referring to instruments, apparati, implements,

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cloning or reproductive technologies as new drugs under the FFDCA. *See generally* Jay M. Zitter, Annotation, *What Is "New Drug" Within Meaning of § 201(p) of Federal Food, Drug, and Cosmetic Act (21 U.C.S.A § 321(p))*, 133 A.L.R. FED. 229 (1997).

[217] *See* Daniel, *supra* note 147, at C3 (quoting Professor Richard Merrill as stating that "[t]he FDA is not supposed to regulate the practice of medicine"); *see also supra* note 186 (discussing FDA authority to regulate the practice of medicine); United States v. Evers, 643 F.2d 1043 (5th Cir. 1981) (concluding that off-label use of prescription drugs by physicians is not prohibited by the FDA); United States v. Evers, 453 F. Supp. 1141 (M.D. Ala. 1978) (finding that the FDA does not regulate the practice of medicine).

[218] 21 U.S.C. § 321(h) (1994) (emphasis added).

[219] *See id.*

[220] *See supra* notes 194-200 and accompanying text (discussing the characterization of human cloning products as "articles" under 21 U.S.C. § 321(g)(1) and the constitutional issues raised by such a classification).

machines, contrivances, in vitro reagents, or *implants.*[221] The common sense understanding and everyday use of these terms dictates that any further consideration of this issue must focus on cloning products as implants — a seemingly plausible interpretation.[222]

If human cloning products are considered implants for purposes of the statute, then it must be determined whether these "cloned implants" were "intended for use in . . . the cure, mitigation, treatment or prevention of disease . . . or [were] intended to affect the structure or function of the body."[223] This statutory language regarding a medical device is very similar to that of the FFDCA drug provision and PHSA biological product provision.[224] Section 201(h)

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[221] *See* CHARLES L. KNAPP & NATHAN M. CRYSTAL, PROBLEMS IN CONTRACT LAW 422 (3d ed. 1993). The maxim "*ejusdem generis*" instructs that "a general term joined with a specific one will be deemed to include only things that are like (of the same genus as) the specific one." *Id.* This "usually leads to a restrictive interpretation." *Id.* Price suggests that inclusion of a "laundry list" of articles, expressly delineated in the medical device provision, illustrates congressional intent to restrict the term "similar or related articles" to tangible, commercial items. *See* Price, *supra* note 28, at 634. Assuming, arguendo, that this is true, human embryos created by cloning techniques, like other present-day embryo donation arrangements, may, in some situations, be commercial in nature and thus satisfy this requirement.

[222] *See supra* notes 210-11 and accompanying text (discussing the medical definition of the term "implant" and its possible relation to the use of human cloning procedures for the treatment of infertility). One medical dictionary defines "implant" as "an object or material, such as an alloplastic or radioactive material or tissue, partially or totally inserted or grafted into the body for prosthetic, therapeutic, diagnostic, or experimental purposes." DORLAND'S ILLUSTRATED MED. DICTIONARY 824 (27th ed. 1988). "Implantation" is also defined as "the insertion of an organ or tissue . . . in a new site in the body [and] the insertion or grafting into the body of biological, living, inert, or radioactive material." *Id.*

[223] 21 U.S.C. § 321(h)(2) & (3) (1994). Several courts have also interpreted this statute. *See, e.g.*, United States v. Article of Device, 731 F.2d 1253 (7th Cir. 1984). The Seventh Circuit, in *Article of Device*, found that (1) instruments used in research are considered "devices" if the intended use includes the diagnosis and treatment of disease or other human conditions; (2) the instruments "need not be the only agent in the curative process"; and (3) instruments used in research are not excluded from the "device" definition because they may threaten the public health during the investigation phase. *Id.* Other federal courts have addressed similar issues. *See, e.g.*, Alabama Tissue Ctr. Of Univ. of Ala. Health Serv. Found., P.C. v. Sullivan, 975 F.2d 373 (7th Cir. 1992) (concluding that a human heart valve allograft that is processed, preserved, and stored prior to implantation into a human recipient is an implant within the meaning of the medical device provisions). The court in *Alabama Tissue* rejected the argument that the definition of "device" only includes man-made or artificial implants. *See id.* at 378. However, the court also noted that heart-valve allografts undergo a cryopreservation process allowing for a considerable shelf life and appear to be artificial "implants" in accordance with a permissible statutory interpretation by the FDA. *See id.* Interestingly, frozen embryos also have an extended "shelf-life," and there is no reason to believe frozen embryos created by somatic cell nuclear transfer technology would be any different.

[224] *See* 221 U.S.C. § 321(h) (1997); 21 U.S.C. § 321(g)(1) (1997); 42 U.S.C. §

refers to medical devices "intended for use in the *diagnosis* of *disease or conditions* or in the cure, mitigation, *treatment, or prevention* of *disease.*"[225] Section 201(g)(1) defines "drugs" as "articles intended for use in the *diagnosis,* cure, mitigation, *treatment or prevention* of *disease.*"[226] Essentially, the medical device provision separates the language concerning "diagnosis" (of disease or conditions) from that relating to "treatment or prevention" (of disease).[227] By contrast, the drug definition groups the term "diagnosis" with the "treatment or prevention" language (referring to disease only).[228] Because human cloning products would have no practical application to the diagnosis of a disease or condition, including pregnancy as a condition, the language at variance is of no relevant significance. The question of whether the FDA has regulatory authority over human cloning under either provision is limited to whether cloning products would be intended to cure, mitigate, treat, or prevent a human disease.[229] A similar approach would also be logical under the PHSA, which likewise refers to biological products as "applicable to the prevention, treatment, or cure of a disease or condition of human beings."[230]

Any proposed regulation of human cloning technology would be primarily targeted at attempts to create a pregnancy and to bring that pregnancy to term. Any attempt to regulate human cloning that characterizes cloning products as "being used in the treatment of pregnancy as a disease" would fail because courts have already made it clear that pregnancy is not a disease.[231] The same argument made under the biological products and drug provision discussions, however, would be applicable to the consideration of cloning products as medical devices intended for use in the treatment of infertility as a disease.[232] A court, conceivably, could find an

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262(i) (1997).

[225] 21 U.S.C. § 321(h) (1997) (emphasis added).

[226] 21 U.S.C. § 321(g)(1) (1997) (emphasis added).

[227] *See* Price, *supra* note 28, at 635. The 1976 Medical Device Amendments added the terms "in vitro reagent" and "or other conditions" to bring the regulation of pregnancy test kits within the scope of FDA authority. "[I]n vitro reagents intended to diagnose 'conditions' such as pregnancy are now considered 'medical devices' under section 201(h)(2)." *Id.* For a discussion regarding the 1976 Medical Device Amendments and their relation to the *Ova II* case and regulation of pregnancy test kits, see HUTT & MERRILL, *supra* note 180, at 746-47.

[228] 21 U.S.C. § 321(g)(1).

[229] *See* Price, *supra* note 28, at 635.

[230] 42 U.S.C. § 262(i) (1997).

[231] *See supra* notes 188-89, 206 and accompanying text (discussing judicial proclamation that pregnancy is not a disease).

[232] *See supra* notes 190-92, 208 and accompanying text (positing that the definition of the term "disease" may encompass infertility).

implication of congressional intent to confer authority upon the FDA to regulate human cloning products as implants intended for use in the treatment of infertility.

Another question is whether human cloning products could be regulated as medical devices because they "affect the structure or any function of the body." The medical device definition is the same as the drug definition in § 201(g)(1)(c), except that it adds 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."[233] The primary intended purposes of human cloning articles and implants would be to affect the structure or function of the woman's body in order to bring the cloned embryo to term.[234] Recognizing that "primary intended purposes" is set forth in the plural and that the phrase also refers to effects upon *any* function of the body, this terminology alone should not pose a bar to regulation. However, the language of exclusion for devices that are dependent upon chemical action or metabolism for their effect does create an uncertainty for proponents of regulatory jurisdiction under this provision. This additional language specifies that the intended effect of the implanted cloned embryo must be "accomplished through mechanical rather than chemical or physiological means."[235] Although an implanted embryo causes distinct physical changes in the woman's body to allow gestation to continue, it is unlikely that these physical changes would equate to mechanical action and still remain faithful to congressional intent. The effect that an implanted embryo has upon the structure or function of the body more likely would be described as physiological or chemical (i.e., hormonal).[236]

Even though credible arguments could be advanced to justify regulation of human cloning products as medical devices (i.e., implants) intended for use in the treatment of the human disease of infertility,[237] there are additional roadblocks to regulation. One

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[233] 21 U.S.C. § 321(h)(3) (1994).

[234] *See supra* notes 209-15 and accompanying text (discussing regulation of cloning articles as drugs intended to "affect the structure or any function of the body").

[235] Price, *supra* note 28, at 638. Price notes that medical devices, unlike drugs, "do not achieve their primary purpose through chemical action or metabolism." *Id.*

[236] *See id.*

[237] *See* HUTT & MERRILL, *supra* note 180, at 745-46, 752-57 (discussing 1976 Medical Device Amendments and establishment of three classes of medical devices). Considering the uncertainties of human cloning and the widely debated safety concerns of such procedures, any finding of FDA regulatory authority over human

problem is that, as noted above, the FDA has not previously asserted jurisdiction over other human infertility procedures. The FDA also clearly lacks regulatory authority over the practice of medicine.[238] The uncertainty regarding the interpretation of statutory language and of congressional intent, the constitutional concerns with respect to procreative liberties, the lack of FDA regulatory precedent in the field of infertility procedures, and the lack of FDA authority to regulate medical practice all combine to preclude any attempts to regulate human cloning as a medical device.

CONCLUSION

In reflecting on the moral, ethical, and political considerations involving the issue of human cloning, the first question that comes to mind is why the FDA would want to assert regulatory authority in this controversial area.[239] The FDA might have been searching for an efficient way, at least in the United States, to impede the seemingly hasty efforts of human cloning mavericks such as Richard Seed.[240] Another explanation may lie in the FDA's desire to expand its regulatory jurisdiction unencumbered by often poorly drafted and politically influenced statutory language.[241] As noted in the discussion regarding legislative attempts to ban the cloning of human beings, such congressional efforts at legislation might very well inhibit, or ban completely, important scientific research that utilizes cloning techniques to treat a variety of human maladies.[242] The FDA might

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cloning pursuant to the medical device section of the FFDCA would require the designation of cloning technology as Class III medical devices. *See id.* Such classification would require submission of an application to the FDA, prior to use in the marketplace, demonstrating the safety and efficacy of the procedures. *See id.* In finding that a human replacement heart valve allograft was a medical device, the *Alabama Tissue* court declared that "the Supreme Court[] has allowed liberal construction of the FDC Act consistent with its purpose of protecting the public health." *See* Alabama Tissue Ctr. of Univ. of Ala. Health Serv. Found., P.C. v. Sullivan, 975 F.2d 373, 378 (7th Cir. 1992) (citing United States v. 25 Cases, More or Less, of an Article of Device, 942 F.2d 1179, 1183 (7th Cir. 1991)). "The FDA has consistently interpreted 'device' in a very expansive manner." *Id.* (quoting *25 Cases*, 942 F.2d at 1182 (internal quotations omitted)).

[238] *See supra* notes 185-86, 214-17 and accompanying text (discussing failure of the FDA to assert authority over reproductive technologies and lack of FDA jurisdiction over the practice of medicine).

[239] *See* Price, *supra* note 28, at 628.

[240] *See id.*

[241] *See id.* at 629.

[242] *See id.*; *see also supra* notes 40-43, 52-58 and accompanying text (discussing the application of cloning technology to produce new medicines, develop tissues and organs for transplantation, and advance primordial stem-cell research).

want to avert this possibility by assuming regulatory control. One final reason, perhaps, is that the FDA believes that it possesses the expertise and resources to regulate this high-profile area more effectively than can present-day or newly contemplated governmental bodies.

Whether the FDA can sustain its assertion of jurisdiction over human cloning technology will likely depend on a judicial interpretation of the agency's enabling statutes.[243] If a reviewing court determines that "Congress has not directly addressed the precise question at issue," as is clearly the case with cloning, "the court [will] not simply impose its own construction on the statute, as would be necessary in the absence of administrative interpretation."[244] When a statute is ambiguous or silent on the matter in dispute, the judicial inquiry becomes "whether the agency's answer is based on a permissible construction of the statute."[245] Agency interpretation of a statutory provision is entitled to substantial deference.[246] In addition, courts historically have permitted Congress to delegate rulemaking authority to administrative agencies[247] without finding that such delegation offends the United States Constitution.[248]

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[243] *See* 42 U.S.C. § 262 (1998); 21 U.S.C § 321 (g)(1) (1994); 21 U.S.C. § 321(h) (1994).

[244] Chevron v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-43 (1984).

[245] *Id.*

[246] *See id.* at 843. "Legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute. Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit." *Id.* Congress inadvertently or intentionally may not resolve competing interests, instead leaving resolution of the issues to "the agency charged with administration of the statute in light of everyday realities." *Id.* "When a challenge to an agency's construction of a statutory provision . . . centers on the wisdom of the agency's policy, rather than whether it is a reasonable choice within a gap left open by Congress, the challenge must fail." *Id.* The Seventh Circuit has also found that an agency's interpretation of its own regulation will be sustained unless it is clearly erroneous or inconsistent with the regulatory language. *See* Wisconsin Elec. Power Co. v. Reilly, 893 F.2d 901, 907 (7th Cir. 1990).

[247] *See* WILLIAM F. FUNK ET AL., ADMINISTRATIVE PROCEDURE AND PRACTICE, 471-74 (1997). Until the 1930s, the United States Supreme Court rejected all nondelegation challenges. *See id.* at 472. In 1935, the Court invalidated two statutes on this ground. *See id.* at 472-73 (discussing Panama Refining Co. v. Ryan, 293 U.S. 388 (1935) and A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495 (1935)). Since then, all nondelegation challenges have been rejected, although the doctrine has been used to "justify narrowly interpreting an agency's statutory authority." *Id.* at 472.

[248] U.S. CONST. art. I, § 1 (providing that legislative powers are vested in Congress); U.S. CONST. art. I § 8 (authorizing the delegation of rulemaking to agencies because Congress may enact "all laws which shall be necessary and proper").

Assertion of regulatory authority by an agency like the FDA, however, is not without bounds. For example, in *Brown & Williamson Tobacco Corp. v. FDA*,[249] the FDA attempted to expand the scope of its jurisdiction by regulating tobacco products under the "device" provision of the FFDCA.[250] In characterizing the FDA actions as an attempt to introduce an entirely new regime of regulation not established by Congress, the Fourth Circuit rejected the FDA's interpretation of the enabling statute and held that the FDA, "[b]y its ultra vires action, . . . exceeded the authority granted to it by Congress."[251] Thus, the court invalidated the FDA's rulemaking action.[252] It is likely that other courts, for the exact same reasons, would take a similar stance on FDA assertion of jurisdiction over human cloning procedures.

The fact that congressional attempts have been made to directly legislate in this politically charged area evinces a lack of intent to delegate authority over cloning issues to the FDA. Because it appears that Congress itself could not come to a final consensus on this issue, it is unlikely that it would acquiesce to FDA authority over cloning.[253] Courts undoubtedly would be confronted with the significant challenge of attempting to determine what the legislature would have intended had it contemplated the concept of human cloning when it enacted the FFDCA and the PHSA.

Another question that arises is what entity or person would challenge the FDA's assertion of regulatory authority in this area. Surely a scientist, such as Richard Seed, who is enjoined from the practice of cloning human beings would have standing.[254] Congress itself may take offense to the FDA's assertions and may elect to hold congressional hearings on this matter. In addition, couples denied access to human reproductive cloning procedures might mount a constitutional challenge to FDA attempts to prohibit such efforts.[255]

The remaining question is whether the reach of FDA authority

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[249] 153 F.3d 155 (4th Cir. 1998).

[250] *See* Coynne Beahm, Inc. v. FDA., 958 F. Supp. 1060, *rev'd* 153 F.3d 155 (4th Cir. 1998) (detailing the FDA proffer that cigarettes are combination products consisting of the drug nicotine and a nicotine-delivery device).

[251] Brown & Williamson Tobacco Corp. v. Food and Drug Admin., 153 F.3d 155, 176 (4th Cir. 1998).

[252] *See id.*

[253] *See, e.g., Armey, supra* note 146 (quoting House Majority Leader Dick Armey as rejecting the concept of FDA jurisdiction over cloning).

[254] *See supra* note 24 and accompanying text (reporting on Seed's statements regarding an intent to challenge FDA jurisdiction).

[255] *See supra* note 149 (discussing potential constitutional violations regarding the regulation of privacy rights or liberty interests in the area of procreative decisions).

over human cloning is too far a stretch. Although authority to regulate human cloning is a gray area, and although it would be difficult to determine if such authority exists, it is unlikely that the FDA would survive a serious challenge to its purported authority. In order to prevail, the FDA will need to address constitutional challenges and obtain favorable interpretations of the statutory language of the FFDCA or the PHSA, as well as the congressional intent underpinning these statutes. Such judicial interpretations would further be complicated by ethical considerations and public policy concerns. The most serious impediment to FDA authority, however, would be the inescapable conclusion that the FDA does not possess the authority to regulate the practice of medicine, an area into which cloning technology that is used to create life would clearly fall.[256]

One last perspective worthy of discussion is whether the FDA *should* regulate human cloning at all. FDA regulation would insulate science and its accompanying research initiatives from the political issues encountered during past legislative attempts to ban human cloning.[257] Embarking on this route to agency regulation would allow certain cloning research to continue, yet would preclude the cloning of entire human beings. It would also avoid much of the controversial public debate between the scientific community and the

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[256] *See supra* notes 185-86, 214-17, 238 and accompanying text (discussing the FDA's failure to establish jurisdiction over other reproductive technologies, and the lack of FDA authority to regulate human cloning as a drug, device, or biological product because the agency lacks authority to regulate the practice of medicine).

[257] *See* Paul Berg & Maxine Singer, *Regulating Human Cloning*, SCIENCE, Oct. 16, 1998. Berg, the director of the Beckman Center for Molecular and Genetic Medicine at Stanford University, and Singer, president of the Carnegie Institution of Washington, concluded:

> [W]e are concerned that anticloning legislation will resurface in Congress. Sensitive and flexible guidelines overseen by an interagency regulatory body, including the Food and Drug Administration, NIH, and representatives of the general public, would be better than legislation — an approach that avoids the potential delays and vagaries of the legislative process, encourages research, and fosters public engagement.

Id. *But see* Annas, *supra* note 13, at 124-25. Annas prefers a broad-based agency composed almost exclusively of nonphysicians and nonresearchers to "oversee human experimentation in the areas of genetic engineering, research with human embryos, xenografts, artificial organs, and other potentially dangerous boundary-crossing experiments." *Id.* at 124. In this way public values, rather than parochial concerns, are protected. *See id.* "The suggestion that the . . . FDA can substitute for such an agency is fanciful. The FDA has no jurisdiction over either the practice of medicine or human replication and is far too narrowly constituted to represent the public in this area." *Id.* at 125.

pro-life constituency.[258] In addition, regulatory schemes, unlike rigid statutory mandates, are flexible and can adapt to changing science and technology while utilizing agency expertise in the process.[259] The benefits of human cloning regulation under the auspices of the FDA or an FDA-like agency are apparent.[260] It is now incumbent upon Congress to empower such an agency to carry out this important function in a sensible, well-informed, and nonpartisan manner.

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[258] *See supra* notes 112 and 129.

[259] *See* Greely, *supra* note 33, at 151-52. "Legislatures may be able to set general policies, but the proposed human cloning bans provide a nice study of what can happen when legislatures refuse to delegate the implementation of such regulation to expert agencies." *Id.* at 152.

[260] *See* Andrews, *supra* note 67, at B4. Andrews identified the "need to create a governmental body with the authority to license fertility clinics, assess what reproductive technologies may be safely offered and by whom, and require the collection of follow-up data on the children created by these technologies." *Id.* Andrews preferred the British regulatory model over FDA or Congressional cloning bans. *See id.* An independent agency similar to the FDA should be established to assess all cloning research. *See* Wilmut, *supra* note 6, at 74. Another regulatory model was created by the Department of Health and Human Services in the mid-1970s to regulate recombinant DNA experiments, which at that time were thought of as risky. *See* Greeley, *supra* note 33, at 151. This model, the Recombinant Activities Committee (RAC), is now concerned primarily with human gene therapy and has been proposed as a means to regulate human cloning. *See id.* "Unlike the FDA, the RAC undertakes an open process, including public meetings at which objections, both scientific and ethical, to pending protocols are often aired." *Id.* Ruth Macklin of Albert Einstein College of Medicine supported an FDA-like regulatory scheme to oversee research, including experiments on human cloning. *See* F.D.C. Reports, 9 HEALTH NEWS DAILY, No. 52, Mar. 18, 1997, at 5. Macklin explained, "[S]ince there is nothing analogous to the FDA, we might want to put something like that in place . . . [t]here should be something analogous to the structure that exists for drugs and devices that would have to govern cloning research." *Id.* (internal quotations omitted). NBAC member Carol Greider speculated that a scheme similar to the NIH's RAC model might be appropriate to oversee human cloning research. *See id.*