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**Borrowing Trouble:  
Should the FDA Regulate Human Cloning?**

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I.

## Introduction

Less than a year after scientist Ian Wilmut announced the birth of Dolly, the world's first cloned sheep, entrepreneur and physicist Richard Seed stated on National Public Radio that he intended to establish a for-profit clinic to clone human beings as soon as the technology was available.<sup>1</sup> An immediate, visceral reaction to the prospect of human cloning reverberated throughout the nation and the rest of the world, as private and public organizations alike rushed to impose moratoriums,<sup>2</sup> pass legislation,<sup>3</sup> and appeal to scientists' morality<sup>4</sup> to suppress any attempts to clone a human being. In the thick of this debate it became apparent that no existing arm of the federal government had jurisdiction to monitor privately-funded research. The Food and Drug Administration (FDA) then stepped forward and asserted that it, in fact, did have authority to regulate human cloning under the Public Health Service Act and the Federal Food, Drug and Cosmetic Act.<sup>5</sup>

<sup>1</sup>Steve Sternberg, *Entrepreneur Plans to Clone Babies for Childless Couples*, USA Today, January 7, 1998, at 01A.

<sup>2</sup>See, e.g., Executive Summary, *Cloning Human Beings: Report and Recommendations of the National Bioethics Advisory Commission*, June 1997, at iii (recommending a continuation of the moratorium on federal funding for research on human embryos); *AMA Recommends Voluntary Moratorium on Human Cloning*, American Medical Association Press Release, Feb. 17, 1998.

<sup>3</sup>See, e.g., *Cloning Human Beings*, supra note 2, at iv, recommending that federal legislation be enacted to bar any attempts at human cloning. In response to the NBAC's recommendation, Congress introduced The Cloning Prohibition Act of 1997 and the Human Cloning Research Prohibition Act. See Kimberley M. Jackson, *Well, Hello Dolly! The Advent of Cloning Legislation and its Constitutional Implications*, 52 SMU LAW REVIEW 283, 289-291 (1999). The first Act was voted down due to its breadth and the haste with which it was drafted, see Matthew M. Merrill, *The Sheep Heard 'Round the World: Legislation vs. Self-Regulation of Human Cloning*, 7-SPG KAN. J.L. & PUB. POL'Y 169, 179 (Spring 1998); the second bill has yet to pass as well. See Caroline Daniel, *Conflicting Aims Leave Ban on Human Cloning in Limbo*, Washington Post, July 26, 1998, at A8 [hereinafter *Conflicting Aims*].

<sup>4</sup>See, e.g., W.H.A.50.37, Fiftieth World Health Assembly, 10<sup>th</sup> Plenary Mtg, (May 14, 1997) (condemning human cloning as "ethically unacceptable").

<sup>5</sup>See Dear Colleague Letter from Stuart L. Nightingale, Associate Commissioner (Oct. 26,

Since then the dust has settled. More than one legal scholar has questioned the FDA's claim to authority,<sup>6</sup> and the FDA itself concedes to be re-evaluating its position.<sup>7</sup> While legal scholars struggle to define the scope of the FDA's power, ethical scholars appear engaged in a debate over the moral implications of cloning a human.<sup>8</sup> What these groups have failed to address satisfactorily, and what I intend to resolve, is how these two debates are intertwined and how they can be disentangled. While the bounds of FDA authority may appear no more complicated than any other academic legal question, I intend to show that by regulating human cloning the FDA necessarily takes a stand in the currently ongoing ethical debate in which it should remain neutral.

The FDA must both establish its authority to regulate and, if it finds the authority, must do so within the confines of its stated mission. If cloning falls within the FDA's regulatory authority, the agency can either restrict its development in the laboratory or prohibit its post-experimental introduction into interstate commerce. To do so in either case it must find that some threat to human safety exists,<sup>9</sup> either to the clones themselves or to larger society. During

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1998) (available on FDA website).

<sup>6</sup>See, e.g., Elizabeth C. Price, *Does the FDA Have Authority to Regulate Human Cloning?*, 11 HARV. J.L. & TECH. 619 (Summer, 1998) (concluding that a statutory amendment would be necessary); see also *Conflicting Aims*, *supra* note 3, quoting Professors Richard Merrill and Lori Andrews.

<sup>7</sup>See *Conflicting Aims*, *supra* note 3 ("As it turns out, the FDA is not comfortable with its position, and has set up a working group. . .").

<sup>8</sup>See, e.g., Executive Summary, *supra* note 2.

<sup>9</sup>Once a product has reached the marketing stage, the FDA can also seize it if it is deemed "misbranded"; however, since human cloning has yet to be developed and marketed, it is impossible to predict what types of violations might arise on a case by case basis. For this reason I consider the issue of misbranding to be beyond the scope of this paper.

its experimental stage, however, I argue that cloning poses no threat that can be articulated outside of the current moral debate on human embryo research. Once cloning is developed and marketed, moreover, it becomes even more apparent that the fear of immoral consequences, rather than unsafe products, is at work. For these reasons, I will argue that, even should the FDA conclude that it has some authority to regulate human cloning, doing so would violate its mission to remain neutral in the face of ethical disagreement. The desire to regulate human cloning, I contend, stems purely from anticipation of adverse moral consequences, not from safety concerns. Even if one can fit cloning within the bounds of a statutory definition (though I present arguments that one can not), the FDA nonetheless has no authority to take a position in an ethical debate, and therefore should remain uninvolved in the debate on human cloning.

## II.

### The FDA's Claim to Authority is Statutory, Not Moral

The Food and Drug Administration Modernization Act of 1997 states that the mission of the FDA is to “promote the public health by promptly and efficiently reviewing clinical research”<sup>10</sup> and by ensuring that drugs and medical devices are “safe and effective.”<sup>11</sup> If the FDA finds that any product subject

<sup>10</sup>FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997 [hereinafter FDA MODERNIZATION ACT], §406(b)(1).

<sup>11</sup>*Id.* §406(b)(2) and §406(b)(3). *See also* AGRICULTURE, RURAL DEVELOPMENT, AND RELATED AGENCIES APPROPRIATIONS BILL, 1990, S. REP. NO. 101-84 (2d Sess. 1989), stating that the mission of the FDA is to ensure safety and effectiveness of food, cosmetics, human and animal drugs, biological products, and therapeutic devices.

to its regulation does not meet its standards, it may seize the product,<sup>12</sup> bring an injunction restraining its distribution,<sup>13</sup> or seek criminal prosecution of the manufacturer's high-level employees.<sup>14</sup> The FDA does *not* list bioethical inquiry as among its obligations, nor does the agency see itself in such a role. Specific to the context of human cloning, former Chief Counsel to the FDA Richard A. Merrill has stated that “[t]he FDA is not equipped, either by law or personnel, to grapple with... the wider social issues involved.”<sup>15</sup> The government already has such a body, the National Bioethics Advisory Commission (NBAC), to debate such issues when determining when research can ethically receive federal funding.<sup>16</sup> State courts fulfill a similar role for privately-funded research as well as all issues confined to intrastate commerce.<sup>17</sup> I will argue below that the FDA—in the absence of more than a moral debate—should play no role in regulating human cloning technology because this existing framework is sufficient for the government, if it so desires, to take a moral stance on cloning without imposing constraints on private actors who reach different moral conclusions. First, however, I will present evidence in this section that the FDA, moral objections aside, has no statutory authority to regulate human cloning.

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<sup>12</sup>Food, Drug & Cosmetic Act [hereinafter FDCA] §304.

<sup>13</sup>FDCA §302.

<sup>14</sup>FDCA §303.

<sup>15</sup>See *Conflicting Aims*, *supra* note 3.

<sup>16</sup>The NBAC assumed a high-profile role in the debate on the ethics of human cloning, following Wilmut's announcement of his successful experiment with Dolly, and was responsible for advising President Clinton on an appropriate response. See, e.g., *Cloning Human Beings: Responding to the National Bioethics Advisory Commission's Report*, 27 HASTINGS CENTER REP. 6 (Sept-Oct. 1997).

<sup>17</sup>California, for example, has already passed a statute banning human cloning. See Kenton Abel, *1997 California Legislative Service 688 (West)—Human Cloning*, 13 BERKELEY TECH. L.J. 465 (1998).

A.

#### The Statutory Role of the FDA

The FDA derives its authority from the Federal Food, Drug and Cosmetic Act of 1938<sup>18</sup> (FDCA) and related laws<sup>19</sup> to require compliance with standards of safety and effectiveness for anything falling within the statutory definition of a food, a drug, a cosmetic, a medical device, or a biological product. If a product falls within the drug definition of FDCA §201(g) or the device definition of §201(h), it is regulated by §§501-600. The producer of a drug, under these sections of the Act, may not market the product until it has complied with rigorous pre-clinical and clinical trial requirements, subject to oversight by an Institutional Review Board (IRB) and filed a New Drug Application (NDA) pursuant to §505. Similarly, biological products require a biological product license, and medical devices require a pre-market approval application (PMA). The FDA thus regulates how and when these products reach commercial markets, and can impose certain safety requirements on the procedures of the pre-market laboratory research. The FDA does not, however, dictate the types of products that can be developed, nor does it determine whether use of these products meets a pre-determined moral guideline. Its role is confined to oversight of clinical trials, post-experimental assurance of safety and effectiveness of new products, and mandates of compliance with certain manufacturing stan-

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<sup>18</sup>21 U.S.C.A. §§301 *et seq.*

<sup>19</sup>*See, e.g.*, the Biologics Act, 42 U.S.C. §262, the Public Health Service Act, 42 U.S.C. §264, and the Safe Medical Devices Act of 1990, 104 Stat. 4511.

dards.<sup>20</sup> The FDA's ability to regulate human cloning in this manner depends on its ability to fit cloning technology within a precedented construction of one of the definitions for drugs, medical devices, or biological products.

B.

#### Possible FDA Sources of Authority in the Case of Human Cloning

To fit human cloning within the scope of the FDA's statutory authority, one must find a definition within the FDCA or accompanying statute which it meets. For this purpose it is helpful to have a rudimentary understanding of how the cloning technique of scientist Ian Wilmut works. After providing a brief summary of the technology, I will argue that—assuming human cloning technology will work in a similar way—the statutes establishing the FDA's jurisdiction have definitions which would require highly tortured constructions to bring cloning under FDA control.

1.

#### Nuclear Somatic Transfer

Dolly was cloned by a variant of the technique of nuclear somatic transfer (NST) called "fusion." In this process, an egg cell is "enucleated" (the nucleus is removed) and placed next to an adult donor cell and fused with an electric current. This current also activates the egg's development and a pre-embryo be-

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<sup>20</sup>See Statement of Policy for Regulating Biotechnology Products, 51 Fed. Reg. 23,309 (1986).



gins to develop. The fusion process causes the mitochondria of both the donor cell and the egg cell to mix. (In strict NST, only the egg cell's mitochondria are present because the adult cell's nucleus is directly implanted into the enucleated egg without the pulse of the electric current.) This technique, unlike past attempts, allowed Wilmut to use differentiated, specialized adult cells.<sup>21</sup> The egg then must be implanted in a surrogate mother's womb and gestated normally. The implications of this scientific breakthrough extend far beyond the simple ability to create a genetic twin asexually. One author summarizes the possible applications of Wilmut's research:

[Wilmut] believes that his techniques offer great promises for humans. Indeed, many scientists think that his real achievement may not be in cloning but in allowing us to understand and control cellular differentiation, to derive undifferentiated cells from differentiated cells, to understand how cells age, and to treat diseases caused by mitochondrial DNA. There is also the possibility of cell-based therapy with fusion of a nucleus to an egg for some diseases. . . . [Wilmut] also thinks his techniques will be used in biotechnology to accomplish gene targeting, the insertion of a specific human gene in every cell of a lamb's body. . . . The most exciting prospect here is to modify a sheep CTFR gene to create a model of cystic fibrosis (CF) for gene therapy. . . . Finally, Wilmut's techniques should help create genetically-altered organs of pigs, such that these new organs would have less chance of rejection in transplantation into dying humans.<sup>22</sup>

Others have pointed to the possibility of directing development in order to clone human organs for transplant, a technological innovation that could reduce or eliminate today's lengthy waiting lists for organs.<sup>23</sup>

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<sup>21</sup>GREGORY E. PENCE, WHO'S AFRAID OF HUMAN CLONING? 11-12 (1998).

<sup>22</sup>*Id.* at 12-13.

<sup>23</sup>See Price, *supra* note 6, at 631, citing Joan Stephenson, *Threatened Bans on Human Cloning Research Could Hamper Advances*, 270 JAMA 1022, 1023. This paper, however, is not intended to extend to the case of human organs, the therapeutic purpose of which may result in a more plausible classification as a biological product or drug and thus come within FDA jurisdiction.

## 2. The Statutory Definitions

In 1983 the FDA issued a statement conceding that it lacked authority to regulate human organ transplants;<sup>24</sup> this statement, by analogy, also provides a comprehensive guideline for analyzing its authority to regulate human cloning. The FDA acknowledged that, in order to regulate human organs and to take a stance on the possibility of human organ sales, an organ transplant would have to be classified as either a “drug,” a “device,” or a “biological product,” and concluded that to do so would stretch the relevant statutes beyond accepted constructions.<sup>25</sup> Similarly, human cloning must be classified under one of these headings to come under FDA control, and attempting to do so results in the same dubious interpretations of commonly understood terms.

First, it is clear that the process of human cloning should not be considered a drug. The FDCA defines “drug” broadly as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man” and as “articles (other than food) intended to affect the structure or any function of the body of man.”<sup>26</sup> Arguably, both a human organ’s transplantation and a human clone’s creation could fall within this broad definition of “drug” because both affect the structure and function of the body, but the FDA has acknowledged in its own statement that “[s]uch an interpretation, while arguably supportable, would extend the legal definition beyond the traditional medical concept of the

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<sup>24</sup>*Statement by the Food and Drug Administration Concerning its Legal Authority to Regulate Human Organ Transplants and to Prohibit Their Sale: Hearing Before the Subcommittee on Investigations and Oversight, House Committee on Science and Technology, 98<sup>th</sup> Cong., 1<sup>st</sup> Sess. (1983) [hereinafter *Statement by the FDA*]. The FDA has since shown evidence of re-considering this statement.*

<sup>25</sup>*Id.*

<sup>26</sup>FDCA §201(g)(1)(B) and (C).

term ‘drug.’<sup>27</sup> Furthermore, its own administrative interpretation clarified that a drug should be regarded as “a chemical or a combination of chemicals,” not as an actual human structure.<sup>28</sup> Since all stages of NST involve use of biological matter, not manufactured chemicals, and the end result would be the creation of life, interpreting the statutory definition of “drug” to encompass human cloning would stretch the bounds of plausibility.<sup>29</sup>

The second possible source of FDA authority lies in statutory classification of cloning as a “device.” §201(h) of the FDCA defines “device” as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other...article...which is...intended to affect the structure or function of the body of man.”<sup>30</sup> Again, this “structure or function” definition is broad enough to fit human cloning within its scope, but a practical analysis also renders such an interpretation unlikely. The FDA’s statement on organ transplants discounts an extension of this definition to human products. In addition to an argument based on the Act’s legislative history, the FDA reasons that items listed in the definition indicate an intention to include man-made articles only. In vitro reagents, a possible exception to this characterization, are nonetheless used as a means of diagnosis and thus seem included because they are “useful for [their] intended purpose rather than simply being substituted for [their] equivalent material in the human body.”<sup>31</sup> Human cloning escapes this “useful

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<sup>27</sup> *Statement by the FDA, supra* note 19.

<sup>28</sup> *See id.*, quoting 47 FR 46139, (Oct. 15, 1982), Merck Sharp & Dohme Research Laboratories; Reclassification of Lacrisert as an Approved New Drug).

<sup>29</sup> *See also* Price, *supra* note 6, at 630, concluding that classifying human cloning as a drug would create the unlikely result of necessitating FDA approval of all creation of human life.

<sup>30</sup> FDCA §201(h)(3).

<sup>31</sup> *Statement by the FDA, supra* note 19.

for its intended purpose” classification for similar reasons; more than a simple substitution for a body part, cloning creates a new life that does not serve an independent medical purpose.<sup>32</sup>

The final possibility for an FDA claim to regulatory authority is to regard human cloning as within the scope of the Public Health Service Act’s grant of authority to regulate “biological products.” The definition of a “biological product” extends to “any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product. . . applicable to the prevention, treatment, or cure of diseases or injuries of man. . . .”<sup>33</sup> A broad interpretation of “analogous product” might be stretched to include human cloning as a highly-complex analogue to blood, which the FDA calls “essentially a liquid organ,”<sup>34</sup> but it is clear that cloning a human does not, in itself, prevent, treat, or cure a disease or injury. The FDA has also pointed to the legislative history of the Public Health Service Act to conclude that the definition should be interpreted narrowly.<sup>35</sup>

In sum, there is no obvious statutory authority for the FDA to regulate human cloning. One legal scholar has concluded that a statutory amendment could give the FDA this power,<sup>36</sup> but I will argue in the next section that granting the FDA such authority would be contrary to its mission to ensure public safety while refraining from ethical inquiry. As I elaborate below, one cannot find a

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<sup>32</sup>For an argument similar to the FDA’s own reasoning, see Price, *supra* note 6, at 633-638.

<sup>33</sup>42 U.S.C. §262(a).

<sup>34</sup>*Statement by the FDA, supra* note 19.

<sup>35</sup>*See id.*

<sup>36</sup>*See* Price, *supra* note 6 at 641.

threat to human safety in the process of human cloning unless one makes an inquiry into the purely moral question of when human life begins.

### III.

#### The Ethical Dimension

The FDA has conceded more than once that its authority does not extend to ethical inquiry.<sup>37</sup> If one frames the human cloning debate as one consisting exclusively of conflicting moral philosophies—as I will argue that one must—then it becomes clear that granting the FDA authority to regulate human cloning would create an irreparable conflict with the clearly-defined mission of the Administration to focus solely on safety and effectiveness, and would encroach on the rights of states and advisory boards to engage in extended exploration of the technology’s ethical dimensions and to act on their own conclusions.

#### A.

#### The Risk to Human Subjects During the Experimental Stages of Human Cloning

The FDA has asserted that its ability to halt the experimental stages of human cloning technology lies in its power to impose a clinical hold on any study in which safety is uncertain.<sup>38</sup> This is so because, if cloning technology falls within the scope of the FDA’s authority-granting statutes by meeting one of the definitions described in Part II, *supra*, no entity may conduct clinical

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<sup>37</sup>See Richard Merrill’s comments, *supra* note 11. See also *Statement by the FDA, supra* note , stating that “[t]he statutes FDA administers are not intended to deal with the ethical issues that are involved in the sale of therapeutic products [such as human organs],” thus indicating the Agency’s unwillingness to assume a role in moral policymaking.

<sup>38</sup>Dear Colleague Letter, *supra* note 5.

research without submitting an investigational new drug (IND) application to the FDA, in which it must establish satisfactory compliance with the FDA's requirements for such research. These requirements include a detailed plan for research, authorization from an institutional review board (IRB), and informed consent from all human subjects.<sup>39</sup> The FDA has stated that its "primary objectives in reviewing an IND are, in all phases of the investigation, to assure the safety and rights of subjects, and... to help assure that the quality of the scientific evaluation of drugs is adequate to permit an evaluation of the drug's effectiveness and safety."<sup>40</sup> Consistent with its unwillingness to involve itself in ethical inquiries, then, the FDA would be limited to ensuring human safety during the experimental phases of human cloning.

If the FDA wants to impose a clinical hold on cloning experimentation, therefore, it must first identify a threat to human safety. Two possibilities for such harm can be assumed: either the FDA, in its claim to regulatory authority, anticipates some danger to the adult participants who donate human cells and surrogate wombs, or it senses that experimental harm may befall the cloned human during its development. In the first instance, the risks are sufficiently small to regard informed consent for those subjects as adequate; although some groups have expressed concern that clones might be developed from cells without the donor's consent, the existing medical guidelines requiring informed consent in combination with Constitutional traditions of privacy and reproductive free-

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<sup>39</sup>FDCA §505(i).

<sup>40</sup>21 C.F.R. §312.22(a).

dom are adequate to remedy any violations without FDA oversight.<sup>41</sup> I therefore confine my discussion to the more controversial consideration of what risks experimentation will pose to the cloned humans themselves.

The risks to cloned humans articulated in the debate on NST technology are of two kinds: those that will be inflicted externally on the child or the larger society by virtue of his being a clone, and those that will be inflicted structurally on the child due to imperfections in the cloning process. Since the external harms would occur during the post-experimental stage of cloning technology, I address these below in Part III.B. The structural harms, however, are relevant to the experimental phases of the technology, and include the increased risk of disease, growth abnormalities, DNA mutations caused by environmental and lifestyle factors of the adult donor, and an accelerated aging process.<sup>42</sup> These risks all apply to the individual clone only; no suspected risks to the public during the experimental phase can be identified among these projections.

While all of these risks are real, they are in place at the cellular level, and for this reason the FDA's claim to authority becomes attenuated.<sup>43</sup> Before the FDA can intervene in cloning experiments to ensure the safety of the possible resulting clones, it must first have reached a determination that a potential human

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<sup>41</sup>See Report of the Council on Ethical and Judicial Affairs of the American Medical Association (June 1999). Although *Moore v. Regents of the University of California* indicates that one cannot assert a proprietary interest in one's cells, the opinion does state that a cause of action exists for *non-consensual* harvesting of another's biological matter if the intended use is not adequately disclosed. 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990), *cert. denied*, 111 S.Ct. 1388 (1991).

<sup>42</sup>See Merrill, *supra* note 3, at 171.

<sup>43</sup>Once the cloned human has been gestated, FDA authority to protect its safety attaches less ambiguously (still assuming that cloning meets one of its statutorily-defined areas of authority), but because it argues that it has the power to place a clinical hold on cloning experiments, see Dear Colleague Letter, *supra* note 5, it clearly intends to protect these humans much earlier in their development.

incurs the moral obligation of protection that it extends to fully-developed (post-natal) humans. The problem with making such a judgment is that philosophers and governmental bodies alike disagree as to when potential human life should incur legal protection at the expense of existing human life.<sup>44</sup> The Human Embryo Research panel of ethical experts established by the National Institute of Health issued a report in 1994 favoring federal funding for experiments on human embryos. In 1995, in contrast, Congress banned funding for most such experiments.<sup>45</sup> Meanwhile, Louisiana law defines an embryo as a “juridical person,”<sup>46</sup> but the Supreme Court case of *Planned Parenthood of Southeastern Pennsylvania v. Casey* doesn’t find a fetus’s claim to life compelling until it reaches viability.<sup>47</sup> These parallel debates on human embryo research and the ethics of abortion have produced a wide range of legally expressed viewpoints from which it would be inappropriate for the FDA, as a purely regulatory body, to choose by unilaterally determining that a human cell should be protected as a fully-developed human.

The NBAC also characterized the experimental risks to clones as ones grounded in ethics rather than public safety: “[T]he Commission believes it would violate important *ethical* obligations were clinicians or researchers to attempt to create a child using these particular technologies, which are likely to involve

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<sup>44</sup>For philosophical discussion of this debate, see Mary Warren, *Do Potential People Have Moral Rights?*, in OBLIGATIONS TO FUTURE GENERATIONS 14 (R.I. Sikora & B. Barry eds., 1978); Peter Singer & Karen Dawson, *IVF Technology and the Argument From Potential*, 17 PHILOSOPHY & PUBLIC AFFAIRS 87 (1988).

<sup>45</sup>Ronald M. Green, *Stopping Embryo Research*, 9 HEALTH MATRIX 235, 238-239 (Summer, 1999).

<sup>46</sup>*Id.* at 240.

<sup>47</sup>505 U.S. 833 (1992).



unacceptable risks to the fetus and/or potential child” (emphasis supplied).<sup>48</sup> This statement clearly indicates the NBAC’s belief that weighing the risks to potential humans against the benefits to the existing humans’ body of scientific knowledge is an ethically-based balancing test, not one of pure objective risks. Even if the *risks* to the proto-human matter can be determined objectively, deciding what *weight* to assign to the interests of the unborn—as a counter to the interests of living humans—invokes a hotly contested debate in which the FDA does not have the resources to engage. Because the NBAC is an advisory committee on ethics, its assumption in this context that risks to pre-natal humans are sometimes unacceptable is not adverse to its mission. For the FDA to extend its regulatory power to prohibit these risks, however, it, too, must play a role in making ethical determinations as to when a human life should be created under threat of risk and when it should not.

The cell-based nature of risks to human clones poses a further complication for the FDA’s claim to authority. While it clearly harms a human if one creates a child with a technique which inflicts defects when a safer technique would have produced the *same* child without the defects, the risks anticipated in cloning a child (accelerated aging, expression of detrimental traits, growth abnormalities) are caused by problems intrinsic to the cell, rather than the technique, and therefore the harm is to *different* children—the one developed from an inferior cell, and the one developed from a superior cell.<sup>49</sup> Although one might argue that the technique, rather than the cell, is inherently risky if it does not include

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<sup>48</sup> *Cloning Human Beings*, *supra* note 2, at iii.

<sup>49</sup>For a more developed philosophical analysis of “same people choices” versus “different people choices,” *see generally* Derek Parfit, REASONS AND PERSONS (1984).

a mechanism for suppressing expression of cellular-level defects, the result is still the same: the technique which allows the expression creates one child, while the technique that bypasses the expression creates another. Therefore, in deeming unsafe a technique which allows expression of some undesirable cellular-level defects, the FDA is necessarily pronouncing a moral preference for one type of human life over another. In that sense it is not *protecting* human life, but rather is *selecting* among lives.

The obvious opposition to this argument is that there is a difference between deliberately creating a child with defects in a laboratory and inadvertently creating one through traditional means of procreation. On an intuitive level, it feels like less of a harm when “nature,” rather than a lab technician, allows development of an embryo with cellular-level defects, but I propose that this distinction is illusory.<sup>50</sup> Presumably the scientist creating a human clone has found a family that desires to raise it, since slavery—even to scientists—is not legal in the United States; therefore, this family has consented to the risks inherent in producing a child asexually in exactly the same way another couple implicitly consents to the risks when it creates a child through traditional intercourse. In other words, some assumption of risk is inherent in any decision to create life, regardless of how or where; deciding what kinds of procreative risks are acceptable, assuming that such a decision by government is Constitutionally permissible,<sup>51</sup> is not properly within the mission of the FDA. At the very least,

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<sup>50</sup>The argument that the embryo cannot *consent* to its creation is irrelevant to this inquiry, because no embryo can ever consent to its creation, regardless of the method.

<sup>51</sup>For an exploration of the implications of the Constitutional right of reproductive freedom for human cloning, see Cass R. Sunstein, *The Constitution and the Clone*, in CLONES AND CLONES 207 (Martha C. Nussbaum and Cass R. Sunstein, eds., 1998). See also Kimberly

an FDA regulation which protects human safety by prescribing when and how humans may procreate paints out the feared risks with too broad a brush. At the worst, the FDA would be ignoring its purely regulatory mission and promoting itself to moral arbiter, a role better reserved to others more qualified and better equipped to make such determinations.

If the FDA wants to place a clinical hold (or any other kind of limitation) on the experimental stages of human cloning, it must articulate a safety reason for doing so. I have argued in this section that finding a threat to human safety requires the FDA first to ignore divergent legal and public opinions to conclude that potential humans require legal protection from an administrative body. Next, it must render moral judgments. It must conclude that these potential humans face unacceptable risks in the laboratory which are not outweighed by the interests of living humans and, ultimately, it must determine that humans born in the face of these risks will be worse off than if they were never born at all. In sum, it is not enough for the FDA to conclude that risks to potential humans exist, because these risks only take shape in a dimension of moral inquiry. Instead, the FDA must argue that these potential risks to potential humans pose some larger threat to public safety, and that they simply have not done.

B.

#### The Risks to Public Safety in Post-Experimental Human Cloning

M. Jackson, *Well, Hello Dolly! The Advent of Cloning Legislation and its Constitutional Implications*, 52 SMU L. REV. 283, 295-296 (Winter 1999).

The majority of those who fear human cloning technology tend to do so because of its possible malicious applications once beyond the experimental stage and widely available. If the FDA can gain statutory authority to regulate human cloning, the uses to which the technology is put will also fall within its jurisdiction and it can prohibit cloning altogether if it deems that the consequences of doing so would be unsafe or ineffective. It seems impossible, however, to find a threat to human safety outside of a conclusion that cloning is somehow *morally* harmful. In the words of Professor Laurence Tribe, “the cloning objection . . . takes the form of an irreducible appeal to human nature, whether or not divinely ordained, as the normative source of the case for legal prohibition.”<sup>52</sup> It is this “appeal to human nature” that so clearly extends beyond the bounds of the FDA’s regulatory mission. In this section I will discuss the most commonly predicted undesirable outcomes of widely available technology to clone humans, propose that such fears are either exaggerated or misplaced, and conclude that FDA regulation is not appropriate as a means for protecting either society or the clones themselves.

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#### Post-Experimental Harms to Cloned Children

Common objections to cloning tend to focus on speculation of psychological harm to the cloned child. The American Medical Association (AMA), in its re-

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<sup>52</sup>Laurence Tribe, *On Not Banning Cloning for the Wrong Reasons*, in *CLONES AND CLONES* 221, 227 (Martha C. Nussbaum and Cass R. Sunstein eds., 1998).

port on human cloning, has predicted that it might be psychologically damaging for a child to know its “genetic predispositions” through knowledge of his genetic twin’s own health. “Having insight into one’s potential,” the AMA theorizes, “may cause enormous pressures to live up to expectations (or inappropriately relieve pressure to do so), even more so than those generally experienced by children.” Furthermore, cloning humans “may exacerbate disturbing motivations for having children.”<sup>53</sup> Leaving aside the obvious observation that many parents of non-cloned children place unreasonable expectations on them, it is important to note that those expectations which might be specific to cloning would result from an information asymmetry between scientists and parents, and not from an FDCA-prohibited ineffective product. The solution, therefore, is to provide more information rather than ban the technology altogether for fear of its misapprehension.

As one commentator points out, “many initial impressions of the ability to clone humans are not based in scientific fact. The thought that a person will be exactly like his or her ancestor disregards the fact of social nurturing in the process of human development.”<sup>54</sup> Encompassed within the doctrine of informed consent would clearly be the obligation of cloning clinics to explain what parents could and could not reasonably expect from their cloned child, and thus close the information gap. Also, as cloning technology becomes available and more familiar to the public, it is likely that the public will come to understand it

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<sup>53</sup>*Report of the Council on Ethical and Judicial Affairs of the American Medical Association*, June 1999.

<sup>54</sup>Matthew M. Merrill, *The Sheep Heard ‘Round the World: Legislation vs. Self-Regulation of Human Cloning*, 7-SPG KAN. J.L. & PUB. POL’Y 169, 175-176 (1998).

better:

Social expectations are malleable and can quickly change. True, parents might initially have expectations that are too high and other people might regard such children with prejudice. But just as such inappropriate attitudes faded after the first cases of in vitro fertilization, so they would fade here too.<sup>55</sup>

Another reason that many find human cloning disturbing is because it gives parents the power to determine the genetic make-up of their children, and raises the possibility of a growth in societal discrimination against the genetically imperfect if it is possible to always reproduce with certain knowledge of the genetic outcome.<sup>56</sup> At best this fear is speculative. At worst, an attempt to regulate human cloning based on it runs afoul of the equal protection principle the Supreme Court articulated in *Palmore v. Sidoti*: “The Constitution cannot control such prejudices but neither can it tolerate them. Private biases may be outside the reach of the law, but the law cannot, directly or indirectly, give them effect.”<sup>57</sup>

While it is true that parents may have children for the “wrong” reasons and that cloning technology “may exacerbate” these “disturbing motivations,” for the FDA to prohibit cloning because it fears consumers may use the technology irresponsibly is, like banning drugs solely to prevent off-label uses when the approved uses are safe and effective, a total prohibition on benefits in favor of preventing an unproven risk. As bioethicist Gregory Pence questions, “[m]ost popular discussions about cloning a human assume the worst possible motives

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<sup>55</sup>Gregory E. Pence, WHO’S AFRAID OF HUMAN CLONING? 138 (1998).

<sup>56</sup>*See, e.g.*, Report of the Council on Ethical and Judicial Affairs of the American Medical Association (June 1999). *See also* Merrill, *supra* note 54 at 173, pointing to criticisms arguing that any power to manipulate genes will give rise to a eugenics movement similar to the one in China.

<sup>57</sup>466 U.S. 429, 433, 104 S.Ct. 1879 (1984).

in parents, but why on earth make such assumptions? Without evidence?”<sup>58</sup> Furthermore, unlike the clear-cut cases of approved and non-approved drug use, it would be impossible for the FDA to determine what constitutes an “off-label” use of cloning technology without making some moral determination as to what constitutes an appropriate motivation for having a child. Again, FDA involvement in the application of cloning technology would exceed its traditional role of ethical neutrality.

2.

#### Post-Experimental Harms to Society

Beyond the fear of psychosocial harms to cloned children themselves is the fear that widespread human cloning will have an adverse effect on the human gene pool. Unlike the speculative harms that I described in the preceding section, a technology that threatens the gene pool would pose a clearly articulated threat to public safety which could fall within the FDA’s purview. The AMA describes this potential danger:

In order for human cloning to have a significant effect on the gene pool, cloning would have to be widespread, and clones would have to reproduce. If cloning became widespread, human genetic diversity would decrease. Over time, the benefits of genetic diversity, from having individuals with disease immunity to fostering a population with a wide variety of talents, have helped human beings survive and succeed.<sup>59</sup>

Although lack of genetic diversity can genuinely weaken the health of a species, regulating human cloning on the basis of this threat would pose a logistical problem bordering on the morally-intrusive for the FDA. First, the AMA

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<sup>58</sup>Pence, *supra* note 55 at 65.

<sup>59</sup>Report of the Council on Ethical and Judicial Affairs of the American Medical Association (June 1999).

concedes that gene pool shrinkage is “not the most imminent threat” inherent in human cloning;<sup>60</sup> as Gregory Pence clarifies, to argue that human cloning will cause such a prominent problem “commits the all-or-nothing fallacy: either all human reproduction is going to be asexual reproduction or none is.” As long as sexual reproduction continues on a substantial scale, problems with the gene pool should not surface. In fact, asexual reproduction is unlikely to outstrip traditional procreation in popularity, if for no other reason than that it will always be the more expensive of the two.<sup>61</sup>

If, however, the FDA decided to impose restrictions on the rate with which people could reproduce asexually, it would once more find itself meddling in the reproductive choices of private individuals, something it has chosen not to do in the case of private in vitro fertilization clinics. If it enjoins reproduction by cloning it will have foreclosed a reproductive possibility for many. Although a national health risk would militate some such response, its necessarily intimate consequences should be subject to more political accountability and bioethical discussion than that to which the FDA is currently subject. Furthermore, if the FDA were to abandon its precedent for non-involvement in reproductive decisions, for the sole purpose of prohibiting human cloning, the result would look suspiciously like a distinction based on the moral repugnance of cloning, not on the relative safety of one technique over the other.<sup>62</sup> Once more the

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<sup>60</sup>*Id.*

<sup>61</sup>See Pence, *supra* note 55 at 130, citing comments by NIH Director Harold Varmus.

<sup>62</sup>Legal commentator Susan Wolf argues that it is premature to conclude that cloning is more dangerous than other forms of reproduction, and proposes that *all* private sector reproductive technology should be regulated—with the aid of an advisory board of ethical experts. Susan M. Wolf, *Ban Cloning?: Why NBAC is Wrong*, 27 HASTINGS CENTER REP. 12 (Sept.-Oct. 1997).



FDA would be exceeding the scope of its mission.

#### IV.

##### Alternative Forms of Regulation

When the FDA proclaimed its authority to regulate human cloning, it did so in an environment that lacked federal control over private research and clinics and at a time when scientists seemed poised on the brink of committing a moral outrage. As I have argued above, however, calm reflection reveals that the FDA is not the body best suited to making the moral judgments necessary to regulate human reproduction; here I will argue that the FDA need not overstep its authority for fear that lack of regulation will result in catastrophe. My reasons for this argument are twofold: first, adequate safeguards are either already in place or else can be established by existing organizations; second, no scientist or other entity—even the aspirations of Richard Seed—has evinced an intent to do harm, and therefore issuing prospective and potentially limiting regulations would be premature.

Currently a patchwork of legislative and regulatory regimes govern scientific research. Industry self-regulation and ethical guidelines control the rate at which new technology is developed and introduced at a threshold level.<sup>63</sup> Research that is federally funded is subject to protective regulations for human subjects, and any other restrictions based on ethical objections developed in conjunction

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<sup>63</sup>See Matthew Merrill, *supra* note 54 at 184-185.

with the NBAC.<sup>64</sup> Beyond that, both states and Congress can pass legislation placing wide bans on certain types of research, whether privately or publicly funded.<sup>65</sup>

Contrary to widespread belief that the advent of cloning would result in ethical chaos within the scientific community, those actors who could make such technology available have already indicated an unwillingness to rush to do so. For example, the biotechnology industry imposed on itself a moratorium on human cloning following the birth of Dolly.<sup>66</sup> While Richard Seed's announcement that he nonetheless intends to establish human cloning clinics appears to render industry self-regulation ineffective, in reality Dr. Seed would need that industry's resources and participation to make his ambition a reality. Furthermore, his business would require customers who were themselves comfortable with the technology in order to stay afloat. His intention to make the technology available for a profit was clearly in anticipation of a market demand,<sup>67</sup> not to force unwanted and immoral lifeforms on society.

Once cloning technology has been developed, it will also require the participation of the medical profession to apply the technology to individual consumers, and here one encounters another layer of protection—that of the AMA's ethical guidelines. In response to the advent of cloning, the AMA issued a thorough discussion of the ethical implications of cloning to the medical community, and

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<sup>64</sup>Wolf, *supra* note 62.

<sup>65</sup>See Matthew Merrill, *supra* note 54 at 183

<sup>66</sup>*Id.* at 184.

<sup>67</sup>For an exploration of the potential market demand for human cloning, see Eric A. Posner and Richard A. Posner, *The Demand for Human Cloning*, in CLONES AND CLONES 233 (Martha C. Nussbaum and Cass R. Sunstein eds., 1998).

stated a series of admonitions that physicians not facilitate human cloning until some ethical consensus can be achieved:

Individuals do not have a right to demand that physicians participate in human cloning. Before physicians would be justified in participating in human cloning, the harms and benefits need to be evaluated further with some issues requiring discussion on a societal level. . . . There are limits on the types of procedures to which parents can consent. . . . One of standards the Council recommends is a “best interests test” based on the principles of beneficence and nonmaleficence. . . . The possibility that physicians might play a part in deciding which persons are or are not “worthy” of cloning is contrary to professional medical values by all respectable accounts. . . . The application of cloning for eugenic or discriminatory practices is incompatible with the ethical norms of medical practice.<sup>68</sup>

Finally, international organizations such as the World Medical Association and the World Health Organization (WHO) have issued their own ethical guidelines for human cloning. The World Health Assembly, for example, recommended establishing an investigative body to explore the scientific benefits and ethical risks posed by human cloning, and ultimately recommended a moratorium on cloning until such an inquiry was complete.<sup>69</sup> Despite public perception that scientists always pursue technological innovation in complete disregard for its ethical consequences,<sup>70</sup> therefore, it seems clear that these scientists and the bodies that support their work can be trusted on at least a preliminary level to monitor themselves.

Beyond the realm of self-regulation exist both state and federal safety nets.

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<sup>68</sup>Report of the Council on Ethical and Judicial Affairs of the American Medical Association (June 1999).

<sup>69</sup>*Ethical, Scientific and Social Implications of Cloning in Human Health*, W.H.A.51.10, Fifty-First World Health Assembly, Agenda Item 10, (May 16, 1998)

<sup>70</sup>Scientists certainly have a checkered past when it comes to respecting the rights of human subjects, see Kimberly Jackson, *supra* note 3 at 293, but my assumption here is that the subsequent rise of the informed consent doctrine as well as increased publicity of experimental conditions has largely eradicated the likelihood that scientists will create moral atrocities for the sake of discovery.

President Clinton has already demonstrated his power to dictate public policy by banning all federal funds for cloning and ordering the NBAC to conduct an investigation into its ethical implications.<sup>71</sup> In 1995 Congress passed appropriations legislation that made federally-funded research on human embryos an impossibility,<sup>72</sup> demonstrating that all research dependent on federal funds can be brought firmly under the thumb of the federal government. The gap left by privately-funded research can be covered by state legislatures, as California has already demonstrated, and as a number of other states have proposed.<sup>73</sup>

Legislatures and professional organizations, unlike the FDA, are structured specifically to conduct ethical and local political debates and render consequent determinations in response to a controversial new technology. The biotechnology industry and medical community's willingness to self-regulate demonstrates a clear sense of individual responsibility for caution and reflection in the face of a national debate. The legislative measures of some states, but not others, indicates a possibility of geographical variations in opinion and supports an argument that local regulation may be a preferable alternative to centralized oversight. These data suggest that the moral disaster feared from human cloning is more imaginary than real, and, until some evidence of genuine intent to do harm comes to light, certainly mandate no role for the FDA. As Professor Richard Epstein has argued, "these new developments call for no immediate legal response: Watchful waiting is far preferable to hasty or ill-conceived legis-

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<sup>71</sup>See Wolf, *supra* note 62.

<sup>72</sup>Ronald M. Green, *Stopping Embryo Research*, 9 HEALTH MATRIX 235, 238-239 (Summer 1999).

<sup>73</sup>See Matthew Merrill, *supra* note 54 at 183.

lation whose anticipated consequences are likely to do more harm than good.”<sup>74</sup>

V.

Conclusion

When the NBAC conducted its 90-day investigation into the ethical implications of human cloning, it gathered together a panel of experts covering a range of disciplines: law professors, physicians, research scientists, business leaders, psychologists, economists, religious members, and bioethicists.<sup>75</sup> Its deliberations included assessments of scientific benefits, religious views, cultural values, and psychological projections.<sup>76</sup> The AMA, the WHO, and the biotechnology industries all conducted their own ethical inquiries into human cloning, and made independent recommendations for indefinite moratoriums on such research.<sup>77</sup> State legislatures have entertained bills that would ban or limit the development of human cloning in accordance with local sentiment, and the federal government has long ago banned funding for research on human embryos.<sup>78</sup> The FDA, meanwhile, has limited resources and a demanding mission to review food, drugs, cosmetics, and medical devices for safety and effectiveness, and yet has tried to project its authority into this complicated ethical debate. As I have argued in Parts II and III above, its statutory authority to do so is tenuous under a strictly legal construction of the FDCA and related acts, and is incon-

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<sup>74</sup>Richard A. Epstein, *A Rush to Caution: Cloning Human Beings*, in CLONES AND CLONES (Martha C. Nussbaum and Cass R. Sunstein eds., 1998).

<sup>75</sup>Susan Cohen, *A House Divided*, Washington Post, Oct. 12, 1997, Magazine at W12.

<sup>76</sup>Executive Summary, *Cloning Human Beings: Report and Recommendations of the National Bioethics Advisory Commission*, June 1997, at ii-iii.

<sup>77</sup>See Part IV, *supra*, and supporting documents.

<sup>78</sup>See *id.*

sistent with its stated mission to ensure safety and remain uninvolved in ethical or moral debates. Furthermore, unlike under the existing forms of regulation to which I pointed in Part IV, as a federally-appointed agency the FDA has neither the popular accountability nor the local representation to justify its involvement in what should rightfully be a public debate. For these reasons I conclude that the FDA—even if it *could* find authority to regulate human cloning—should not do so.