

### Regulatory Environment for Human Cloning

Human cloning has been variously defined, but is generally understood as comprising a laboratory procedure called somatic cell nuclear transfer (SCNT) in which an embryo is created by placing the nucleus of a somatic cell, which contains the genome, into an oocyte from which the nucleus has been removed.<sup>1</sup> The resulting embryo contains the identical nuclear genetic material of another individual. Human reproductive cloning involves the placement of that embryo in a woman's uterus for gestation. The baby born as a result of this procedure is considered to be a clone, or genetic copy, of the individual from whom the genetic material was derived. Clones are sometimes referred to as "later born twins" since they share genetic identity with the donor of genetic material in the same way that identical twins do. Typically the genetic identity is based only on the nuclear genetic material; the genetic material present in mitochondria of the cloned individual may or may not be identical to that of the individual being cloned.

Human reproductive cloning can be distinguished from what has been termed "research," or "therapeutic," cloning in that in the latter there is no intent to create a human being and the cloned embryo is not transferred to a woman for gestation. Rather, cells (called "stem cells") derived from the embryo are studied for their potential use in treating certain disorders. However, the underlying laboratory techniques used to make a human clone and to clone cells for research purposes are the same.

#### Federal Laws Restricting Cloning

Since the cloning of Dolly the sheep in 1997, Congress has held hearings on human cloning, several bills have been introduced, and a bill banning cloning was passed in the House but was not acted on in the Senate. While there is general consensus in Congress and among scientific and advocacy groups that reproductive cloning should not be attempted at present, many groups oppose a ban on research cloning because of the belief that it has the potential to lead to cures for many serious diseases. In the 107th Congress, Senator Brownback sponsored several versions of the Human Cloning Prohibition Act that would ban both reproductive and research cloning. This bill was endorsed by President Bush.<sup>2</sup>

While no federal laws specifically addressing human reproductive or therapeutic cloning have been enacted, existing federal laws may restrict human cloning activities. Since 1996 federal law has prohibited funding of human embryo research by the Department of Health and Human Services (DHHS).<sup>3</sup> Furthermore, in August 2001, President Bush announced that federal funding for embryonic stem cell research would be limited to existing stem cell lines. These laws mean that federal funding is prohibited for both the derivation and use of new embryonic stem cell lines,<sup>4</sup> and any attempt to create an embryo either to make a baby or to make stem cells can be done only with private funds.

#### Food and Drug Administration Regulation of Human Reproductive Cloning

FDA's statutory authority derives from the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Public Health Service Act (PHS Act). Beginning in 1998, FDA has, through a series of informal public communications, asserted that these statutory authorities, as currently written, confer jurisdiction to regulate human reproductive cloning.<sup>5</sup> First, in a January 12, 1998 interview with Diane Rehm on National

Public Radio, then Acting Commissioner Michael Friedman asserted that FDA had regulatory authority over human reproductive cloning and was prepared to assert that authority. While he stopped short of stating that FDA would ban attempts to clone humans, he stressed that FDA "would ask for the scientific data that shows that 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."<sup>6</sup> FDA reiterated its position a month later in a letter to Senator Edward Kennedy, who was sponsoring legislation to ban human cloning. The letter assured the Senator that FDA's authority was sufficient to ensure that human reproductive cloning "does not proceed until basic questions about safety are answered."<sup>7</sup>

In October 1998, Stuart Nightingale, then Associate Commissioner for Medical Affairs, sent a letter to several hundred institutional review boards "confirming" FDA's jurisdiction over "clinical research using cloning technology to create a human being,"<sup>8</sup> and informing the IRBs of the FDA regulatory process required before an investigator could proceed with such a clinical investigation. The letter stated that, in accordance with FDA regulations applicable to all regulated products, anyone seeking to conduct clinical research to create a human being would first be required to submit an investigational new drug (IND) application to FDA. However, "since FDA believes that there are major unresolved safety questions pertaining to the use of cloning technology to create a human being, until those questions are appropriately addressed in the IND, FDA would not permit any such investigation to proceed."<sup>9</sup>

On March 28, 2001, Dr. Kathy Zoon, Director of FDA's Center for Biologics Evaluation and Research (CBER), testified before a House subcommittee hearing concerning federal regulation of human cloning. She identified the regulatory documents underlying FDA regulation of a variety of biological products and the statutory and regulatory bases for FDA's jurisdiction over drugs, biological products, somatic cell therapies, and gene therapies, and asserted that the "use of cloning technology to clone a human being would be subject to both the biologics provisions of the Public Health Service (PHS) Act and the drug and device provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act."<sup>10</sup>

Most recently, on July 6, 2001, FDA sent another letter to sponsors and investigators of human research, this time addressing FDA regulation of "human cells used in therapy involving the transfer of genetic material by means other than the union of gamete nuclei." The letter stated that examples of such genetic material include, but are not limited to, (1) cell nuclei (e.g., for cloning), (2) oocyte nuclei, (3) ooplasm, which contains mitochondrial genetic material, and (4) genetic material contained in a genetic vector, transferred into gametes or other cells. The letter further stated that "the use of such genetically manipulated cells (and/or their derivatives) in humans constitutes a clinical investigation and requires submission of an Investigational New Drug application (IND) to FDA."<sup>11</sup>

Although FDA, in these various iterations of policy, has mentioned its existing statutory and regulatory authority over somatic cells, human tissue, and gene therapy, as well as its authority to regulate drugs, the agency has not explicitly articulated the precise nature of the "product" or "products" of human reproductive cloning that FDA had identified as the subject of regulation or the regulatory "category" into which these products would fall. FDA appears to have relied instead on its authority to regulate clinical studies of unapproved new drugs<sup>12</sup> (which also apply to biological products).

No legal challenge to FDA's asserted jurisdiction over human reproductive cloning has occurred to date, thus has been no opportunity for a court to review the legal basis for FDA's assertion of jurisdiction. It is unclear whether a court would uphold FDA's assertion of jurisdiction or the manner in which FDA communicated its jurisdiction. It is also unclear whether, even if such authority were upheld, FDA currently possesses the resources or has in place a regulatory framework sufficient to permit the agency to do an effective job at regulating human reproductive cloning and to address both the scientific and ethical issues raised by such an endeavor, should researchers seek an IND for this purpose.<sup>13</sup> For the moment, FDA's

pronouncements appear to have had the intended effect of inhibiting attempts to make cloned human beings in the United States.<sup>14</sup>

It should also be noted that FDA regulates stem cell therapies, and such jurisdiction would no doubt encompass therapies derived from human embryonic stem cells. A discussion of FDA regulation of therapeutic stem cell products is beyond the scope of this document.

### **State Regulation of Cloning**

Seven states currently have laws prohibiting human cloning. These are: (1) California, (2) Iowa, (3) Louisiana, (4) Michigan, (5) Missouri, (6) Rhode Island, and (7) Virginia.<sup>15</sup> The laws vary in their breadth and scope, with some prohibiting only state funding of human cloning research and others prohibiting the conduct of both research and therapeutic cloning. It should also be noted that California, while prohibiting reproductive cloning, became the first state to enact legislation supporting therapeutic stem cell research,<sup>16</sup> and other states are currently considering similar legislation. No legal challenge has been brought against state statutes banning cloning, but some legal scholars have questioned whether governmental restrictions on human cloning, whether state or federal, would violate the U.S. Constitution.<sup>17</sup>

### **Organizational Policies and Recommendations**

Several governmental bodies, scientific organizations, advocacy groups, and trade organizations have issued policy statements and/or recommendations addressing reproductive and therapeutic cloning. These organizations have opposed, at least for the time being, any attempt to create a human being through cloning. Some groups have supported a voluntary five-year moratorium on cloning human beings.<sup>18</sup> For the most part, both scientific and patient advocacy groups have urged that research relating to therapeutic cloning be permitted to proceed.<sup>19</sup> In contrast, the President's Council on Bioethics, a group appointed by President Bush to advise on bioethical issues related to advances in biomedical science and technology, has recommended a four-year voluntary moratorium on therapeutic cloning. The recommendation is supported by ten of the Council's eighteen members. All members of the President's Council have supported a recommendation to ban cloning to produce children.<sup>20</sup> The National Bioethics Advisory Commission (which preceded the President's Council) and the National Academy of Sciences also have previously issued reports concluding that human reproductive cloning should be prohibited.<sup>21</sup>

<sup>1</sup>Another cloning method involves removing one or more cells from an embryo at the blastocyst stage and using it to form a new embryo.

<sup>2</sup> [President Bush Calls on Senate to Back Human Cloning Ban, Remarks by the President on Human Cloning Legislation](#) (Apr. 10, 2002).

<sup>3</sup> The law provides that none of the funds appropriated for activities of DHHS may be used for “the creation of a human embryo or embryos for research purposes,” or “research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero . . . .” P.L. 107-116 (2002).

<sup>4</sup> [Notice of Criteria for Federal Funding of Research on Existing Human Embryonic Stem Cells and Establishment of NIH Human Embryonic Stem Cell Registry](#) (Nov. 7, 2001).

<sup>5</sup> For an in-depth analysis of the subject, see Richard A. Merrill, Bryan J. Rose, *FDA Regulation of Human Cloning: Usurpation of Statesmanship?* 15 *Harv. J. Law & Tec* 85 (2001).

<sup>6</sup> *Human Cloning Subject to FDA Regulation As a Biological Product, Agency Says*, *FDC Reports -- The Gray Sheet*, Jan. 19, 1998; 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.

<sup>7</sup> Letter from Sharon Smith Holston, Deputy Commissioner for External Affairs, FDA, to Senator Edward M. Kennedy (Feb. 10, 1998) (published in 144 Cong. Rec. S561 (1998)), quoted in Merrill, *supra* note 5, at 100.

<sup>8</sup> [Letter from Dr. Stuart Nightingale concerning FDA jurisdiction to regulate human cloning \(Oct. 26, 1998\)](#).

<sup>9</sup> *Id.* <sup>10</sup> Statement By Kathryn C. Zoon, Ph.D., Director, Center for Biological Evaluation and Research, Food and Drug Administration, Department of Health and Human Services, Before the Subcommittee on Oversight and Investigations, United States House of Representatives (Mar. 28, 2001).

<sup>11</sup> Kathryn C. Zoon, [Letter to Sponsors/Researchers - Human Cells Used in Therapy Involving the Transfer of Genetic Material By Means Other Than the Union of Gamete Nuclei](#) (July 6, 2001).

<sup>12</sup> Merrill, *supra* note 5, at 109.

<sup>13</sup> *Id.* at 133-139.

<sup>14</sup> *Id.* at 102.

<sup>15</sup> See National Conference of State Legislatures, [State Human Cloning Laws](#) (Updated 10/14/02); U.S. Conference of Catholic Bishops, [Current State Laws on Human Cloning](#)

<sup>16</sup> 2002 Cal Adv. Legis. Serv. 789.

<sup>17</sup> See, e.g., Cass R. Sunstein, Symposium: Conceiving A Code For Creation: The Legal Debate Surrounding Human Cloning: Is There a Constitutional Right to Clone? 53 *Hastings L.J.* 987 (2002); Elizabeth Price Foley, The Constitutional Implications of Human Cloning, 42 *Ariz. L. Rev.* 647 (2000); Matthew B. Hsu, Banning Human Cloning: An Acceptable Limit on Scientific Inquiry or An Unconstitutional Restriction of Symbolic Speech? 87 *Geo. L.J.* 2399 (1999); Lori B. Andrews, Is There A Right to Clone? Constitutional Challenges to Bans on Human Cloning, 11 *Harv. J. Law & Tec* 643 (1998); John A. Robertson, Liberty, Identity, and Human Cloning, 76 *Tex. L. Rev.* 1371 (1998); But see Clarke D. Forsythe, Legal Perspectives on Cloning: Human Cloning and the Constitution, 32 *Val. U.L. Rev.* 469 (1998). <sup>18</sup> See, e.g., Society for Developmental Biology, [Voluntary Moratorium on Cloning Human Beings](#) (1997); [Faseb Endorses Voluntary Moratorium on Cloning Human Beings](#), FASEBnews, Sept. 18, 1997; American Medical Association, [H-460.937 Cloning and Human Embryo Research](#).

<sup>19</sup> See, e.g., [Statement of Sharon F. Terry](#), Genetic Alliance Vice President for Consumers, Before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations (Mar. 28, 2001); American Association for the Advancement of Science, [AAAS Resolution: Statement on Human Cloning](#) (Feb. 14, 2002); American Medical Association, [E-2.147 Human Cloning](#) (Dec. 1999); American Society for Reproductive Medicine, [President's Council on Bioethics an Unfortunate Recommendation: Ban Reproductive Cloning: Institute Four-Year Moratorium on Cloning for Research](#), ASRM Bulletin, Vol. 4, No. 28 (July 12, 2002).

<sup>20</sup> The President's Council on Bioethics, [Human Cloning and Human Dignity: An Ethical Inquiry](#) (July 2002).

<sup>21</sup> National Bioethics Advisory Commission, [Cloning Human Beings](#) (June 1997); Committee on Science, Engineering, and Public Policy et al., *Scientific and Medical Aspects of Human Reproductive Cloning* (2002).

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