

Cinderella’s Dilemma: Does the *In Vitro* Statute Fit? Cloning and Science in French and American Law

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I. INTRODUCTION

Modern science is inching toward the possibility of cloning humans. Using somatic cell nuclear transfer technology, the process used to create the Scottish sheep Dolly, scientists are theoretically able to produce a human clone.¹ While this technique is banned in most European nations,

1. See Rick Weiss, *Lost in the Search for a Wolf Are Benefits in Sheep’s Cloning*, WASH. POST, Mar. 3, 1997, at A3. Somatic cell nuclear transfer introduces new DNA into an egg that has

U.S. legislation regarding reproductive research appears to create a loophole for scientists wishing to conduct experiments in cloning a human genotype. This revelation has generated strong international reactions, particularly after Dr. G. Richard Seed, a Chicago scientist, announced that he would attempt to clone a human being.²

Scientifically, cloning may be possible. Yet for many, ethical concerns, such as humanity's interference in the entropy of the gene pool, the quality of life of the cloned individual, and the respect for human dignity, outweigh the advantages of progress. Living out a previously experienced genotype would destroy an individual's notion of freedom and uniqueness in the world.³ Who would want to be the next Margaret Thatcher or Liberace? Why would individuals want to place identical genetic copies of themselves on this planet if it were not out of a motivation to "try again" or to tinker with reality? If a famous person were to be cloned, social expectations would unrealistically dominate that individual's life because it is doubtful that genetic makeup is the only factor in producing individuals of important social stature.⁴

Despite its superficial shock value, cloning raises some of the most fundamental questions of our time and presents humanity with a serious identity crisis. How far should science go before exercising restraint? How should the law respond to the interface between science and human dignity?

In this Comment, the recent French codification of the law governing respect for the human body will be contrasted with the American protection of reproductive rights. Next, this Comment will weigh the individual's right to dignity against the scientist's right to pursue "pure knowledge" and highlight the essential difference between

had its DNA removed, providing a "fertilized" egg. *See id.* This "combination cell" is brought to life with a "nutrient broth and a jolt of electricity." *See id.* It was considered impossible to clone adult mammals before Ian Wilmut and his colleagues cloned Dolly because adult mammal cells are differentiated. *See id.* Adult mammal cells have grown from the DNA combination formed in fertilization and have different DNA patterns than newly fertilized embryos. *See id.* As a mammal develops, genetic codes are turned on and off in each cell in order to create a brain cell or an eye cell. *See id.* While all cells retain the original code, deactivation of sections of DNA occurs, differentiating the code from other DNA codes. *See id.* Scientists thought differentiation was irreversible until Wilmut's team "starved" a sheep's udder cell before cloning it. *See id.* Starving the cell of essential nutrients made the DNA program "turn off," creating a DNA string that resembled the DNA of an undifferentiated embryonic cell ready for implanting. *See id.*

2. *See L'Europe Contre Le Clonage Humain* [Europe Against Human Cloning], LE MONDE (PARIS), Jan. 13, 1998, at 1.

3. *See* Rick Weiss, *Scientist Plans to Clone Humans*, WASH. POST, Jan. 7, 1998, at A3 [hereinafter Weiss, *Scientist Plans*]; *see also* George P. Smith II, *Pathways to Immortality in the New Millennium: Human Responsibility, Theological Direction, or Legal Mandate*, 15 ST. LOUIS U. PUB. L. REV. 447, 456 (1996).

4. *See* Smith, *supra* note 3.

French and American law. Finally, the recent agreements signed by the Council of Europe demonstrate international consensus on the issue, while the FDA has only just recently declared the cloning of humans a regulated and, therefore, prohibited practice based on the Food, Drug and Cosmetic Act.⁵ This Comment will conclude by contrasting these developments in order to elucidate some of the principles of law that bind us as sharers of a common vision, and divide us as ideologically distinct nations.

II. FRANCE

In Article 16 and its subparts of the French Civil Code,⁶ the French legislature codified the law regulating the “right to dignity” of the human body, the donation of organs, and the use of the human body in research.⁷ Article 16 itself establishes that “[t]he law assures the primacy of the individual, prohibits any infringement on the dignity of the individual and guarantees the respect for a human being from the moment of the beginning of his life.”⁸ The twelve sub-parts of the article expand the rights of the individual from a philosophical perspective that holds dignity as the central tenet of the human experience.⁹ The twelve sub-parts of Article 16 expand upon this general rule.

A. *Constitutional Review*

French law prescribes constitutional review prior to the promulgation of a law, regulation, or administrative order. Such a framework is unlike Anglo-Saxon law, which reviews a law after legislative enactment.¹⁰ Constitutional review by the Conseil constitutionnel is established upon the request of sixty members of either the Senate, the National Assembly, the president of either house, or the

5. See Rick Weiss, *Human Clone Research Will Be Regulated*, WASH. POST, Jan. 20, 1998, at A1 [hereinafter Weiss, *Human Clone Research*].

6. See CODE CIVIL [C. CIV.], Law no. 94-653 of July 29, 1994, art. 16 (Ed. Petits Codes Dalloz, 1996) (Fr.) (author's translations).

7. See *id.* Article 16 is the result of a movement to recognize bioethics as a part of law. See CONS. CONST., D. 1995 Chron. 205, note Bernard Edelman (Fr.) [hereinafter Edelman]. The movement was, and continues to be headed by such figures as Mme. Noelle Lenoir, member of the Conseil constitutionnel, and president of the Unesco Ethics Committee. See *L'Europe Contre le Clonage Humain*, *supra* note 2.

8. See C. CIV., *supra* note 6, art. 16.

9. See *id.* arts. 16 - 16(12).

10. See generally Raymond Barraine, *Dictionnaire de Droit* 89-90, Librairie générale de droit et de jurisprudence (1967) (Fr.). Constitutional review in France is not undertaken for the sake of striking down law, but more as a consultative device, where an inquiry is made to the council and ameliorations to the law are suggested. See *id.*

president of the Republic.¹¹ Article 16 and its subsections were referred to in the Conseil constitutionnel and were decided upon in July of 1994.¹² The Conseil constitutionnel was asked to determine whether the law's "conformity with the Constitution could not be affected by any uncertainty."¹³

The Conseil constitutionnel examined the conformity of the laws to the constitution on the basis of two standards, the dignity of man and the liberty of man.¹⁴ The Conseil found that each standard had its roots in French constitutional history.¹⁵ According to the Conseil, the Preamble to the Constitution of 1946 guaranteed the dignity of man against all forms of servitude and degradation, while the Declaration of 1789 affirmed individual liberty as a guaranteed constitutional right.¹⁶

The 1946 Preamble proclaims that "following the victory carried by the free societies over those regimes which attempted to subjugate and degrade the human person, the French people proclaim, anew, that all humans . . . possess inalienable and sacred rights."¹⁷ Some commentators writing on the use of this section of the 1946 Preamble by the Conseil constitutionnel argue that it appears "somewhat audacious" to couch the constitutional guarantee of the dignity of the human person within the ambit of the Preamble.¹⁸ The commentators concede, however, that historically, the 1946 Preamble refers indirectly to the medical practices carried out in Nazi Germany and that the "constitutional condemnation of

11. *See id.*

12. *See* Cons. const., July 27, 1994, D. 1995, 237, note Bertrand Mathieu (Fr.) (author's translation) [hereinafter Mathieu].

13. *Id.* The review of the 1994 laws was long awaited in France. *See id.* at 238. Mathieu notes that "the considerable progress of biomedical science the last few years made it all the more necessary that a juridical framework of constitutional proportions be traced." *See id.*

14. *See id.* at 238. Criticism of the Conseil's decision focuses on the "imprecise" nature of the norms applied in the review. *See id.*

15. *See id.* Established by Charles de Gaulle in 1958, the Conseil constitutionnel was not originally intended to review laws for conformity to the constitution. *See* FRANCOIS LUCHAIRE, LE CONSEIL CONSTITUTIONNEL 19 (1980). Instead, it was formed to limit Parliamentary power which, unstable between 1946 and 1958, resulted in the crisis with Algeria in the late 1950s. *See id.* at 19-20. The Conseil constitutionnel expanded its power in 1971 to that of a "true" court. *See id.* In its 1971 decision, the court held that it could refer to both the 1958 Constitution and to two documents that were reaffirmed in its Preamble, the Declaration of the Rights of Man and of Citizens of 1789 and the Preamble of the Constitution of 1946, in judging the conformity of legislation to the constitution. *See* PIERRE AVRIL & OLIVIER DUHAMEL, LE CONSEIL CONSTITUTIONNEL 13 (Éditions Pouvoirs) (1986).

16. *See id.*

17. Mathieu, *supra* note 12, at 237.

18. *Id.* at 239. In Mathieu's view, the "audacious" aspect of the application of the 1946 Preamble is the linking of the constitution to the recognition of dignity. History, he concludes, explains what he perceives as a leap of logic. *See* Edelman, *supra* note 7.

human degradation necessarily carries with it the acknowledgment of human dignity.”¹⁹

Second, the Conseil constitutionnel made a prior decision using the Preamble of 1946 Constitution for guidance.²⁰ In a 1975 decision concerning an abortion law, the Conseil constitutionnel held that the law in question conformed to the constitutional principle that no act in contravention of the principle of respect for human life from its beginning could be considered tolerable.²¹ Only within certain limited exceptions and conditions could any derogation to such a fundamental principle be allowed.²² Because the concept of *stare decisis* is not a facet of French law, the prior decision functioned only as a guide to the 1994 review of the legislation.²³ Nevertheless, the Conseil constitutionnel still continued to build upon the 1975 decision despite this and expanded the principle in its 1994 decision.²⁴

Thus, based on this right, the Conseil constitutionnel concluded that the principles set forth by the legislature in Article 16 both tended to assure the constitutional value of human dignity and freedom and were, therefore, consistent with the Preamble to the Constitution of 1946.²⁵ The Conseil constitutionnel found that the following general principles set out by the legislature in Article 16 agreed with the constitution: the primacy of the human person, the respect for human beings from the beginning of life, the prohibition of desecration of the human body, the integrity of the human species, and the prohibition of all eugenic practices²⁶ tending towards organized selection of individuals.²⁷

Moreover, the Declaration of 1789 founded a second pillar upon which the law could rest, according to the Conseil constitutionnel.²⁸ Individual liberty, asserted the Conseil, is established by Articles 1, 2 and 4 of the Declaration.²⁹ Article 1 declares the equality of men and citizens; Article 2 establishes the natural and inalienable character of liberty; and Article 4 defines liberty as the power to act in any way that does not harm

19. Mathieu, *supra* note 12, at 238-39.

20. *See id.* at 239.

21. *See id.*

22. *See id.*

23. *See* RENÉ DAVID, FRENCH LAW, ITS STRUCTURE, SOURCES AND METHODOLOGY 55 (1972). Case law is not viewed as binding authority in France. *See id.* Only “written,” or codified law, holds such status. *See id.*

24. *See* J.C.P. 1994, II, 3796, Note Guy Raymond (Fr.) [hereinafter Raymond].

25. *See* Mathieu, *supra* note 12, at 239.

26. *See* Cons. Const., July 27, 1994, D. 1995, 237 (Fr.).

27. *See id.*

28. *See id.* at 237. For an explanation of the applicable constitutional standards, see *supra* note 13.

29. *See* Edelman, *supra* note 7.

others.³⁰ Bertrand Mathieu, professor of law at the University of Dijon, calls the confrontation of individual freedom with other principles of constitutional value a “classical” confrontation of freedoms.³¹

1. Technology Cleaves the Embryo

Despite the conclusions drawn by the Conseil constitutionnel regarding the liberty and dignity of humanity, the Conseil constitutionnel declined to use the standards of judgment employed by the legislature to measure the conformity of the laws to the constitution.³²

It is not within the power of the Conseil constitutionnel to consider or make a decision identical to that of the Parliament. Therefore, the standards used by the legislator, regarding the general state of knowledge or technology, to determine that the principle of respect for all human beings from the moment of the beginning of life was not applicable to embryos conceived *in vitro*, are not within Conseil constitutionnel’s power of review.³³

The principle of separation of powers, central to the French legal system, requires that the Conseil constitutionnel review legislation separately from the legislature’s motivation to enact the law.³⁴ This is based on the concept that the legislature is elected by the people and has the authority to act on behalf of the nation. At the same time, the nonelected members of the Conseil constitutionnel can act against the legislature only as a body that measures the law against the norms prescribed by the French Constitution.³⁵

According to Bernard Edelman, the Conseil constitutionnel’s silence, regarding the use of technology that may interfere with early life, creates an ambiguity in the law as to when full rights accrue to *in vitro* embryos.³⁶ Because the Conseil did not pass on the status of embryos as affected by technology, a differentiation appears between the treatment of *in utero* embryos and *ex utero* embryos. *In utero* embryos, it is argued, are granted a greater degree of protection than *ex utero* embryos.³⁷

30. *See id.* at 239.

31. *See id.*

32. *See id.* at 237.

33. *Id.* (author’s translation). The Conseil constitutionnel’s refusal to review the interface between science and human dignity as perceived by the legislature is at the heart of the debate between Edelman, Raymond and Mathieu.

34. *See generally* Barraine, *supra* note 10, at 90. The French separation of powers doctrine stems from Montesquieu’s political treatises that established separate but interdependent organs of state. *See id.*

35. *See* DAVID, *supra* note 23, at 27.

36. *See* Mathieu, *supra* note 12, at 239; Edelman, *supra* note 7, at 206-07.

37. *See* Edelman, *supra* note 7, at 206-07; Mathieu, *supra* note 12, at 237; Raymond, *supra* note 24, at 460.

2. The Embryo's Two Sides

The problem lies with the necessary pragmatism of permitting parents to select an embryo for implantation after *in vitro* conception and to consent to research on *in vitro* embryos.³⁸ The two camps are in dispute as to whether this relegates embryos to the status of "objects" or "subjects" of the law.³⁹ Professor Mathieu claims that such a distinction makes "these embryos . . . not the subjects of law, but objects of the law."⁴⁰ In diametrical opposition, Guy Raymond, professor of law at the University of Poitiers, claims that "[t]hese texts erase all doubt on the status of the embryo: it is the subject of the law, and not the object."⁴¹

Professor Mathieu's argument, that the failure to protect the embryo is paradoxical, rests on the principle of Article 16: that all humans, from the moment of the beginning of their life,⁴² are accorded the respect and dignity due to human life.⁴³ Yet the embryo is removed from constitutional protection by two conditions: "the first concerns the state of knowledge and technology; the second rests on the fact the Conseil constitutionnel, without speaking to other cases, only focuses on embryos conceived *in vitro* that are not implanted."⁴⁴ The technological interference with the development of embryos permitted by Article 16 includes freezing, therapeutic research on embryos, and the destruction of extra embryos that are not to be used for implanting.⁴⁵

Professor Mathieu argues that the legislature viewed life as a continual process and refused to grant the embryo any special status, just as children and the elderly are given no special status before the law.⁴⁶ Therefore, the Conseil's limited permission to interfere in the development

38. See Mathieu, *supra* note 12, at 240.

39. See Raymond, *supra* note 24, at 460; Edelman, *supra* note 7, at 206; Mathieu, *supra* note 12, at 240.

40. Mathieu, *supra* note 12, at 240.

41. Raymond, *supra* note 24, at 460. These contentions inject secular morality into the debate. Raymond questions the law's ability to survive over time:

We find ourselves with little candles whose flickering flames won't wait to go out in the strong wind of change of biomedical science. In five years, because law is of limited application in time, the lights will be extinguished, "scientific progress" permitting us to go further along the path that makes man think he's becoming God, and the legislature, in the name of human dignity, will organize without doubt that which Aldous Huxley called the "Brave New World."

Id. (author's translation).

42. See C. Civ., *supra* note 6, art. 16.

43. See Mathieu, *supra* note 12, at 240-41; see also C. CIV., *supra* note 6, art. 16.

44. See Mathieu, *supra* note 12, at 240.

45. See *id.* at 240-41. Meanwhile, research on embryos is protected by the CODE DE LA SANTÉ PUBLIQUE art. R. 152(8) 1, May 27, 1997, J.O., June 1, 1997, available in Lexis (LOIREG library, CODES file).

46. See *id.* at 240.

of some embryos removes them from the recognized process of life, deals with them as objects, and removes them from the treatment they deserve as subjects of a law commanding respect for the human body.⁴⁷ This, he concludes, is contrary to the dignity and integrity of human life as announced in the overarching rule of Article 16.⁴⁸

Professor Raymond, on the other hand, maintains the view that the embryo remains the subject and not the object of the law. Beginning with the premise that the law establishes what a "juridical person is, not what a human person is," the law "guarantees the respect for human beings from the beginning of his life."⁴⁹ According to Professor Raymond, the human nature of the embryo is recognized by the fact that the law requires the anonymity of donors.⁵⁰ This is significant, he argues, because Article 24 of the French Civil Code commands that the identity of a donor, who supplies the elements and products of the human body, remains anonymous, and grants the embryo this anonymity, thereby according it the human respect it deserves.⁵¹ In addition, the embryo is legally assimilated to the status of the infant. Thereby, a procedure analogous to that of adoption, rather than donation exists.⁵² "It is no longer considered donating, but a welcoming," states Professor Raymond.⁵³ He continues that the switch in terminology was a significant improvement in the debated legislation, as the original text divided human life into the embryo conceived *in vitro* and the embryo conceived *in vivo*,⁵⁴ with the first being capable of donation and the subject of extensive research.⁵⁵ Thus, inscribing donated embryos into the laws of adoption removed them from being treated as objects and granted them the status of a subject of the law.⁵⁶

Furthermore, while French law permits some research on human embryos, Article 16(4) underlines that all research must have demonstrable therapeutic ends and cannot have the destruction of the

47. *See id.*

48. *See id.*; *see also* Edelman, *supra* note 7, at 207-09 (expressing an even more vocal attack on this point).

49. Raymond, *supra* note 24, at 460.

50. *See id.* Raymond, however, questions the ability of the law to persist in time. *See* Raymond, *supra* note 24.

51. *See id.*

52. *See id.*

53. *Id.* The laws were the result of a number of reports and hearings. Two reports were significant in the legislative discussion in the hearings, that of Madame Lenoir and Monsieur Mattei. *See also* Edelman, *supra* note 7, at 206.

54. "*In vivo*" refers to something contained with the human body. "*In vitro*," translated literally from Latin, means "in glass." *See* WEBSTER'S NEW INTERNATIONAL DICTIONARY (3d ed. 1986).

55. *See* Raymond, *supra* note 24, at 453.

56. *See id.*

embryo as its object.⁵⁷ Under the Code de la santé publique,⁵⁸ embryos cannot be conceived or used for commercial or industrial ends.⁵⁹ This, Professor Raymond argues, is further proof that embryos are granted the dignity they deserve by becoming the subject of the law.⁶⁰

The only regret Professor Raymond expresses about the new law is that the Conseil constitutionnel found that the principle of equality does not inhere to embryos even though embryos possess the right to dignity as all humans do.⁶¹ The legislature recognized that the embryo, regardless of its form of conception, is human life, but that the principles of equality had to be limited to permit the freezing of embryos and the recognition of the mother's right to voluntarily terminate her pregnancy.⁶² This, Raymond claims, grants frozen embryos a superior status, as frozen embryos can live up to five years, while an embryo *in utero* has only ten weeks before the window for an abortion closes.⁶³ This distinction, he argues, is gratuitous and has no basis in the law.⁶⁴

B. *Protecting the Embryo in France*

Although human beings may accord themselves the right to liberty, dignity, and freedom from persecution, respect for human life is circumscribed by the need for scientific research on the human body.⁶⁵ The researcher's ability to technically interfere with human life can conflict with the embryo's right to dignity and liberty if not judicially controlled.⁶⁶ Article 16 imposes general restrictions on researchers, but it is the Code de la santé publique that is more specific in its regulation of scientific research in the area of embryological studies.

Article 16(3) states that "[i]t shall be prohibited to compromise the integrity of the human body except in the case of therapeutic necessity."⁶⁷ Furthermore, Article 16(4) proscribes all eugenic practices as well as any

57. See C. CIV., *supra* note 6, art. 16(4).

58. See CODE DE LA SANTÉ PUBLIQUE [C. SANTÉ PUBL.] art. L. 152(7) May 27, 1997, J.O., June 1, 1997, 8623. See *id.*

59. See *id.*

60. See Raymond, *supra* note 24.

61. See *id.* at 461.

62. See *id.*

63. See *id.*

64. See *id.*

65. See George P. Smith, II, *Toward an International Standard of Scientific Inquiry*, 2 HEALTH MATRIX 167, 175-76 (1992). "The wisest policy is, by consensus, that which promotes a good social, economic or otherwise for the greatest number. Thus, human need and well-being shape the degree of positive good resulting from one policy as opposed to another." *Id.*

66. See Christian Byle, *Bioéthique: Législation, jurisprudence et avis des instances d'éthique*, J.C.P. 1995, I, no. 20, 3848.

67. See C. CIV., *supra* note 6, art. 16(3).

“transformations made to genetic characteristics in the goal of modifying the hereditary characteristics of the person.”⁶⁸

While Article 16 and its subparts cover the canvas with broad strokes, the Code de la santé publique pinpoints the precise intrusions of science on the embryo's tranquillity: prior authorization is required for all studies carried out on embryos, the studies must be supervised by practitioners, the studies must be carried out at accredited institutions, medically assisted procreation must be to further the goal of assisting an infertile couple, both parents must still be alive, the embryo must not be conceived for commercial or industrial ends, the genetic makeup of the embryo must not be affected, and the research must favor the development of the embryo.⁶⁹ Furthermore, research is only permissible during the first fourteen days of development, after which, no experimentation is permitted.⁷⁰ Violations of the Code de la santé publique incur penalties of \$100,000 and seven years imprisonment.⁷¹

C. *Dignity Assured*

Since the inception of the 1994 laws, legal doctrine in France has not questioned the right of the government to restrict science's domain in order to show the respect due to the human body. Rather, commentators like Christian Byk and Pierre Murat note that the compromise between the opposed parties has resulted in a workable definition of the embryo as a subject of necessary research and family planning, and as a potential human life to be treated with respect and dignity.⁷²

Pierre Murat, a professor of law at the University of Chambéry, writes:

Whatever the juridical nature of the embryo . . . what is important in the definitive, is that the statute which is becoming elaborated slowly along the line of difficulties created by medical practices is establishing a protection that is judged to be sufficient, so that the possibilities opened by science do not reduce bit by bit the embryo to nothing but an object among others.⁷³

68. See *id.* art. 16(4).

69. See C. SANTÉ PUBL., *supra* note 58, arts. 152(8)(2) to (4), 152(8)(7) to (8); see also C. SANTÉ PUBL., *supra* note 58, art. R. 152(8)(1) (Fr.).

70. See *id.*

71. See C. SANTÉ PUBL., *supra* note 58, art. L. 152(11).

72. See generally Pierre Murat, *Respect et Protection du Corps Humain*, JURIS CLASSEUR CIVIL 12 (1997), Art. 11 à 16-12, Fasc. 42, 2 Feb. 1997, at 12 (Fr.) (author's translation); Byk, J.C.P. I, 3848, 222. “Thus, the ‘juridical void,’ which, for jurists, never was a substantial reality, loses its mythical reality. But most of all, the question of law's capacity to respond to the challenges of a science that tightens its grip on mankind no longer has reason for being.”

73. Murat, *supra* note 72, at 12 (author's translation).

Murat argues that despite the Conseil constitutionnel's division of the rights granted to *in vitro* and *in utero* embryos, the embryo has been granted a form of dignity.⁷⁴ When guaranteed to the embryo, dignity imposes a search for the best protection from those interests that would seek to promote science over the rights of the embryo.⁷⁵ To this end, Professor Murat notes that the legislators formulated three points:

[T]he creation of embryos must have medically assisted procreation as a goal; the use of the embryo for purposes other than medically assisted procreation is in principle prohibited; pre-implantation diagnosis must remain an exceptional measure. It is possible that in the future and in the process of technical evolution, that this ensemble, while still modest, will be pushed to completion.⁷⁶

Thus, it is interesting to contrast the legal status of the embryo in the United States with the protection it is offered in France. As outlined above, the embryo's rights in France are predicated upon a constitutional value of respect and dignity that is offered the human body. This tension between science and dignity is the catalyst of discussion in both countries.

III. THE UNITED STATES

American law in this area is not based on a concept of dignity. The embryo is not the subject of any rights under federal law in the United States.⁷⁷ The freedom of scientists to pursue their research, as guaranteed by the First Amendment, may present a challenge to the concept of prenatal rights.⁷⁸ Within the state system, Louisiana is the sole jurisdiction to recognize the fetus or the embryo as a juridical person with statutory rights.⁷⁹ Since the announcement of Dolly's cloning in 1997, however, there has been a rush in nineteen states to pass legislation to ban human cloning.⁸⁰ Until recently, it was only through restrictions on federal funding that the federal government could attempt to dissuade scientists from pursuing research on human embryos. However, by manipulating the Food and Drug Administration's (FDA) oversight of scientific

74. *See id.*

75. *See id.*

76. *Id.*

77. *See* *Roe v. Wade*, 410 U.S. 113, 157-59 (1973). "All this . . . persuades us that the word 'person,' as used in the Fourteenth Amendment, does not include the unborn." *Id.* at 158.

78. *See* Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U. L.J. 7, 26 (1993).

79. *See* LA. REV. STAT. §§ 9:121-9:133 (West 1986); *see also* Bartha Knoppers & Sonia LeBris, *Recent Advances in Medically Assisted Conception: Legal, Ethical and Social Issues*, 17 AM. J.L. & MED. 329, 335 (1991).

80. *See* Arthur L. Caplan, *Why the Rush to Ban Cloning?* N.Y. TIMES, Jan. 28, 1998, at A27.

research in the United States, the present administration has been able to close the loophole on implanting cloned human embryos.⁸¹

A. *Federal Law*

The regulations of the Department of Health and Human Services (DHHS) should naturally govern human cloning because the Code of Federal Regulations outlines the power of the DHHS to oversee research and development involving the fetus, pregnant women, and *in vitro* fertilization.⁸² The protections the DHHS offers the fetus and the pregnant mother include the requirement of informed consent of the pregnant woman, overall institutional review by an Ethical Advisory Board,⁸³ appropriate prior studies performed on animals, demonstration that the risk to the fetus is minimal, no monetary inducement to the participant, the development of important biomedical knowledge as the purpose of research, enhanced possibility of survival for the fetus through the research, and the inability of the development of knowledge by other means.⁸⁴

Despite its superficial appearance as a statute that might protect embryos from cloning, the federal regulations apply only to creation of life through fertilization and to women that are already pregnant.⁸⁵ Cloning of a genotype and alteration of a human egg cell through somatic cell nuclear transfer technology is therefore beyond the statute's control.⁸⁶ Moreover, the regulation does not apply to genetic manipulation, which is the focus of cloning research.⁸⁷ Although cloning research produces offspring, it does not attempt to manipulate the embryo once life has been created.⁸⁸ Furthermore, a cloning program is consistent with some elements of the statute, as it favors life and its purpose is the development of important biomedical knowledge.⁸⁹

81. See Weiss, *Human Clone Research*, *supra* note 5, at A10.

82. See 45 C.F.R. §§ 46.201-46.211 (1996).

83. See *id.*

84. See 45 C.F.R. §§ 46.204(a) 46.205(a)(2), .206(a)(1)-(4), .206(b), .209(a)(1), (3) (1996).

85. See 45 C.F.R. § 46.201(a) (1996).

86. *But see* 45 C.F.R. § 209 (c) (1996) ("In the event the fetus *ex utero* is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other subparts of this part."). Whether this subpart covers embryos is debatable.

87. See generally 45 C.F.R. §§ 46.201-46.211 (1996).

88. See 45 C.F.R. § 46.209 (1996).

89. See *id.*

1. The Food and Drug Administration

To fill the gap in the DHHS statute, the FDA has declared that it has the authority to regulate human cloning because it is a form of cellular and genetic therapy requiring prior FDA approval.⁹⁰ FDA officials have stated that any researchers interested in cloning experiments must file an “investigational new drug application” (IND) to experiment on human subjects.⁹¹ Failure to submit an application to the FDA would result in legal action, as prior approval is necessary for experiments involving “more than minimal manipulation” of human cells, or MTMM.⁹² The MTMM standard, as set out by the FDA, is the cutoff between experiments with human tissues that require administrative approval and those that do not.⁹³ It is unlikely that permission would be granted to cloning research on humans, because such research must demonstrate that the proposed experiment “does not pose unreasonable risk of harm to human subjects.”⁹⁴ The requisite proof that danger to a potential human life is minimal is not yet available.

2. Congressional Attempts at Legislation

The announcement that the FDA may control cloning research comes amidst a furor in Congress over how to ban the research. At least two bills were submitted in Congress during the spring of 1997 to halt human cloning.⁹⁵

In March of 1997, Representative Vernon Ehlers of Michigan announced publicly that he had proposed a bill to permanently ban human cloning research and impose penalties on any researcher who attempted to clone a human being.⁹⁶ Quickly, the debate expanded to include elements of the anti-abortion lobby, which sought to impose a ban on any pre-natal research utilizing fetal tissue or embryos.⁹⁷ By August of 1997, Representative Ehler’s bill had been substantially reduced in scope.⁹⁸ In

90. See Weiss, *Human Clone Research*, *supra* note 5, at A10 (quoting acting FDA Commissioner Michael A. Freidman, “Through the Food, Drug and Cosmetic Act we do have the authority to regulate human cloning, and we are prepared to assert that authority.”)

91. See *id.*

92. See *id.*

93. See *id.*

94. See *id.* (quoting acting FDA Commissioner Friedman, “They will have to answer questions like, ‘Have you established animal models? Can you improve the odds? Have you looked at safer alternatives?’”).

95. See H.R. 922, 105th Cong. (1997); S. 368, 105th Cong. (1997).

96. See H.R. 922, 105th Cong. (1997); see also Rick Weiss, *Human Clone Ban Opposed*, WASH. POST, Mar. 6, 1997, at A1 [hereinafter Weiss, *Human Clone Ban*].

97. See Weiss, *Human Clone Ban*, *supra* note 96.

98. See H.R. 922, 105th Cong. (1997).

its final version, the bill sought only to prohibit the federal funding of any research on the cloning of humans, allowing all other areas of therapeutic research to continue on embryos.⁹⁹ In addition to Representative Ehler's bill, Senator Christopher Bond from Missouri has also submitted a bill proposing to ban federal funding of research on embryos for the purpose of human cloning.¹⁰⁰

3. The Executive Office Steps In

In an Executive Memorandum, dated March 1997, President Clinton announced a prohibition on federal funding for human cloning research after consultation with the National Bioethics Advisory Commission.¹⁰¹ The President asked the commission to conduct an emergency analysis of the legal implications of the advances in cloning that were announced in Oregon and Scotland.¹⁰²

The commission's decision, that the federal government should prohibit funding for research and eventually enact a law prohibiting the creation of human being by cloning, was based on the concern that scientists would be restricted from continuing potentially valuable genetic experiments if a complete ban on creation of cloned human embryos for research purposes was imposed instead.¹⁰³ A broad ban on any cloning of embryos would eliminate proposed cloning-related research that offers

99. *See id.* Representative Ehler's bill reads:

Nothing in this Act shall restrict other areas of scientific research not specifically prohibited by this Act, including promising work that involves: (1) the use of somatic cell nuclear transfer or other technologies to clone molecules, DNA, cells other than human embryo cells, or tissues; or (2) the use of somatic cell nuclear transfer techniques to create animals other than humans.

See id.

100. *See* Weiss, *Human Clone Research*, *supra* note 5, at A1; *see also* S. 368, 105th Cong. (1997) (Senator Bond's bill reads simply "Prohibits the use of Federal funds for research regarding the cloning of humans.")

101. *See* Memorandum on the Prohibition on Federal Funding for Cloning of Human Beings, in 33 WEEKLY COMP. PRES. DOC. 281 (Mar. 4, 1997). The Commission is comprised of eighteen members that review the legal, medical and ethical implications of advances in biomedicine. *See* Susan Cohen, *A House Divided*, WASH. POST, Oct. 12, 1997, at W12. The commission is comprised of members such as Alexander M. Capron, co-director of the Pacific Center for Health Policy and Ethics at the university of Southern California in Los Angeles; Harold M. Shapiro, President of Princeton University; Alta Charo, professor of law at the University of Wisconsin at Madison, and Thomas Murray, director of the Center for Biomedical Ethics at Case Western Reserve University. *See id.*

102. *See* Weiss, *Human Clone Ban*, *supra* note 96, at A4. Researchers at the Oregon Primate Research Center announced soon after the news of Dolly's cloning that they had successfully cloned two monkey embryos. *See id.* However, Dolly's news was primary material because it was announced earlier and Dolly was cloned from adult cells, not embryos, which would have been less "differentiated." *See id.*

103. *See* Rick Weiss, *Bioethics Panel Urges Ban on Human Cloning*, WASH. POST, June 8, 1997, at A19.

promise in the areas of Parkinson's Disease, genetically transmitted cancer, infertility, growth of new skin for burn victims, cultured bone marrow for cancer patients, regeneration of damaged nerve cells, cystic fibrosis, somatic cell therapy, germ line therapy, cures for sickle-cell anemia, and the preservation of species close to extinction.¹⁰⁴

The commission concluded that it would be advisable to ban federal funding of human cloning projects, but that private research was beyond the reach of federal law.¹⁰⁵ Therefore, cloning and experimentation on embryos would remain an unregulated activity as long as scientists were able to find private funding for their projects. Anti-abortion groups responded to the recommendation, arguing that such a restriction of funds would be "in essence, . . . a ban with a wink. It would be okay to clone as long as you kill," and pushed for more restrictive federal legislation to halt all forms of human embryological research.¹⁰⁶ Other commentators, as varied as Senator Tom Harkin and Cardinal John O'Connor, have urged regulators to avoid a hastily drawn and over-inclusive ban and seek a precisely tailored regulation of the procedures.¹⁰⁷ Indeed, a *Washington Post* editorial commented, "[o]pen-eyed caution is a better defense . . . than determined ignorance."¹⁰⁸

Federal regulation stems from the tension that binds the debaters in the right-to-life versus the right to scientific inquiry debacle. Presently, science has the upper hand, perhaps because "the discussion is actually running ahead of the science."¹⁰⁹ While technically imaginable, the application of the technology developed for sheep to human cloning is "extremely difficult" and is probably more appropriately used in treatment of disease than actual cloning.¹¹⁰

104. See Curt Suplee, *Top Scientists Warn Against Cloning Panic*, WASH. POST, Mar. 13, 1997, at A3; see also Arthur L. Caplan, *Why the Rush to Ban Cloning?* N.Y. TIMES, Jan. 28, 1997, at A27. This list is noninclusive and some projects are controversial. Germ-line therapy is specifically banned in France, as Article 16(4) commands that no experiments result in the alteration of "hereditary characteristics." See C. CIV., *supra* note 6, art. 16(4). Germ-line therapy eliminates "problem" genes, that some argue are the result of natural selection and are necessary to survival. See Caplan, *supra*, at A27.

105. See Rick Weiss, *Panel Backs Some Human Clone Work*, WASH. POST, June 4, 1997, at A1.

106. See *id.* (quoting John Cavanaugh-O'Keefe of the America Life League).

107. See Editorial, *Cloning Chatter*, WASH. POST, Mar. 15, 1997, at A22.

108. See *id.*; see also Katz, *supra* note 78, at 51-53.

109. See Suplee, *supra* note 104, at A3 (quoting Harold E. Varmus, director of the National Institute of Health).

110. See *id.* (quoting Harold E. Varmus, Director of the National Institutes of Health).

B. State Law

A further danger would be present if the federal government fails to regulate on a national level and passes the issue to the states.

[C]loning is not an activity that should be handled at the state level [S]uch local efforts—which have included proposals to ban all forms of cloning, to make any manipulation of human embryos illegal and to ban any use of human genes in genetic engineering—are a cure far worse than the disease.¹¹¹

Presently, only two states, Louisiana and California, have enacted laws favoring the rights of the embryo over that of scientific research.¹¹² However, with the recent development of cloning technology, some states are responding with different initiatives to ban embryo or cloning research. Nineteen States have introduced bills, and a moratorium on human cloning was enacted in California in October of 1997.¹¹³

1. Pending Bills

As typical examples of the pending legislation, Alabama's two bills prohibit state funds from being allocated human cloning research. Alabama's Senate bill seeks to prohibit the intentional cloning of a human being by qualifying such activity as a Class B felony.¹¹⁴ The bill in the Alabama House of Representatives seeks to "prohibit the use of state facilities or funds for the purpose of conducting research into the cloning of entire human embryos," or the "cloning, or conducting research into the cloning, of animals or autonomous human organs."¹¹⁵

The Minnesota legislature has a bill in both the House of Representatives and in the Senate.¹¹⁶ These bills declare that engaging in human cloning or selling an ovum, zygote, embryo or fetus for the purposes of cloning is a punishable criminal offense.¹¹⁷ Furthermore, any individual found in violation of the proposed law would have his license revoked by the appropriate health board.¹¹⁸

The bills in Alabama and Minnesota provide incentives to halt scientific inquiry into cloning. Alabama's Senate bill is a broad ban that

111. See Caplan, *supra* note 104, at A27.

112. See LA. REV. STAT. §§ 9:121-9:133 (West 1986); S. 1344, Reg. Sess. (Ca. 1997) (enacted).

113. See, e.g., S. 2423, 80th Reg. Sess. (Minn. 1997); S. 68, Reg. Sess. (Al. 1998); H. 1082, Reg. Sess. (Al. 1998).

114. See S. 68, Reg. Sess., § 2 (Al. 1998).

115. See H.R. 1082, Reg. Sess. (Al. 1997).

116. See S. 2423, 80th Reg. Sess. (Minn. 1997); H.R. 2730, 80th Reg. Sess. (Minn. 1997).

117. See H.R. 2730, 80th Reg. Sess. (Minn. 1997).

118. See *id.*

draws no distinction as to the purpose of the cloning or whether cloning research into fetal tissue is prohibited.¹¹⁹ To date, the Alabama House bill permits state funds to go to research in the cloning of animals for agricultural or medical benefits, and for the cloning of autonomous human organs, for therapeutic benefit.¹²⁰

Minnesota's current bills fail to distinguish between research and reproduction using a cloned embryo.¹²¹ The Senate Bill, in its first section, declares that "it is unlawful for any person to engage in human cloning."¹²² In its third section, it declares that cloning is the practice of "creating or attempting to create a [cloned] human being . . . for the purpose of initiating a pregnancy that could result in the birth of a human being."¹²³ By using such vague language as "initiating a pregnancy," and "creating a human being," the statute fails to distinguish between pure research and a concerted effort to bring a cloned embryo to term.¹²⁴ The statute declares that any act contravening the statute results in a felony, thus dissuading researchers from attempting any form of therapeutic research on *in vitro* embryos, with no intent to implant them *in vivo*.¹²⁵

One of a number of bills introduced in New York raises an interesting comparison with the French laws.¹²⁶ A bill in the New York Assembly declares that: "The greatest danger posed by the cloning of human beings lies in [the] terrible exploitation of innocent human beings for the basest of purposes. Human life would be trivialized and demeaned. The legislature therefore finds that it is necessary to prohibit human cloning . . ."¹²⁷

The significance of the proposed New York bill is that respect for human life and the dignity of man is found in the preamble of the statute. In New York, dignity is not recognized as law, but as the rationale upon which the law is built.¹²⁸ Respect for human life exists in the United States, but it is not "written" law, as in Article 16 of the French Civil Code.

119. See S. 68, Reg. Sess. (Al. 1998).

120. See H.R. 1082, Reg. Sess. (Al. 1998).

121. See generally H.R. 2423, 80th Reg. Sess. (Minn. 1997).

122. H.R. 2423, 80th Reg. Sess. § 1 (Minn. 1997).

123. H.R. 2423, 80th Reg. Sess. § 3 (Minn. 1997).

124. H.R. 2423, 80th Reg. Sess. § 3 (Minn. 1997).

125. See H.R. 2423, 80th Reg. Sess. § 2 (Minn. 1997).

126. See H.R. 9183, 221 Ann. Leg. Sess. § 1 (N.Y. 1997).

127. See *id.*

128. See *id.*

2. California's Statute

California's recently enacted statute prohibits the cloning of human beings and permits the Director of Health Services to levy fines for any such violations: \$1,000,000 against a corporation, clinic, or laboratory or \$250,000 against an individual.¹²⁹ The terms of the legislation include a sunset clause¹³⁰ that repeals the bill in 2003.¹³¹ The bill states: "It is the intent of the Legislature to place a five-year moratorium on the cloning of an entire human being in order to evaluate profound medical, ethical and social implications that such a possibility raises."¹³²

The bill specifies that it is not the intent of the legislature to apply the moratorium to the cloning of human cells, human tissue, or human organs.¹³³ Only the replication of an *entire* human being is prohibited by the act.¹³⁴ Furthermore, the bill proposes that a panel of seven members be established, such that there is one representative for each relevant area, including biotechnology, genetics, law, bioethics, medicine, religion and the general public. The members would serve to evaluate the implications of human cloning and to make recommendations to the legislature as to how to proceed.¹³⁵

3. Louisiana's Civil Code

Louisiana's civil code stands out from the legislation in the other states because it predates the concept of human cloning.¹³⁶ Like the French Civil Code, the Louisiana Civil Code accords the *in vitro* embryo "certain rights granted by law" and protects the embryo from intrusion by researchers or commercial applications.¹³⁷ However, the Louisiana Civil Code is more protective of the embryo than the French Civil Code, as it permits no interference with the embryo once a physician has fertilized a human ovum *in vitro* and grants the embryo full recognition as a juridical person prior to implantation in the womb.¹³⁸ The physician is even named a temporary guardian of the embryo if the parents are unidentifiable.¹³⁹

129. See S. 1344, Reg. Sess. (Ca. 1997) (enacted).

130. See *id.*

131. See *id.*

132. See *id.* Compare H.R. 1658, 155th Sess. (N.H. 1997) and S. 5993, 221st Ann. Leg. Sess. (N.Y. 1998). Both bills propose a five-year moratorium on human cloning in order to evaluate the medical, social and ethical implications of human cloning.

133. See S. 1344, Reg. Sess. (Ca. 1997) (enacted).

134. See *id.*

135. See *id.*

136. See LA. REV. STAT. §§ 9:121-9:133 (West 1986).

137. See *id.* § 9:121.

138. See *id.* §§ 9:129, 9:123-6.

139. See *id.* § 9:126.

Furthermore, the physician must not intentionally destroy the embryo and must freeze all extra embryos indefinitely.¹⁴⁰

The two codes reflect the tendency of civil law systems to define the "person" and attach specific rights and duties to him or her.¹⁴¹ Both codes recognize the embryo as retaining the rights of a human being, and both are concerned with inheritance and the ability to trace familial descent.¹⁴² Moreover, both place special emphasis on medically assisted procreation as having the unique purpose of creating an embryo for implantation.¹⁴³ In addition, similar provisions exist in the codes for the supervision of clinicians by a professional medical board that sets the standards for safety and procedure.¹⁴⁴ Creating embryos specifically for research purposes is, therefore, not permitted in Louisiana, as it is in other states.

The problem with such varying state statutes, as Caplan underlines, is that the lack of conformity between the state laws would inhibit the already difficult progress in a field that promises much potential for biomedicine.¹⁴⁵ Caplan suggests that the goal of legislation should be "to buy us the time to insure the safety and proper oversight of human cloning work. Put a moratorium of a few years on any effort to create a human being by means of cloning."¹⁴⁶

The approach adopted in California appears to be the most forgiving to the often conflicting values of science and moral judgment. By permitting some forms of research and establishing a panel for a review of the question, the Californian method appears to be relatively synchronous with, if not superior to, the approach of the executive office. A ban on federal funding does not stop private research, and the procedures for FDA approval are piecemeal and have yet to be disclosed in greater detail than general public statements.¹⁴⁷ Overall, the current approach to this issue in American law is not uniform and is in search of an organizing principle from which to operate. This principle should come from the federal government, while the example from California appears, currently, to be the most appropriate response.¹⁴⁸

140. *See id.* § 9:129.

141. *See* DAVID, *supra* note 23, at 108.

142. *See* C. SANTÉ PUBL. art. L. 152(3), art. R. 184(2)(2) (Fr.); LA. REV. STAT. § 9:133 (West 1986).

143. *See* C. SANTÉ PUBL. art. L. 152(3) (Fr.); LA. REV. STAT. § 9:122 (West 1986).

144. *See* C. SANTÉ PUBL. art. R. 152(8)(4) (Fr.); LA. REV. STAT. § 9:128 (West 1986).

145. *See* Caplan, *supra* note 104, at A27.

146. *See id.*

147. *See* Weiss, *Human Clone Research*, *supra* note 5, at A1.

148. *See id.*

C. *Constitutional Challenges*

Ordered knowledge¹⁴⁹ is held in great esteem by mankind because it aids us in our search for truth in an uncertain and fleeting world. Despite the discomfort truth often brings, we value self-awareness over the anesthetized pain of ignorance. One bioethics scholar defines science as the search of probabilities yielding such a high degree of certainty as to be ordered knowledge.¹⁵⁰ But such knowledge becomes controversial when it conflicts with established values.¹⁵¹

The heart of a democratic society, according to Professor Thomas Emerson, is nourished by the freedom of expression:

[T]he right of all members of society to form their own beliefs and communicate them freely to others must be regarded as an essential principle This is, of course, especially true of political decisions. But the basic theory carrie[s] beyond the political realm. It embrace[s] the right to participate in the building of the whole culture, and include[s] freedom of expression in religion, literature, art, science and all areas of human learning and knowledge.¹⁵²

Even where social discourse is logically flawed, Emerson maintains that it has great social value, as knowledge of any truth is, at most, elusive and incomplete.¹⁵³ The ability to hear and weigh differing opinions, no matter their degree of depravity serves to create a more informed society made up of people better able to participate in responsive societal decisions.¹⁵⁴

But scientific discoveries may be antisocial as well as beneficial to mankind. Science, therefore, holds both ends of the sword and requires encouragement and restriction. This conflict is readily apparent in the debate over human cloning. Some believe genetic research to be the next stage in the technological revolution, while others find it a threat to human well-being.¹⁵⁵ It is necessary to inquire whether the U.S. Constitution allows science a right of inquiry and privacy greater than the interests of dignity and freedom of the individual.

149. See Smith, *supra* note 65, at 448.

150. See *id.* at 447-48. But Smith argues that “[p]robabilities are at the center of scientific inquiry. As such, an absolute form of truth is not within its scope of realization.” See *id.*

151. See *id.*

152. See Thomas Emerson, *Toward a General Theory of the First Amendment*, 72 *YALE L.J.* 877, 883 (1963).

153. See *id.* at 882.

154. See *id.*

155. See Smith, *supra* note 65, at 454.

1. The Scientist's Right to Freedom of Expression

The first question is whether a ban on cloning research constitutes a violation of the scientist's right to freedom of expression.¹⁵⁶ It is a constitutional right to express one's views without the state's interference. However, under certain conditions, the state may intervene.¹⁵⁷ For example, the burning of a draft card represents not verbalized speech, but quasi-speech, that is symbolic action.¹⁵⁸ Symbolic speech may be punished not for its antisocial elements, but only when "a sufficiently important governmental interest in regulating the nonspeech element can justify incidental limitations on First Amendment freedoms."¹⁵⁹ In *United States v. O'Brien*, the symbolic act was not considered a punishable offense, but burning a draft card in which the state had an interest was deemed to be such. Such symbolic forms of speech, or "speech plus," are controllable only through government statutes that are sensitive to free speech interests.¹⁶⁰

The *O'Brien* decision traces the essential distinction between "knowledge" and "action" that is applicable in a First Amendment analysis of scientific experiments.¹⁶¹ This distinction is aided by reference to the granting of patents for technological developments.¹⁶² In *Diamond v. Chakrabarty*, a scientist cloned a species of bacteria capable of separating oil compounds.¹⁶³ Although the bacteria itself, *Pseudomonas*, was incapable of "eating" oil, its utility in cleaning up oil spills was revealed when its DNA structure was altered with other genetic materials.¹⁶⁴ The new organism therefore became the subject of controversy over whether life forms were patentable.¹⁶⁵

The Supreme Court held that Chakrabarty's organism was a "manufacture,"¹⁶⁶ finding that the organism constituted a "useful composition of matter"¹⁶⁷ within the meaning of the congressional patent statute.¹⁶⁸ But if a microorganism is patentable, why would Watson and

156. *See id.* at 452.

157. *See* IRA H. CARMEN, CLONING AND THE CONSTITUTION 35-36 (1986).

158. *United States v. O'Brien*, 391 U.S. 367, 376 (1968); *see also* CARMEN, *supra* note 157, at 39.

159. *O'Brien*, 391 U.S. at 376.

160. *See* CARMEN, *supra* note 157, at 39.

161. *See id.* at 40.

162. *See* *O'Brien*, 391 U.S. at 376.

163. *Diamond v. Chakrabarty*, 447 U.S. 303, 305-06 (1980).

164. *See Chakrabarty*, 447 U.S. at 305.

165. *See id.* at 306.

166. *See id.* at 303.

167. *See id.*

168. *See id.*

Crick's DNA double helix discovery not qualify as a patent?¹⁶⁹ The distinction drawn by the *Chakrabarty* court was that "laws of nature, physical phenomena, and abstract ideas" are unpatentable, whereas a "nonnaturally occurring manufacture or composition of matter" that is a useful invention, is patentable.¹⁷⁰ The discovery of the AIDS virus, for example, or Galileo's calculations of the movement of the heavens, are unpatentable because they are concepts open to debate in the marketplace of ideas,¹⁷¹ without any state-granted exclusivity.¹⁷² That is, where natural truths are uncontrollable bits of information, the government cannot intervene and deprive the marketplace of an idea.¹⁷³ However, when an idea has tangible social utility, or in our case, potential social danger, the government may have reason to monitor the idea once it becomes "action."¹⁷⁴

Thus, free speech is conditioned on "time, place, and manner" regulations.¹⁷⁵ While parading is permitted by the First Amendment as a freedom of expression, parading in front of a courthouse may not be allowed because of its interference with the proper administration of justice.¹⁷⁶ Such "time, place, and manner" regulations would apply to scientific experiments in cases where the research poses a threat to the citizenry.¹⁷⁷

Pursuit of a science then, is qualified by the degree of "speech" that the scientist pursues. The questions are "what is the scientist doing?" and

169. See STEVEN GOLDBERG, *CULTURE CLASH, LAW AND SCIENCE IN AMERICA* 115 (1994). James Watson and Francis Crick set forth the double helix structure of DNA in 1953. Golberg writes: "[a] rapid series of later discoveries filled in the precise nature of the genetic code." *Id.* at 115-16. If knowledge were patentable, the later discoveries would not have been possible.

170. See *Chakrabarty*, 447 U.S. at 309.

171. See *id.*

172. See *id.* at 309-10. "Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. . . . Such discoveries are 'manifestations . . . of nature, free to all men and reserved exclusively to none.'" *Id.* (citing *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

173. See *id.*

174. See CARMEN, *supra* note 157, at 39-40.

175. See *id.*

176. *Cox v. Louisiana*, 379 U.S. 559 (1965). "Since we are committed to a government of laws and not of men, it is of the utmost importance that the administration of justice be absolutely fair and orderly." *Id.* at 562.

177. See *Paris Adult Theatre I v. Slaton*, 413 U.S. 49 (1973). While *Paris Adult Theatre* dealt with obscenity, its holding covers all forms of danger to the public through "expression":

In particular, we hold that there are legitimate state interests at stake in stemming the tide of commercialized obscenity. Rights and interests "other than those of the advocates are involved." These include the interest of the public in the quality of life and the total community environment, the tone of commerce in the great city centers, and possibly, the public safety itself.

Id. at 57-58 (citing *Beard v. Alexandria*, 341 U.S. 622, 642 (1951)).

“how is he going about doing it?”¹⁷⁸ If cloning constitutes the expression of pursuit of knowledge, then it is not controllable by the state.¹⁷⁹ If cloning constitutes action falling within a specific state interest, then it is controllable.¹⁸⁰

Ira Carmen writes that a law distinguishing between cloning as a “‘way of knowing’ and cloning essentially as a means for producing that which allegedly possesses specific social utility . . . [is] constitutionally permissible.”¹⁸¹ Such a law, he explains, would need to be sensitive to the condition that cloning “as a way of knowing” is “expressive activity.”¹⁸² On the other hand, cloning as “that which allegedly possesses specific social utility” could be qualified by the law as being pernicious to social interest, and therefore rationally addressed by a “time, place, and manner” regulation imposed by the state. Thus, cloning serves to restrict the “non-speech” element of scientific experimentation.¹⁸³ As a result, the research scientist’s right to freedom of expression is harnessed by the limits that the state may impose on him out of concern for public health and safety.

2. The Scientist’s Right to Privacy

The second constitutional question concerns the scientist’s right to privacy. In *Griswold v. Connecticut*, the Supreme Court established the principle that the right to freedom of speech includes freedom of inquiry, freedom of thought, and freedom to teach.¹⁸⁴ Private citizens pursuing hobbies or professions within the home are the mythical image of the inventor, and the privacy of the individual is guaranteed by the penumbras¹⁸⁵ emanating from the First, Third, Fourth, Fifth and Ninth Amendments.¹⁸⁶ In addition to this privacy, the notion of the pursuit of science as “expression,” rather than regulated “pernicious action,” would tip the balance towards the individual, experimenting at home, over any

178. See Emerson, *supra* note 152, at 888. “The guiding principle must be to determine which element is preponderant in the conduct under consideration. Is the expression the major element and the action only secondary? Or is the action in the essence and the expression incidental?” CARMEN, *supra* note 157, at 47.

179. See *id.*

180. See *id.*

181. See CARMEN, *supra* note 157, at 46; see also GOLDBERG, *supra* note 169, at 86-87.

182. See CARMEN, *supra* note 157, at 46.

183. See *id.*

184. See *Griswold v. Connecticut*, 381 U.S. 479, 482 (1965). “The foregoing cases suggest that specific guarantees of the Bill of Rights have penumbras, formed by emanations from those guarantees that help give them life and substance.” *Id.* at 484 (citing *Poe v. Ullman*, 367 U.S. 497, 516-22 (1961)).

185. See *id.*

186. See *id.*

state interest to curtail such activity.¹⁸⁷ But once the research has an effect beyond the confines of the scientist's private domain, the state has ample rights to interfere.¹⁸⁸

3. Federal Funding

However, the present state of scientific research does not permit private research.¹⁸⁹ The need for funds implicates wealthy donors, blurring the distinction between private and public arenas.¹⁹⁰ As the wealthiest donor, the federal government is the largest financier of scientific research.¹⁹¹ When research becomes dependent on federal grants, the state does not need to forward any compelling interests to cease funding a program, because federal funds are granted on a discretionary basis and are limited.¹⁹² The Constitution places no duty upon the government to fund scientific research; consequently, withdrawal of funding is at the government's will.¹⁹³ The only standard of constitutional analysis would be that of a rational purpose in conferring federal funds to one project over another.¹⁹⁴

Once the control of the conditions of research are financially implicated, the state has every interest in protecting the subjects of research, and may, therefore, restrict the scientist's freedom in opposition to the rights of the individual.¹⁹⁵ Again, through taking the form of "time, place, and manner" regulations, like the DHHS restrictions on research involving pregnant women and fetuses, the state may conclude that the subject's freedoms are of greater importance than the scientist's and regulate the experiment accordingly.¹⁹⁶

Even in the private arena, researchers in cloning technology cannot perform their experiments without involving human subjects.¹⁹⁷ The government would be unable to impinge upon researchers studying inanimate objects unless the research posed a threat to the general public.¹⁹⁸ For circumstances in which the scientist is performing tests on potential lives, the FDA may assert its authority under the "time, place,

187. See CARMEN, *supra* note 157, at 38; see also *Griswold*, 381 U.S. at 482.

188. See GOLDBERG, *supra* note 169, at 86-87.

189. See CARMEN, *supra* note 157, at 48.

190. See *id.*

191. See GOLDBERG, *supra* note 169, at 31.

192. See CARMEN, *supra* note 157, at 49.

193. See *id.*

194. See George P. Smith II, *Genetics, Ethics and Freedom* 130, Associated Faculty Press, (1981); see also CARMEN, *supra* note 157, at 48-49.

195. See CARMEN, *supra* note 157, at 52-53.

196. See *id.*

197. See *id.*

198. See generally CARMEN, *supra* note 157, GOLDBERG, *supra* note 169.

and manner” theory of curtailing the rights of the scientist.¹⁹⁹ Thus the “public” element of the “private” research is the juncture at which the government may make its presence felt.²⁰⁰

The above questions shed light on the Executive Memorandum issued in March of 1997, the pending legislation in the state legislatures, and the attempt by Congress to regulate human cloning. Because the government can constitutionally restrict the funds it grants to research, and because a large portion of research depends on government funds, the prohibition is bound to affect the progress of research in genetic manipulation.²⁰¹ Conversely, research that is entirely privately funded cannot be controlled by the federal government, except as it regards the interests of the subject or the general public affected by the research.²⁰² As a consequence, the United States, by carefully regulating research grants, may achieve the same result as in France, but without invoking the principle of dignity as the basis for regulation.

IV. THE “WORRISOME DRIFTS” BETWEEN AMERICAN LAW AND THE INTERNATIONAL CONSENSUS

Because the United States possesses a strong scientific community capable of rapid advancement in the arena of human cloning, international reaction to Dr. Richard Seed’s announcement that he would seek to clone a human being was swift.²⁰³ Ironically, at the same time Seed became a public figure, an Additional Protocol to the Council of Europe’s Convention on Human Rights and Biomedicine was being signed in Paris.²⁰⁴

In January of 1998, at the opening ceremonies in Paris, French President Jacques Chirac explained that a prohibition on human cloning would need to have an international scope if the states hoped to resolve the issue. Chirac stated, “It is such a consensus that the UNESCO International Committee on Bioethics was able to create through the Universal Declaration on the Human Genome And it is thus that the worrisome drifts that have just recently become publicly acknowledged in the United States will be controllable.”²⁰⁵

199. See CARMEN, *supra* note 157, at 52-53.

200. See *id.*

201. See *id.*

202. See *id.*

203. See *L’Europe Contre le Clonage Humain*, *supra* note 2, at 1.

204. See *id.*

205. See Jacques Chirac: “Empêcher des Dérives Inquiétantes,” LE MONDE, Jan. 13, 1998, at 2 (author’s translation). (“We will resolve nothing in banning certain practices in one country if researchers and doctors can develop them elsewhere,” Chirac concluded).

The Additional Protocol was added to the Convention on Human Rights and Biomedicine which was signed in Oviedo, Spain, in April of 1997.²⁰⁶ The Convention sets out in its Preamble that science and medicine are at the service of the human right to dignity and freedom.²⁰⁷ It recognizes science's capacity for beneficial and harmful purposes and stresses international cooperation to ensure that the right to dignity is conferred on all people.²⁰⁸ The Additional Protocol signed in Paris focuses one area of the Convention on human cloning.²⁰⁹ Reaffirming that "dignity of the human being" is the basis for prohibiting cloning and that human cloning represents a misuse of biology and medicine, the first article of the Protocol prohibits "any intervention seeking to create a human being genetically identical to another."²¹⁰ Importantly, the Additional Protocol does not prohibit cloning research into nonhumans²¹¹ and recognizes the "progress that some cloning techniques themselves may bring to scientific knowledge and its medical application."²¹²

Thus far, twenty-two members of the Council of Europe have signed the Convention and seventeen have signed the Additional Protocol to the Convention, which remains open to non-European states.²¹³ Germany and Great Britain have not signed the Protocol; Germany finds that its own laws provide for stricter standards, while Great Britain refuses to recognize the right of the state to interfere with research.²¹⁴

Meanwhile, the ability of the United States to sign the Convention on Human Rights and Biomedicine and its Additional Protocol is hampered by the current status of law on human cloning in the United States.²¹⁵ Although the FDA has announced its ability to monitor cloning research, it is likely that congressional action over the next year will continue to focus on the question.²¹⁶ The United States must arrive at a legally watertight solution before it may sign international agreements prohibiting human cloning.²¹⁷

206. See Convention on Human Rights and Biomedicine, April 4, 1997, Council of Europe, 36 I.L.M. 817 (1997).

207. See *id.* at 821.

208. See *id.* at 821.

209. See Draft Additional Protocol to the Convention on Human Rights and Biomedicine, Sept. 22, 1997, 37 I.L.M. 1415, 1417 [hereinafter Additional Protocol].

210. See *id.* at 1417.

211. See *id.*

212. See *id.*

213. See *L'Europe Contre le Clonage Humain*, *supra* note 2, at 1.

214. See *id.*

215. See Additional Protocol, *supra* note 209, at 1417.

216. See *id.*

217. See *id.*

Secondly, the Convention recognizes human dignity and freedom as ultimate goals, while the right to dignity is not explicitly enumerated in the American Constitution.²¹⁸ While human dignity is by no means repugnant to the concept of freedom in the United States, and was one of the chief ends of the American Revolution, it remains outside the realm of constitutional values, unless it can potentially be drawn into the protections granted by the Constitution under the penumbras of due process or by some other constitutional interpretation. This right, because it has been recognized in the French Constitution of 1946, and because it is mirrored in Article 16 of the French Civil Code, permits a greater sense of ease to lawmakers in France than it would in the United States.²¹⁹ A prime example of this is the proposed legislation in the New York Assembly.²²⁰

V. CONCLUSION

With the news that two cattle were cloned in Massachusetts using elements of human genes to help the cows produce milk needed by hemophiliacs,²²¹ it is evident that the gap between current technology and human application of the cloning process is narrowing. Although not imminent, human cloning presents constitutional, ethical, legal and philosophical questions. Do we value the fruits of the research over the impact cloning may impart on our self-perception?

The above questions must be resolved at both the individual and the collective level because the nations of the world must decide whether they will embrace the advances of science or reject them as incompatible with the concepts of human dignity and value. The reactions in Europe are indicative of the Continent's experience during World War II.²²² Contrasted to France and the majority of Europe's regulation of this research, the slow progress in the United States reflects the limited development in the area of individual dignity and the predominance of science and economics in constitutional theory.

Contrasting the American and the French systems brings forth the approach used by the state to harness the scientist's freedom of expression. France does so through dignity. The United States may do so through "time, place and manner" regulations. Both Constitutions respect the individual, and demand controlled state power. But neither permits the scientist complete freedom. Despite the inherent values of self-

218. *See id.*

219. *See Trois Questions à Noelle Lenoir*, LE MONDE, Jan. 13, 1997, at 2.

220. *See* H.R. 9183, 221, Ann. Leg. Sess. (N.Y. 1998).

221. *See The Moo Two: Any Way You Splice It*, NEWSWEEK, Feb. 2, 1998, at 65.

222. *See Trois Questions à Noelle Lenoir*, *supra* note 219.

discovery and self-awareness, the balance tips in favor of the interests of society over science. Professor Emerson's ideally democratic people would be dominated by a preferred group and speech that becomes dangerous action would be subject to limitation. In the United States, public safety is the controlling factor. In France, it is the notion of dignity that has received attention in the last few years, rising to a Constitutional standard *par excellence*. Thus, although the means may be different, the ends are the same: cloning research can and will be regulated.