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Government Regulation Of In Vitro Fertilization, Recombinan DNA and Cloning Biotechnologies: Where Powers End And Rights Begin

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Abstract

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KEYWORDS: DNA, In Vitro, Fertilization

Government Regulation of In Vitro Fertilization, Recombinant DNA and Cloning Biotechnologies: Where Powers End and Rights Begin

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In this age of bureaucratic proliferation it is hard to imagine any aspect of our lives that is not somehow affected by government regulation. In particular realms, the power of the government to regulate is regarded not as an option but as a duty. The American legal system has traditionally held that the protection of the public health is one of the first duties of government,¹ and that there is no public policy more important than

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1. U.S. CONST., preamble, states: "We the People of the United States, in Order to . . . promote the general Welfare . . . do ordain and establish this Constitution for the United States of America." For a discussion of the government's responsibility to protect the public health, see Tobey, *Public Health and the Police Power*, 4 N.Y.U. L.REV. 126 (1927). The United States Supreme Court affirmed this tenet in *Powell v. Pennsylvania*, 127 U.S. 678 (1888). Subsequently, a number of cases from various jurisdictions have based their decisions on the premise that the protection of the public health is one of the first duties of government. See, e.g., *People v. Robertson*, 302 Ill. 422, 134 N.E. 815 (1922) (quarantine imposed by legislature held constitutional as an exercise of government's duty to preserve the public health); *Patrick v. Riley*, 209 Cal. 350, 287 P. 455 (1930) (Bovine Tuberculosis law is designed to promote the public health and is thus a matter on which the government is necessarily authorized to take action); *Central States Life Ins. Co. v. State*, 80 S.W.2d 628 (Ark. 1935) (since one of the first duties of government is the protection of the public health, funds set aside by legislature to promote the public health is a necessary expense of any government, and thus constitutional); *United States v. Darby*, 312 U.S. 100 (1941) (it is the duty of Congress to exclude from commerce articles which may be injurious to the public health or welfare); *Lewis Food Co. v. State Dept. of Public Health*, 110 Cal. App.2d 759, 243 P.2d 802 (1st DCA 1952) (statute regulating the sale of horse meat is a reasonable exercise of the government's duty to conserve the health of its citizens); *Yaworski v. Town of Canterbury*, 21 Conn. Supp. 347, 154 A.2d 758 (1959) (ordinances relating to garbage disposal are reasonable exercises of government's duty to safeguard the health of its people); *Ellis v. City of Grand Rapids*, 257 F. Supp. 564 (D.D.C. 1966) (renewal

the protection of citizens from practices which may injure their health.²

Historically, the promotion or protection of public health and safety has been a matter particularly for the state government.³ Where the federal government has acted to regulate a particular field of health and safety, a state or local government cannot act⁴ unless the state or local regulation is consistent with and does not invalidate any section of the federal law.⁵ If the federal government has not acted, the state is free to legislate regulations, for a state has broad power to make and enforce standards to promote the health of those within its borders.⁶

In the not too distant future, the promotion of the public health will take on added meanings. Members of the human race will have wide-

and expansion of medical care centers through urban renewal projects is a public service in accordance with the government's responsibility to protect the public health and welfare).

2. See, e.g., *State ex rel. Anderson v. Fadely*, 180 Kan.652, 308 P.2d 537 (1957) (statute authorizing allocations for the protection of persons and property from "extraordinary conditions" should be liberally construed, since no obligation of government is more important than the preservation of the public health); *Friedlander v. Cimino*, M.D., 385 F. Supp. 1357 (D. D.C. 1974), *rev'd on other grounds and remanded*, 520 F.2d 318 (2nd Cir. 1975) (proficiency testing programs for laboratories operated by nonphysicians are essential to protect the public health, which is the most important of all public policies).

3. *Tobey*, *supra* note 1. For cases, see, e.g., *In re Seiferth*, 137 N.Y.S.2d 35 (1955), *rev'd on other grounds*, 127 N.E.2d 820 (Ct. App. 1955) (Act ordering surgical care of neglected children is valid, since the state has an enormous interest in the physical and mental health of its inhabitants); *Borough of West Caldwell v. Borough of Caldwell*, 138 A.2d 402 (N.J. 1958) (the power of the state government to regulate and control public health and sanitation is an essential governmental function, and cannot be surrendered or impaired by contract).

4. For preemption provision, see *Chemical Specialties Mfrs. Ass'n., Inc. v. Lowery*, 452 F.2d 431 (2nd Cir. 1971) (because in enacting the Federal Hazardous Substances Act, Congress used the phrase "precautionary labeling" in preemption provision to refer to all labeling of hazardous substances covered by the Act, city regulations in question are inconsistent with FHSA, and thus preempted).

5. See, e.g., *Cohen v. Bredehoeft*, 290 F. Supp. 1001 (1968), *aff'd*, 402 F.2d 61 (5th Cir. 1968), *cert. denied*, 393 U.S. 1086 (1969) (city ordinance ordering the destruction of any fireworks within the city's jurisdiction is valid and enforceable where state and federal statutes do not restrict the power of home rule city to enact such ordinances).

6. See, e.g., *Barsky v. Board of Regents of University of State of New York*, N.Y., 347 U.S. 442 (1954) (New York State Education Law is not unconstitutional, as the state has broad power to protect the public health); *Stephens v. Dennis*, 293 F. Supp. 589 (D.D.C. 1968) (a state has broad power to protect the health of its citizens; including the plenary power to fix terms of admission into the practice of any profession concerned with health).

spread access to new technologies which will critically affect the public health and safety: the biotechnologies of in vitro fertilization,⁷ recombinant DNA,⁸ and cloning.⁹ Since the potential effects of these techniques could significantly transform our world and even life as we know it, the public policy decisions made regarding their use are of great importance.

The effects of these biotechnologies are frequently fantasized in a science-fiction like manner by the media and, as a result, are rarely examined in a rational, systematic manner. The constitutional basis and need for regulation in this field have been all but ignored. It is crucial, however, that the constitutional ramifications of these technologies be fully explored. Accordingly, it is the intent of the author to help fill this void by formulating a solid constitutional framework for assessing the implications of these three biotechnologies.

Part 1 focuses on the ninth amendment's guarantee of individual rights in this area and Part 2 addresses the issue of the extent to which the commerce clause can be invoked as a basis for government regulation. In Part 3 a model for making constitutional public policy decisions of a regulatory nature is proposed. Parts 4, 5 and 6 apply this model to the biotechnologies of in vitro fertilization, recombinant DNA and cloning, ultimately suggesting the extent to which government regulatory policy is necessary and proper in each field.

1. THE ROLE OF THE NINTH AMENDMENT

In matters of government regulation, the courts have assumed that the power to regulate lies somewhere, whether it be with the federal, state or local governments. This assumption has been based at least in part on the tenth amendment: "*The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.*"¹⁰

The widespread preoccupation with the power of the government to regulate has resulted in a failure to give the last words of the tenth

7. See text accompanying notes 93 through 96 *infra* for an explanation of this technique.

8. See text accompanying notes 119 through 134 *infra* for an explanation of this process.

9. See text accompanying notes 224 through 230 *infra* for an explanation of this technique.

10. U.S. CONST. amend. X.

amendment the attention they merit. The fact that this amendment reserves powers to the people themselves, as well as the states, has been largely ignored.¹¹

Furthermore, rights which preclude grants of power are also reserved to the people¹² in the ninth amendment of the Constitution: "*The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.*"¹³

A. Historical Interpretations

Upon a preliminary reading, one might conclude that the ninth amendment is a fountainhead of rights.¹⁴ Instead, this single sentence has emerged over the years as a fountainhead of consternation and controversy, and widely varying theories of interpretation have been proposed.

Perhaps the predominant method of construing the ninth amendment has been simply to avoid it. Feelings of uncertainty regarding how to approach this cryptic amendment are common even among experts, such as Mr. Justice Jackson: "[T]he ninth amendment rights which are not to be disturbed . . . are still a mystery to me."¹⁵ Thus, rather than wander into this uncharted territory, many constitutional scholars have refrained from entering the mainstream of ninth amendment controversy.

A second theory of interpretation was highlighted in *Griswold v. Connecticut*,¹⁶ one of the few recent Supreme Court cases to deal with the ninth amendment issue.¹⁷ In his concurring opinion, Mr. Justice

11. Kelsey, *The Ninth Amendment of the Federal Constitution*, 11 INDIANA L.J. 309 (1936).

12. *Id.* at 309.

13. U.S. CONST. amend. IX.

14. Kelley, *The Uncertain Renaissance of the Ninth Amendment*, 33 U.CHI. L. REV. 814 (1966).

15. JACKSON, *THE SUPREME COURT IN THE AMERICAN SYSTEM OF GOVERNMENT*, 74-75 (1955).

16. 381 U.S. 479 (1965).

17. Previous Supreme Court cases interpreting the ninth amendment are *Ashwander v. Tennessee Valley Authority*, 297 U.S. 288 (1936) (the ninth amendment's insuring of rights retained by the people does not negate the government's constitutional authority to dispose of electric energy generated at the Wilson Dam); *Tennessee Elec. Power Co. v. Tennessee Valley Authority*, 306 U.S. 118 (1939) (the ninth amendment gives power companies no standing to object to TVA power activities); *United Public Workers v. Mitchell*, 330 U.S. 75 (1947) (upholding constitutionality of Hatch Act limitations

Goldberg concluded that the ninth amendment is only a rule of construction to apply to the Constitution as a whole. The Justice saw it as a guidepost, the sole purpose of which was to call the courts' attention to other portions of the Constitution, such as the due process clauses of the fifth and fourteenth amendments. While these selected portions might then be used as a vehicle for unenumerated rights, the Justice did not see the ninth amendment as a source of and vehicle for protecting unenumerated rights in itself.¹⁸

B. A Positive Declaration of Unenumerated Rights

Even proponents of the above theories admit that they do not help solve the problem of "where one draws the dividing line between . . . the rightful exercise of . . . powers and unconstitutional infringement of individual rights."¹⁹ This problem lies at the very heart of the philosophy of limited government and individual rights, as expressed in the Constitution.²⁰ Indeed, the fundamental theory of American government is founded upon the concepts of reserved rights and delegated powers.²¹ The ninth amendment of the Constitution refers to reserved rights, and the tenth amendment refers to delegated powers.

The fact that both these provisions were included in the Constitution and the fact that they were placed side by side in the Bill of Rights makes it evident that there was some distinction in the minds of the framers between declaration of right and limitations on power.²² If this had not been the case, the limitations of power and reservations of rights contained in the body of the Constitution, taken along with the tenth

on federal employees' political activities against ninth amendment claims); *Roth v. United States*, 354 U.S. 476 (1957) (obscenity is not protected through ninth amendment rights).

18. Since the *Griswold* decision, there has been a good deal of scholarly activity regarding ninth amendment theories and issues. See Franklin, *The Ninth Amendment*, 40 TUL. L. REV. 172 (1966); Kitner, *Neglected Ninth Amendment: The Other Rights Retained by the People*, 51 MARQ. L. REV. 121 (1967); Comment, *Ninth Amendment Vindication of Unenumerated Fundamental Rights*, 42 TEMP. L.Q. 46 (1968); Moore, *Ninth Amendment — Its Origins and Meaning*, 7 NEW ENGLAND L. REV. 215 (1972); Rhoades, *Ninth Amendment: A Survey of Theory and Practice in the Federal Courts Since Griswold v. Connecticut*, 50 DENVER L.J. 153 (1973); Towe, *Natural Law and the Ninth Amendment*, 2 PEPPERDINE L. REV. 270 (1975).

19. Kelley, *supra* note 14, at 834.

20. Kelsey, *supra* note 11, at 309.

21. *Id.* at 310.

22. *Id.*

amendment reservation of power to the states and to the people would have sufficed, and the ninth amendment would have been unnecessary.²³

Thus, the ninth amendment cannot simply be ignored. It has been held that, when interpreting the Constitution, no section, sentence or even word is unnecessary.²⁴ No word was included needlessly, and subsequently nothing in the Constitution can be held to be superfluous.²⁵

It is inconsistent with such a holding that the ninth amendment could be viewed as a mere rule of construction, a guidepost pointing to other sections of the Constitution, as Mr. Justice Goldberg maintained in *Griswold v. Connecticut*.²⁶ Rather, "[i]t must be a positive declaration of existing through unnamed rights, which may be vindicated under the authority of the amendment whenever and if ever any governmental authority shall aspire to ungranted power in contravention of 'unenumerated rights.'"²⁷

The theory that the ninth amendment is indeed a positive declaration of rights is not a new one. Mr. Justice Story said of the ninth amendment:

This clause was manifestly introduced to prevent any perverse or ingenious misapplication of the well known maxim, that an affirmation in particular cases implies a negation in all others²⁸ . . . a conclusive answer is, that such an attempt may be interdicted (as it has been) by a positive declaration in such a bill of rights, that the enumeration of certain rights shall not be construed to deny or disparage others retained by the people.²⁹

C. Finding the Unenumerated Rights

The rights enumerated in the Constitution³⁰ constitute an impos-

23. *Id.*

24. *Id.*

25. *Id.* at 323.

26. 381 U.S. 479 (1965).

27. Kelsey, *supra* note 11, at 323.

28. STORY, COMMENTARIES ON THE CONSTITUTION OF THE UNITED STATES, Vol. II, 623-27 (1833).

29. *Id.* at 626, §1867.

30. The enumerated rights include: freedom of speech, religion, the press, assemblage, petition (amend. I); to keep and bear arms (amend. II) on quartering troops (amend. III); from search and seizure (amend. IV); of presentment and indictment, against double jeopardy, against self-incrimination, against deprivation of life, liberty

ing catalogue of human rights.³¹ The positive declaration theory of interpreting the ninth amendment asserts that rights enumerated in the Constitution by means of guarantee, limitation or prohibition do not preclude the existence of other rights retained by the people. With this rule of construction in mind, it is necessary to operate under the assumption that, in the minds of the framers, other non-enumerated rights did exist. The next question is how to determine what these rights are.

(1) INTENT OF THE FRAMERS

One method of determining the unenumerated rights protected by the ninth amendment is to consult the several documentations of the basic human values and liberties that were most likely among those cherished by the framers of the Constitution.³² Perhaps these rights were best expressed and most familiar to the framers and colonists alike in Blackstone's Commentaries, nearly as many copies of which were sold in the colonies as in England.³³ Blackstone classified the natural rights of human beings under three categories: (I) Personal Security, (II) Personal Liberty and (III) Private Property.³⁴ To these, Blackstone's American counterpart Chancellor Kent added the American contribution of (IV) Religious Freedom.³⁵

Two rights cherished by the framers are crucial in formulating regulatory policy. One of the rights most important to the framers was the right of the people to have a government which functions in the public interest and for the common good.³⁶ Statements to this effect

or property, against taking of property, (amend. V); for fair and speedy criminal trials (amend. VI); for jury trials in civil suits at common law (amend. VII); against excessive bail, against cruel and unusual punishments (amend. VIII); against abridgement of privileges and immunities, deprivation of life, liberty or property without due process of law, for equal protection of the law (amend. XIV); against denial of suffrage (amends. XV, XIX, XXIV and XXVI); limitations on taxation (art. I, sec. 8, cl. 1 and art. I, sec. 9, cl. 4 and 5); limitations on suspension of the writ of habeas corpus (art. I, sec. 9, cl. 2); freedom from bills of attainder, ex post facto laws, laws impairing the obligation of contract (art. I, sec. 10, cl. 1); limitations on conviction of treason (art. III, sec. 3); prohibitions on corruption of blood or forfeiture (art. III, sec. 3, cl. 2); the guarantee of a republican form of government (art. IV, sec. 4).

31. Kelsey, *supra* note 11, at 312.

32. Paust, *Human Rights and the Ninth Amendment — A New Form of Guarantee*, 60 CORNELL L. REV. 231 (1975).

33. Kelsey, *supra* note 11, at 313.

34. W. BLACKSTONE, 1 COMMENTARIES OF THE LAW OF ENGLAND 129-45 (1884).

35. J. KENT, COMMENTARIES ON AMERICAN LAW (1858).

36. Call, *Federalism and the Ninth Amendment*, 64 DICKINSON L. REV. 122

were included in the constitutions of the various colonies.³⁷

In addition, the framers believed that each citizen had an equal political interest in all questions of public policy and that each had equal political rights, including access to the governmental process and the right to have a voice in its decision. This right has been expressed as the right of "access to a free and full shaping and sharing of power,"³⁸ and Thomas Paine regarded it as one of the foremost redeeming qualities of a representative democracy.³⁹ It follows that effective denial of the individual's right to political participation in governmental decision-making, resulting from deference to the minority views of special interest groups, is in itself a denial or disparagement by decisional bodies of the citizens' right to full participation in government—an "undue" process of law and government.⁴⁰

(2) JUDICIAL DETERMINATION

The second and perhaps best method of determining which enumerated rights are protected by the ninth amendment is the gradual process of judicial determination by inclusion and exclusion.⁴¹ Apart from *Griswold*, no case has decided the scope of the ninth amendment, even in part.⁴² Furthermore, no opinions have cited the ninth amendment as the basis for the assertion or vindication of a right.⁴³

However, certain rights have been confirmed or rejected on the basis of whether or not they are "natural rights." For example, the right to attend state educational institutions⁴⁴ and to serve as a juror⁴⁵ have

(1959). See also Declaration of Independence (1776); U.S. CONST. preamble.

37. E.g., The Constitution of Pennsylvania, as adopted on September 28, 1776 states: "All powers are inherent in the people, and all free governments are founded on their authority, and instituted for their peace, safety, and happiness. The community hath an indisputable, inalienable and indefensible right to reform, alter, or abolish governments, in such a manner as shall be, by that community, judged most productive to the common total. All officers of the government are their trustees and servants, and at all times accountable to them."

38. Paust, *supra* note 32, at 261.

39. See T. PAINE, 2 THE RIGHTS OF MAN 26 (1794).

40. Paust, *supra* note 32, at 261.

41. 16 AM. JUR.2D, *Constitutional Law*, §331 (1964). See also *In re Morgan*, 58 P. 1070 (Wash. 1899); *Blair v. Ridgely*, 41 Mo. 63 (1867).

42. See note 17 *supra*.

43. Kelsey, *supra* note 11, at 319.

44. *Board of Trustees of University of Mississippi v. Waugh*, 62 So. 827 (Miss. 1913), *aff'd*, 237 U.S. 589 (1915).

45. *People ex. rel. Murray v. Holmes*, 341 Ill. 23, 173 N.E. 145 (1930).

been found not to be natural rights, but rather gifts of our civilization and the legislature. Rights judged to be natural and inherent include the right of a natural affection between parents and offspring,⁴⁶ the right to travel from state to state,⁴⁷ and the right to certain governmental services.⁴⁸

Two such natural rights are directly affected by government regulation of biotechnology. In dictum in *Griswold v. Connecticut*,⁴⁹ the Supreme Court suggested that the right of "freedom of inquiry" is a fundamental right within the penumbra of rights entitled to constitutional protection. This freedom, which scientists have struggled to achieve since the time of Galileo,⁵⁰ has been an important factor in the formulation of scientific policy.⁵¹

Another right which the courts have determined to be natural and constitutional is the right to beget children.⁵² Although this right was upheld over fifty years ago in a lower court, the right has never been subsequently denied. If judicial determination was indeed to be employed as a means of designating protected ninth amendment rights, perhaps the United States Supreme Court should be viewed as the only court qualified to make such determinations. It must also be considered that predictions of an imminent population explosion might outweigh this right. Nonetheless, the right to beget children has at least been suggested to be a natural right protected by the ninth amendment. Accordingly, regulations burdening decisions to beget children may be justified only by compelling state interests, and must be narrowly drawn to express only those interests.⁵³

46. *Lacher v. Venus*, 177 Wis. 558, 188 N.W. 613 (1922).

47. *Crandall v. Nevada*, 6 Wall 35 (1868).

48. *National League of Cities v. Usery*, 426 U.S. 833 (1976). *See also* notes 77 through 85 and accompanying text *infra*.

49. 381 U.S. 479 (1965).

50. Lederberg, *The Freedoms and the Control of Science: Notes from the Ivory Tower*, 45 S.CAL. L. REV. 596-97 (1972).

51. 41 Fed. Reg. 27, 903 (1976). A central concern of the National Institutes of Health [NIH] was apparently whether or not the guidelines for recombinant DNA research "balanced scientific responsibility to the public with scientific freedom to pursue new knowledge."

52. *Smith v. Command*, 231 Mich. 409, 204 N.W. 140 (1925).

53. *Carey v. Population Services Intern.*, ____ U.S. ____, 97 S. Ct. 2010 (1977) (invalidating state ban on distribution of non-medical contraceptives except through licensed pharmacists).

2. THE REACH OF THE COMMERCE CLAUSE

Although widespread government regulation is an accepted reality, the constitutional basis for and limitations on the power of the government to regulate must be considered. The commerce clause⁵⁴ is the primary constitutional basis for regulation by the federal government in the areas of the environment and public health.⁵⁵ Congress could enact some regulations regarding the interstate shipment of materials pertaining to genetic activity, such as recombinant DNA materials, under the commerce clause.⁵⁶ The ultimate question is to what extent Congress can enact such regulations when they are held to conflict with constitutional rights of the people, especially when the activities in question are intrastate or privately sponsored.

A. The "Affecting Commerce" Standard

The interpretation of the commerce clause as originally articulated by Chief Justice Marshall in *Gibbons v. Ogden*⁵⁷ defined Congress' power as extending to "that commerce which concerns more states than one."⁵⁸ Supreme Court decisions of the late 1930's and early 1940's established that Congress had power under the commerce clause to regulate nearly all aspects of the interrelated American economy.⁵⁹ The courts have indicated that an activity "affects" interstate commerce, so as to be subject to federal regulation under the commerce clause,⁶⁰ as

54. The commerce clause states: "The Congress shall have power . . . to regulate Commerce with foreign Nations, and among the Several States . . ." Art. I, sec. 8, cl. 3. See also Note, *Recombinant DNA and Technology Assessment*, 11 GEORGIA L.REV. 832 (1977).

55. See, e.g., Toxic Substance Control Act, 15 U.S.C. §2601 (Supp. Dec. 1976); Clean Air Act, 42 U.S.C. §1857 (1970); Federal Water Pollution Control Act, 33 U.S.C. §1251 (Supp. II 1972).

56. 41 Fed. Reg. 27, 914 (1976).

57. 22 U.S. (9 Wheat) 1, 194 (1829).

58. *Id.*; see also Stern, *That Commerce Which Concerns More States Than One*, 47 HARV. L.REV. 1335 (1934).

59. Stern, *The Commerce Clause Revisited — The Federalization of Intrastate Crime*, 15 ARIZ. L.REV. 271 (1973). For the story of how the Supreme Court arrived at this conclusion, see BENSON, *THE SUPREME COURT AND THE COMMERCE CLAUSE, 1937-1970* (1970); TRIBE, *THE CONSTITUTIONAL STRUCTURE OF AMERICAN GOVERNMENT — SEPARATION AND DIVISION OF POWERS* (1978); Stern, *The Commerce Clause and the National Economy 1933-46*, 59 HARV. L. REV. 645, 883 (1946).

60. *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1 (1937); *Katzenbach v. McClung*, 379 U.S. 294 (1964).

long as interstate commerce is a “practical” consequence of the activity.⁶¹

The “affecting commerce” rationale was construed so broadly as to subject seemingly all local activities to federal regulation. In *Wickard v. Filburn*⁶² the Supreme Court upheld Federal regulations of the production of wheat grown solely for home consumption on the grounds that such activity in the aggregate could affect the interstate market by depressing the farmer’s demand for wheat or by ultimately being marketed itself.⁶³

The Court went even further in *Perez v. United States*,⁶⁴ where it upheld the application of a statute to a particular intrastate crime without requiring the government to demonstrate any interstate nexus. In this apparent extension of the *Wickard* principle, Mr. Justice Douglas stated, “[w]here the class of activities is regulated and that class is within the reach of federal power, the courts have no power to excise as trivial, individual instances of the class.”⁶⁵

B. Regulations to Further Non-Economic Purposes

In recent cases, it has been shown that Congress may regulate interstate commerce for a variety of reasons, as long as the conditions themselves violate no other constitutional prohibition or grant of rights.⁶⁶ One permissible and especially potent form of federal regulation of commerce is the congressional imposition of “protective conditions” on the privilege of engaging in commerce. The intent of such regulations has been to combat activities disfavored by Congress for primarily non-commercial reasons. The Court has upheld the constitutionality of such legislation since it ruled that legislation banning the interstate transportation of lottery tickets was constitutional in the famous “Lottery Case” of *Champion v. Ames*.⁶⁷

61. 301 U.S. at 41-42.

62. 317 U.S. 111 (1942).

63. *Id.* at 127-29

64. 402 U.S. 146 (1971).

65. *Id.* at 152, 154.

66. *TRIBE, supra* note 59, at 238.

67. 188 U.S. 321 (1903). In the single case of *Hammer v. Dagenhart*, 247 U.S. 251 (1903) the Supreme Court reversed itself in holding that Congress could not prohibit interstate commerce in the products of child labor, since it involved regulating production by standardizing the ages at which children could be lawfully employed, rather than regulating interstate transportation. Apart from this isolated instance, the Supreme

The significant challenges in recent years to the exercise of the federal commerce power have dealt with its application for non-economic purposes. The public accommodation act of the Civil Rights Act of 1964⁶⁸ prohibited racial discrimination by hotels, restaurants or other establishments receiving transients or interstate travelers.⁶⁹ Obviously, this Act was directed at practices especially prevalent in the Southern states, which substantially handicapped and inhibited the interstate movement of many persons, primarily blacks.⁷⁰

In *Heart of Atlanta Motel, Inc. v. United States*,⁷¹ the Supreme Court upheld Congress' power, exercised in Title II of the Civil Rights Act of 1964, to prohibit racial discrimination in places of public accommodation on the grounds that Congress had a rational basis for finding that racial discrimination by motels affected commerce, and that Congress had selected a reasonable and appropriate means to eliminate this evil.⁷² Similarly, in *Katzenbach v. McClung*,⁷³ the Court upheld the Civil Rights Act's extension of the prohibition to all restaurants serving food which had moved in interstate commerce, since the restaurant, due to its failure to serve blacks, was either subject to federal regulation of all of its practices, or would reduce the amount of food moving in commerce.⁷⁴

In these cases the Court reaffirmed current commerce clause doctrines. First, the slightest interstate connection can provide an adequate

Court has upheld such congressional regulations to impose "Protective conditions" on the activities of interstate commerce. See *Hypolite Egg Co. v. United States*, 220 U.S. 45 (1911); *Hale v. United States*, 227 U.S. 308 (1913); *Brooks v. United States*, 267 U.S. 432 (1925) and *United States v. Darby*, 312 U.S. 100 (1941). Here the Court stated its philosophy regarding cases of this nature: "Congress . . . is free to exclude from [such] commerce articles whose use in the states for which they are destined it may conceive to be injurious to the public health, morals, or welfare. . . ." According to Charles Black, the constitutionality of Title II of the Civil Rights Act of 1964 could have been more straight-forwardly justified along the lines of this "protective principle" in *Heart of Atlanta Motel v. United States*, 379 U.S. 241 (1964) and *Katzenbach v. McClung*, 379 U.S. 294 (1964). See BLACK, *STRUCTURE AND RELATIONSHIP IN CONSTITUTIONAL LAW*, 55-57 (1969).

68. 42 U.S.C. §2000(a) *et seq.* (1970).

69. *Id.* at §§ 2000(a), (b)(1), (c).

70. *Heart of Atlanta Motel, Inc. v. United States*, 379 U.S. at 254-58.

71. *Id.*

72. *Id.*

73. 379 U.S. 294 (1964).

74. Stern, *The Commerce Clause Revisited — The Federalization of Intrastate Crime*, *supra* note 59, at 272.

basis even for federal commerce regulations which serve a non-economic purpose.⁷⁵ Second, Congress has the power to regulate acts which in isolation have no significant effect on interstate commerce but are part of a class which as a whole could be said to have such an effect.⁷⁶

C. *A Less Expansive Interpretation*

For the first time since *Wickard*, the Supreme Court has retreated from its expansive interpretation of Congress' power under the commerce clause in a case which is one of the Court's major federalism decisions of the post-1937 era.⁷⁷ In the 1976 case of *National League of Cities v. Usery*,⁷⁸ the Court invalidated the 1974 amendments to the Fair Labor Standards Act which had extended federal maximum hour and minimum wage provisions to all state and municipal employees,⁷⁹ thus holding a congressional regulation of commerce to be an unconstitutional intrusion upon the sovereignty of state and local governments for the first time in forty years.⁸⁰

While the Court's decision in *National League of Cities* that Congress had violated state sovereignty came as a surprise to some, the Court had recently handed down numerous decisions protecting rights of states in the federal system.⁸¹ Yet, this very familiarity of the federalism theme poses the danger that the decision will be read as a general

75. *Id.*

76. 379 U.S. at 300-301.

77. *TRIBE*, *supra* note 59, at 236.

78. 426 U.S. 833 (1976).

79. Pub. L. No. 93-259, §§6(a)(1), (5), (6); 88 Stat. 58 (1974), codified at 29 U.S.C. §§203(d), (s), (x).

80. The latest such holding was *Carter v. Carter Coal Co.*, 298 U.S. 238 (1936).

81. *See, e.g.*, *Younger v. Harris*, 401 U.S. 37 (1971) (absent bad faith or extraordinary circumstances, federal court is precluded from enjoining pending state criminal prosecution by considerations of equity, comity, and federalism); *O'Shea v. Littleton*, 414 U.S. 488 (1974) (holding there is no equitable relief against state criminal magistrate and judge for alleged practice of discriminatory bond setting and sentencing); *Edelman v. Jordan*, 415 U.S. 651 (1974) (eleventh amendment prevents liability for damages payable from state treasury); *Fry v. United States*, 421 U.S. 542 (1975) (holding that Congress may not exercise power in a way that impairs the states' integrity or their ability to function effectively in a federal system); *Rizzo v. Goode*, 423 U.S. 362 (1976) (federal court may not order structural changes in police departments which have invaded constitutional rights unless high-level official encouragement of such misconduct is shown); *Paul v. Davis*, 424 U.S. 693 (1976) (restricting range of property and liberty interests protected by the fourteenth amendment).

vindication of the autonomy of states and municipalities to the detriment of individual rights.⁸² If the case is regarded as such, problematic distinctions arise in the majority opinion of Justice Rehnquist. For example, it seems that the Court is anomalously asserting that Congress retains the power to strike down state regulation of private conduct, but does not possess the same power to control the regulation of state employees.⁸³ Furthermore, this decision and others⁸⁴ make a problematic distinction between federal legislation regulating commerce, and similar legislation enforcing rights under section 5 of the fourteenth amendment.⁸⁵

(1) THE THEORY

Professor Tribe has suggested an alternative interpretation of *National League of Cities* which resolves the conflicting priorities of the decision without doing violence to the Court's established notions both of federalism and of the judicial accommodation of conflicting values.⁸⁶ He sees the decision as one based on the protection of individual rights, in this instance, the right to basic government services.⁸⁷ Basically, the argument is that policy-based congressional legislation which threatens the provision of vital services is unlike similar legislation directed at private parties in that it presents the constitutional problem of endangering efforts by state and local governments to meet their citizens' legiti-

82. For an analysis of the decision as imposing limitation on the congressional power under the commerce clause by asserting the rights of the states under the tenth amendment, see Comment, *Constitutional Implications of a Federal Collective Bargaining Law for State and Local Government Employees*, 11 CREIGHTON L. REV. 863 (1978).

83. TRIBE, *supra* note 59, at 312.

84. See *Fitzpatrick v. Bitzer*, 427 U.S. 445 (1976) (application to state employees of a federal antidiscrimination statute sustained as an exercise of Congress' power under section 5 of the fourteenth amendment).

85. TRIBE, *supra* note 59, at 313.

86. *Id.* at 314. See also Tribe, *Unraveling National League of Cities: The New Federalism and Affirmative Rights to Essential Governmental Services*, 90 HARV. L. REV. 1065 (1977).

87. TRIBE, *supra* note 59, at 313. Tribe's theory has not achieved widespread support, a fact which he anticipated: "That the account suggested here is unconventional seems clear enough . . . others will surely seek to defend *National League of Cities* in terms that focus on state autonomy as such, paying only secondary attention to the underlying concern for adequate provision of essential services . . . Doubling . . . such an explanation, I have relied upon my own quite speculative thesis."

mate expectations of basic government services. The language of Justice Rehnquist could well be read to assert such a theory:

Even if we accept [the Federal Government's] assessments concerning the impact of the [wage and hour regulations], their application will nonetheless significantly alter or displace the states' abilities to structure employer-employee relationships in such areas as fire prevention, police protection, sanitation, public health, and parks and recreation. These activities are typical of those performed by state and local governments . . . Indeed, it is functions such as these which governments are created to provide, such services as these which the states have traditionally afforded their citizens.⁸⁸

If such individual rights against the government for basic services do exist, there must be a means to enforce these rights. *National League of Cities* could be seen as the precedent for enforcing individual rights against the government for certain basic services in areas where the federal government has left to the states and localities the responsibility of providing these services.⁸⁹

(2) RAMIFICATIONS OF THE THEORY

The recognition of rights of individuals to basic governmental services is a two-edged sword. In instances where, due to the national character or other aspects of the problem, congressional action results in a lesser degree of restriction on individual rights than state action, the congressional action would prevail.⁹⁰ Thus, this decision does not propose a wholesale reallocation of powers in our federal system in favor of state and local government. As long as congressional legislation reflects a compelling government interest and does not jeopardize individual rights, the courts should not be expected to object. The crucial point is that, barring overriding governmental concerns,⁹¹ the courts must

88. 426 U.S. at 851. For an analysis dealing with this aspect of the case, see Michelman, *States Rights and States' Roles: The Permutations of 'Sovereignty' in National League of Cities v. Usery*, 86 YALE L.J. 1165 (1977).

89. *TRIBE*, *supra* note 59, at 315.

90. *Id.* at 316-17.

91. In *National League of Cities*, Justice Rehnquist distinguished *Fry v. United States*, 421 U.S. 542 (1975), where the Court upheld the application of the national wage freeze to state and local employees. He noted the emergency character of the legislation and the national scope of the problem. Furthermore, the federal action resulted in reducing rather than increasing the burden upon state budgets, thus enhancing the ability of the state and local governments to provide basic governmental services.

insure a “necessarily over inclusive protection of individual rights.”⁹²

In summary, the Court’s decision in *National League of Cities* asserts two principles of particular relevance to determining the constitutionality of government regulation. The Court did not question the fact that the amendments to the Fair Labor Standards Act were “undoubtedly within the scope of the commerce clause,”⁹³ but rather objected to the legislation on the ground that it deprived the states of the sovereignty necessary to insure individual rights to basic governmental services. Thus, the first principle is that, if federal government regulation imposed via the commerce clause unduly risks infringement of affirmative individual rights, Congress must justify actions which would otherwise clearly be within its powers.⁹⁴ Second, the courts are obliged to insure a necessarily overinclusive protection of individual rights and, when conflicts arise, defer to either the federal or state and local actions by determining which of the two infringes least on the exercise of legitimate individual rights.⁹⁵

3. THE MODEL AND ITS RATIONALE

The following pages will discuss whether and the extent to which research and application of the technologies of in vitro fertilization, recombinant DNA, and cloning should be regulated by the government. In the past, it has been widely assumed that the government had the power and even the duty to regulate such areas. The power was seen as arising from the Court’s interpretation of the commerce clause as allowing Congress to legislate to further its non-economic purposes via the imposition of protective conditions on the privilege of engaging in any activity seen to affect commerce. Furthermore, the promulgation of regulations to protect the public health has traditionally been seen as a foremost duty of both state and federal governments.

However, the Court’s recent construction of the commerce clause in *National League of Cities*, viewed in conjunction with the positive declaration of unenumerated rights theory of the ninth amendment, provides grounds for the formulation of a new approach to government regulation in these areas. I have combined these two themes to derive the following model, which serves as the guidepost to the central theme

92. TRIBE, *supra* note 59, at 316-17.

93. 426 U.S. at 841.

94. TRIBE, *supra* note 59, at 316.

95. *Id.*

of the later sections of this article: *Although the government might technically have the power to regulate in a given area under the commerce clause, if such regulation threatens to infringe upon enumerated rights, or unenumerated rights protected by the ninth amendment, the government must insure a necessarily overinclusive protection of these rights, and must prove that there is a compelling need for the regulation which justifies the infringement of these rights.*

To determine whether the present extent of regulation imposed on the research and application of in vitro fertilization, recombinant DNA, and cloning is appropriate and, if not, to suggest an alternative, both the compelling need for government regulation under the commerce clause, and the individual ninth amendment rights which such regulation would threaten, will be assessed in each respective field.

Four basic regulatory options with respect to the use of these technologies will be considered:⁹⁶

(1) *No regulation/Marketplace* - Decisions made by individuals. Physicians inform persons what can or should be done in a particular case, and individuals make their decisions based on this information.

(2) *Decisions Made by the Medical Community* - Such as medical associations or quasi-public bodies like the National Institutes of Health. While such pronouncements are not legally binding, they have great moral force and can effectively resolve issues which would otherwise be settled in court or by formal regulation.

(3) *Judge-Made Law* - Legal standards relating to the use of genetic technology will eventually emerge as people seek legal remedy for the consequences of such activities. The first such cases will be decided by reference to precedents involving general medical procedures and other relevant precedents. Eventually, however, a body of judge-made laws pertaining specifically to genetic technology will evolve.

(4) *Direct Legislation* - Made either by legislative bodies or by regulatory agencies to which the legislature delegates the authority to regulate.

There are three assumptions implicit in the following analysis. The first is that the unenumerated rights mentioned in Part 1 as being implicit in and protected by the ninth amendment merit the same protec-

96. The following four options are taken from Green, *Law and Policy for the Brave New World*, 48 INDIANA L. J. 559, 572-74 (1973) and TRIBE, CHANNELLING TECHNOLOGY THROUGH LAW 52-60 (1973). Professor Tribe theorized that technologies which meet with public approval will be encouraged by increased public consumption, while those rejected will be limited or eliminated by lack of demand.

tion as rights expressly enumerated in the Constitution. The unenumerated rights considered in this article are: (1) The right of the people to have a government which functions in the public interest and for the common good; (2) The right to full participation in government and access to a free and full shaping and sharing of power through participation in the governmental decision-making process, unencumbered by undue deference to minority views or special interest groups; (3) The right to freedom of inquiry; and (4) the right to beget children.

Second, Professor Tribe's interpretation of the commerce clause as seen through the *National League of Cities* decision is regarded as the status quo. In other words, if federal regulations imposed via the commerce clause infringe upon the rights of individuals, the regulations can be justified only by demonstrating a compelling need for the regulations.

The third and perhaps most crucial premise from which the following conclusions are drawn is *that governs best which governs least*. Government is created to serve the people, rather than for the people to serve government. Regulations are not an end in themselves, and should be imposed only when necessary to protect the exercise of vital individual rights. Thus, regulations should never impose more restrictions on the exercise of rights than would be the case in their absence.

4. IN VITRO FERTILIZATION

With the birth of Louise Brown on July 25, 1978,⁹⁷ the prospect of successful in vitro fertilization has become a reality. The process involved in vitro fertilization is conceptually straightforward.⁹⁸ Ripe eggs are removed from the female's ovary through an incision in the abdominal wall and placed in a glass "petri" dish containing blood serum and nutrients. Sperm cells from the male, which have been prepared for fertilization, are added to the petri dish and, within a few hours, fertilization occurs. The fertilized egg divides for between two and six days until it is approximately a 100-celled embryo called a blastocyst. The blastocyst then is placed in the women's uterus where, if all goes well,

97. *Test-Tube Baby: It's a Girl*, TIME, August 7, 1978 at 68. Since the Brown baby, there have been other reported test-tube births. See, e.g., "Test-Tube Baby" Born in India, Facts on File, October 27, 1978 at 824.

98. For detailed descriptions comprehensible to the lay person, see *In Vitro Fertilization: Is it Safe and Repeatable?* 201 SCIENCE 698 (1978); *The First Test-Tube Baby*, TIME, July 31, 1978 at 58. See also Kass, *Babies by Means of In Vitro Fertilization: Unethical Experiments on the Unborn?* 285 N.E.J. MED. 1174 (1971).

it attaches to the uterus wall and normal embryo development and birth result.⁹⁹

The potential benefits of this technique, if perfected, are significant, since it provides a means whereby women who are infertile due to fallopian tube disorders can have children.¹⁰⁰ In addition, Dr. Carl Pauerstein of the University of Texas states that in vitro research "has the potential for adding greatly to the knowledge of the reproductive biology of our species."¹⁰¹

A. Existing Government Regulation

The government has felt that the risks involved in the process outweigh its advantages, and has imposed an unofficial federal moratorium which has halted all United States research involving in vitro fertilization in humans as of 1975.¹⁰² In a 1975 federal order, the Department of Health, Education and Welfare was barred from funding any in vitro fertilization¹⁰³ experiments unless they were first approved by the National Ethics Advisory Board appointed by the Secretary of HEW.¹⁰⁴

Perhaps due to its controversial nature, this panel was not formed until January of 1978, and did not meet to begin deciding whether or not to recommend that the moratorium be lifted until the following September. Strong opposition to federal financing of in vitro research has surfaced at regional hearings of the Board, although a final determination has not yet been made.¹⁰⁵ In the face of such delays, scientists such as Joseph D. Schulman of the National Institute of Child Health and Human Development lament that, "for every year that we wait,

99. This scenario is taken from the sources *supra* note 98. Since the birth of Louise Brown, Dr. Patrick Steptoe claims to have improved the technique of test tube fertilization and implantation. See *Gain Claimed in Test Tube Baby Method*, *The New York Times*, Dec. 2, 1978, section C at 6.

100. Green, *Law and Policy for the Brave New World*, 48 *INDIANA L. J.* at 562 (1973).

101. *The First Test-Tube Baby*, *supra* note 98, at 59.

102. *Id.* at 62.

103. Private foundations have also hesitated to fund such experiments in the United States. Ironically, America's own Ford Foundation pays the salary through endowment of Robert Edwards, the physiologist responsible for the birth of Louise Brown. See *In Vitro Fertilization: Is it Safe and Repeatable?* *supra* note 98, at 699.

104. *The First Test-Tube Baby*, *supra* note 98, at 62.

105. *In Vitro Fertilization: Is it Safe and Repeatable?* *supra* note 98, at 699. For a report of testimony at one such regional hearing, see *Testimony Opposes Test-Tube Baby Funds*, *The Kansas City Times*, Dec. 5, 1978 at 1.

thousands of infertile American women will, because of their ages, lose forever their opportunity to have children.”¹⁰⁶

*B. The Compelling Need for Government Regulation
Under the Commerce Clause*

The government and others opposed to in vitro research see basically three potential dangers. First, there is the medical danger that the process would result in abnormal babies.¹⁰⁷ As Dr. John Marshall, head of obstetrics and gynecology at Los Angeles County's Harbor General Hospital puts it, “the potential for misadventure is unlimited . . . What if we got an otherwise perfectly formed individual that was a cyclops?”¹⁰⁸

The vast preponderance of research and expert opinions suggest that these fears of biological disaster are totally unfounded. According to Schulman, “there are no data to support the hypothetical fears that in vitro fertilization will lead to abnormal babies.”¹⁰⁹ Schulman points out that, in the course of the substantial amount of work that has been done with animals ranging from mice to sheep, pigs, horses and cows, there has been no confirmed evidence that in vitro fertilization leads to genetic or morphological abnormalities in the offspring of any species.

Furthermore, these pre-implantation embryos are remarkably resistant to manipulation, and may even be fused or frozen and still result in normal offspring.¹¹⁰ Perhaps the ultimate evidence of the process' safety was the birth of normal, healthy Louise Brown, the first “test-tube” baby.

Schulman also contends that, even if there is a risk of abnormality, the decision to have a child should be left to the prospective parents, as is the customary procedure in the medical profession when similar risks are involved.¹¹¹ For example, if one or both parents are thought to carry traits of various genetic diseases, such as hemophilia or sickle cell anemia, the couple is not told that they cannot have children. Rather, they are often encouraged to undergo genetic counseling and to assess the

106. *Id.* For federal legislation regarding this technology, see National Research Act, Pub. L. No. 93-348 (1974); Part 46 of 45 C.F.R. subtitle A and amendments in 43, No. 7 Fed. Reg. 1759 (1978).

107. *In Vitro Fertilization: Is It Safe and Repeatable?* *supra* note 98, at 699.

108. *The First Test-Tube Baby*, *supra* note 98, at 59.

109. *In Vitro Fertilization: Is It Safe and Repeatable?* *supra* note 98, at 699.

110. *Id.*

111. *Id.*

condition of the developing fetus through amniocentesis.¹¹² The ultimate decision is left to the parents. There is no reason why a similar procedure could and should not be used in cases of in vitro fertilization and embryo transplantation.

The second perceived need for government regulation stems from anticipated ethical problems feared to result from in vitro fertilization. In the words of Nobel Laureate James Watson, there is the potential for "all sorts of bad scenarios."¹¹³ Foremost is the question of the morality of this experiment, even with the informed consent of the parties involved, and the specter at the end of the road of maintaining a fetus in vitro to the point of birth.¹¹⁴ There is the possibility of surrogate motherhood, or "wombs for rent" in which a woman's egg would be fertilized and implanted in another woman for biological reasons, for the sake of convenience, or perhaps even without the consent or knowledge of the donors.¹¹⁵ Some fear that so-called "baby factories" could result in which people would be bred for specific desirable traits. Finally, if an embryo developing in vitro were to be terminated at the will of the donors, doctors or both, would this be regarded as murder if done beyond a certain stage of embryonic development?

Fears that such dangers would result from the application of in vitro technology, while commonly held, are largely unfounded. Use of the technology could be restricted to cases in which the donors are a married couple and the fetus is implanted in the uterus of the biological mother. Such situations would not be essentially different from ordinary biological parenthood.¹¹⁶ If in vitro fertilization and embryo transplantation involved using the sperm of a donor, the case would be similar to artificial insemination¹¹⁷ which has been used successfully and without significant controversy for a number of years.¹¹⁸

The chance that widespread human "breeding" would occur seems

112. The surgical procedure of inserting a hollow needle through the abdominal wall into the uterus of a pregnant woman and extracting amniotic fluid for analysis to determine the presence of disease, genetic defects, etc.

113. *The First Test-Tube Baby*, *supra* note 98, at 562-63.

114. Green, *supra* note 100, at 562-63.

115. *Id.*

116. Hudock, *Frankenstein is Still a Myth, But it Should be Read Periodically*, 48 INDIANA L. J. 553 (1973).

117. The impregnation of a female by artificial introduction of semen taken from a male.

118. Hudock, *supra* note 116, at 554; *See also* Sagall, *Artificial Insemination*, 9 TRIAL 59 (1973).

unlikely in view of the fact that, in the past, this has not been attempted by either artificial insemination or natural conception, except perhaps in isolated cases. Standards regarding the "killing" of embryos developing in vitro could be the same as those set for abortions.

Lest the possibility be overlooked, it should be mentioned that maintaining a fetus in vitro to the point of birth could prove to be highly beneficial, in terms of both convenience for the mother,¹¹⁹ and the provision of a controlled and risk-free artificial womb for the fetus.

The third feared danger of in vitro technology is that unmanageable legal complications would result. In the eyes of the law, would the child belong to the donor of the egg, or the surrogate who bears the child?¹²⁰ Who would be responsible for providing monetary support? In the case of death or deformity of the fetus, should responsibility lie with the biological parents, the surrogate mother, the doctor or perhaps even the government?¹²¹

The resolution of such legal questions should not be as difficult as it might first appear. In vitro fertilization and embryo transplantation would be performed only by qualified and licensed persons. Rights, responsibilities, and the potential liabilities of all involved could be contractually pre-determined before any action was taken.¹²² Thus, any legal controversy which arose could be resolved by customary means in the courts of law.

In conclusion, the case foreshowing a compelling need for government regulation of in vitro fertilization is negligible at best in terms of biological dangers, ethical controversies, and legal entanglements.

C. *Threatened Ninth Amendment Rights*

The constitutional rights of individuals which would potentially be infringed if in vitro fertilization was subjected to government regulation¹²³ are several. There is the right to freedom of scientific inquiry and research. Also affected is the right to beget children. The exercise of this right justifies the use of any means which does not subsequently infringe the rights of any other party. Such means might include the taking of fertility drugs, the use of artificial insemination, or application of the technology of in vitro fertilization.

Related is the right of the people to have a government which functions in the public interest and for the common good. It is in the

119. Hudock, *supra* note 116, at 555.

120. Green, *supra* note 100, at 562.

121. *The First Test Tube Baby*, *supra* note 98, at 59.

122. Hudock, *supra* note 116, at 553-55.

123. As has been the practical case since 1975.

common interest to have a government which does not infringe upon constitutional rights of individuals when compelling dangers are not at stake. Since the right to have children is a constitutional right, it is in the public interest to allow for the exercise of this right by artificial insemination, if necessary.

Finally, there is the right to full participation in and access to a free and full sharing of power and shaping of public policy unencumbered by undue deference to minority views of special interest groups. The option which would allow for the greatest public participation in in vitro decisions would be to impose no regulations, and allow decisions regarding this technology to be made in the marketplace or on an individual patient-doctor basis.

D. Policy Assessment

Available evidence suggests that application of in vitro technology poses no danger that would justify the need for government regulations. Scientists should be free to do research in the area, and persons should be free to decide whether, when and to what extent they wish to use these technologies on an individual basis. Any legal controversies arising out of such actions could be settled in the courts.

5. RECOMBINANT DNA

The distinctive traits which characterize each species on earth are determined by inheritance factors known as genes.¹²⁴ These genes have been identified as strings of matter called chromosomes, which consist of segments of deoxyribose nucleic acid [DNA]¹²⁵ and are found in the nucleus of every living cell. It is the myriad of potential sets of molecular combinations of DNA which is responsible for the particular gene pools which define each species. The species maintain their identities because they are unable to mix their gene pools with those of any other species through reproduction.¹²⁶

124. Note, *Recombinant DNA and Technology Assessment*, 11 GEORGIA L.REV. at 791 (1977).

125. Although Mendel first hypothesized the existence of genes in the nineteenth century, their location was not identified for another fifty years until the work of Watson and Crick. See Watson and Crick, *Molecular Structure of Nucleic Acids: A Structure for Deoxyribose Nucleic Acid*, 171 NATURE 737 (1953). See also WATSON, *THE DOUBLE HELIX* (1963).

126. Note, *supra* note 124, at 791. See also MERRELL, *AN INTRODUCTION TO GENETICS*, 555 (1975).

Molecular biologists have recently acquired the remarkable ability to break through these natural barriers by developing techniques to "recombine" or "splice" DNA segments from one species into the DNA chain of another species, where the combined segments will replicate as a part of the normal metabolism of the host cell.¹²⁷ This technique of "gene splicing" or recombinant DNA¹²⁸ was developed in 1972 and, for the first time, allowed researchers to manipulate DNA within cells of lower organisms.¹²⁹ The technique involves utilizing an enzyme¹³⁰ to cut a segment of DNA from the chromosome of one organism and place it in the chromosome of another organism, thus constructing a molecule containing portions of DNA from two organisms. When placed inside a host cell, the cell replicates normally, each subsequent cell containing identical sets of the newly constructed DNA strands.¹³¹

This process was first used to recombine DNA segments from the same bacterial species, *E. coli*.¹³² Subsequently, biologists have successfully combined segments from two unrelated species of bacteria, and DNA from a toad into *E. coli*.¹³³ All recombined molecules have demonstrated normal replication and metabolism, in addition to showing the appropriate cellular effect of the spliced gene. Theoretically, it is now possible to isolate a DNA segment from any species of plant or animal and recombine it into a new host cell, which would then exhibit certain specific characteristics of the foreign species.¹³⁴

The development of recombinant DNA technology represents a major breakthrough in the field of the biological sciences.¹³⁵ An obvious

127. For a detailed description of this technique, see Cohen, *The Manipulation of Genes*, 233 SCI. AMER. 24 (1975).

128. For scientific discussion of recombinant DNA research intelligible to the lay person see, e.g., Grobstein, *The Recombinant DNA Debate*, 237 SCIENTIFIC AM. 22 (1976); *Recombinant DNA: Impacts and Advances*, 109 SCIENCE NEWS 389 (1976); Miller, *Recombinant DNA Research*, 111 SCI. NEWS 216 (1977); Schneider, *Genetic Engineering: Threat and Promise*, TECH. REV. (1976).

129. Comment, *Law v. Science: Legal Control of Genetic Research*, 65 KENTUCKY L.J. 880 (1977).

130. A type of protein that promotes the chemical processes of life without itself being altered or destroyed.

131. Comment, *supra* note 129, at 881.

132. Cohen, *supra* note 127, at 31. *E. coli* stands for *Escherichia coli*. Strain K-12 is the most commonly used.

133. *Id.*

134. Note, *supra* note 124, at 792.

135. See *Recombinant DNA Research Guidelines, Draft Environmental Impact Statement*, 41 Fed. Reg. 38, 426, 431-32 (1976).

advantage of this work is the advancement of scientific knowledge,¹³⁶ specifically of the biological processes. The technique could be used for the cheap and efficient production of medically important substances such as insulin, for which a world-wide shortage appears imminent.¹³⁷ Certain genetic diseases such as sickle-cell anemia might be cured simply by replacing the responsible gene.¹³⁸ Pollutants could be neutralized by manufactured microbes.¹³⁹ The number of potentially beneficial applications of this technology is indeed staggering.

A. Existing Government Regulation

There are presently various existing and proposed regulations regarding research on and application of recombinant DNA technology. Shortly after the recombinant DNA technique was developed, scientists became concerned with the potential for danger and a worldwide moratorium was called until hazards could be evaluated and standards developed.¹⁴⁰ Eight months later, the first attempt at regulating the research came from the scientists themselves at the international Asilomar Conference which was held in California in 1975.¹⁴¹ The prominent researchers participating in the Conference agreed that subsequent recombinant DNA research should proceed under a set of guidelines adopted by the Conference.¹⁴² The adopted guidelines lifted the worldwide moratorium and imposed a voluntary ban on research judged to be too dangerous under any circumstances.¹⁴³ All other experiments were allowed to proceed, provided that set safety conditions were maintained to insure that the experimental organisms were adequately "contained."¹⁴⁴ Although not legally enforceable, these guidelines were generally followed.¹⁴⁵

136. Cohen, *Recombinant DNA: Fact and Fiction*, 195 Sci. 654-55 (1977).

137. Note, *supra* note 124, at 792-93.

138. *Id.*

139. General Electric reported the creation of a petroleum consuming microbe potentially useful in the eradication of oil spills. See NAT'L. GEOGRAPHIC, September 1976, at 374-75.

140. Committee on Recombinant DNA molecules, *Potential Biohazards of Recombinant DNA Molecules*, 185 Sci. 303 (1974).

141. Comment, *supra* note 129, at 884-85.

142. *Id.*

143. Wade, *Genetics: Conference Sets Strict Controls to Replace Moratorium*, 187 Sci. 931-33 (1975). See also *Summary Statement of the Asilomar Conference on Recombinant DNA Molecules*, 188 Sci. 991 (1975).

144. *Id.*

145. Comment, *The Potential for Genetic Engineering: A Proposal for Interna-*

The Asilomar guidelines served as a basis for the first controls imposed by the federal government, the National Institutes of Health¹⁴⁶ Guidelines which govern federally funded research.¹⁴⁷ Though both scientists and the general public were consulted in the development of the guidelines,¹⁴⁸ the result remained essentially scientific self-regulation. Compliance with the NIH Guideline is mandatory only for all NIH funded research, and compliance in research done by private industries such as pharmaceutical companies¹⁴⁹ is strictly voluntary.

Recently, HEW Secretary Califano announced that the NIH Guidelines will be relaxed, due to the fact that the likelihood of harm now appears more remote than was once believed. The revised guidelines, while continuing the ban on six categories of potentially dangerous research such as that involving deadly disease organisms, will exempt one-third of the genetic research covered by the present rules. In addition, the new guidelines will permit the National Institutes of Health director to grant case-by-case exemptions.

Although the new guidelines will still be mandatory only for federally financed research, Califano said that, for the first time, the government will seek to require the compliance of private industry through the Food and Drug Administration, which will propose regulations applying to all the industries it regulates.¹⁵⁰ Whether or not the FDA will in fact impose such regulations, and the impact that these regulations might have, remain to be seen.

A number of existing laws can be viewed as enabling the federal government to control some aspects of recombinant DNA research.¹⁵¹ One statute under which such regulation could be promulgated is the

tional Legal Control, 16 VA. J. INT'L. L. 403, 420 (1976).

146. Hereinafter referred to as NIH.

147. 41 Fed. Reg. 27, 902 (1976) and 41 Fed. Reg. 38, 427 (1976).

148. Roblin, *Reflections on Issues Posed by Recombinant DNA Molecule Technology*, 265 ANNALS N.Y. ACAD. SCI. 59 (1976) and Wade, *Recombinant DNA: Guidelines Debated at Public Hearing*, 191 SCI. 834 (1976).

149. Grobstein, *Recombinant DNA Research: Beyond the NIH Guidelines*, 194 SCI. 1133-34 (1976). At least several major pharmaceutical companies are actively involved in recombinant DNA research. Comment, *Considerations in the Regulation of Biological Research*, 126 UNIV. PENN. L. REV. 1420 (1978); Wade, *Gene-Splicing: At Grass-Roots Level a Hundred Flowers Bloom*, 195 SCI. 558 (1977).

150. *U.S. Set to Relax Guidelines for Gene-Splitting Research*, The Washington Post, Dec. 17, 1978, sec. C at 1. See also *The Public Interest in Gene Splitting*, The Washington Post, Jan. 13, 1979 at 18.

151. See generally Balmer, *Recombinant DNA: Legal Responses to a New Biohazard*, 7 INVT'L. L. 293, 308 (1977).

Public Health Services Act.¹⁵² Under the PHSA, the Surgeon General, with the approval of the Secretary of HEW, has the power to create and enforce regulations "as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases,"¹⁵³ such as might result from an organism with unknown properties created via gene-splicing.¹⁵⁴

The National Environmental Policy Act¹⁵⁵ gives the federal agencies certain procedural and substantive duties to promote a national policy of environmental protection. Since recombinant DNA biotechnology poses a risk of disrupting the environment through the creation of new and harmful species, NEPA offers an opportunity for public review of federally sponsored recombinant DNA research.¹⁵⁶

The Toxic Substances Control Act¹⁵⁷ requires users of potentially dangerous chemical substances to notify the Environmental Protection Agency,¹⁵⁸ which will test the substance's environmental or health risks. If results suggest imminent danger, the EPA may enact controls as it deems appropriate.¹⁵⁹

The Occupational Safety and Health Act,¹⁶⁰ administered by the Occupational Safety and Health Administration, protects employees from injury by employment-related toxic substances.¹⁶¹ Thus, it could be used to enforce appropriate safety regulations in laboratories engaged in work with recombinant DNA.¹⁶²

For two years, Congress has been struggling to enact legislation to control recombinant DNA research but, as of yet, no bill has been passed into law. In February of 1977, Senator Dale Bumpers introduced a bill entitled The DNA Research Act of 1977,¹⁶³ which would require the Secretary of HEW to promulgate guidelines for such research within

152. 42 U.S.C. § 201 (1970) [hereinafter referred to as PHSA].

153. 42 U.S.C. § 264 (1970).

154. Balmer, *supra* note 151, at 310-11.

155. 42 U.S.C. §4321 (1970 and Supp. IV 1974) [hereinafter referred to as NEPA].

156. Parenteau and Catz, *Public Assessment of Biological Technologies: Can NEPA Answer the Challenge?* 64 GEO. L. REV. 679 (1976).

157. 15 U.S.C. §§ 2601-29 (1976) [hereinafter referred to as TSCA].

158. Hereinafter referred to as EPA.

159. 15 U.S.C. §2603(4) (1976).

160. 29 U.S.C. §§651-78 (1970).

161. 29 U.S.C. §655(b)(5) (1970).

162. Balmer, *supra* note 151, at 312, n. 99.

163. S. 621, 95th Cong., 1st Sess., 123 Cong. Rec. 2272 (1977).

ninety days of the bill's enactment.¹⁶⁴ During and since that time, both houses have considered a number of similar bills,¹⁶⁵ the most recent of which include bills sponsored by Representative Rodgers,¹⁶⁶ Senator Nelson,¹⁶⁷ and Senator Kennedy.¹⁶⁸

When Congress may approve legislation in this area and the ultimate nature of the legislation are uncertain. Whether such legislation will ever be passed has itself become questionable. In a recent letter to HEW Secretary Califano,¹⁶⁹ Senator Kennedy threw the recombinant DNA initiative back into the lap of the administration, suggesting that Congress is no closer to passing legislation to control recombinant DNA research than it was two years ago.

B. *The Compelling Need for Government Regulation Under the Commerce Clause*

There are three areas of public concern regarding the biotechnology of recombinant DNA. The most common fear is that a dangerous new microorganism might escape from the laboratory, causing the death of millions as the result of a bubonic-like plague.¹⁷⁰ Since this technique creates essentially new species of organisms, these organisms could possibly produce some unnatural or unpredicted substances which might become serious pests.¹⁷¹

The spread of recombinant organisms might be irreversible, and thus the possibility that these molecules may escape from laboratories into the environment must be regarded with great concern.¹⁷² The likelihood of such danger is enhanced by the fact that the organism most commonly used in recombinant DNA research is *E. coli.*, a bacterium

164. *Id.* at §4.

165. *See, e.g.*, S.945, 95th Cong., 1st Sess., 123 Cong. Rec. 3699 (1977); S.1217, 95th Cong., 1st Sess., 123 Cong. Rec. 5335 (1977); H.R. 3191, 95th Cong., 1st Sess., 123 Cong. Rec. 917 (1977); H.R. 4232, 95th Cong., 1st Sess., 123 Cong. Rec. 1552 (1977); H.R. 4759, 95th Cong., 1st Sess., 123 Cong. Rec. 1929 (1977).

166. H.R. 11192, 95th Cong., 2d Sess. (1978).

167. S. 1217, amend. No. 754, 95th Cong., 1st Sess. (1977).

168. S. 1217, amend. No. 1713, 95th Cong., 2d Sess. (1978).

169. *Senate Passes Back Gene-Splice Cup*, 200 SCI. 1368 (1978).

170. Kilpatrick, *Regulation and the Search for Truth*, NATION'S BUSINESS, Jan. 1978 at 13-14.

171. Bennett and Gurin, *Science That Frightens Scientists*, 239 THE ATLANTIC, Feb. 1977 at 44.

172. *See Recombinant DNA Research Guidelines, Draft Environmental Impact Statement*, 41 Fed. Reg. 38, 429-31 (1976).

that inhabits the human gut.¹⁷³ Although *E. coli.* in its natural state is relatively harmless, the fear is that an escaped pathogenic strain of recombinant *E. coli.* would colonize in the intestines of humans.¹⁷⁴

Many experts have predicted that the risks involved in recombinant DNA biotechnology would lead to the above mentioned disasters.¹⁷⁵ However, such risks are entirely potential and speculative, and have never, in any way, been demonstrated.¹⁷⁶ Scientists have pointed out the extreme unlikelihood that such risks would be manifested, and have de-emphasized the dangers of this research.¹⁷⁷ Nobel Laureate Watson, the discoverer of DNA's structure, has commented, "the dangers involved [in recombinant DNA research] are probably no greater than working in a hospital."¹⁷⁸

The inescapable conclusion, however, is that the likelihood of danger resulting from recombinant DNA research is simply not known.¹⁷⁹ Therefore, according to Dr. Philip Handler, president of the National Academy of Sciences, some regulations of recombinant DNA biotechnology are necessary in the interest of the public health and safety.¹⁸⁰

At least three recent incidents have demonstrated potential risks and hazards.¹⁸¹ Yet, the scientific community is in general agreement that an outright ban is not warranted. The situation has been compared with the remote possibility of pathogenic organisms being returned to earth by the Apollo missions.¹⁸² In that instance, rather than forfeit the missions, reasonable safeguards were imposed. The potential risk involved in recombinant DNA research is sufficient to justify the imposition of similar safeguards.

Perhaps the most ominous justification for controlling recombinant DNA research is the possibility that the technology could be deliberately misused for such purposes as biological warfare.¹⁸³ These fears are

173. Comment, *supra* note 129, at 882.

174. 41 Fed. Reg. 38, 430 (1976).

175. Sinsheimer, *An Evolutionary Perspective for Genetic Engineering*, 73 NEW SCIENTIST 150 (1977).

176. Berg, *Potential Biohazards of Recombinant DNA Molecules*, 185 SCI. 303 (1974).

177. A British scientist illustrated this view via the use of mathematical probabilities. Holliday, *Should Genetic Engineers Be Contained?* 73 NEW SCIENTIST 399 (1977).

178. Wade, *supra* note 143, at 933.

179. Comment, *supra* note 129, at 883.

180. Kilpatrick, *supra* note 170, at 14.

181. Wade, *Dicing With Nature; Three Narrow Escapes*, 195 SCI. 378 (1977).

182. *A Scientist-Senator on Recombinant DNA Research*, 201 SCI. 15 (1978).

183. *Gene War? Reds Play Catch-Up in Genetic Research*, Atlanta Journal &

reminiscent of the waves of controversy that erupted when the techniques of atomic fission and fusion were understood to embrace the capacity for both social good and social catastrophe.¹⁸⁴ Some might argue that, in retrospect, the A-bomb should never have been put together.¹⁸⁵

The ideal solution would be to impose regulations which would allow society to reap all the benefits of the technology and risk none of the disasters. Unfortunately, such a solution might be possible only in a Utopia. Perhaps the next best remedy would be not to ban recombinant DNA research entirely, but to impose regulations tight enough to minimize opportunities for deliberate misuse of the technology.

A third appeal for the imposition of governmental regulations has been made on ethical grounds by those who do not wish to see a world in which babies are "custom made to order." The argument given in such cases is that it would be best to prevent the development of such capabilities by permanently halting all research on recombinant DNA on the grounds that there are some facts that members of the human race are better off not knowing.¹⁸⁶

Such appeals are reminiscent of the Promethean¹⁸⁷ myth and, carried a step further, echo of Pandora and her box of troubles. Application of this biotechnology has been regarded as crossing a barrier between the "will of God" and the acts of humanity by tinkering with the evolutionary process.¹⁸⁸ Other critics have suggested that the creation of new species through gene splicing would upset the precarious "balance of nature," and result in environmental chaos.¹⁸⁹

There is little likelihood that such arguments would be used as grounds for a case showing compelling need for government regulation. In the United States the traditional view has been that it is more dangerous to live in ignorance than to live with knowledge.¹⁹⁰ Unlike some totalitarian governments, it is not the policy of the United States to regulate ideas simply out of fear of the ideas themselves.¹⁹¹ Thus, the

Constitution, Feb. 20, 1977, sec. C at 16, col. 1.

184. Kilpatrick, *supra* note 170, at 14.

185. *Id.*

186. *Id.*

187. In Greek mythology, Prometheus created the human race by stealing knowledge that Zeus wanted to keep to himself. In his anger, Zeus punished Prometheus by nailing him to a mountain and dooming him to the eternal fate of having an eagle tear out his liver every day, only to have it grow back every night.

188. Kilpatrick, *supra* note 170, at 14.

189. Sinsheimer, *supra* note 175, at 150.

190. Kilpatrick, *supra* note 170, at 14.

191. *Id.*

prospects of using the power of government to regulate recombinant DNA research for the purpose of suppressing ideas that might otherwise flow from such research are slim.

C. Threatened Ninth Amendment Rights

The right most commonly debated in the field of recombinant DNA research is the right to freedom of inquiry, which has been held to be guaranteed by the first and ninth amendments.¹⁹² Since pure research has traditionally been unregulated,¹⁹³ scientists are generally fearful of the imposition of any legal control,¹⁹⁴ and warn of the "dangers facing modern society if it chooses to foreclose avenues of knowledge and discovery which might lead to the emancipation of mankind from the chains of ignorance and disease."¹⁹⁵ The prospect of any controls on research is often equated with the Vatican's inquisition of Galileo.¹⁹⁶

However, inquiry loses its constitutional protection when research constitutes a threat to the public health,¹⁹⁷ as is the case with recombinant DNA research. Thus, while scientists could claim constitutional protection in their desire to conduct research free from restrictions, the degree of their success would be limited by deference to official assessments of the degree to which the public health and environment would be endangered by the research activity.¹⁹⁸ Perhaps the most that scientists could reasonably expect is that regulations ultimately implemented would be drawn with utmost deference to imposing minimal infringements on the right to freedom of inquiry.¹⁹⁹

The constitutional right to beget children does not imply that this would include the right to "custom made" or even healthy offspring. Thus, regulation of recombinant DNA research would not seem to infringe upon the right to beget children.

Whether or not such regulation would violate the right to have a government which functions in the public interest and for the common

192. *Griswold v. Connecticut*, 381 U.S. 479 (1965). See also text accompanying notes 30 through 53 *supra*.

193. Comment, *supra* note 145, at 417.

194. Lederberg, *supra* note 50.

195. Comment, *supra* note 143, at 416.

196. Lederberg, *supra* note 50, at 596-97.

197. Note, *supra* note 124, at 836.

198. Comment, *supra* note 129, at 886-87.

199. *Id.* at 887.

good is not an easy issue to resolve. Scientists would undoubtedly contend that such regulations were not in their interest.²⁰⁰ Similarly, there might be those who would maintain that the creation of a race of blond-haired, blue-eyed giants would indeed be in the common good.²⁰¹

The interests of such special interest groups aside, there is no function of the government that is more in the public interest and for the common good than the protection of its citizens, especially from epidemic and widespread loss of life. It is certainly in the interest of persons to survive. Indeed, the survival instinct has been said to be the primary goal of all living organisms. Thus, government regulation of recombinant DNA would serve to enhance the right of the people to have a government which functions in the common interest and for the common good.

D. Policy Assessment

The above paragraphs suggest that there is indeed a compelling need for some form of institutionalized preventive control over the research and application of recombinant DNA techniques. Unlike in vitro technology, application of recombinant DNA techniques posts a potential threat to the public health and safety that could result from laboratory escape or deliberate misuse. While there is no apparent cause for a ban on such research altogether, the remote possibility of mass contamination is cause for comprehensive governmental regulation of the area. In the words of G. Raltray Taylor,

I am therefore forced to the conclusion that society will have to control the pace of research, if it can, and will certainly have to regulate the release of these new powers. There will have to be a biological "icebox" in which the new techniques can be placed until society is ready for them . . . the social consequences . . . could be so disastrous—nothing less than the breakup of civilization as we know it—that the attempt must be made.²⁰²

The questions which remain to be answered are whether the status quo satisfies this need and, if not, what course of action should be pursued.

Upon examination it becomes apparent that existing measures are

200. *Id.*

201. HITLER, *MEIN KAMPF* (1925).

202. TAYLOR, *THE BIOLOGICAL TIME BOMB* (1968).

not sufficient. The NIH Guidelines are not legally enforceable,²⁰³ and apply only to federally funded research.²⁰⁴ The PHSA is ill-equipped to act as a basis of regulation of biological research,²⁰⁵ since the purpose of the act is to "prevent the spread of disease."²⁰⁶ Because of this language and the Act's historical usage, an interpretation of the Public Health Services Act as allowing for control over the spread of a particular DNA molecule would be an extremely liberal if not implausible construction.²⁰⁷

The problem with environmental acts such as the National Environmental Policy Act is that they deal with preventing the discharge of hazardous substances in harmful quantities.²⁰⁸ Since there are no known safe exposure links of the new organisms which could potentially be created by gene splicing, such laws provide no useful basis for the formulation of regulations in the area.²⁰⁹

The Toxic Substances Control Act would not be an appropriate vehicle in this area for a variety of reasons. Directed to chemical substances, the Act would have to be amended to apply also to biological organisms.²¹⁰ The efficiency of this Act as a source of regulation is diminished by the fact that EPA uses the TSCA as a statute of last resort when no other statute will solve a pressing problem.²¹¹ Perhaps most importantly, the TSCA is used to test chemical substances before commercial production: with recombinant DNA, the issue is regulation of the research itself, regardless of possible future exploitation.²¹²

Finally the Occupational Safety and Health Act does not meet the need because the Act covers neither government employees nor workers employed by other federal government agencies,²¹³ two categories in which recombinant DNA researchers are concentrated.

Having determined that some new form of governmental control over recombinant DNA research is necessary, the next issue to be re-

203. *Supra* note 147.

204. Comment, *supra* note 129, at 885.

205. Comment, *supra* note 149, at 1437.

206. 42 U.S.C. §264 (1970).

207. Balmer, *supra* note 151, at 310-12.

208. Kraus, *Environmental Carcinogenesis: Regulation on the Frontiers of Science*, 7 ENV'T L. at 87-89 (1976).

209. Comment, *supra* note 149, at 1438.

210. *Id.* at 1436.

211. 15 U.S.C. §§ 2605(c), 2608(a) and (b) (1976).

212. Comment, *supra* note 149, at 1436.

213. 29 U.S.C. §§ 652 and 653 (1970).

solved is whether such legislation should emanate from the federal or the state and local level.²¹⁴ Upon examining the alternatives, there seem to be compelling reasons for the federal government to totally preempt regulations in this field.²¹⁵

Rather than giving sufficient deference to the scientific right of free inquiry, states and localities might politicize the decision-making process by responding to scare tactics and uninformed public hysteria.²¹⁶ Furthermore, it is questionable "whether a system of piecemeal regulation would be effective in protecting the public, for microbes fleeing from a low-safeguard locality are unlikely to recognize the political boundary of an adjacent high-safeguard jurisdiction."²¹⁷

A final reason for federal control is that local regulators could not reasonably be expected to have access to the same quality of information available to a national body.²¹⁸ The federal government is best equipped to keep in step with the most recent scientific developments.²¹⁹ If localities were allowed to regulate independently, it is likely that a time lag in the receipt of current scientific data would result in standards that would be either too restrictive for optimal research or not restrictive enough, thus either unnecessarily preventing valuable discoveries or creating an unreasonable risk to public health.²²⁰ For these reasons, it is not surprising that the scientific community strongly favors federal rather than state and local regulation.²²¹

The final key issue in implementing regulations on DNA research is whether Congress should assume responsibility for making the basic policy decisions, or delegate this responsibility to an administrative agency.²²² In the past, when Congress has legislated in areas of considerable controversy, factual uncertainty, and unknown policy impact, it has

214. Comment, *supra* note 149, at 1424.

215. *Id.* at 1425.

216. *Id.* Although the Cambridge Laboratory Experimentation Review Board and City Council passed useful and legitimate guidelines in this area in 1977, other localities might not be as "enlightened" as Cambridge. Furthermore, the board itself believed that federal controls should be implemented. See *Cambridge Experimental Review Board*, 33 BULL. ATOM. SCI. 23 (1977) and Culliton, *Recombinant DNA: Cambridge City Council Votes Moratorium*, 143 SCI. at 301.

217. Comment, *supra* note 149, at 161.

218. Guilbert, *The Relationship Between State and Federal Regulation of Air Polluting Energy Sources in Oregon*, 54 ORE. L. REV. 525 (1975).

219. Comment, *supra* note 149, at 1426.

220. *Id.*

221. *Gene Legislation: NAS Urges Caution*, 211 SCI. NEWS 293 (1977).

222. Comment, *supra* note 149, at 1438.

deferred to the judgment of administrative agencies, as was the case regarding the Nuclear Regulatory Commission.²²³ Recently proposed DNA regulation bills similarly delegate significant decision making to non-legislative bodies.²²⁴ While this pattern of delegation should not be automatically assumed, it is not practical to expect members of Congress to acquire expertise in all of the wide ranging and complex activities in which our government is involved today.²²⁵

No existing agency has a membership of scientists and laypersons suited to making the difficult value and policy choices necessary for adequate regulation of this area.²²⁶ A suitable guide for Congress to follow in establishing a commission to regulate the field of recombinant DNA is the composition of other bodies which make policy decisions of uncertain scientific or technological risks, such as the Nuclear Regulatory Commission.²²⁷

An especially apt membership example, on which the latest House bill is based,²²⁸ is the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which is composed of eleven persons coming from the fields of "medicine, law, ethics, theology, the biological, physical, behavioral and social sciences, philosophy, humanities, health administration, government, and public affairs."²²⁹ A commission of similar composition would be capable not only of evaluating the technical data involved, but also of representing the public interest at large in the formulation of recombinant DNA regulations.²³⁰

6. CLONING

The technique of cloning²³¹ has received a great deal of recent attention from the media. Unlike in vitro fertilization, which lets nature

223. 42 U.S.C. §2201(b) (1970). This Commission was authorized to impose regulations on the use of nuclear materials as it deemed necessary to promote the common defense and protect the public health.

224. H.R. 11192, 95th Cong., 2d Sess., § 201 (1978); S. 1217, amend. No. 1713, 95th Cong., 2d Sess. § 201 (1978); S. 1217, amend. No. 754, 95th Cong., 1st Sess., § 481 (1977).

225. Bazelon, *Coping with Technology Through the Legal Process*, 62 CORNELL L. REV. 817, 829 (1977).

226. Comment, *supra* note 149, at 1440.

227. *Id.*

228. H.R. 11192, 95th Cong., 2d Sess. (1978).

229. 42 U.S.C. § 218(f) (Supp. 1974).

230. Comment, *supra* note 149, at 1440.

231. From the Greek *klon*, meaning twig.

take its course in a test tube, cloning produces a genetic copy of its single parent through asexual reproduction.²³² This technique is facilitated by the biological fact that every cell in a living organism carries the same genetic material as every other cell in the organism. The cause of differentiated cell functions is that different genes are “turned on” in, for example, a blood cell than in a skin cell.²³³ In cloning, the nucleus of an egg or sperm cell, which contains only half the normal number of chromosomes, is replaced by the nucleus of a body cell containing the full number of the organism’s chromosomes. The cell, having been “fooled” into thinking it has been fertilized, begins to divide and develops as would a normal embryo.²³⁴ The end result is an organism biologically identical to that which donated the nucleus, thus enabling the production of multiple biological “carbon copies” of any given organism.²³⁵

This technique has tremendous implications for animal husbandry and laboratory research. For example, a particular strain of mouse needed for crucial experiments could be duplicated in mass; prize dairy cows, sheep and pigs could be mass produced, thus improving the quality of the world’s food supply.²³⁶ Theoretically, it would also be possible to make clones of great humans, ultimately creating a “superrace” or perhaps even a new species of human being entirely.²³⁷

A. Existing Government Regulation

There are presently no specific constraints on cloning research or the application of the biotechnology.

B. The Compelling Need for Government Regulation Under the Commerce Clause

Few people feel that the cloning of mice or of “grade-A” cattle is a danger creating a compelling need for government regulation. By contrast, the prospect of cloning humans evokes a sharply different response of fear, and even hysteria, provoked by thoughts of misuse

232. *A Test-Tube Baby is Not a Clone*, TIME, July 31, 1978 at 65.

233. *Id.*

234. Green, *supra* note 100, at 563.

235. *Id.*

236. *A Test-Tube Baby is Not a Clone*, *supra* note 232.

237. Green, *supra* note 100, at 563, 573.

such as tyrannical clones taking over the world. While such scenarios might not endanger the public health as such, they could cause sufficient emotional, political and social trauma to justify the imposition of government controls if it is determined that these fears are justified.

An examination of the most recent evidence suggests that these feared effects of human cloning are unjustified, as the chances for effective human cloning are minimal. According to Nobel Laureate James Watson, "there's no future in [cloning]." ²³⁸ While researchers in the field can now effectively clone frogs, the cloning of mammals is much more complex and, by expert estimations, "a long way off." ²³⁹ This is due in large part to the fact that mammalian eggs are one-tenth to one-twentieth the size of frog eggs and thus much harder to manipulate. ²⁴⁰

Yet, even if scientists were some day able to clone humans, ²⁴¹ there is reason to believe that the effectiveness of the human cloning process would be minimal. In the first place, unlike domesticated or laboratory animals, *Homo sapiens* is a mongrel breed, still containing a number of harmful or even lethal genes. ²⁴² While such genes exist in the recessive state and are thus normally suppressed by dominant normal genes, certain cloning methods would allow these recessives to express themselves, thus causing deformities, genetic illness, or even the death of the clone. ²⁴³

The second probable obstacle to effective human cloning stems from the difference between genotype ²⁴⁴ and phenotype. ²⁴⁵ Cloning would produce a person genetically identical to its nuclear donor. ²⁴⁶ However, the genotype of an organism alone does not completely determine the phenotype, which is instead the result of the interaction between the genotype and the environment. ²⁴⁷ The same genotype can produce very different phenotypes in the presence of variant physical and social influences. ²⁴⁸ Thus, even if human clones were produced, the

238. *A Test-Tube Baby is Not a Clone*, *supra* note 232.

239. *Id.*

240. *Id.*

241. Hudock, *supra* note 116, at 555.

242. *Id.*

243. *A Test-Tube Baby is Not a Clone*, *supra* note 232.

244. Genetic make-up of an organism; All genes present in the nucleus of a cell, both dominant and expressed, recessive and unexpressed.

245. Manifest characteristics of an organism; dominant and expressed traits such as skin color and blood type that result from both heredity and environment.

246. Hudock, *supra* note 116, at 555.

247. *Id.* For example, phenotypic differences in identical twins.

248. *Id.*

clones would not necessarily exhibit the desired traits of the nuclear donor.²⁴⁹

Until conflicting and valid evidence or conditions are at hand, the difficulties and probable ineffectiveness of human cloning do not pose risks which would compel government regulation of technology. The effects of such efforts would apparently be benign. In the words of Watson,

What's to be gained? A carbon copy of yourself? Oh, if the Shah of Iran wanted to spend his oil millions on cloning himself, that's fine with me. But if either of my young sons wanted to become a scientist I would suggest he stay away from research in cloning humans. There's no future in it.²⁵⁰

C. *Threatened Ninth Amendment Rights*

Since there is not presently a compelling need for government regulation of cloning, individual rights in this area could be fully exercised without the threat of infringement. Researchers could exercise their right to freedom of inquiry. Results of such research, such as improvements in the world's food supply, would be in the public interest and for the common good. While it could be argued that cloning oneself is not protected by the right to beget children,²⁵¹ there is no reason for restricting this benign activity. As it is the right of individuals to have full access to the decision-making process, the decision whether or not to clone oneself should be left with the people.

D. *Policy Assessment*

The cloning biotechnology should be conducted without the imposition of government regulations. If future evidence suggests that effective human cloning is indeed possible, the need for government regulation should at that time be reassessed. Until such a time, the status quo should be maintained.

249. *Id.*

250. *A Test-Tube Baby is Not a Clone*, *supra* note 232.

251. Cloning is asexual reproduction. Sexual reproduction is implicit in the definition of beget.

7. CONCLUSION

Once a technology is developed, it is very difficult to "turn off."²⁵² It is unlikely that society could completely prevent the emergence of the applications of new genetic knowledge even if it so desired. The best that can be hoped for is that the consequences of these technologies be carefully considered, and that they be wisely used.²⁵³

While some government regulations will always be necessary, in the words of Commerce Secretary Jerry Jasinowski, "our regulatory system is out of control."²⁵⁴ The excessive regulation by our bulging bureaucracy is expensive and unnecessary, and our nation needs desperately to find a reasonable midpoint between too much regulation and too little. Recent legislation freeing the airline industry from federal regulation, the first instance of deregulating a major industry in decades, has resulted in better passenger service and lower prices.²⁵⁵

This experience should serve as a lesson that government regulation is not the best solution to all problems. It is true that movement toward the "brave new world" should be the result of conscious decision by society, taking into consideration the ultimate social consequences. However, there is a place in this scenario for both government regulation and individual, marketplace decision-making.

Finally, this article has demonstrated that these biotechnological issues can indeed be considered in a rational and systematic manner. By viewing their implications from a constitutional perspective, with a focus on the compelling need for government regulation under the commerce clause balanced against threatened ninth amendment rights, reasonable policy decisions can be made. This kind of logical assessment has unfortunately been markedly absent in the past. Hopefully, it will become the rule rather than the exception in the future.

However, the establishment of the much discussed "science court,"²⁵⁶ which would seek to resolve close technical issues in an adversary setting, is unnecessary. Scientific "facts" in many areas, such as DNA research, are conjectural and not amenable to resolution in an adversary process.²⁵⁷

252. Green, *supra* note 100, at 574.

253. *Id.* at 575.

254. Palmer, *The Rising Risks of Regulation*, TIME, Nov. 27, 1978 at 85-87.

255. *Flying the Crowded Skies*, TIME, Aug. 14, 1978 at 50-55. See also *Help for Full Fares*, TIME, Oct. 16, 1978 at 90-91.

256. Martin, *The Proposed "Science Court,"* 75 MICH. LAW REV. 1058 (1977).

257. Comment, *supra* note 149, at 1444-45.

Recombinant DNA research should be regulated by a newly created administrative agency. However, the biotechnologies of in vitro fertilization and cloning should be left unregulated. Controversies arising from individual applications of these techniques could be handled in the traditional courts of law,²⁵⁸ facilitated by the eventual evolution of a body of case law pertaining specifically to these biotechnological questions.

258. At least two such cases have already been resolved. *See Mack v. Califano*, 447 F. Supp. 668 (D.D.C. 1978) (holding that government scientists cannot be preliminarily enjoined from recombinant DNA research which is in accordance with National Institutes of Health Guidelines); *see also DelVio v. Presbyterian Hospital*, Facts on File October 13, 1978 at 770 (Federal court jury awarded Doris and Don DelVio \$37,000 for emotional stress suffered when their laboratory-conceived baby was halted the day after its test tube fertilization).