Regulating Science: An Evaluation of the Regulation of Biotechnology Research

Part 1

by

Valerie M. Fogleman

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ARTICLE

REGULATING SCIENCE: AN EVALUATION OF THE REGULATION OF BIOTECHNOLOGY RESEARCH

BY
VALERIE M. FOGLEMAN*

In 1984 the White House Office of Science and Technology Policy proposed a Coordinated Framework for the regulation of biotechnology. Under the framework, which was revised in 1986, various federal agencies regulate biotechnology research and products under existing laws. These laws, however, were designed to regulate technological end products, not scientific research. The result has been regulations and guidelines which appear to satisfy no one, and which threaten to increase in complexity. In lieu of the Coordinated Framework the author recommends regulating biotechnology research separately from technological products. The new system would recognize the unique problems involved in regulating scientific research while concurrently protecting the public health and safety, and the environment.

I. INTRODUCTION

Regulation of scientific research is rare. Requests by scientists to be regulated are even rarer. Thus, in 1973 when a group of prominent scientists suggested that their research be subject to controls,[1] unprecedented public attention focused on that re-

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* Natural Resources Law Fellow, Northwestern School of Law of Lewis and Clark College. J.D. 1986, B.L.A. 1983, Texas Tech University. I would like to express my gratitude to Professor Frank F. Skillern of Texas Tech University School of Law for his help and encouragement in the preparation of this Article.

1. *See* Berg, Baltimore, Boyer, Cohen, Davis, Hogness, Nathans, Roblin, Watson, Weissman & Zinder, *Potential Biohazards of Recombinant DNA Molecules*, 181 SCIENCE 1114, 1114 (1973) [hereinafter Berg letter].

search.[2] The issue of whether recombinant deoxyribonucleic acid (rDNA) technology is unique—and thus requires special regulations—is still not totally settled.[3]

The scientific advances leading to rDNA technology were spectacular. In 1953 the double helical structure of DNA was discovered.[4] When scientists subsequently deciphered the genetic code, they could manipulate DNA by stripping pieces of it with restriction enzymes and combining the pieces with other DNA.[5] Insertion of the combined DNA into living cells completed the technique known as rDNA technology.[6] Molecular biologists were no longer passive observers of life; they became its creators.[7] The public, with an imagination spurred by visions of mad scientists creating chimeras and Frankenstein monsters,[8] demanded input into research decisions.[9]

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2. *See* Fielding, *Biotechnology: The Promise and the Peril*, 4 ENVTL. F. 13, 16 (Aug. 1985).

3. *See, e.g.*, Recombinant DNA Research: Proposed Revised Guidelines, 46 Fed. Reg. 59,368, 59,382 (1981) (questioning whether dangers of rDNA research are qualitatively unique).

4. *See* Watson & Crick, *Molecular Structure of Nucleic Acids: A Structure for Deoxyribose Nucleic Acid*, 171 NATURE 737 (1953) (proposing double helix as model for DNA).

5. Zinder, *From Genetics to Genetic Engineering*, in FROM GENETIC EXPERIMENTATION TO BIOTECHNOLOGY—THE CRITICAL TRANSITION 13, 14-17 (1982).

6. The term "rDNA technology" is misleading. Scientists investigating the nature of organisms by using rDNA technology in laboratories are engaged in science while the use of rDNA technology to manufacture commercial products is technology. No bright line between science and technology exists. One scientist has even argued that rDNA technology fuses both terms. *See* Cavalieri, *Science as Technology*, 51 S. CAL. L. REV. 1153 (1978). Under either term, however, experimentation in rDNA technology is an integral part of scientific research because it is part of the search for knowledge, not the use made of that knowledge. *Cf.* Markey, *Needed: A Judicial Welcome for Technology—Star Wars or Stare Decisis?*, 79 F.R.D. 209, 209 (1979) ("Science is learning—the search for knowledge. Technology is the use we make of what science learns.").

7. *See* Weinberg, *The Molecules of Life*, 252 SCI. AM. 48, 48 (Oct. 1985).

8. *See* Chargaff, *On the Dangers of Genetic Meddling*, 192 SCIENCE 938, 938 (1976) (referring to "second degree molecular biology"; and stating "[i]f Dr. Frankenstein must go on producing his little biological monsters"); *see also* Fielding, *supra* note 2, at 16-17 (describing reports of "strange orange-eyed creature" and "hairy nine-foot creature"). *But see* Singer & Berg, *Recombinant DNA: NIH Guidelines*, 193 SCIENCE 186, 187 (1976) (disputing Chargaff's arguments).

9. *See* Singer, Szybalski, Richmond, Pritchard, Peacock & Coombes, *What Lessons Does the Recombinant DNA Debate Teach Us: A Round Table Discussion*, in RECOMBINANT DNA AND GENETIC EXPERIMENTATION 223, 231 (1979) [here-

Initially, controls were exercised only over rDNA technology. Current controls, however, cover other methods of biotechnology such as recombinant ribonucleic acid technology and cell fusion. Biotechnology, which has been defined as "any technique that uses living organisms (or parts of organisms) to make or modify products, or to improve plants or animals for beneficial use,"[10] will be used in this Article to include rDNA technology.

This Article evaluates methods of regulating one aspect of biotechnology—direct release experimentation. Direct release experiments pose a unique problem. Regulators must base permission to conduct experiments on whether inherent risks are unreasonable. Risks, however, cannot be completely assessed until after an experiment has been conducted. Part II of the Article argues that whereas a content-based prohibition on biotechnology experimentation would probably be unconstitutional, incidental regulation of experimentation based on protection of the environment and public health and safety is proper. Part III evaluates arguments by scientists and the public regarding the structure and scope of regulation. Part IV examines the federal scheme for regulating direct release experimentation. Part V recommends a regulatory structure that differentiates between controls on scientific processes and controls on technological products. The author concludes that the present multi-agency regulatory system should be abandoned in favor of a single agency charged by Congress with regulating scientific research in biotechnology.

II. CONSTITUTIONAL ISSUES RAISED BY BIOTECHNOLOGY EXPERIMENTATION

Scientific expression has two components: formulation and communication of ideas via spoken and written words, and formulation of ideas via experimentation. Neither component has express constitutional protection. The dichotomy presents problems. Although a persuasive argument can be made that the

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inafter Singer & Szybalski] (statement of J. Coombes). One commentator refers to the years 1976 (when the National Institutes of Health issued the first *Guidelines*) to 1978 as the "Recombinant DNA War." Zinder, *supra* note 5, at 16.

10. U.S. DEP'T OF HEALTH AND HUMAN SERVICES, THE NIH ROLE IN FOSTERING THE NATION'S LEADERSHIP IN BIOTECHNOLOGY, PROCEEDINGS OF THE 51ST MEETING OF THE ADVISORY COMMITTEE TO THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH 1 (1985) [hereinafter NIH ROLE].

pursuit of knowledge is implied in the first amendment protection of free speech,[11] such protection would encompass only communicative aspects of scientific speech.[12] Scientific experimentation taking place outside a person's mind[13] invariably involves conduct, and is thus "speech plus."[14] The traditional constitutional distinction between speech and action is not easily applied to the distinction between scientific hypotheses and experiments.[15] Because scientific inquiry cannot proceed without scientific experi-

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11. *See* Sweezy v. New Hampshire, 354 U.S. 234, 263 (1957) (Frankfurter, J., concurring) ("Freedom to reason and freedom for disputation on the basis of observation and experiment are the necessary conditions for the advancement of scientific knowledge."); *see also* Goldberg, *The Constitutional Status of American Science*, 1979 U. ILL. L.F. 1, 1 ("the Constitution contains an *implied* science clause" (emphasis in original)); Green, *A Legal Perspective of Recombinant DNA Research*, in RECOMBINANT DNA: SCIENCE, ETHICS, AND POLITICS 193, 201 (J. Richards ed. 1978) ("I am prepared to argue that freedom of scientific inquiry is implicit in the First Amendment guarantee of freedom of speech and press"); Robertson, *The Scientist's Right to Research: A Constitutional Analysis*, 51 S. CAL. L. REV. 1203, 1216 (1978) ("[S]cientific knowledge and information is . . . clearly within the protection of the first amendment.").

An argument can be made that scientific experimentation is simply "the information-gathering step in the scientific process; . . ." Delgado & Millen, *God, Galileo, and Government: Toward Constitutional Protection for Scientific Inquiry*, 53 WASH. L. REV. 349, 375 (1978). Experimentation should receive constitutional protection under this analysis because of its similarity to news-gathering. *See* Branzburg v. Hayes, 408 U.S. 665, 681-82 (1972); *see also* Delgado & Millen, *supra*, at 375 (discussing analogy of information-gathering and news-gathering); *cf.* J. RIFKIN, ALGENY 240 (1983) ("[K]nowledge has been reduced to information.").

12. *See generally* L. TRIBE, AMERICAN CONSTITUTIONAL LAW 580-82 (1978).

13. A thought experiment is one in which a scientist imagines specific natural or unnatural conditions and events in order to increase his scientific knowledge. *See* Kuhn, *A Function for Thought Experiments*, in 2 L'AVENTURE DE LA SCIENCE, MELANGES ALEXANDRE KOYRE 307 (1964), *reprinted in* SCIENTIFIC REVOLUTIONS 6 (I. Hacking ed. 1983).

14. NAACP v. Button, 371 U.S. 415, 455 (1963) (Harlan, J., dissenting) (referring to conduct associated with speech as speech plus). Professor Spece considers that the pure speech/speech plus distinction might apply to the regulation of biotechnology research. Spece, *A Purposive Analysis of Constitutional Standards of Judicial Review and a Practical Assessment of the Constitutionality of Regulating Recombinant DNA Research*, 51 S. CAL. L. REV. 1281, 1286 n.12 (1978). Professor Spece categorizes regulations aimed at physical safety as regulating conduct, and regulations aimed at preventing knowledge as regulating speech. *Id.*

15. *Science Policy Implications of DNA Recombinant Molecule Research, Hearings Before the Subcomm. on Science, Research, and Technology of the House Comm. on Science and Technology*, 95th Cong., 1st Sess. 862 (1977) [hereinafter *DNA Hearings*] (statement of J. Barron, Professor, National Law Center).

mentation, one commentator argues that some experiments are necessarily expression.[16] However, this analysis excludes experiments possessing the potential to harm the public.[17]

In the case of biotechnology experimentation the state has a legitimate interest in protecting the environment, public health, and safety.[18] This state interest should be "sufficiently important" to justify regulating the nonspeech element of experimentation.[19] If regulations were narrowly drafted to address only safety measures,[20] a rational basis for the regulations would probably be sufficient. If regulations were suppressing knowledge, however, the state would probably be required to show a compelling interest for the regulation.[21]

While a problem is raised by content-based regulations aimed specifically at biotechnology research, regulations directed solely at potential dangers of noncommunicative aspects of experimentation—the release of novel organisms into the environment—should rest on solid constitutional ground.[22] Such regula-

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16. SUBCOMM. ON SCIENCE, RESEARCH AND TECHNOLOGY OF THE HOUSE COMM. ON SCIENCE AND TECHNOLOGY, 95TH CONG., 2D SESS., SCIENCE POLICY IMPLICATIONS OF DNA RECOMBINANT MOLECULE RESEARCH 60 (Comm. Print 1978) [hereinafter SCIENCE POLICY REPORT] (statement of T. Emerson, Professor, Yale School of Law).

17. *Id.*

18. *Cf.* United States v. O'Brien, 391 U.S. 367, 381-82 (1968) (state has legitimate interest in regulating noncommunicative impact of conduct); *see also* Green, *supra* note 11, at 204 (no reason why biotechnology "should not be regulated to same extent as other activities that raise a threat of injury to the health and safety of the public or to the environment"). If the right to research were accorded constitutional protection, the state would be required to show that its interest in regulating was compelling or substantial. *See generally* Robertson, *supra* note 11, at 1210.

19. *See O'Brien*, 391 U.S. at 376 ("When 'speech' and 'nonspeech' elements are combined in the same course of conduct, a sufficiently important governmental interest in regulating the nonspeech element can justify incidental limitations on First Amendment freedoms.").

20. *See* Chaplinsky v. New Hampshire, 315 U.S. 568, 573 (1942) (nexus between means and ends must be narrowly drawn); *cf.* Spence v. Washington, 418 U.S. 405, 414 n.9 (1974) (per curiam) (noting "nearly limitless sweep" of unconstitutional statute).

21. *See generally* Spece, *supra* note 14, at 1307 & n.82.

22. *See* United States v. O'Brien, 391 U.S. 367, 381-82 (1968); Konigsberg v. State Bar, 366 U.S. 36, 50-51 (1961). *See generally Regulation of Recombinant DNA Research: Hearings Before the Subcomm. on Science, Technology, and Space of the Senate Comm. on Commerce, Science, and Transportation*, 95th

tions would merely limit the time, manner, and place of experiments.[23]

As long as regulations on biotechnology experiments do not seek to prohibit experiments in the guise of regulating them, the regulations should withstand constitutional scrutiny.[24] The regu-

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Cong., 1st Sess. 355-56 (1977) [hereinafter *Recombinant DNA Research Hearings*] (statement of D. Newburger, Assistant Professor of Law, Washington University) (describing federal regulation of nuclear power and fluorocarbons to attain public policy goals); Note, *Recombinant DNA and Technology Assessment*, 11 GA. L. REV. 785, 836 (1977) (arguing that " 'inquiry' clearly loses its constitutional protection when intellectual discourse is transformed into hazardous activity"). *But see* 124 CONG. REC. 3395 (1978) (statement of Rep. Ottinger) (arguing that research per se is not protected by the first amendment, only advocacy of research).

23. *See* Cox v. New Hampshire, 312 U.S. 569, 576 (1941); *see also* 124 CONG. REC. 3395-96 (1978) (statement of Rep. Ottinger) (analogizing biotechnology research to clear and present danger to which time, place, and manner regulations may be applied). *But see DNA Hearings*, *supra* note 15, at 881 (statement of T. Emerson, Professor, Yale School of Law) ("Clear and present danger test [in biotechnology context] does not seem to me acceptable."). *See generally* Setlow, *How the NIH Recombinant DNA Molecule Committee Works in 1979*, in RECOMBINANT DNA AND GENETIC EXPERIMENTATION 161, 165 (1979) (comment of E. Weiss) (stating general agreement that time and manner restraints on scientific research are constitutional).

The Department of Health and Human Services regulations protecting human subjects in biomedical and behaviorial research illustrate how some regulations directly affect scientific research. 45 C.F.R. §§ 46.101-.211 (1986). These regulations balance the benefit to society of the research with the personal integrity of the human subject involved. *See generally* Lappe & Martin, *The Place of the Public in the Conduct of Science*, 51 S. CAL. L. REV. 1535, 1543-47 (1978) (describing regulations on biomedical and behaviorial research). Professor Emerson argued, however, that because biotechnology research is on "a fundamental molecular or cell level of control not involving humans or animals, [regulating it] really goes further and has more serious implications than anything that has been done so far." *DNA Hearings*, *supra* note 15, at 912.

24. *Cf.* Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748, 770 (1976) (choice "between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us"); Meyer v. Nebraska, 262 U.S. 390, 403 (1923) (invalidating statute forbidding German language being taught as unconstitutional).

A due process argument also exists that regulations on scientific research violate a scientist's right to research. Professor Emerson has argued, however, that the first amendment gives broader protection, thereby superseding a due process argument. *DNA Hearings*, *supra* note 15, at 913; *see also* Delgado, Bradley, Burkenroad, Chavez, Doering, Lardiere, Reeves, Smith & Windhausen, *Can Science Be Inopportune? Constitutional Validity of Governmental Restrictions on Race-IQ Research*, 31 UCLA L. REV. 128, 173 n.273 (1983) (arguing that no fundamental constitutional right to research exists); Robertson, *supra* note 11, at 1212-

lations, therefore, should address only concerns involving the safety of the public and the environment. The experiment's purpose in testing a scientific hypothesis must remain beyond the regulations' scope.

III. Issues in Structuring Regulations for Biotechnology Experimentation

In order to protect public health and safety and the environment while not intruding too severely on scientific experimentation, the scope of biotechnology regulations must be clearly delineated. Three critical issues must be determined: (1) who will regulate, (2) what issues will be addressed by the regulations, and (3) what criteria will be used to assess the safety of experiments.

A. Decision Makers

The issue of who should regulate scientific experimentation in biotechnology is controversial.[25] The controversy began in the early 1970s when a small group of scientists[26] became concerned that rDNA technology could be intentionally misused. The scientists convinced themselves of the need for regulation and suggested that certain experiments that could potentially cause cancer be banned temporarily. They also recommended the formulation of guidelines.[27]

The "Berg letter" which contained the suggested moratorium was not a scientific document. One author admitted that the letter (published in the journal, *Science*) was based on emotionalism instead of scientific data.[28] Indeed, no scientific basis for anticipating a hazard even existed.[29] Unfortunately, the credentials of

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14 (arguing the same).

25. *See generally* Holman & Dutton, *A Case for Public Participation in Science Policy Formulation and Practice*, 51 S. Cal. L. Rev. 1505, 1509-10 (1978) (describing positions of scientists and public on whether experimentation should be regulated).

26. Five of the scientists were tumor virologists, and one was engaged in research involving *Escherichia coli* (the commonly used vector in rDNA technology). Watson, *Why the "Berg" Letter Was Written*, in Recombinant DNA and Genetic Experimentation 187, 190 (1979).

27. *Id.* at 191; *see* Berg letter, *supra* note 1, at 1114.

28. Singer & Szybalski, *supra* note 9, at 236 (comment of J. Watson).

29. Warner, *The Public Perception of Risk*, in Recombinant DNA and Ge-

the letter's authors easily transcended its scientific worth.[30] The public began to suspect the safety of biotechnology. Suspicion turned to certainty when, after eminent scientists held a meeting to discuss rDNA technology,[31] the National Institutes of Health issued restrictive guidelines controlling research in 1976.[32]

The issue of public participation in the control of biotechnology experimentation has intensified since 1976. Relaxation of the guidelines has tended to increase public suspicion that scientists are not revealing the danger of biotechnology because of self-interest[33] and lucrative deals with industry.[34] Involved scientists,

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NETIC EXPERIMENTATION 289, 296 (1979) (comment of S. Cohen). Scientists involved in microbiology and clinical and epidemiologic aspects of infectious diseases were greatly surprised by the suggestions for a moratorium and guidelines because the scientists suggesting caution were involved in biochemistry and genetics rather than in the study of pathogens or disease incitants. Lennette, *Recombinant DNA: A Public Health Viewpoint*, in RECOMBINANT DNA AND GENETIC EXPERIMENTATION 261, 261 (1979). After experts in epidemiology, infectious diseases, and medical microbiology were included in discussions of the risks of rDNA technology, the risks were discovered to be overstated. Halvorson, *DNA and the Law*, 51 S. CAL. L. REV. 1167, 1170 (1978).

30. Warner, *supra* note 29, at 296 (comment of S. Cohen).

31. At the four-day meeting at Asilomar, California, Dr. Berg told scientists that if they did not impose regulations on themselves, someone else would do it for them. *See* J. GOODFIELD, PLAYING GOD 110 (1977).

32. Decision of the Director of NIH to Release Guidelines for Research on Recombinant DNA Molecules, 41 Fed. Reg. 27,902 (1976). The Guidelines were restrictive because the scientific drafters had instructions from the NIH to draft guidelines reflecting a willingness to self-regulate, acknowledge social responsibility, and show a lack of self-interest. Singer & Szybalski, *supra* note 9, at 224. No evidence existed showing dangers of the research, however. When the Guidelines were issued, hazards beyond the low-level risk associated with source materials were speculative and unquantifiable. Decision of the Director, *supra*, at 27,904.

33. *See* Novick, *Present Controls Are Just a Start*, 33 BULL. ATOM. SCIENTISTS, 16, 16 (May 1977) (expressing personal inability to distinguish between: (1) conviction that rDNA experiments are not dangerous, and therefore can be conducted; and (2) conviction that rDNA experiments are safe because of personal desire to conduct them); *see also* Green, *The Recombinant DNA Controversy: A Model of Public Influence*, 34 BULL. ATOM. SCIENTISTS 12, 14 (Nov. 1978) (public tendency to regard assessments of risks that are lower than originally perceived as having a " 'trust big brother because he knows best' overtone").

34. *See* King, *New Diseases in New Niches*, 276 NATURE 4, 6-7 (1978); *see also* Zinder, *supra* note 5, at 16 (reversal of scientists' positions seemed irrational to public). *But see* Wade, *The Roles of God and Mammon in Molecular Biology*, in FROM GENETIC EXPERIMENTATION TO BIOTECHNOLOGY—THE CRITICAL TRANSITION 203, 208 (1982) (in scientific community, scientists' opinions accepted on their merits regardless of the research sponsor).

meanwhile, view themselves as characters in a black comedy that they helped create[35] when they paused and then proceeded with caution in the face of uncertain risks. The scientists feel that the public overreacted, thereby allowing opponents of biotechnology to exploit the situation.[36] Although most scientists now believe that biotechnology is not hazardous,[37] they are unable to convince the public of the safety of the research.

Scientists argue that risks of experimentation in biotechnology cannot be discussed rationally unless participants understand the subject matter.[38] According to this argument, because potential dangers are merely conjectural at the research level, public participation should take place after research is completed but

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The public's image of the scientific community in this regard was partially flawed due to a misunderstanding of events. The Berg letter was not a scientific document, and its theories were not subjected to peer review. Singer & Szybalski, *supra* note 9, at 231 (comment of J. Coombes). The public was not made aware of this fact, but assumed that the scientists' actions were based on logical conclusions derived from hard facts. *See id.* at 224 (statement of W. Szybalski); *see also* Rowe, *Guidelines that Do the Job*, 33 BULL. ATOM. SCIENTISTS, 14, 14 (May 1977) (speculation as to risks construed as fact). When the scientists later determined—on the basis of hard facts—that the suspected dangers had not materialized, the public was skeptical at the about-face. Because it was not generally understood that scientists are trained to have open minds, such behavior appeared irrational. *See* Singer & Szybalski, *supra* note 9, at 223 (statement of W. Szybalski); *see also* Zinder, *supra* note 5, at 16 (discussing fact that around 1976 molecular biologists reversed their beliefs regarding the hazardous nature of rDNA technology).

35. *See* Watson, *An Imaginary Monster*, 33 BULL. ATOM. SCIENTISTS 12, 13 (May 1977).

36. *See* Fredrickson, *A History of the Recombinant DNA Guidelines in the United States*, in RECOMBINANT DNA AND GENETIC EXPERIMENTATION 151, 156 (1979).

37. Evaluation of the Risks Associated with Recombinant DNA Research, 46 Fed. Reg. 59,385, 59,391 (1981).

38. *See* Fredrickson, *supra* note 36, at 152 (The first town meeting held to discuss biotechnology "demonstrated the difficulties of holding a town meeting on molecular biology and exposed the full range of opinions on the risks of the new technology."). Only a small percentage of the public has had formal training in biology; an even smaller percentage has had training in molecular biology. *See* PANEL ON BIOETHICAL CONCERNS, NATIONAL COUNCIL OF THE CHURCHES OF CHRIST/USA, GENETIC ENGINEERING—SOCIAL AND ETHICAL CONSEQUENCES 8 (1984) [hereinafter SOCIAL AND ETHICAL CONSEQUENCES]; *see also* M. ROGERS, BIOHAZARD 179 (1977) (describing bewilderment of elite public group when listening to discussions on molecular genetics); Singer & Szybalski, *supra* note 9, at 239 (comment of M. Singer) (public's lack of knowledge regarding science and scientific method).

before commercial production begins.[39] Only then—after a thorough investigation of benefits and risks has been conducted—can a meaningful exchange of ideas take place.[40] According to many scientists, rapidly-moving research simply is not amenable to safety regulations by nonscientific decision makers.[41]

The scientists' argument has merit. Discussions on the safety of biotechnology experiments are necessarily scientific and technical. Public participants in scientific discussions tend to be intimidated by scientists,[42] and are hesitant to raise technical issues for fear of embarrassment.[43] Public demands for accountability, however, are not satisfied by what appears to be elitism and arrogance on the part of scientists.[44] Scientific knowledge belongs to everyone, not merely the scientific community.[45] Public access to and comments regarding safety criteria are an analog to scientific peer review allowing criticism of experiments within the scope of

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39. *See* Notice of Actions Under NIH Guidelines for Research Involving Recombinant DNA Molecules, 50 Fed. Reg. 9760, 9762 (1985) (comment by B. Horecker, Roche Institute of Molecular Biology) ("[H]ow the results of such research are implemented becomes a matter for regulation, but not the conduct of the research *per se*.").

40. *See* J. GOODFIELD, *supra* note 31, at 146 (degree of benefits is social, not scientific, decision); Novick, *The Dangers of Unrestricted Research: The Case of Recombinant DNA*, in RECOMBINANT DNA: SCIENCE, ETHICS, AND POLITICS 71, 72-73 (J. Richards ed. 1978) (risks and benefits of basic research are not quantifiable).

41. *See* G. NOSSAL, RESHAPING LIFE: KEY ISSUES IN GENETIC ENGINEERING 125-26 (1985) (outlining difficulties in drafting legislation to regulate changing scientific knowledge); Szybalski, *Chairman's Introduction*, in RECOMBINANT DNA AND GENETIC EXPERIMENTATION, 147, 147 (1979) (arguing that regulations are impractical in controlling rapidly developing research).

42. *See, e.g.*, Holman & Dutton, *supra* note 25, at 1531 (role of public can be undermined and trivialized by expertise of scientists); Krimsky, *A Citizen Court in the Recombinant DNA Debate*, 34 BULL. ATOM. SCIENTISTS 37, 42 (Oct. 1978) (public tendency to be intimidated by scientists when technical or scientific issues are discussed).

43. *See Recombinant DNA Research Hearings*, *supra* note 22, at 100-01 (statement of M. Shapo, Professor, University of Virginia School of Law).

44. *See, e.g.*, 124 CONG. REC. 3395 (1978) (statement of Rep. Ottinger). Congressman Ottinger stated: "[Scientists] apparently think themselves omniscient and infallible. 'We're the experts,' the saying goes, 'and you can't possibly understand whereof you speak.' I resent that, and I resent it extremely; and the American public will destroy you if you maintain that attitude." *Id.*

45. *See* Holman & Dutton, *supra* note 25, at 1520 (Science is the cumulative experience of human history because scientists base their work on efforts and experiences of others.).

the experiment's safety. The public has the right to regulate potential risks to its safety,[46] rather than trust in self-regulation by the scientific community.[47]

Environmental disasters such as the accidental introduction of gypsy moths and fire ants into the United States are common knowledge. Problems involving DDT and toxic wastes have been attributed to a myopic view of benefits without adequate consideration of risks.[48] If risks from biotechnology materialize, the ability of genetically engineered organisms[49] to reproduce could affect people and the environment worldwide.[50] It is indisputable that microorganisms possess an ability to affect significantly people and animals, as witnessed by the spread of antibiotic resistant bacteria.[51] One-half of the pests in the United States are introduced organisms.[52] In the face of such legitimate concerns, the public has a valid reason not to blindly trust uncommunicative scientists.

Unless the public is permitted to know the scientists' basis

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46. *See* Engelhardt, *Taking Risks: Some Background Issues in the Debate Concerning Recombinant DNA Research*, 51 S. CAL. L. REV. 1141, 1150 (1978); Green, *The Risk-Benefit Calculus in Safety Determinations*, 43 GEO. WASH. L. REV. 791, 792 (1975). The theory of informed consent is probably impractical in a discussion of risks of rDNA technology. If harmful novel organisms escape, they would not be limited by political boundaries. Thus, people who were not given the opportunity to consent, as well as those people who declined to consent, would be unable to avoid consequences of the research. *Id. But see* Cohen, *Recombinant DNA: Fact and Fiction*, 195 SCIENCE 654, 654 (1977) (arguing that rDNA technology is merely a set of techniques used in a large variety of experiments—and that no risks have been shown to exist).

47. *See* Bok, *Freedom and Risk*, 107 DAEDALUS 115, 118-19 (1978).

48. *See* M. LAPPE, BROKEN CODE: THE EXPLOITATION OF DNA 178 (1984).

49. The term "genetically engineered organisms" is used throughout this Article to mean organisms manipulated by biotechnology. The term "genetic engineering" originally referred only to the replacement of genes in people. *See* Baltimore, *Limiting Science: A Biologist's Perspective*, 107 DAEDALUS 37, 39-40 (1978). Current popular usage of the term refers to all organisms manipulated by biotechnology. *See* Thomas, *Overview: Regulating Biotechnology*, 3 YALE L. & POL'Y REV. 309, 309 (1985).

50. *See* Halvorson, *supra* note 29, at 1178.

51. *Id.* at 1177.

52. *See* Recombinant DNA Advisory Committee, National Institutes of Health, Minutes of June 1, 1984 Meeting 45 (statement of D. Pimentel, Cornell Univ., ad hoc consultant to RAC); *see also* Johnson, Regulation of Recombinant DNA Products 9 (Cong. Research Serv. Issue Brief 1223) (Nov. 1, 1985) (the only domestic food crop originating in the United States is the sunflower).

for determining that risk is minimal or nonexistent, the public will find its own criteria by which to assess risk.[53] These criteria will probably be provided by the media, which have become notorious for their disenchantment with science and technology.[54] Without effective communication, the scientific community's and the public's perception of risks polarizes.[55] Scientists have communicated successfully with the public on biotechnology in the past.[56] Rather than protest that the subject matter is too technical, involved scientists should strive to communicate essential issues to the public[57] to win its confidence.[58]

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53. *See generally* Fischhoff, Slovic & Lichtenstein, *"The Public" vs. "The Experts": Perceived vs. Actual Disagreements About Risks of Nuclear Power*, in THE ANALYSIS OF ACTUAL VERSUS PERCEIVED RISKS 235, 246-47 (1981). In March 1986, Monsanto, which had previously fought the Environmental Protection Agency's (EPA) suggestion that it release data on a genetically engineered microbe it wished to test in a direct release experiment, made public nearly all information it had submitted to EPA. *See* Sun, *Monsanto Opens File on Genetic Release Test*, 231 SCIENCE 1065, 1065 (1986).

54. *See generally Risk/Benefit Analysis in the Legislative Process: Joint Hearings Before the Subcomm. on Science, Research, and Technology of the House Comm. on Science and Technology and the Subcomm. on Science, Technology, and Space of the Senate Comm. on Commerce, Science, and Transportation, and the Congress/Science Forum with the American Association for the Advancement of Science*, 96th Cong., 1st Sess. 42 (1979) [hereinafter *Risk/Benefit Hearings*] (statement of E. Diamond, Professor, Massachusetts Institute of Technology) (explaining that media's "gee whiz" approach to science and technology has been replaced with skepticism; and commenting that "[a]s the pendulum in the press swings wildly, the public feels that science and technology mistakes will bury us"); Petersen, *Citizen Participation in Science Policy*, in CITIZEN PARTICIPATION IN SCIENCE POLICY 1, 11 (J. Petersen ed. 1984) (explaining that one reason for low quality media coverage of science is that only about 50 newspapers employ full-time science reporters).

55. *See, e.g., Report of IBC Chairperson's Meeting*, 4 RECOMBINANT DNA TECHNICAL BULL. 26, 26 (1981) (difference in perception of risks can be substantial).

56. *See, e.g.*, Levin, *Changing Views of the Hazards of Recombinant DNA Manipulation and the Regulation of these Procedures*, 7 RECOMBINANT DNA TECHNICAL BULL. 107, 113 (1984) (praising preparedness and quality of arguments of lay people in local rDNA committee); Krimsky, *supra* note 42, at 42 (describing success of Cambridge citizen court in reviewing safety of rDNA experiments conducted by scientists at Harvard and Massachusetts Institute of Technology).

57. *See* Lederberg, *The Freedoms and the Control of Science: Notes from the Ivory Tower*, 45 S. CAL. L. REV. 596, 611 (1972); *see also* 124 CONG. REC. 3396 (1978) (statement of Rep. Ottinger) ("Cooperation and explanation—in English, rather than in scientific jargon—is what the scientific community should be offering, not elitism . . . . If [scientists] do not move in that direction, [they] will in-

Opponents of biotechnology research, such as Jeremy Rifkin, are skillful in exploiting fear of the research by arguing ideology in the guise of science.[59] Public fears about biotechnology will not be allayed if scientists ignore those fears. Scientists initially raised the issue of whether biotechnology was dangerous. It seems only reasonable that scientists show they were mistaken.[60] The problem is, of course, that when the scientists were arguing for restrictions they were arguing against their self-interest. The scientists' credibility is weakened when they argue later for relaxation of regulations.[61]

B. Scope of Issues

Closely tied to the issue of who will regulate biotechnology experimentation is the scope of the regulations. Two types of risk arise in biotechnology: social risk and physical risk.[62] The first, social risk, encompasses arguments such as "[a]ll that can be known need not be known if in advance it clearly appears that

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vite vastly more serious mistrust . . . than [they] have ever seen to date . . . .").

58. *See generally* Carter, *The Bellman, the Snark, and the Biohazard Debate*, 3 YALE L. & POL'Y REV. 358, 361 (1985) (arguing that if scientists do not win public confidence, regulation of science will increase).

59. *See* Singer, *Genetics and the Law: A Scientist's View*, 3 YALE L. & POL'Y REV. 315, 326-34 (1985).

60. *See* Green, *supra* note 33, at 13 (even if scientists did not intend rDNA technology to become public issue, drama inherent in their actions ensured that public controversy was inevitable); *see also* Bertani, *Laboratory Genetic Manipulations*, in RECOMBINANT DNA AND SCIENTIFIC EXPERIMENTATION 37, 44 (1979) (comment of H. Kornberg) ("It is *we* who first alerted the public to possible risks, and it is due to us that there is public concern: the public now has the right to a critical assessment of the validity or otherwise of the dangers.") (emphasis in original).

61. *See* Chalker & Catz, *A Case Analysis of NEPA Implementation: NIH and DNA Recombinant Research*, 1978 DUKE L.J. 58, 87 n.148 (suggesting that scientists may be downplaying risks to avoid regulations that "would cripple American science and their own particular ambitions"); Williams, *Ethical Theories Underlying the Recombinant DNA Controversy*, in RECOMBINANT DNA: SCIENCE, ETHICS, AND POLITICS 177, 188-89 (J. Richards ed. 1978) (stating personal sacrifice is evidence of good motives); *see also* Dutton, *The Impact of Public Participation in Biomedical Policy: Evidence from Four Case Studies*, in CITIZEN PARTICIPATION IN SCIENCE POLICY 147, 161-62 (J. Petersen ed. 1984) (critics charging that involvement in politics of once-pristine professional scientific societies was a "self-serving attempt to protect professional autonomy").

62. *See* Engelhardt, *supra* note 46, at 1145 (discussing ambiguity of risks).

the risks are inordinate."[63] In this context, knowledge of biotechnology is viewed as dangerous[64] or against the public interest.[65] In the face of fears about future uses of biotechnology (such as genetic alteration of people),[66] the continued pursuit of biotechnology research is viewed as morally wrong;[67] scientists are viewed as arrogant characters attempting to "play God."[68]

Although surveys show that social risk is not a predominant concern in applying biotechnology to plants,[69] such application

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63. SOCIAL AND ETHICAL CONSEQUENCES, *supra* note 38, at 25.

64. *See, e.g.*, Address by Pope John Paul II to UNESCO, *quoted in* G. NOSSAL, *supra* note 41, at 119 ("future of man and mankind is threatened, radically threatened . . . by men of science"). *But see* Grobstein, *Regulation and Basic Research: Implications of Recombinant DNA*, 51 S. CAL. L. REV. 1181, 1194 (1978) (arguing that no phenomena are dangerous to understand).

65. *See, e.g.*, Amicus Brief on Behalf of People's Business Commission at 5, 13, United States v. Chakrabarty, 447 U.S. 303 (1980) (arguing that "genetic engineering [is] not in the public interest") (available Feb. 1, 1987, on LEXIS, Genfed library, Briefs file). *But see* Notice of Actions Under NIH Guidelines for Research Involving Recombinant DNA Molecules, 50 Fed. Reg. 9760, 9762 (1985) (comment by O. Smithies, University of Wisconsin-Madison) ("Mr. Rifkin is asking for a blanket prohibition *on moral grounds*. In doing this he shows that his view of morality is sorely limited . . . .") (emphasis in original).

66. *See* Novick, *What Is Wrong with Biotechnology?*, 4 ENVTL. F. 31, 34 (Nov. 1985) (describing imagined horrors of future if human life is tampered with).

67. *See* Fletcher, *Ethics and Recombinant DNA Research*, 51 S. CAL. L. REV. 1131, 1133 (1978) (stating that right to implement rDNA technology has moral limits). *But see* Grobstein, *supra* note 64, at 1191-92 ("[N]onquantifiable but time-tested benefit of new knowledge must take priority over risks that are hypothetical and equally nonquantifiable.").

68. *See* PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, SPLICING LIFE, A REPORT ON THE SOCIAL AND ETHICAL ISSUES OF GENETIC ENGINEERING WITH HUMAN BEINGS 55 (Nov. 1982), *reprinted in Human Genetic Engineering: Hearings Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 97th Cong., 2d Sess. 5, 78 (1982) [hereinafter *Human Genetic Engineering Hearings*].

The Commission stated that it was hubris to some religious thought that scientists were "playing God" in manufacturing genetically engineered organisms because "all human activities, including gene splicing proceed according to the scientific laws that describe natural processes [and] only God can interfere with the descriptive laws of nature . . . ." *Id.* The Commission further stated that it "could find no ground for concluding that any current or planned forms of genetic engineering, whether using human or nonhuman material, are intrinsically wrong or irreligious per se." *Id.* at 77, *reprinted in Human Genetic Engineering Hearings, supra*, at 104.

69. *See* Miller, *The Attitudes of Religious, Environmental, and Science Pol-*

can be viewed as the precursor to a limitless use of biotechnology. The leading opponent of biotechnology, Jeremy Rifkin, argues that it will lead to a "designed" world rather than a natural one.[70] He advocates that biotechnology research be forsaken in place of a "a different knowledge path . . . whose goal is to foresee how better to participate with rather than to dominate nature."[71] Unfortunately, Rifkin does not delineate the criteria for choosing the different knowledge path. To continue research in selected aspects of molecular biology would be impossible under Rifkin's formula. Good scientific research is not predictable.[72] An excellent example of the difficulties inherent in attempting to control scientific research involves rDNA itself. The discoveries leading to rDNA technology were unanticipated and unrelated. The only way to have prevented their occurrence would have been to prohibit all research in cell biology and genetics.[73]

Opponents of the social risk argument state that no one can know whether unknown knowledge is dangerous.[74] They argue that sociological and ethical judgments are necessarily value judgments,[75] and, because knowledge per se has no intrinsic value,[76]

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icy Leaders Toward Biotechnology, 8 RECOMBINANT DNA TECHNICAL BULL. 141, 155 (1985).

70. J. RIFKIN, *supra* note 11, at 18-19.

71. *Id.* at 251.

72. Dr. Lewis Thomas described the problem: "You either have science or you don't, and if you have it you are obliged to accept the surprising and disturbing pieces of information, even the overwhelming and upheaving ones, along with the neat and promptly useful bits." Thomas, *Notes of a Biology-Watcher, The Hazards of Science*, 296 N. ENG. J. MED. 324, 327 (1977). Dr. Thomas recognized that discussions on regulating biotechnology had been twisted into the issue of whether there were "some things in science we should not be learning about." *Id.* at 325. Thomas concluded that because "we are still far too ignorant [in biologic and medical sciences] to begin making judgments about what sorts of things we should be learning or not learning . . . we ought to be grateful for whatever snatches we can get hold of . . . ." *Id.* at 326.

73. *See* Thomas, *The Limitations of Medicine as a Science*, in THE MANIPULATION OF LIFE 1, 18-19 (R. Esbjornson ed. 1984); *see also* Zimmerman, *Beyond Recombinant DNA: Two Views of the Future*, in RECOMBINANT DNA: SCIENCE, ETHICS, AND POLITICS 273, 299 (J. Richards ed. 1978) (suppressing acquisition of knowledge has never been successful).

74. *See* Fletcher, *supra* note 67, at 1137 (citing Lederberg, *Orthobiosis, The Perfection of Man*, in THE PLACE OF VALUE IN A WORLD OF FACTS 174 (1970)).

75. Thus, when scientists give value judgments, their judgments should not be entitled to any greater credibility than if they had been given by any other member of society. *See* Singer & Szybalski, *supra* note 9, at 231 (statement of J.

such judgments should not be made before knowledge is applied to some purpose.[77] Only then, after benefits and costs become quantifiable,[78] should a rational decision be made as to whether application of knowledge is in the public interest. Attempting to stifle the creation of knowledge prematurely precludes the ability to base value judgments on sound scientific evidence.[79]

On a purely practical level, the ability to ban new knowledge is probably nonexistent. Even if the United States banned all research in molecular biology, the sociological and ethical issues would not be eliminated. Research would continue in other countries.[80]

It is difficult to address social risk in the context of regulating biotechnology research. The fact that regulations exist implies that a decision has been made that research will proceed. The

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Coombes).

76. *See* B. ZIMMERMAN, BIOFUTURE, CONFRONTING THE GENETIC ERA 72-73 (1984). *But see* Cavalieri, *supra* note 6, at 1165 (disputing value free role of modern science).

77. Some commentators are concerned, however, that the accomplished design of a technology can impel its use. *See Recombinant DNA Research Hearings*, *supra* note 22, at 310 (statement of S. Thacher, member of Science for the People). However, unless a particular field of research is totally prohibited, it is difficult to envision how knowledge leading to the design of a new technology could be limited. Professor Graham stated that "[t]he alternative of controlling fundamental research instead of technology is illusory, because it assumes the impossible: the foreseeing of the results of fundamental inquiry." Graham, *Concerns About Science and Attempts to Regulate Inquiry*, 107 DAEDALUS 1, 11 (1978).

78. *See* Grobstein, *supra* note 64, at 1190 (As knowledge approaches use, benefits become quantifiable.).

79. *See* Novick, *supra* note 66, at 35 (Political questions are reduced and defused "by expanding the circle of scientific light.").

80. *See* Halvorson, *supra* note 29, at 1168-69 (No country has a monopoly on the acquisition of knowledge.). An argument can be made that a ban on biotechnology research could not be effectively enforced. As one observer wrote:

> There is something faintly ludicrous about august lawmaking bodies seriously discussing what they will and will not allow biologists to do with DNA and where they must do it.
>
> When is somebody going to tell them that this is not like nuclear bomb research where one needs a billion dollars and a major facility to get started? When is somebody going to tell them that a dedicated amateur might graft botulism to *E. coli* in his own cellar, and all the spies of the sky would see nothing? Even if the village policeman called (and why would he?), he would have great difficulty disproving that one was merely developing a new kind of soup.

Letter from M. Thackray, 34 BULL. ATOM. SCIENTISTS 6, 7 (Feb. 1978).

issue to be addressed by the regulations becomes the physical risk inherent in the research. The remainder of this Article discusses the regulation of physical risk in biotechnology research.

Physical risk in biotechnology experiments has three components: (1) construction of a unique organism not existing in nature, (2) the organism's establishment in the environment, and (3) harm caused by the novel organism to the environment and/or people.[81] If any one of these components was shown to be totally false, the biohazards[82] of biotechnology would be proven unfounded.[83] Unfortunately, "[a]bsence of evidence is not evidence of absence."[84] Not only is it virtually impossible to prove that risks do not exist in scientific experimentation,[85] but risks inherent in direct release experiments cannot become apparent until after an experiment is conducted.[86] The dilemma facing regulators is ensuring that public health and safety and the environment are not adversely affected, while permitting experiments to

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81. Evaluation of the Risks Associated with Recombinant DNA Research, 46 Fed. Reg. 59,385, 59,386 (1981). For purposes of this Article it has been assumed that there may be risks in biotechnology. This assumption is subject to dispute, however. *Cf.* Szybalski, *Genetic Engineering in Agriculture*, 229 SCIENCE 111, 115 (1985) (letter) (Risks in rDNA technology "are nonexistent from the *practical*, societal point of view.") (emphasis in original).

Three analyses should be conducted in a risk assessment of the industrial use of biotechnology: (1) a thorough characterization of the genetically engineered organism, including its ability to harm other organisms, and its possible products and byproducts; (2) if harm is revealed, an estimation of the probability for harm; and (3) an evaluation of risks to organisms and the environment of the chemical products and byproducts of the process. McGarity & Bayer, *Federal Regulation of Emerging Genetic Technologies*, 36 VAND. L. REV. 461, 479-80 (1983).

82. A biohazard has been defined as "any man-made development, process, substance, etc., that results in an inadvertent modification of the terrestrial biosphere, regardless of whether or not the process or substance in question is in the main beneficial to man or other species." Novick, *supra* note 40, at 79 (emphasis omitted).

83. Evaluation of the Risks Associated with Recombinant DNA Research, 46 Fed. Reg. 59,385, 59,386 (1981).

84. Bertani, *supra* note 60, at 44 (statement of H. Kornberg).

85. Setlow, *supra* note 23, at 164 (statement of F. Rolleston).

86. *See* Brill, *Genetic Engineering in Agriculture*, 229 SCIENCE 115, 118 (1985) ("[F]ield testing is the only way to prove that recombinant organisms are safe.") (letter); Harsanyi, *Biotechnology and the Environment: An Overview*, in BIOTECHNOLOGY AND THE ENVIRONMENT: RISK AND REGULATION 15, 22 (1985) (statement of Z. Harsanyi) ("[M]odels and formulas will not work in situations in the natural environment, since so many unique factors are involved.").

proceed.

C. Criteria Assessment

Regulating biotechnology research is especially difficult. Not only is it rare to regulate scientific research,[87] thus guaranteeing an adversarial reaction from those being regulated, but criteria on which to base regulations are scarce. When regulations were first being formulated, no dangers from biotechnology had been unequivocally shown.[88] This situation has not changed. Regulators must compensate for missing data by conducting experiments to assess potential risks. Unfortunately, the potential risks posed by such experiments are the reason for promulgating the regulations.[89]

The analytical tool chosen for regulating biotechnology research is risk assessment,[90] which has been defined as "the quali-

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87. The regulation of biotechnology research does not mark the first time that science has been regulated. Atomic energy, for example, was first regulated in 1946. *See* Atomic Energy Act of 1946, Pub. L. No. 79-585, § 10, 60 Stat. 755, 766. A critical difference between regulation of atomic energy in 1946 and of biotechnology now, however, is that atomic energy was viewed in a military context, resulting in the willingness of atomic scientists to be regulated. *See generally* Green, *supra* note 33, at 15. Other scientific research has been regulated periodically, but the regulation of biotechnology research is the first time that science per se has been comprehensively regulated in a purely civilian context, *see id.* at 12, 15, and the first time that a scientific technique has been subject to close scrutiny before its application. *See Recombinant DNA Research Hearings*, *supra* note 22, at 103 (statement of M. Lappe, Chief, Office of Health, Law and Values, California Dep't of Health).

Regulation of scientific research may be the culmination of a trend towards regulating prospectively, resulting in regulations being promulgated earlier and earlier. *See* Huber, *Exorcists vs. Gatekeepers in Risk Regulation*, REGULATION 23, 24 (Nov./Dec. 1983).

88. J. CHERFAS, MAN-MADE LIFE: A GENETIC ENGINEERING PRIMER 132 (1982); *see also* Setlow, *supra* note 23, at 164 (statement of H. Stetten) (commenting that no actuarial data of risks exist).

89. In order to conduct one risk assessment experiment, the NIH spent $250,000 converting a former chemical and germ warfare facility in Fort Detrick, Maryland, into the only laboratory in the United States that met the strictest containment standards of the Guidelines. Two Fort Detrick residents challenged the worst case risk assessment test scheduled at the laboratory. *See* S. KRIMSKY, GENETIC ALCHEMY: THE SOCIAL HISTORY OF THE RECOMBINANT DNA CONTROVERSY 246-47 (1982). The NIH won the ensuing lawsuit two years later. *See* Mack v. Califano, 447 F. Supp. 668, 670 (D.D.C. 1978).

90. *See* H.R. REP. No. 99, 99th Cong., 1st Sess. 13 (1985).

tative or quantitative characterization of the potential health effects of particular substances on individuals or populations."[91] Risk assessment has four components: "hazard identification, dose-regime assessment, exposure assessment, and risk characterization."[92] The process, used extensively throughout the federal regulatory agencies for health and environmental decision making, is scientifically based. By using risk assessment, questions involving the extent of a hazard can be quantified to reduce subjectivity in decision making.[93]

Risk assessment is the best method in existence for quantifying and qualifying potential hazards to public safety and the environment.[94] Indeed, the Council on Environmental Quality (CEQ) has described it as "the *only* tool available for making discriminations among environmental health problems."[95] Nevertheless, the process is still in its infancy, and is as much an art as a science.[96] Risk assessments are not equivalent to scientific findings.[97] Selection of scientifically-based assumptions involves value judgments, as does the choice of methodologies for extrapolating and interpreting data.[98] The weight given to available evidence is

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91. NATIONAL RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 38 (1983) [hereinafter RISK ASSESSMENT IN THE FEDERAL GOVERNMENT].

92. *Id.* at 19-20.

93. *See* Colwell, Norse, Pimentel, Sharples & Simberloff, *Genetic Engineering in Agriculture*, 229 SCIENCE 111, 111 (1985) (letter).

94. *See The Risk Assessment Research and Demonstration Act of 1983: Hearings on H.R. 4192 Before the Subcomm. on Natural Resources, Agriculture Research and Environment of the House Comm. on Science and Technology*, 98th Cong., 2d Sess. 58 (1984) [hereinafter *Risk Assessment Hearings*] (statement of J. Rodricks, Environ Corp.).

95. COUNCIL ON ENVIRONMENTAL QUALITY, ENVIRONMENTAL QUALITY 1984: FIFTEENTH ANNUAL REPORT 217 (1986) (emphasis in original) [hereinafter FIFTEENTH ANNUAL REPORT].

96. *See Risk Assessment Hearings*, *supra* note 94, at 105 (statement of M. Jacobson, Executive Director, Center for Science in the Public Interest). For an excellent evaluation of judicial review of risk assessment, see Davis, *The "Shotgun Wedding" of Science and Law: Risk Assessment and Judicial Review*, 10 COLUM. J. ENVTL. L. 67 (1985).

97. *See* RISK ASSESSMENT IN THE FEDERAL GOVERNMENT, *supra* note 91, at 164.

98. *See id.* at 33-37. *See also Panel Discussion—The Weaknesses and Strengths of Worst Case Analysis in the Management Decision Process*, in PROCEEDINGS OF A SYMPOSIUM ON WORST CASE ANALYSIS 101, 112 (May 19-21, 1985) (symposium sponsored by School of Forestry, Northern Arizona University)

influenced significantly by the scientific disciplines represented in a decision-making body.[99]

The use of risk assessment for new techniques such as biotechnology is especially value-laden due to dependence on theoretical analyses to compensate for lack of empirical data.[100] No consensus exists on a methodology for measuring the low probability of a catastrophe.[101] As a result, such risk assessments contain substantial value judgments, resulting in extreme splits of opinion among experts, and between experts and the public.[102] Scientific research in biotechnology poses the additional problem that the risk being assessed is inherent in the research itself rather than in an end product of technology.[103]

Even after risk assessment is completed, it is only the first step in decision making. Regulators must determine how to manage the assessed risk. Risk management is defined as "the process of evaluating alternative regulatory options and selecting among them."[104] The choice of alternatives is influenced by the decision-making agency,[105] the statute under which the decision is made,[106] and political, social, and economic factors.

Risk management, therefore, involves a science policy rather

(statement of A. Hirsch, Director, Office of Federal Activities, EPA) ("[A]nyone that has been involved in risk assessment knows that it is a highly judgmental, highly tentative art as much as it is a science.").

99. *See* Ashford, *Advisory Committees in OSHA and EPA: Their Use in Regulatory Decisionmaking*, 9 SCI., TECHNOLOGY & HUMAN VALUES 72, 77-78 (Winter 1984).

100. *See* Slovic, Fischhoff & Lichtenstein, *Risk Assessment: Technical and Behavioral Issues, reprinted in Risk/Benefit Hearings*, *supra* note 54, at 133, 136-37.

101. *See* M. SAGOFF, RISK-BENEFIT ANALYSIS IN DECISIONS CONCERNING PUBLIC SAFETY AND HEALTH 24 (1985).

102. *See Risk/Benefit Hearings*, *supra* note 54, at 184 (statement of P. Slovic, Research Associate, Decision Research).

103. *See id.* at 210 (statement of W. Lowrance, Visiting Associate Professor, Program in Human Biology, Stanford University).

104. RISK ASSESSMENT IN THE FEDERAL GOVERNMENT, *supra* note 91, at 38.

105. *See, e.g., Risk Assessment Hearings*, *supra* note 94, at 430-37 (describing use of risk assessments in Food and Drug Administration); *id.* at 289-300 (describing use of risk assessments in EPA).

106. *E.g.*, Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 348(c)(3)(A) (1982) (no risk permitted for food additives); Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136(bb) (1982) (balancing); Toxic Substances Control Act, 15 U.S.C. §§ 2603(a), 2605(a) (1982) (balancing).

than a scientific decision. Decisions made on issues involving significant scientific uncertainty—such as biotechnology research—tend to become social policy decisions rather than factual determinations.[107] If biotechnology research is regulated by a statute containing a risk-benefit requirement, decision making is especially vulnerable. Risk-benefit analysis implies that risks and benefits are known, quantifiable, and subject to comparison.[108] This analysis necessarily involves substantial value judgments,[109] especially in biotechnology research, in which risks and benefits are uncertain.[110]

In the face of the potential for abuse, it is imperative that a

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107. *See* Industrial Union Dep't, AFL-CIO v. Hodgson, 499 F.2d 467, 474-75 (D.C. Cir. 1974) (decision making in issues involving significant scientific uncertainty based on policy instead of facts).

108. *E.g.*, FIFTEENTH ANNUAL REPORT, *supra* note 95, at 211 (citing speech by William Ruckelshaus, former Administrator, EPA, at National Academy of Sciences, 1983) (risk management assumes assessment of health risks, plus factoring of benefits and costs in decision).

109. *See* Lederberg, *supra* note 57, at 609-10. Dr. Lederberg, who was a member of expert panels evaluating environmental radiation from nuclear energy, stated that panel members were often unable to analyze benefits precisely. Therefore, even though members of a panel acted conscientiously, the panel did not provide an accurate balancing of benefits with costs. In fact, Dr. Lederberg believes that "what was demanded of such committees was a policy judgment cloaked in technical detail." *Id.* at 610. *See also* Handler, Introduction to National Academy of Sciences Forum on "How Safe Is Safe"?, Address delivered at National Academy of Sciences Forum (May 1973), *reprinted in* Green, *supra* note 46, at 799 ("[A]ll cost and risk-benefit analyses entail a greater or lesser degree of social, political, or ethical judgment."). *Cf.* Hutt, *Safety Regulation in the Real World*, 28 FOOD DRUG COSM. L.J. 460, 466 (1973) ("[A] mathematical benefit/risk formula or computer program may eventually be able to quantitate the risk or uncertainty that inheres in a given [experiment], but it is not even relevant to the moral and ethical issues involved in deciding whether that risk or uncertainty is acceptable.").

110. *See* SCIENCE POLICY REPORT, *supra* note 16, at 37 (statement of W. Lowrance, Department of State) ("DNA issue . . . fits into the category of those issues where formal risk-benefit analysis does not have an application"); *id.* at 39 (statement of D. Michael, University of Michigan) ("[E]ven with a beginning flow of data a risk-benefit analysis alone would not be adequate.").

The regulation of biotechnology could foreseeably be eased if regulations were based on a risk-benefit analysis. Professor Green questioned whether "obvious and important expected benefits induce a decision to proceed with development of a technology in the face of uncertain effects?" Green, *Technology Assessment and the Law: Introduction and Perspective*, 36 GEO. WASH. L. REV. 1033, 1041 (1968).

decision-making agency retain its credibility with the public.[111] This means that agencies charged with protecting the public safety must communicate effectively with the public,[112] and that regulatory controls must appear strict rather than permissive.[113] Credibility is also aided by establishment of independent scientific advisory boards to review agency rulemaking and decisions.[114] Scientific advisory boards have the advantage not only of being independent from the risk assessment process and the agency conducting it, but of providing peer review of the risk assessment itself.[115]

Finally, regulations must be flexible. As scientific knowledge advances, controls must also advance. A rigid structure can freeze procedures long after their necessity has passed, resulting in the unnecessary expenditure of time and money.

In summary, selection of a regulatory body, the scope of its review, and the criteria used by it to assess proposals for conducting experiments are critical. The decision makers must possess the scientific expertise to comprehend all aspects and probable impacts of the proposed experiments. Equally important, however, is the public's perception that its views are considered and its interests protected. Regardless of how scientifically accurate a decision may be, unless the public participated in it, they will not accept it.

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111. *See* Ward, *Communicating on Environmental Risk*, 4 ENVTL. F. 7, 8 (Jan. 1986) (risk assessment and risk management viewed by public as impartial to gain acceptance). *Cf. id.* (describing popular perception "that risk assessment and risk management are merely fancy ways of telling the public it has to accept *more* risk and *more* pollution") (emphasis in original); Yuhnke, *EPA's Risk Assessment Process . . . A Critique*, 4 ENVTL. F. 19, 24 (July 1985) (arguing that policy decisions in risk management have resulted in decisions on environmental risk being made by administrative agencies instead of Congress).

112. *See* Slovic, Fischhoff & Lichtenstein, *supra* note 100, at 133, 137.

113. *See Risk/Benefit Hearings*, *supra* note 54, at 37 (statement of H. Green, Professor, George Washington School of Law).

114. *See* Ashford, *supra* note 99, at 73.

115. *See Risk Assessment Hearings*, *supra* note 94, at 256 (letter from P. Deisler, Jr., Vice President of Health, Safety and Environment, Shell Oil Company, to S. Samuels, Chairman, Subcomm. on Environmental Carcinogenesis, National Cancer Advisory Board, Industrial Union Department, AFL-CIO (Jan. 19, 1982)).

IV. THE FEDERAL REGULATORY SYSTEM

A. *The Initial Regulatory System*

The traditional regulatory scheme for biotechnology experimentation was under the jurisdiction of the National Institutes of Health (NIH). The NIH Guidelines, drafted under sections 301, 307, and 361 of the Public Health Service Act,[116] are subject to the National Environmental Policy Act (NEPA).[117]

1. The National Institutes of Health Guidelines

The most experienced body currently regulating biotechnology is the Recombinant DNA Advisory Committee (RAC) chartered in 1974 by the NIH. The RAC, which regulates only rDNA technology,[118] advises the Director of the NIH (Director) by developing, modifying, and interpreting the NIH Guidelines,[119]

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116. 42 U.S.C. §§ 241, 242l, 264 (1982). Section 241 provides a broad grant of power to the Secretary of Health and Human Services to conduct and encourage research. Section 242l provides for international cooperation. Section 264 provides authority to regulate communicable diseases.

The original Guidelines did not refer to any statutory authority, but authority was provided in the environmental impact statement following their publication. *See* National Institutes of Health, Recombinant DNA Research Guidelines, Draft Environmental Impact Statement, 41 Fed. Reg. 38,426, 38,427 (1976). *See generally* Korwek, *The NIH Guidelines for Recombinant DNA Research and the Authority of the FDA to Require Compliance with the Guidelines*, 35 FOOD DRUG COSM. L.J. 633, 636 & n.16 (1980).

117. 42 U.S.C. §§ 4321-4361 (1982).

118. The NIH Guidelines do not cover all types of biotechnology, but are limited to the regulation of technology involving two pieces of DNA spliced outside living cells. *See* National Institutes of Health, Recombinant DNA Advisory Committee; Meeting, 49 Fed. Reg. 696, 697 (1984). In 1987 the RAC rejected amending the definition of rDNA to mean "(i) molecules which are constructed outside living cells by joining *foreign* synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) DNA molecules that result from the replication of those described in (i) above." Recombinant DNA Advisory Committee; Meeting, 51 Fed. Reg. 45,650, 45,651 (1986) (emphasis in original). *See* NIH Advisory Group Approves Proposals Eliminating Approval Step, Refining Release, 10 CHEM. REG. REP. (BNA) 1398, 1398 (Feb. 6, 1987).

119. Recombinant DNA Research, Proposed Revised Guidelines, 43 Fed. Reg. 33,042, 33,067 (1978). The Executive Secretary of the RAC is the Director of the Office of Recombinant DNA Activities (ORDA) at NIH. ORDA is a nationwide coordinator and clearinghouse for rDNA activities. *Id.* at 33,068.

"Guidelines" is probably a misnomer. The original Guidelines were issued after notice and comment procedures. *See* Recombinant DNA Research Guidelines,

which were formulated in 1976 to replace informal restrictions on rDNA technology.[120] Most members of the RAC are scientists.[121] Meetings are public, whenever possible, after publication of notice in the *Federal Register*.[122] The RAC disseminates reports of

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41 Fed. Reg. 27,902, 27,902 (1976). The current version contains mandatory language. *E.g.*, Guidelines for Research Involving Recombinant DNA Molecules, 51 Fed. Reg. 16,958, 16,960 (1986) [hereinafter Guidelines for Research] ("[e]xperiments . . . *cannot* be initiated without submission of relevant information" (emphasis added)); *id.* at 16,965 ("[A]ll NIH-funded projects involving recombinant DNA techniques *must* comply with the NIH Guidelines.") (emphasis added).

In practice, the Guidelines are treated as regulations. *See* Evaluation of the Risks Associated with Recombinant DNA Research, 46 Fed. Reg. 59,385, 59,391 (1981). The Guidelines have been described as "an informal regulatory process." *See* Recombinant DNA Research; Actions Under Guidelines, 47 Fed. Reg. 17,166, 17,167 (1982). Some scientists involved in rDNA technology, however, seem to regard the Guidelines as precatory rather than mandatory. *E.g.*, Minutes of Feb. 6, 1984 Recombinant DNA Advisory Committee Meeting 30 (statement of S. Gottesman) ("Guidelines have worked well; they have been modified frequently based on the evolution of the technology. Regulations would not have this degree of flexibility.").

120. Recombinant DNA Research Guidelines, 41 Fed. Reg. 27,902 (1976).

121. Recombinant DNA Research Guidelines, 51 Fed. Reg. 16,958, 16,964 (1986). In 1978 the RAC had 11 members, including two nonscientists. Responding to criticism of its composition, the committee's membership was diversified and quadrupled to include voting and nonvoting members. *See* Setlow, *supra* note 23, at 162.

Voting members, of which there are currently 25, include scientists, a housewife, an occupational safety expert, a bioethicist, a lawyer, practicing physicians, and a former state legislator. Nonvoting members include representatives of federal agencies. *The Potential Environmental Consequences of Genetic Engineering: Hearings Before the Subcomm. on Toxic Substances and Environmental Oversight of the Senate Comm. on Environment and Public Works*, 98th Cong., 2d Sess. 3 (1984) [hereinafter *Potential Consequences Hearing*] (statement of B. Talbot, Acting Director, National Institute of Allergy and Infectious Diseases, NIH).

The inclusion of lay members has been criticized as tokenism that legitimizes the status quo by including dissenters who, although generally powerless against the majority, give the appearance of balancing decision making by the committee. Dutton, *supra* note 61, at 167-68. *But see Human Genetic Engineering Hearings*, *supra* note 68, at 501 (statement of E. Nightingale, Senior Scholar in Residence, Institute of Medicine, National Academy of Sciences, quoting D. Frederickson, Director of NIH) (nonscientists on RAC serve purpose of "observ[ing] the experts to see if they appear to be listening to each other and paying some attention to the evidence").

122. Guidelines for Research, *supra* note 119, at 16,964. In order to provide public access to RAC discussions, notice of RAC meetings is also included in the *Recombinant DNA Technical Bulletin* published by ORDA. Commentaries and

its actions and encourages public comments.[123] The NIH Advisory Committee to the Director (DAC) provides public oversight of the RAC.[124]

The NIH Guidelines, formulated by the RAC, are specifically designed for basic academic research in rDNA technology.[125] The Guidelines are, however, binding only on institutions conducting or sponsoring rDNA research if such an institution receives NIH funding.[126] If the Guidelines are violated, NIH's sole recourse is to cut off the institution's funding.[127] Other research institutions may comply voluntarily.[128] If voluntary review is not requested, or if a request for review is withdrawn during RAC's consideration of it, the NIH is powerless to act.[129]

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transcripts of hearings and meetings on the guidelines are disseminated. Recombinant DNA Research, Revised Guidelines, 43 Fed. Reg. 60,080, 60,087 (1978).

123. RAC regularly publishes comments to its proposals as well as portions of commentary and minutes from its meetings in the *Federal Register*. *See, e.g.*, Notice of Actions Under NIH Guidelines for Research Involving Recombinant DNA Molecules, 50 Fed. Reg. 9760 (1985) (quoting from comments to proposal to amend Guidelines, and reprinting draft minutes of RAC meeting); Recombinant DNA Research; Proposed Actions Under Guidelines, 49 Fed. Reg. 696 (1984) (including quotes from comments to proposed amendments).

124. Recombinant DNA Research, Proposed Revised Guidelines, 43 Fed. Reg. 33,042, 33,043 (1978).

125. *See* Korwek, *supra* note 116, at 648.

126. Guidelines for Research, *supra* note 119, at 16,965. In December 1986 the NIH was allegedly interpreting the Guidelines to require approval of experiments conducted overseas only if NIH money was used to pay for the experiment regardless of whether the supporting research had been funded by NIH. *See Foundation on Economic Trends Challenges NIH Official's Decision on Foreign Tests*, 10 CHEM. REG. REP. (BNA) 1172, 1172 (Dec. 5, 1986).

127. Guidelines for Research, *supra* note 119, at 16,965.

128. *Id.* The NIH, which is not a regulatory agency, implements the Guidelines by relying on self-enforcement by institutions receiving grants. *Id.* at 16,962.

Some private research institutions may be required to follow the NIH Guidelines because they have been adopted by the local government where the university is located. *See generally* S. KRIMSKY, *supra* note 89, at 294-311 (1982). Jeremy Rifkin argued that the Guidelines cover private research because most companies conducting private research are licensees of patents on rDNA techniques held by Stanford University and the University of California, and the patents' terms require compliance with NIH Guidelines. *See* Johnson, *Recombinant DNA: Legal Challenges to Deliberate Release Experiments* 4-5 (Cong. Research Serv. 85-502-SPR, Jan. 7, 1985).

129. *See, e.g.*, Recombinant DNA Research; Request for Comment on Need for a Programmatic Environmental Impact Statement, 50 Fed. Reg. 14,794, 14,795 (1985) (voluntary proposal withdrawn during RAC review process). The federal

The current Guidelines apply to both contained and direct release experiments, and divide experiments into four classes: (1) experiments requiring review by the RAC plus approval by the NIH and the local institution's Institutional Biosafety Committee (IBC); (2) experiments requiring approval of the appropriate IBC; (3) experiments requiring notification of the appropriate IBC; and (4) exempt experiments.[130] Under this decentralized system of classification, only ten to twenty percent of all experiments involving rDNA technology require RAC review and NIH approval.[131]

Direct release experiments were expressly prohibited in the original version of the NIH Guidelines in 1976.[132] The Director stated that "[w]ith the present limited state of knowledge, it seems highly unlikely that there will be in the near future any recombinant organism that is universally accepted as being beneficial to introduce into the environment."[133] The Director added that he would alter the Guidelines when scientific evidence of benefits became available.[134]

Two years later, in 1978, the Guidelines' prohibition on direct release experiments was revised to allow the Director to grant waivers[135] after review of proposals by the RAC.[136] The Director stated that "all waiver decisions will include a careful consideration of the potential environmental impact."[137] The current ver-

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District Court for the District of Columbia held that private companies need not obtain approval of direct release experiments from the NIH. Foundation for Economic Trends v. Heckler, No. 83-2714 (D.D.C. June 27, 1985), *cited in* Withers, *Biotechnology: An Industry Perspective*, 34 U. KAN. L. REV. 665, 666 nn.2-3 (1986).

130. Guidelines for Research, *supra* note 119, at 16,969.

131. *See* Zoon, *Regulation of Recombinant DNA-Derived Products and Synthetic Peptides*, 37 FOOD DRUG COSM. L.J. 382, 384 (1982).

132. *See* Recombinant DNA Research Guidelines, 41 Fed. Reg. 27,902, 27,915 (1976).

133. *Id.* at 27,907.

134. *Id.*

135. Recombinant DNA Research, Revised Guidelines, 43 Fed. Reg. 60,080, 60,108 (1978).

136. Deliberate release experiment waivers were termed major action by the Director, *id.*, thus triggering the requirement for advice of the RAC, as well as the opportunity for comments by federal agencies and the public. *See* Guidelines for Research, *supra* note 119, at 16,960.

137. Recombinant DNA Research, Revised Guidelines, 43 Fed. Reg. 60,080, 60,083 (1978).

sion of the Guidelines requires RAC review and NIH and IBC approval for direct release experiments unless the released organism is an exempt plant.[138]

Waivers have added flexibility to the Guidelines, but they have also added complexity. A tendency has arisen to respond to specific requests involving single issues by modifying the Guidelines on a piecemeal basis. As a result the Guidelines have become difficult to read, even for scientists.[139] Flexibility, however, is a major advantage because of the rapidly expanding data base. Thus, the "[g]uidelines will never be complete or final . . . ."[140]

NIH promotes biotechnology risk assessment experiments.[141] A risk assessment subcommittee provides input from the scientific community and the public on the need for different types of risk assessment experiments.[142] The public is also involved in the decision-making process through local review of safety procedures. IBCs allow community input into safety decisions,[143] thus aiding in dispelling public fear of biotechnology.[144]

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138. Guidelines for Research, *supra* note 119, at 16,960, 16,984-85. Exempt plants include: (1) species of cultivated crops of a genus containing no noxious weed species; (2) plants, the introduced DNA of which is composed of well-characterized genes with no sequences harmful to people, animals, or plants; (3) plants, the DNA vector of which meets enumerated specifications; and (4) plants grown in controlled access fields under conditions reviewed by the appropriate IBC. *Id.* at 16,985. If a genetically engineered plant is included in one of the above categories, approval for the experiment can be granted by ORDA, acting in consultation with the Plant Working Group of the RAC, and the appropriate IBC. *Id.*

139. *See* Evaluation of the Risks Associated with Recombinant DNA Research, 46 Fed. Reg. 59,385, 59,385 (1981). The Director recognizes that the Guidelines are "long, cumbersome, and detailed," but realizes that this situation may be unavoidable because of the rapidly-growing nature of rDNA technology and the impossibility of covering all possible experiments. *Id.* at 59,391. A 1981 proposal to abolish the Guidelines failed. *See* Recombinant DNA Research; Actions Under Guidelines, 47 Fed. Reg. 17,166, 17,173-76 (1982).

140. Guidelines for Research, *supra* note 119, at 16,961.

141. *See* Recombinant DNA Research; Final Plan for a Program to Assess the Risks of Recombinant DNA Research, 46 Fed. Reg. 30,772 (1981); Program to Assess the Risks of Recombinant DNA Research: Proposed First Annual Update, 45 Fed. Reg. 61,874 (1980).

142. Setlow, *supra* note 121, at 162. The risk assessment subcommittee is only one of several subcommittees of the RAC. *Id.*

143. *See* Krimsky, Wilson & Milewski, *Procedures and Operations*, 4 RECOMBINANT DNA TECHNICAL BULL. 24, 25 (1981).

144. *See* Talbot, King & Boyer, *The IBC as a Means of Implementing Institutional Oversight*, 4 RECOMBINANT DNA TECHNICAL BULL. 19, 19-20 (1981).

The RAC's statutory authority—section 361 of the Public Health Service Act—has been construed broadly,[145] but it is questionable whether it could be read to cover all biotechnology research.[146] Another disadvantage is that section 361's purpose, to protect people from communicable diseases, does not include protection of the environment. The NIH Guidelines, therefore, have been validly criticized as not being designed to protect against environmental impacts of direct release experiments.[147] Nevertheless, the broad statutory authority of section 361 provides the NIH with power to implement regulations that it deems appropriate to cover biotechnology.[148] The choice of regulatory system is not limited by narrow statutory requirements.

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145. *See, e.g.*, Louisiana v. Matthews, 427 F. Supp. 174, 176 (E.D. La. 1977) (power to protect public against spread of communicable disease is broad and flexible); United States v. Shinnick, 219 F. Supp. 789, 790 (E.D.N.Y. 1963) (Judgment of public health officials that risk existed can be superseded only by reliable showing of error.).

146. *Cf.* Letter from Joseph Califano, Jr., Secretary of Health, Education, and Welfare, to Senator Edward Kennedy (Sept. 12, 1978), *reprinted in* Recombinant DNA Research, Revised Guidelines, 43 Fed. Reg. 60,104, 60,104-05 (1978). Secretary Califano wrote that the Federal Interagency Committee on Recombinant DNA Research had determined that to apply section 361 comprehensively would entail concluding that all rDNA research products caused or could cause human disease. The committee considered such a conclusion tenuous. *Id.*; *see* 42 U.S.C. § 264 (1982). *But see* Petition of Environmental Defense Fund, Inc. and Natural Resources Defense Council, Inc. to the Secretary of Health, Education, and Welfare to Hold Hearings and Promulgate Regulations Under the Public Health Service Act Governing Recombinant DNA Activities, *reprinted in DNA Hearings*, *supra* note 15, at 260, 274 (arguing that "[b]ecause microorganisms produced by recombinant DNA activities may spread disease among humans, it has already been recognized that regulations promulgated under § 361 control transportation of DNA materials, [therefore] the same risk of communicable disease . . . gives [the Secretary] the authority to regulate all recombinant DNA activities"); Chalker & Catz, *supra* note 61, at 81 ("HEW clearly has the authority to regulate all DNA recombinant activities.").

147. *See Environmental Implications of Genetic Engineering: Hearing Before the Subcomm. on Investigations and Oversight and the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology*, 98th Cong., 1st Sess. 48 (1983) [hereinafter *Environmental Implications Hearing*] (statement of G. Karny, Senior Analyst, Biological Applications Program, Office of Technology Assessment). *But see id.* at 228 (statement of A. Chakrabarty, Professor of Microbiology, University of Illinois at Chicago) (written answer to committee question) ("NIH guidelines basically address the problems of accidental release of organisms.").

148. *Potential Consequences Hearing*, *supra* note 121, at 22 (statement of T. McGarity, Professor of Law, University of Texas at Austin).

Commentators have criticized the RAC's review of direct release proposals as "amorphous, with no standardized method for assessing the environmental risks of field testing, nor even any criteria for deciding what information is necessary for such an assessment."[149] This criticism, however, overlooks the fact that individual experiments involve different organisms in different environments. The RAC published a "Points to Consider" document to aid researchers in preparing proposals for direct release experiments,[150] but standardized protocols at this stage of scientific research are not feasible.[151]

Another criticism levelled at the NIH is that it is not a regulatory agency and does not monitor compliance with the Guidelines.[152] Rather, NIH's mission to promote biomedical research places it in the conflicting position of promoting and regulating biotechnology concurrently.[153] This conflict gives the agency the appearance of not always regulating rigorously.[154] Indeed, the Guidelines were drawn up on the premise that they were not to unduly hamper rDNA research.[155] Thus, the NIH stands out in marked contrast to regulatory agencies that subject potential risks from new scientific advances to strict controls.[156]

2. *The National Environmental Policy Act*

The NIH must comply with NEPA in promulgating its

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149. Gore & Owens, *The Challenge of Biotechnology*, 3 YALE L. & POL'Y REV. 336, 345 (1985).

150. Proposed Points to Consider for Environmental Testing of Microorganisms, 50 Fed. Reg. 12,456 (1985).

151. *See* Recombinant DNA Advisory Committee, Minutes of June 1, 1984 Meeting 33 (response of the working group on release into the environment).

152. *See* Korwek, *supra* note 116, at 634 n.7.

153. *See* Karny, *Regulation of Genetic Engineering: Less Concern About Frankensteins but Time for Action on Commercial Production*, 12 U. TOL. L. REV. 815, 840 (1981); *see also* NIH ROLE, *supra* note 10, at 41 (In fiscal year 1984 NIH contributed $408 million to research directly related to biotechnology.).

154. *See* S. KRIMSKY, *supra* note 89, at 234. NIH's regulation of scientific research does not merely affect the interests of its own scientific constituency. The regulation of research sets a precedent disliked by the entire scientific community. *See id.*

155. *See* M. LAPPE, *supra* note 48, at 29.

156. *See generally* Huber, *The Old-New Division in Risk Regulation*, 69 VA. L. REV. 1025 (1983) (contrasting stricter standards imposed on new risks with lower standards imposed on old risks).

Guidelines and in approving individual experiments. An environmental impact statement (EIS) was published after the original Guidelines had been issued.[157] In 1978, in an action challenging a high risk laboratory experiment permitted under the Guidelines, the federal District Court for the District of Columbia held that the EIS was adequate.[158] When NIH revised the Guidelines in 1978, the agency issued an environmental assessment (EA) concluding that the revisions did not significantly affect the human environment.[159]

NIH's actions were challenged again in *Foundation on Economic Trends v. Heckler*.[160] Judge Sirica held that the NIH had failed to address adequately the environmental consequences of granting permission for direct release experiments (which had not been permitted under the original Guidelines).[161] Judge Sirica granted a preliminary injunction against initiation of a University of California experiment and against NIH approval of other direct release experiments.[162] In addition, NIH was ordered to prepare a programmatic EIS for its review program for direct release experiments.[163]

On appeal, the District of Columbia Circuit upheld the injunction against the University of California pending preparation of an EA for the experiment.[164] The court found that dispersal of the novel organisms had not been addressed, and that actions taken by the RAC in reviewing the experiment were not the func-

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157. Recombinant DNA Research Guidelines, Draft Environmental Impact Statement, 41 Fed. Reg. 38,426 (1976) [hereinafter Recombinant DNA Research Guidelines]. Notice of the availability of the final EIS was published in the *Federal Register*. 42 Fed. Reg. 60,588 (1977). The draft EIS was published after the original Guidelines were issued because the scientists preparing the EIS stated that they believed the public interest would be better served by publishing the Guidelines when they were ready instead of withholding publication pending completion of the EIS. Fredrickson, *supra* note 36, at 153-54.

158. Mack v. Califano, 447 F. Supp. 668, 670 (D.D.C. 1978).

159. Environmental Impact Assessment of a Proposal to Release Revised NIH Guidelines for Research Involving Recombinant DNA Molecules, 43 Fed. Reg. 33,096 (1978); Environmental Impact of the Final Guidelines, 43 Fed. Reg. 60,101 (1978).

160. 587 F. Supp. 753 (D.D.C. 1984), *aff'd in part and vacated in part*, 756 F.2d 143 (D.C. Cir. 1985).

161. *Id.* at 762.

162. *Id.* at 768.

163. *Id.* at 764.

164. 756 F.2d at 154.

tional equivalent of compliance with NEPA.[165] According to the court, the Director's acceptance of the RAC's recommendation to conduct the experiment was conclusory because no reasons for acceptance were specified.[166] The court vacated the district court's injunction against NIH approval of other direct release experiments,[167] but strongly suggested that the NIH consider preparation of a programmatic EIS.[168]

When it scrutinized the University of California experiment, the District of Columbia Circuit compared the Director's stated intentions to consider environmental effects in direct release experiments with his lack of public discussion of such effects when he approved an experiment.[169] As a result of the Director's omission, the court had little difficulty holding that NEPA had not been complied with.[170] The Director did indeed neglect to state reasons for his acceptance of RAC's recommendations, but those recommendations plus a discussion of the potential environmental effects of the experiment were published with the Director's acceptance.[171] The court elevated form over substance. Only by implying that the Director's reasons for accepting RAC's recommendations were alien to those recommendations can the Director's decision be termed conclusory.

The agency's argument that the review, modification, and ap-

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165. *Id.* at 153-54. In the lower court, Judge Sirica had held that the NIH would not enforce any statutory or regulatory standards by permitting direct release experiments, and that the RAC review process was not binding on the Director, and was not recorded in an environmental document. Therefore, the process was not the functional equivalent of NEPA. 587 F. Supp. at 766.

166. 756 F.2d at 154 (citing 48 Fed. Reg. 24,548, 24,548 (1983)).

167. *Id.* at 158.

168. *Id.* at 159-60.

169. *Compare* Environmental Impact Assessment of a Proposal to Release Revised NIH Guidelines for Research Involving Recombinant DNA Molecules, 43 Fed. Reg. 33,096, 33,110 (1978) ("prohibition of deliberate release into the environment of recombinant-DNA-containing organisms can be waived if all the requirements for a waiver (and those of the National Environmental Policy Act) are met") *with* Recombinant DNA Research; Actions Under Guidelines, 48 Fed. Reg. 24,548, 24,549-50 (1983) ("Permission is granted to Drs. Steven Lindow and Nickolas Panopoulos of the University of California, Berkeley, to release under specified conditions *Pseudomonas* pv. *syringae* and *Erwinia herbicola* carrying *in vitro* generated deletions of all or part of the genes involved in ice nucleation.").

170. 756 F.2d at 154.

171. *See* Notice of Activities Under NIH Guidelines for Research Involving Recombinant DNA Molecules, 48 Fed. Reg. 24,548, 24,548-50 (1983).

proval of the experiment were the functional equivalent of compliance with NEPA was easily rejected by the court.[172] The NIH formulated the Guidelines to regulate genetically engineered organisms in laboratories rather than in the environment.[173] As the court noted, though the NIH's EIS mentioned organism dispersal as a major environmental concern,[174] the RAC members who reviewed the experiment did not include experts in environmental dispersal of the novel organisms. (The situation has since been remedied, and RAC membership now includes ecologists.)[175]

Evidence shows, however, that the RAC had carefully evaluated the proposal to release bacteria, from which ice-nucleating genes had been deleted, onto potato plants.[176] Notice of RAC's

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172. 756 F.2d at 154; *see* Environmental Defense Fund, Inc. v. EPA, 489 F.2d 1247, 1257 (D.C. Cir. 1973) (outlining elements of functional equivalence doctrine); Maryland v. Train, 415 F. Supp. 116, 121-22 (D. Md. 1976) (citing cases supporting functional equivalence doctrine).

173. *See* Cooper, *The Impact of Biotechnology on the Pharmaceutical Industry*, in BIOTECHNOLOGY AND THE ENVIRONMENT: RISK AND REGULATION 61, 69 (1985).

174. 756 F.2d at 153.

175. *See NIH Recombinant Advisory Role Gains Friends*, 15 SCI. & GOV'T REP. 5, 5 (May 15, 1985) [hereinafter *Advisory Role*].

176. *See* Notice of Actions Under NIH Guidelines for Research Involving Recombinant DNA Molecules, 48 Fed. Reg. 24,548 (1983). The experiment's aim was to spray potato plants with genetically engineered bacteria. The natural form of the bacteria caused ice to nucleate on plants at temperatures between 0° and -5°C. The genetically engineered bacteria had all or part of the genes involved in ice nucleation deleted. *Id.* at 24,549. The proposal for the experiment had been reviewed by the RAC in October 1982, at which time its approval was recommended. The proposal was revised, however, to respond to specific concerns of several RAC members. The revised proposal was published in the *Federal Register*. *Id.* at 9441. The revised proposal, which had also been reviewed and approved by the USDA Recombinant DNA Committee, was subsequently approved by the RAC. *Id.* at 24,549.

The fact that the RAC had requested that the experiment be revised to mitigate environmental effects implies that the RAC had taken a hard look at the proposal. Brief of the Regents of the University of California at 44, Foundation for Economic Trends v. Heckler, 756 F.2d 143 (D.C. Cir. 1985); *see* Cabinet Mountains Wilderness/Scotchman's Peak Grizzly Bears v. Peterson, 685 F.2d 678, 684 (D.C. Cir. 1982).

Biosafety concerns had been addressed by the proposal. *See* NATIONAL INSTITUTES OF HEALTH, ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT 7 (Jan. 21, 1985) [hereinafter ENVIRONMENTAL ASSESSMENT] (application of Drs. Steven Lindow & Nickolas Panopoulos, University of California, Berkeley). The RAC that approved the experiment, however, did not include ecologists. *Cf.*

actions was published in the *Federal Register* and comments were sought.[177] The NIH deferred approval of the proposal until revisions, which included a decrease in the number of test plots, had been made.[178] This action is consistent with NEPA's mitigation requirement.[179] Given such facts, the court could reasonably have found that the NIH had taken a "hard look" at the experiment's environmental effects.[180]

The court's finding that the NIH's major omission was the lack of discussion of dispersal of the genetically engineered organisms is problematic.[181] The University of California's proposal stated that dispersal of the bacteria did not pose a significant risk because of the small size of the experiment and the limited survival capacity of the novel bacteria.[182] Not only had the genetically-engineered bacteria not been shown to be hazardous or even harmful, but wild bacteria with the same chemical composition existed in nature with no known adverse effects. In addition, chemically-altered bacteria with the same composition had been introduced into the environment with no harmful effects.[183] No

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M. LAPPE, *supra* note 48, at 179 (arguing that many genetic engineers do not understand ecology); Kolata, *How Safe Are Engineered Organisms?*, 229 SCIENCE 34, 34 (1985) (describing reaction of ecologists to molecular biologists' plans to release engineered organisms into environment); Ruse, *The Dangers of Unrestricted Research: The Case of Recombinant DNA, A Response to Novick*, in RECOMBINANT DNA: SCIENCE, ETHICS, AND POLITICS 103, 112 (J. Richards ed. 1978) (arguing that most molecular biologists are outside their field of expertise when discussing dangers of rDNA technology).

177. *See* Notice of Actions Under NIH Guidelines for Research Involving Recombinant DNA Molecules, 48 Fed. Reg. 24,548, 24,549 (1983) (one favorable comment received); *id.* at 1157 (no comments received).

178. Recombinant DNA Research; Actions Under Guidelines, 48 Fed. Reg. 24,548, 24,549 (1983).

179. *See generally* Rodgers, *Benefits, Costs, and Risks: Oversight of Health and Environmental Decisionmaking*, 4 HARV. ENVTL. L. REV. 191, 213 (1980) ("NEPA's dominant substantive standard is that of maximum mitigation."). *Cf.* Friends of Endangered Species, Inc. v. Jantzen, 760 F.2d 976, 987 (9th Cir. 1985) (concluding that agency had "acted reasonably in not issuing an Environmental Impact Statement" upon finding that agency had "conducted a thorough analysis of the proposed action and imposed specific mitigation measures").

180. *See* Kleppe v. Sierra Club, 427 U.S. 390, 410 n.21 (1976); Vieux Carre Property Owners Residents & Assocs. v. Pierce, 719 F.2d 1272, 1282 (5th Cir. 1983).

181. 756 F.2d at 153.

182. ENVIRONMENTAL ASSESSMENT, *supra* note 176, at 3.

183. The risk involved in releasing chemically mutated organisms has been

evidence existed that either the chemically-altered or the genetically-engineered bacteria had replaced bacteria with ice-nucleating capacity.[184]

The researchers' isolation and subsequent introduction into the environment of the naturally altered bacteria was, in effect, a risk assessment of their proposed experiment. The risk assessment demonstrated that dispersal of the genetically engineered bacteria would probably not affect the environment beyond the field where they were applied.[185] Thus, evidence of the harmful effects of dispersal was not discussed because no harmful effects had been shown during the risk assessment.

If the Director had formally discussed the risk of dispersal, then it is foreseeable that his determination that the risk was insignificant would have survived the court's "hard look."[186] Courts, including the District of Columbia Circuit, have traditionally exercised great deference in reviewing agency decisions involving scientific issues.[187] Thus, a determination based on scientific un-

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termed greater than that involved in releasing genetically engineered organisms having the same composition. Karny, Perpich & Levin, *Environmental Aspects of Biotechnology: A Discussion*, in BIOTECHNOLOGY AND THE ENVIRONMENT: RISK AND REGULATION 192, 194-95 (1985) (statement of M. Levin). *But see infra* note 190 (arguing reverse).

184. ENVIRONMENTAL ASSESSMENT, *supra* note 176, at 44.

185. *See* Singer, *supra* note 59, at 332.

186. *See* Baltimore Gas & Elec. Co. v. Natural Resources Defense Council, Inc., 462 U.S. 87, 97 (1983), *rev'g* 685 F.2d 633 (D.C. Cir. 1982); *see also* O'Brien, *The Courts and Science-Policy Disputes: A Review and Commentary on the Role of the Judiciary in Regulatory Politics*, 4 J. ENERGY L. & POL'Y 81, 108 (1983) ("'hard look' approach . . . may provide a pretense for judicial activism rather than judicial self-restraint").

187. *See* Lead Indus. Ass'n v. EPA, 647 F.2d 1130, 1160 (D.C. Cir. 1980) (Skelly Wright, J.) ("[D]isagreement among the experts is inevitable when the issues involved are at the 'very frontiers of scientific knowledge,' and such disagreement does not preclude us from finding that . . . decisions are adequately supported by the evidence in the record."), *cert. denied*, 449 U.S. 1042 (1980); Ethyl Corp. v. EPA, 541 F.2d 1, 28 (D.C. Cir. 1976) (en banc) ("[R]igorous step-by-step proof of cause and effect" is not required when "evidence [is] difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge."), *cert. denied*, 426 U.S. 941 (1976); *see also* United Steelworkers v. Marshall, 647 F.2d 1189, 1259 (D.C. Cir. 1980) (agency determination based on scientific evidence must be deferred to); Reserve Mining Co. v. EPA, 514 F.2d 492, 519-20 (8th Cir. 1975) (deferring to agency decision based on medical and scientific conclusions on "frontiers of scientific knowledge"); Society of Plastics Indus., Inc. v. OSHA, 509 F.2d 1301, 1308 (2d Cir. 1975) (deferring to agency's decision because

certainty may have been deferred to if the court had been able to review evidence of adequate agency consideration of available scientific data.[188] With no evidence to review, the court appears to have conducted its own risk assessment without identifying the values it used or quantifying the evidence it considered.[189] The court simply mentioned in a footnote that the genetically engineered organisms had been shown to survive longer than chemically mutated organisms of the same composition.[190]

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ultimate facts were on "frontiers of scientific knowledge"), *cert. denied*, 421 U.S. 992 (1975); Industrial Union Dep't AFL-CIO v. Hodgson, 499 F.2d 467, 474 (D.C. Cir. 1974) ("[S]ome of the questions involved in the promulgation of these standards are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination. Decision making must in that circumstance depend to a greater extent upon policy judgments and less upon purely factual analysis.").

188. *See Baltimore Gas & Elec. Co.*, 464 U.S. at 103 (courts must generally be at their "most deferential" when reviewing agency determinations "within [their] area of special expertise, at the frontiers of science"). *See generally* Rodgers, *supra* note 179, at 216-18 (discussing "soft glance" standard of judicial review); Comment, Vermont Yankee *Revisited: High Court Upholds NRC's S-3 Table for Second Time*, 13 ENVTL. L. REP. (Envtl. L. Inst.) 10,239, 10,242 (1983) (discussing contrast in Supreme Court's deference to agency finding involving scientific issues versus District of Columbia Circuit's finding that agency had ignored scientific uncertainties).

Judge Bazelon argued that courts are especially important in ensuring that decisions are based on a thorough consideration of the issues because of the judiciary's position outside the scientific and political arenas. Bazelon, *Risk and Responsibility*, 65 ABA J. 1066, 1068 (1979).

189. *See* O'Brien, *supra* note 186, at 114-15; *see also* Abraham & Merrill, *Scientific Uncertainty in the Courts*, 2 ISSUES IN SCI. & TECH. 93, 98-99 (Winter 1986) (criticizing Fifth Circuit treatment of scientific data in Gulf South Insulation Co. v. Consumer Prods. Safety Comm'n, 701 F.2d 1137 (5th Cir. 1983), as leading to "unpredictable and uncontrollable" judicial decisions); Yellin, *High Technology and the Courts: Nuclear Power and the Need for Institutional Reform*, 94 HARV. L. REV. 489, 512-13 (1981) (describing the District of Columbia Circuit's decision in International Union of Elec., Radio & Mach. Workers v. United States, 280 F.2d 645 (D.C. Cir. 1960), *rev'd sub nom.* Power Reactor Dev. Co. v. International Union of Elec., Radio & Mach. Workers, 367 U.S. 397 (1961), as creating its own risk assessment); *cf. Risk/Benefit Hearings*, *supra* note 54, at 98 (statement of Chief Judge Markey, United States Court of Customs and Patent Appeals) ("I trust and hope that neither Congress nor the courts will ever undertake to assess science.").

190. 756 F.2d at 153 n.6. The Foundation on Economic Trends has argued that bacteria produced by biotechnology have the potential to cause greater environmental harm because of their stability in comparison to bacteria altered by classical genetic engineering methods, which tend to revert. *See* Note, *Regulating the Environmental Release of Genetically Engineered Organisms:* Foundation on

By stating that dispersal was a "significant environmental concern,"[191] the court illustrated the lack of effective communication between scientists involved in biotechnology research and the public. The Foundation on Economic Trends used dubious scientific data[192] to convince the court that dispersal was a significant risk. If the scientists involved in biotechnology research had communicated more effectively with the public to allay fears regarding biotechnology, the court's foray into scientific decision making may have been avoided. In the absence of effective communication, the court's decision seems to have mirrored public concerns.

Heckler demonstrates the difficulty involved in applying NEPA to the regulation of scientific research. Judge Skelly Wright, writing for the District of Columbia Circuit, stated that the case challenged the court "to ensure that the bold words and vigorous spirit of NEPA are not . . . lost or misdirected in the brisk frontiers of science."[193] The court also referred to concern expressed in NEPA's legislative history regarding the ability of people to control technology's impact on the environment.[194] At the scientific experimentation stage, however, there are no guarantees that an approved experiment will even succeed, much less

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Economic Trends v. Heckler, 12 FLA. ST. U.L. REV. 891, 906 (1985) (citing interview with E. Lee Rogers, Counsel for Foundation on Economic Trends, (July 2, 1984)).

191. 756 F.2d at 154. *Cf. Potential Consequences Hearing, supra* note 121, at 84 (statement of D. Jackson, Senior Vice President and Chief Scientific Officer, Genex Corp.) ("[R]eal reason prohibition [was] sought [was] that the organisms [were] genetically engineered.").

192. Jeremy Rifkin, whose organization, Foundation on Economic Trends, sued to stop the University of California experiment, based his main objection to the experiment on the potential effect of the genetically engineered bacteria on precipitation. Ice nuclei in the atmosphere affect precipitation. If bacteria with ice-nucleating capacity are replaced by genetically engineered bacteria without that capacity, rainfall could foreseeably be reduced. Odum, *Biotechnology and the Biosphere*, 229 SCIENCE 1338, 1338 (1985) (letter). The researcher on whose work Rifkin relied, however, stated that small experiments were not a cause for concern and that the relationship between the ice-nucleating bacteria and precipitation was circumstantial and not proven. *See* Sun, *EPA Approves Field Test of Altered Microbes*, 230 SCIENCE 1015, 1015 (1985).

193. 756 F.2d at 145. *But see* Amoco Oil Co. v. EPA, 501 F.2d 722, 741 (D.C. Cir. 1974) (Wright, J.) (When "regulations turn on choices of policy, on an assessment of risks, or on predictions dealing with matters on the frontiers of scientific knowledge, we will demand adequate reasons and explanations, but not 'findings' of the sort familiar from the world of adjudication.").

194. 756 F.2d at 146 (citing S. REP. No. 296, 91st Cong., 1st Sess. 6 (1969)).

that it will evolve into a new technology that significantly affects the environment.[195] NEPA was enacted to assure full decision making on the impact of technology on the environment,[196] not on the conduct of scientific research.

Compliance with NEPA has been described by the Director as "a nightmare."[197] Whereas "[t]he essence of the EIS process is the application of science (as contrasted with guesswork) to ascertain the environmental impacts of government actions,"[198] science cannot be fully applied in direct release experiments unless the experiments are conducted. Scientific research is simply not amenable to the cost-benefit analysis implicit in NEPA.[199] Realistic assessments of costs, benefits, and risks involve value judgments that are inappropriate when assessing the risks of scientific research.[200] Indeed, no risks have been proven in biotechnology research. As Director Fredrickson stated: "Although an EIS has become common in proposals to level mountains or build dams, [it

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195. Recombinant DNA Research; Availability of Environmental Assessment for Public Comment; Request for Comments on Need for a Programmatic Environmental Impact Statement, 50 Fed. Reg. 14,794, 14,795 (1985).

196. *See* H.R. REP. No. 378, 91st Cong., 1st Sess., *reprinted in* 1969 U.S. CODE CONG. & AD. NEWS 2751, 2758 (House report on NEPA) (referring to "basic research information and its technological implementation" as separate subject matter). The Senate report on NEPA described "unplanned and often unforeseen consequences" arising from the "quest for scientific knowledge" as "resource depletion, pollution, ill-conceived urbanization, and other aspects of environmental degradation." S. REP. No. 296, 91st Cong., 1st Sess. 13 (1969). These impacts are typical results of the application of science in the form of technology; they are not typical impacts of scientific research.

There is no bright line between science and technology. In biotechnology, the line that is "almost impossible to draw" is that between basic and applied science. Koshland, *Excursions in Biotechnology*, 229 SCIENCE 1191, 1191 (1985).

197. Fredrickson, *supra* note 36, at 153.

198. L. CALDWELL, SCIENCE AND THE NATIONAL ENVIRONMENTAL POLICY ACT 124 (1982).

199. *See* Jones v. District of Columbia Redevelopment Land Agency, 499 F.2d 502, 512 (D.C. Cir. 1974) ("NEPA was intended to ensure that decisions would be made only after [informed decisions] that the public benefit flowing from [federal] actions outweighed their environmental costs."); Calvert Cliffs' Coordinating Comm. v. AEC, 449 F.2d 1109, 1113 (D.C. Cir. 1971) ("NEPA mandates a rather finely tuned and 'systematic' balancing analysis."). *See generally* Rodgers, *supra* note 179, at 211 (Although a cost-benefit analysis is not specifically mandated by NEPA, courts have construed the statute as requiring one.).

200. *Cf.* Johnston v. Davis, 698 F.2d 1088, 1095 (10th Cir. 1983) (Cost-benefit analysis failed "to provide the public and the decisionmaker with an informed comparison of alternatives" when benefits were described unrealistically.).

is not as readily adaptable] to conjectural hazards of laboratory research . . . ."[201]

The EIS and EAs produced by NIH are valiant attempts to meet the spirit of NEPA but the frustration of the drafters in attempting to analyze the unknown is vividly apparent.[202] Similarly, a congressional committee concluded, after holding hearings on environmental implications of direct release experiments, that "predicting the specific type, magnitude, or probability of environmental effects associated with the deliberate release of genetically engineered organisms will be extremely difficult, if not impossible, at the present time."[203] The committee concluded that there was a "low probability, high consequence risk,"[204] and recommended minimum interference with the research and commercialization of biotechnology as long as environmental and public health concerns were adequately addressed.[205]

NIH subsequently requested comments on whether to draft a

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201. Fredrickson, *supra* note 36, at 153. *See also Potential Consequences Hearing*, *supra* note 121, at 22 (statement of M. Alexander, Professor, Department of Agronomy, Cornell University) ("in the absence of a substantive body of scientific information to allow for reliable predictions, and in the absence of data from tests designed to provide information on individual genetically engineered organisms, it is utterly foolhardy to anticipate what may or may not happen in nature"); *Environmental Implications Hearing*, *supra* note 147, at 218 (letter from F. Sharples, Oak Ridge National Laboratory) (written answer to committee question) ("Although I am a firm believer in the value of impact statements . . . , I am not convinced that an EIS would help much at this point. There is not enough concrete information available for anything other than an extremely generic treatment . . . .").

202. *See, e.g.*, Environmental Impact Assessment of a Proposal to Release Revised NIH Guidelines for Research Involving Recombinant DNA Molecules, 43 Fed. Reg. 33,096, 33,102 (1978) ("Research, by definition, is investigation of the unknown. The results of research, whether beneficial, neutral, detrimental, or some combination of these, cannot be fully predicted ahead of time."); *id.* ("The following discussion [of risks] is speculative."); Recombinant DNA Research Guidelines, *supra* note 157, at 38,431 (1976) ("At this time the practical applications are, of course, speculative."). For a criticism of the 1976 EIS, see Chalker & Catz, *supra* note 61.

203. STAFF REPORT PREPARED BY THE SUBCOMM. ON INVESTIGATIONS AND OVERSIGHT, TRANSMITTED TO THE HOUSE COMM. ON SCIENCE AND TECHNOLOGY, 98TH CONG., 2D SESS., THE ENVIRONMENTAL IMPLICATIONS OF GENETIC ENGINEERING 20 (Comm. Print 1984) [hereinafter ENVIRONMENTAL IMPLICATIONS REPORT].

204. *Id.* at 13.

205. *Id.* at 11-12.

programmatic EIS,[206] as suggested by the *Heckler* court.[207] A "Points to Consider" document was also published.[208] The document, which represents a compromise between ecologists and microbiologists,[209] is a guide to aid researchers in structuring proposals for experiments rather than a guide for preparing EAs.[210]

Arguably, the NIH's actions in issuing guidance for proposal preparation and in continuing to consider individual proposals indicates the agency's commitment to a program of granting permits for experiments involving rDNA technology. If a court makes this finding, the NIH may have to prepare the programmatic EIS suggested by the *Heckler* court due to the connected[211]

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206. Recombinant DNA Research; Availability of Environmental Assessment for Public Comment; Request for Comments on Need for Programmatic Environmental Impact Statement, 50 Fed. Reg. 14,794 (1985).

207. 756 F.2d at 159-60. *But see id.* at 161 (MacKinnon, J., concurring) ("programmatic EIS at this time would be neither justified, practical, nor prudent").

208. Recombinant DNA Research; Proposed Actions Under Guidelines, 50 Fed. Reg. 12,456 (1985). The RAC will continue to review applications on a case-by-case basis because of the variables involved in individual experiments. *Id.* at 12,456.

Every experiment has its own distinct variables, including "ecological niche[s available at the experiment site], pathogenicity, viability and ability [of novel organisms] to escape from the field test site." Recombinant DNA Research; Availability of Environmental Assessment for Public Comment; Request for Comments on Need for a Programmatic Environmental Impact Statement, 50 Fed. Reg. 14,794, 14,795 (1985). In the experiments for which NIH had granted permission before issuing the "Points to Consider," no common environmental effect had been identified. *Id.* "Points to Consider" is intended to be a guide that can be easily modified as new data are collected. *See* Milewski, *Field Testing of Microorganisms Modified by Recombinant DNA Techniques: Applications, Issues, and Development of "Points to Consider" Document*, 8 RECOMBINANT DNA TECHNICAL BULL. 102, 107 (1985).

209. Recombinant DNA Advisory Committee, Minutes of May 3, 1985 Meeting 7 (statement of R. Clowes, committee member).

210. *Id.* at 9 (statement of G. McGarrity, Institute for Medical Research, ad hoc consultant to committee). *See also* Recombinant DNA Advisory Committee, Minutes of Oct. 29, 1984 Meeting 8 (statement of G. McGarrity). Because of the diversity of direct release experiments, the document is not expected to be followed step-by-step in preparing proposals. Recombinant DNA Advisory Committee, Minutes of May 3, 1985 Meeting 8 (statement of S. Gottesman, committee member).

211. 40 C.F.R. § 1508.25(a)(1) (1986). *Cf.* Thomas v. Peterson, 753 F.2d 754, 758 (9th Cir. 1985) (Proposed timber sales were connected actions of a road built in order to make the timber accessible.). In *Thomas*, but for one action of the agency (timber sales), the other action (building a road through a national forest)

and cumulative[212] nature of the NIH's actions.

On the other hand, the NIH does not plan, conduct, or support a program of deliberate release experiments.[213] In fact, two of the first three direct release experiments approved by the NIH were not even funded by the NIH. No connection or similarity existed between the various experiments, which were initiated by individual researchers at different institutions without NIH promotion.[214] One experiment involved genetically engineered corn plants, while another involved genetically engineered bacteria. The third approved experiment did not proceed because of scientific reasons.[215] The only common linkage was the technique used to create the novel organisms.

The diversity of potential organisms and environments involved in direct release experiments would make preparation of a programmatic EIS difficult. The NIH cannot even project what types of direct release experiments will be reviewed by the RAC;[216] indeed, because of the diversity of experiments, standard scientific protocols for direct release experiments are not feasi-

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would not have taken place. *Id.* at 758.

212. 40 C.F.R. § 1508.25(a)(2) (1986). *Cf. Thomas*, 753 F.2d at 759-60. The *Thomas* court held that timber sales were not uncertain because they justified the construction of a road through a national forest. 753 F.2d at 760 (citing Davis v. Coleman, 521 F.2d 661, 667-76 (9th Cir. 1975)). *See generally* Hapke, Thomas v. Peterson; *The Ninth Circuit Breathes New Life Into CEQ's Cumulative and Connected Actions Regulations*, 15 ENVTL. L. REP. (Envtl. L. Inst.) 10,289, 10,293 (1985). Analogizing *Thomas* to the NIH situation, if the NIH did not intend to continue reviewing direct release experiment proposals, it would have been unnecessary to publish guidance for formulating proposals. The justification for the "Points to Consider" document was the continuing review by NIH of experiment proposals.

213. *Cf.* Kleppe v. Sierra Club, 427 U.S. 390, 400-02 (1976) (programmatic EIS not required in absence of concrete program). The granting of permits for biotechnology is not the type of program that the District of Columbia Circuit referred to in Scientists' Inst. for Public Information v. AEC, 481 F.2d 1079 (D.C. Cir. 1973), which pertained to a research and development program involving the construction of liquid metal fast breeder reactors. NIH has no program for direct release experiments in biotechnology, and therefore has made no irretrievable commitment to it. *See* Council on Environmental Quality, Final Regulations for Implementation of NEPA, 40 C.F.R. § 1502.4(c)(3) (1986).

214. *See* Recombinant DNA Research; Availability of Environmental Assessment for Public Comment, Request for Comments on Need for a Programmatic Environmental Impact Statement, 50 Fed. Reg. 14,794, 14,795 (1985).

215. *Id.*

216. *Id.*

ble.[217] The difficulty of complying with NEPA is lessened somewhat when EAs for individual experiments are drafted because specific tests can be cited,[218] but the preparation of a programmatic EIS at the research stage would mean that the NIH would have to balance speculative risks with potential benefits to determine whether to continue investigating the unknown.

The Foundation on Economic Trends' argument that the NIH violated NEPA because it failed to prepare an EIS or an EA containing a worst case analysis[219] was not addressed by the *Heckler* court. Subsequent rescission of the worst case analysis rule[220] means that worst case scenarios need not be considered.[221]

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217. *See* Recombinant DNA Advisory Committee, Minutes of Oct. 29, 1984 Meeting 8 (statement of R. Clowes, committee member).

218. In the EA on the University of California experiment, the NIH was able to cite specific tests that were conducted with the genetically engineered bacteria. ENVIRONMENTAL ASSESSMENT, *supra* note 176, at 22-28. The EA also discussed environmental conditions at the experiment site. *Id.* at 34-39.

219. Memorandum of Points and Authorities in Support of Motion for Preliminary Injunction at 19-20, Foundation on Economic Trends v. Heckler, 756 F.2d 143 (D.C. Cir. 1985). The Foundation on Economic Trends also raised the issue of requiring a worst case analysis in an EA in Foundation on Economic Trends v. Weinberger, 610 F. Supp. 829, 836 (D.D.C. 1985). The *Weinberger* court held that the EA was inadequate, *id.* at 841, but did not mention whether a worst case analysis would be required.

220. Council on Environmental Quality, National Environmental Policy Act Regulations; Incomplete or Unavailable Information, 51 Fed. Reg. 15,618 (1986). Rescission followed a lengthy period during which proposals to change the worst case analysis rule had been published, heatedly opposed, and withdrawn. *See* Council on Environmental Quality, Notice of Proposed Information Guidance and Request for Comments, 48 Fed. Reg. 36,486 (1983) (proposal by Council on Environmental Quality (CEQ) to base worst case analysis regulation on "credible scientific evidence, rather than consequences that are purely hypothetical or conjectural"); Council on Environmental Quality, Notice—Withdrawal of Proposed Guidance Memorandum for Federal Agency NEPA Liaisons, 49 Fed. Reg. 4803 (1984) (withdrawing proposal); Council on Environmental Quality, National Environmental Policy Act; Incomplete or Unavailable Information, *id.* at 50,744 (new proposal to amend rule); Council on Environmental Quality, Proposed Amendment to 40 C.F.R. § 1502.22, 50 Fed. Reg. 32,234 (1985) (proposing to amend rule to conform to NEPA's rule of reason); *see also* Yost, *Don't Gut Worst Case Analysis*, 13 ENVTL. L. REP. (Envtl. L. Inst.) 10,394, 10,396 (1983) (describing proposed amendment as "illegal and unwise"); Letter to A. Alan Hill, Chairman, CEQ, from Senators J. Randolph, R. Stafford, D. Durenberger & M. Baucus (Feb. 22, 1984) (amendment would "weaken substantially the effectiveness of the National Environmental Policy Act").

221. An argument can be made that worst case analyses are required by NEPA case law, and are thus beyond the power of the CEQ to rescind. Although

Instead, an evaluation of incomplete or unavailable information based on "credible scientific evidence" and NEPA's rule of reason is required.[222] The low probability of a catastrophe, such as the release of harmful genetically engineered organisms into the environment, would still remain within the scope of the new rule,[223]

CEQ regulations are binding on federal agencies, Andrus v. Sierra Club, 442 U.S. 347, 357 (1979), the agency's interpretation of NEPA is only "entitled to substantial deference." *Id.* at 358; *see* Deukmejian v. NRC, 751 F.2d 1287, 1302 n.77 (D.C. Cir. 1984) (citing Cabinet Mountains Wilderness/Scotchman's Peak Grizzly Bears v. Peterson, 685 F.2d 678, 682 (D.C. Cir. 1982) (declining to accord substantial deference to CEQ's "Forty Questions")).

The CEQ clumsily attempted to answer the argument that it does not have the power to rescind the rule in its supplementary information accompanying rescission of the worst case analysis rule. *See* 51 Fed. Reg. at 15,625. The CEQ first answered the comment that it was "collaterally estopped from overruling Ninth Circuit decisions [on worst case analysis]," *id.*, by attacking the language "collaterally estopped" instead of addressing whether its actions were an administrative attempt to overrule judicial precedent. The agency subsequently cited a commentary on NEPA as authority for its actions, *see id.* (citing Comment, *New Rules for the NEPA Process: CEQ Establishes Uniform Procedures to Improve Implementation*, 9 ENVTL. L. REP. (Envtl L. Inst.) 10,005, 10,008 (1979)). This was followed by a selective cite to a Fifth Circuit case stating that the worst case analysis requirement was "recognized [as] an innovation of CEQ." *Id.* (citing Sierra Club v. Sigler, 695 F.2d 957, 972 (5th Cir. 1983)). Although the Fifth Circuit did indeed state that the rule was an innovation, it found "ample support for the [worst case analysis] regulation in the statute, its legislative history, and case law." *Id.* at 972; *see also id.* at 971 ("CEQ's worst case analysis regulation merely codifies . . . judicially created principles").

222. 40 C.F.R. § 1502.22(b) (1986). "Credible" is defined by the CEQ as " 'capable of being believed' . . . ." 51 Fed. Reg. at 15,622-23 (quoting WEBSTER'S II NEW RIVERSIDE DICTIONARY (1984)). Case law under NEPA has read a rule of reason into the statute. *See* Natural Resources Defense Council, Inc. v. NRC, 685 F.2d 459, 476 n.89 (D.C. Cir. 1982) ("[u]nder NEPA's Rule of Reason, an agency must consider only 'reasonably foreseeable' environmental impacts"), *rev'd on other grounds sub nom.* Baltimore Gas & Elec. Co. v. Natural Resources Defense Council, Inc., 462 U.S. 87 (1983); Iowa Citizens for Environmental Quality, Inc. v. Volpe, 487 F.2d 849, 852 (8th Cir. 1973) (NEPA "must be construed in the light of reason"); Environmental Defense Fund, Inc. v. Corps of Engineers, 492 F.2d 1123, 1131 (5th Cir. 1974) ("[w]e must interpret the requirements of NEPA according to a 'rule of reason' ").

223. *See* 40 C.F.R. § 1502.22(b) (1986). The low probability of a catastrophe was the type of event that the worst case analysis was designed to highlight. *See* Yost, *Worst Case Analysis in Natural Resources Management*, in PROCEEDINGS OF A SYMPOSIUM ON WORST CASE ANALYSIS 62, 62 (May 19-21, 1985) (symposium sponsored by School of Forestry, Northern Arizona University). Nicholas Yost, General Counsel for CEQ when the worst case analysis regulation was drafted, described the regulation as a "what if" regulation, that is, "what if an impact,

but evaluation of the catastrophe would be limited to "theoretical approaches or research methods generally accepted in the scientific community."[224] The CEQ specifically stated that the evaluation is not required in an EA.[225]

If the NIH has to prepare a programmatic EIS, it would fall under the new rule because information regarding dispersal of novel organisms is incomplete or unavailable. A discussion of whether the missing data was relevant "to evaluating reasonably foreseeable significant adverse impacts on the human environment"[226] would probably not be required, however. The new rule

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perhaps improbable, but of severe consequences, were to occur?" *Id. See also* Save Our Ecosystems v. Clark, 747 F.2d 1240, 1245 n.6 (9th Cir. 1984) (1:10,000 possibility of catastrophic event relevant to informed decision making); Sierra Club v. Sigler, 695 F.2d 957, 974 (5th Cir. 1983) (worst case analysis not barred by its remoteness); Council on Environmental Quality, Forty Most Asked Questions Concerning CEQ's National Environmental Policy Act Regulations, 46 Fed. Reg. 18,026, 18,032 (1981) (questions 20a & 20b withdrawn) (scope of worst case analysis includes "low probability/catastrophic impact event").

224. *See* 40 C.F.R. § 1502.22(b) (1986). The agency may exercise discretion as to scientific availability of missing information. 51 Fed. Reg. at 15,622.

225. 40 C.F.R. § 1502.22(c) (1986). A Ninth Circuit decision requiring a worst case analysis in an EA prepared without a subsequent EIS had been criticized as a misinterpretation of the CEQ regulations. Bear, *Worst Case Analysis: The Federal Regulation, 40 C.F.R. 1502.22*, in PROCEEDINGS OF A SYMPOSIUM ON WORST CASE ANALYSIS 3, 4 (May 19-21, 1985) (symposium sponsored by School of Forestry, Northern Arizona University); *see* Village of False Pass v. Clark, 733 F.2d 605, 616 (9th Cir. 1984) (citing Southern Oregon Citizens Against Toxic Sprays, Inc. v. Clark, 720 F.2d 1475, 1480-81 (9th Cir. 1983)).

The EA that was subsequently submitted for the University of California experiment (prior to rescission of the worst case analysis rule) stated that a worst case analysis was not required, but cautiously included "worst case considerations." ENVIRONMENTAL ASSESSMENT, *supra* note 176, at 46.

The FDA has required worst case analyses in EAs filed for premarket approval of products since at least 1981. If this requirement is continued by the FDA, manufacturers of genetically engineered organisms subject to FDA review would be required to include worst case analyses in EAs when applying for premarket approval. *See* Goldberg & Miller, *The Role of the Food and Drug Administration in the Regulation of the Products of Recombinant DNA Technology*, 4 RECOMBINANT DNA TECHNICAL BULL. 15, 17 (1981); *see also* OFFICE OF MANAGEMENT AND BUDGET, THE REGULATION OF NEW CHEMICALS UNDER THE TOXIC SUBSTANCES CONTROL ACT 5 (Mar. 15 1984), *reprinted in Risk Assessment Hearings*, *supra* note 94, at 349 (EPA uses worst case assumptions in making risk findings during premanufacture notice review under Toxic Substances Control Act.).

226. 40 C.F.R. § 1502.22(b) (1986). The NIH bases some sections of its Guidelines on "worst case scenarios." Recombinant DNA Advisory Committee, Minutes of May 3, 1985 Meeting 18 (statement of R. Clowes, Committee member).

only requires an evaluation if an "analysis of the impacts is supported by credible scientific evidence, is not based on pure conjecture, and is within the rule of reason."[227] No evidence exists that genetically engineered organisms will disperse successfully or that they are harmful. Presumably, therefore, a simple statement that dispersal information was unavailable would be adequate.

Although the new rule eliminates the need for an EIS based on possibilities[228] rather than probabilities, improbabilities such as accidents at nuclear power plants and failed dams have occurred. The introduction of a novel organism into an ecosystem is unpredictable.[229] Although a worst case analysis could mutate science into science fiction with the negative consequence of officially alarming the public,[230] an analysis based on possibilities

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227. 40 C.F.R. § 1502.22(b) (1986). Prior to the new rule, the Ninth Circuit had ordered the Bureau of Land Management to prepare a worst case analysis based on the hypothesis that herbicides proposed for spraying by the Bureau would cause cancer. *See* Save Our Ecosystems v. Clark, 747 F.2d 1240, 1245-46 (9th Cir. 1984). Despite a judicial determination that credible scientific evidence existed showing that the herbicides could cause cancer, *id.* at 1246, the Bureau and the CEQ continued to contend that none had been shown. *See* Council on Environmental Quality, Proposed Amendment to 40 C.F.R. § 1502.22, 50 Fed. Reg. 32,234, 32,236 (1985). The situation was thus different from that involved in biotechnology. Medical evidence of the harmful effects of the herbicides conflicted. *See* Comment, *Update: The NEPA Worst Case Analysis Regulation, 14* ENVTL. L. REP. (Envtl. L. Inst.) 10,267, 10,271 (1984). No evidence of any harmful effects associated with biotechnology has been shown.

One commentator has argued that the original worst case analysis regulation changed the court's deference in decisions involving scientific uncertainty to a hard look standard. Note, *Scientific Uncertainty and the National Environmental Policy Act—The Council on Environmental Quality's Regulation 40 C.F.R. Section 1502.22*, 60 WASH. L. REV. 101, 112 (1984). The amendment, therefore, may reverse the hard look standard to the traditional soft glance because agencies could be selective in including scientific evidence they believed credibly supported areas of scientific uncertainty. *See* Rosenbaum, *Amending CEQ's Worst Case Analysis Rule: Towards Better Decisionmaking?*, 15 ENVTL. L. REP. (Envtl. L. Inst.) 10,275, 10,277 (1985).

228. *See* 51 Fed. Reg. at 15,625 (withdrawing questions 20a and 20b of Council on Environmental Quality, Forty Most Asked Questions Concerning CEQ's National Environmental Policy Act Regulations, 46 Fed. Reg. 18,026, 18,032 (1981)) (requiring inclusion of "all known *possible* environmental consequences of agency action" in all EISs) (emphasis in original).

229. *See* Sharples, *Spread of Organisms with Novel Genotypes: Thoughts from an Ecological Perspective*, 6 RECOMBINANT DNA TECHNICAL BULL. 43, 55 (1983).

230. Recombinant DNA is "a reminder of bad dreams . . . ." Thomas, *supra*

could aid in a decision whether to allow an experiment close to a large population center or crop producing region.[231] A biohazard occurring outside the limits for which precautions were taken could cripple the nascent biotechnology industry.

The *Heckler* court anticipated that the NIH was "about to begin a process of reviewing what will be a stream of applications for approval of a new technology with unknown environmental consequences."[232] The flow failed to materialize, however. The

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note 72, at 362; *see also* Sun, *Biotechnology Movie Debut Worries Industry*, 229 SCIENCE 950, 950 (1985) (director of movie with biotechnology theme described movie as "*China Syndrome* meets *Night of the Living Dead*").

Discussions of the risks of biotechnology inevitably become discussions of "catastrophic epidemics or the creation of new and uncontrollable harmful organisms." REPORT PREPARED FOR THE SUBCOMM. ON SCIENCE, RESEARCH AND TECHNOLOGY OF THE HOUSE COMM. ON SCIENCE AND TECHNOLOGY BY THE SCIENCE POLICY RESEARCH DIVISION OF THE CONGRESSIONAL RESEARCH SERVICE, 94TH CONG. 2D SESS., GENETIC ENGINEERING, HUMAN GENETICS, AND CELL BIOLOGY 36 (Comm. Print 1976).

Once a worst case scenario has been outlined, public emphasis on the possibility that it could occur tends to outweigh emphasis on the probability that it will occur. For example, a proposal for siting a research laboratory in Morris Township, New Jersey, suggested storing 1500 gallons of liquid hydrogen on the laboratory roof. A consultant for opponents of the proposal described a worst case scenario involving a leak in the hydrogen tank, resulting in an explosion, resulting in the rupture of toxic gas containers in the laboratory, resulting in toxic gases drifting into neighboring residences. The laboratory could not persuade the opponents to accept a worst credible scenario it had conceived in lieu of the worst possible scenario. The community adopted the worst possible scenario as the standard for judging the risk of siting the laboratory in that community. *See* U.S. CONGRESS OFFICE OF TECHNOLOGY ASSESSMENT, THE REGULATORY ENVIRONMENT FOR SCIENCES: A TECHNICAL MEMORANDUM, APPENDIX C., ENVIRONMENTAL CONCERNS AND LABORATORY SITING: THE MORRIS TOWNSHIP-BELLCORE CASE 136-39 (1986); *see also Fish and Wildlife Miscellaneous—Part 5: Hearing on Council of Environmental Quality Reauthorization and Oversight—H.R. 4585, Before the Subcomm. on Fisheries and Wildlife Conservation and the Environment of the House Comm. on Merchant Marine and Fisheries*, 98th Cong., 2d Sess. 56 (1984) [hereinafter *CEQ Hearing*] (statement of Rep. Breaux) (worst case analysis frequently becomes central feature of project, and only aspect reported by media).

231. *See Panel Discussion—Future Directions of Worst Case Analysis*, in PROCEEDINGS OF A SYMPOSIUM ON WORST CASE ANALYSIS 132, 146-47 (May 19-21, 1985) (symposium sponsored by School of Forestry, Northern Arizona University) (statement of N. Yost, former General Counsel, CEQ) (outlining discussions that took place when worst case analysis regulation was formulated, and commenting on discussions of usefulness of regulation in deciding whether to locate potentially hazardous activities in remote areas).

232. 756 F.2d at 159-60.

Heckler decision implied that applications for NIH approval had to be accompanied by an EA, which may or may not be judged adequate. The court's decision thus transformed NIH approval of voluntary applications from a benefit into an obstruction to be bypassed.[233]

The NIH would not have welcomed a stream of applications for direct release experiments because review of such experiments detracts from the agency's biomedical mission.[234] The agency is not a regulatory body, and members of the RAC expressed concern about reviewing the increasing number of research applications from private commercial enterprises,[235] even though the RAC had encouraged those enterprises to comply with the Guidelines. Even before *Heckler* was decided, however, other federal agencies were proposing alternate review committees for direct release experiments and products[236] as the fledgling biotechnology industry began to grow.[237]

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233. *See* Sun, *Rifkin and NIH Win in Court Ruling*, 227 SCIENCE 1321, 1321 (1985); *see also Advisory Role*, *supra* note 175, at 5-6 (describing Monsanto's decision not to seek NIH approval because of possibility that experiment's proposal would be challenged in court).

234. *See Planned Releases of Genetically-Altered Organisms: The Status of Government Research and Regulation, Hearing Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 99th Cong., 1st Sess. 186, 188-89 (1985) [hereinafter *Planned Releases Hearing*] (letter from J. Jordan, Administrator, Cooperative State Research Service, USDA, to Rep. Volkmer (undated), stating "[i]n February 1985, NIH announced that it did not feel that decisions concerning the environmental fate of genetically-engineered organisms fell within its scientific expertise, and as such would decline to consider proposals which included the intentional release of genetically-altered organisms").

235. *See Biotechnology Regulation: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 98th Cong., 2d Sess. 90-91 (1984) [hereinafter *Biotechnology Hearing*] (statement of B. Bulkley, Deputy Director, Office of Science and Technology Policy).

236. *See* Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856 (1984) [hereinafter Proposal for a Coordinated Framework].

237. *See* UNITED STATES INTERNATIONAL TRADE COMMISSION, INTERNATIONAL DEVELOPMENTS IN BIOTECHNOLOGY AND THEIR POSSIBLE IMPACT ON CERTAIN SECTORS OF THE U.S. CHEMICAL INDUSTRY xi (1984). In 1983, about $2.5 billion was invested in biotechnology in the United States. *Id. See also* Alexander, *Going for the Green Gene*, TIME, Nov. 4, 1985, at 56 (describing growth potential of biotechnology firms).

B. *The White House Office of Science and Technology Policy*

In April 1984, the White House Cabinet Council on Natural Resources and the Environment created the Interagency Working Group on Biotechnology (Working Group) to formulate a coordinated framework for biotechnology regulation.[238] In December 1984 the White House Office of Science and Technology Policy (OSTP) published the proposed framework in the *Federal Register*.[239] The proposal recommended that the five federal agencies involved (the NIH, the Environmental Protection Agency (EPA), the United States Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the National Science Foundation (NSF)) regulate biotechnology under existing laws.[240] The

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238. Proposal for a Coordinated Framework, *supra* note 236, at 50,857.

The Environmental Policy Institute reported that the reaction of an Office of Management and Budget official to perceived damage to biotechnology companies by EPA's proposed regulation of biotechnology spurred creation of the Working Group on Biotechnology. *See* Comments of the Environmental Policy Institute on OSTP Proposal for a Coordinated Framework for Regulation of Biotechnology 26 n.* (Apr. 15, 1985), *reprinted in Biotechnology and Agriculture: Hearings Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 99th Cong., 1st Sess. 204, 229 n.* (1985) [hereinafter *Biotechnology and Agriculture Hearings*]; *see also* OFFICE OF MANAGEMENT AND BUDGET, *The Regulation of New Chemicals Under the Toxic Substances Control Act* 23 (Mar. 15, 1984), *reprinted in Risk Assessment Hearings*, *supra* note 94, at 366 ("Innovation, particularly at small firms, is not merely important in this industry—it *is* the industry. Erecting new regulatory barriers without careful consideration of their effects could jeopardize the progress that the U.S. . . . is making.") (emphasis in original).

239. Proposal for a Coordinated Framework, *supra* note 236, at 50,856.

240. *Id.* at 50,858, 50,905. Congress held hearings during the 1970s on whether new laws were needed to regulate biotechnology. *See, e.g., Industrial Applications of Recombinant DNA Techniques: Hearing Before the Subcomm. on Science, Technology, and Space of the Senate Comm. on Commerce, Science, and Transportation*, 96th Cong., 2d Sess. (1980); *Recombinant DNA Research Hearings*, *supra* note 22. Many bills were introduced, but none passed. *E.g.*, S. 1217, 95th Cong., 1st Sess. (1977); S. 621, 95th Cong., 1st Sess. (1977); H.R. 4759, 95th Cong., 1st Sess. (1977). *See generally* Talbot, *Introduction to Recombinant DNA Research, Development and Evolution of the NIH Guidelines, and Proposed Legislation*, 12 U. TOL. L. REV. 804, 810 (1981) (describing proposed legislation).

When it became apparent to Congress that the hypothetical risks were not materializing, pressure for a law specifically regulating biotechnology eased. *See* Letter to Joseph Califano, Jr., Secretary of Health, Education and Welfare, from Senators Edward Kennedy, Jacob Javits, Gaylord Nelson, Adlai Stevenson, Harrison Williams, Jr. & Richard Schweiker (June 1, 1978), *reprinted in* Recombinant

final version of the proposal, published in June 1986, restated this policy.[241]

Under the Coordinated Framework, as it is known, the agencies established scientific advisory committees to review biotechnology products and processes on a case-by-case basis.[242] Agency jurisdiction is based primarily on the intended use of a product.[243] If jurisdiction overlaps, an agency may occasionally defer to another agency's regulations, or a lead agency is designated.[244]

The Biotechnology Science Coordinating Committee (BSCC),[245] chartered on October 30, 1986,[246] coordinates the vari-

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DNA Research Revised Guidelines, 43 Fed. Reg. 60,103, 60,104 (1978). *But see* Dutton, *supra* note 61, at 161-62 (suggesting that one reason for withdrawal of congressional support for law regulating biotechnology was lobbying by scientists).

241. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,302-03 (1986) [hereinafter Coordinated Framework].

242. *Id.* at 23,305.

243. *See id.* at 23,304-05. For example, genetically engineered food additives and drugs would be regulated by the FDA; pesticides and industrial products by the EPA; and plant pests, animal biologicals, and other agricultural products by the USDA. *Id.* at 23,304. The agencies published their final policy statements in the *Federal Register*. *See id.* at 23,309 (FDA); *id.* at 23,313 (EPA); *id.* at 23,336 (USDA); *id.* at 23,347 (OSHA); *id.* at 23,349 (NIH). Because the FDA does not regulate direct release experiments, regulations promulgated by that agency are not discussed in this Article. For a discussion of the FDA's regulation of biotechnology, *see* Note, *An Overview of FDA Regulation of Biotechnology Derived Products: Dealing with the Collision of Science and Society*, 11 RUTGERS COMPUTER & TECH. L.J. 501 (1985).

244. Coordinated Framework, *supra* note 241, at 23,305.

245. *See* Coordinated Framework for Regulation of Biotechnology; Establishment of Biotechnology Science Coordinating Committee, 50 Fed. Reg. 47,174, 47,176 (1985) [hereinafter Establishment of Committee].

246. Charter of the Biotechnology Science Coordinating Committee of the Federal Coordinating Council for Science, Engineering, and Technology, 51 Fed. Reg. 24,221 (1986). After two years, renewal of the charter will be reviewed. *Id.*

The OSTP initially proposed a parent board, chartered by the Department of Health and Human Services, to evaluate each agency's scientific committee's review procedures and to develop generic scientific guidelines for similar applications. 49 Fed. Reg. at 50,863. The board, to be named the Biotechnology Science Board (BSB) was to have 25 members including two from each agency's scientific advisory committee. To utilize the experience and expertise of the RAC, ten present or former members of the RAC were to be initial members of the BSB. *See* Culliton, *New Biotech Review Board Planned*, 229 SCIENCE 736, 737 (1985).

The original proposal for the BSB would thus have created a "super-RAC," administered by the present RAC's staff. After NIH and NSF declined to house the larger committee, the published scheme (a compromise), was developed. Re-

ous agencies' policies. The BSCC's role is to share scientific information among the agencies and promote consistency in review procedures and assessments.[247] Initial members of the BSCC include two officials each from the USDA and the EPA, and one official each from the FDA, NIH, and NSF. Potential applicants for experiment permits have been assured that the BSCC is not a second tier review that could delay the processing of applications. Meetings of the BSCC are generally closed except those meetings "on issues of generic interagency concern."[248]

The closed-door policy of BSCC suggests political influence even if such influence is nonexistent. Indeed, OSTP's Coordinated Framework sharply curtails public participation. In contrast to the RAC's public hearings, individual proposals heard by agencies are generally closed to the public.[249]

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combinant DNA Advisory Committee, Working Group on Biotechnology Coordination, Minutes of Mar. 1, 1985 Meeting 10 (statement of W. Gartland).

During 1985 the Working Group received and evaluated comments to its proposal. Of concern to many commentators was the new board's potential to undermine the RAC. *See* Culliton, *supra* at 737. To avoid this problem, the proposal was revised to relocate the board to the OSTP, where it would operate under the Federal Coordinating Council for Science, Engineering and Technology. *See* Miller, *Gene Splicing: "Final" Federal Plan*, 128 SCI. NEWS 198, 198 (1985). The Federal Coordinating Council for Science, Engineering and Technology is authorized by 42 U.S.C. § 6651 (1982), which establishes its role as a policy coordinating body for federal agency programs, but which does not mention the coordination of agency regulations. In response to critics perceiving no necessity for an additional advisory body, the board was modified from an advisory committee to an interagency coordinating committee. *See* Establishment of Committee, *supra* note 245, at 47,175.

247. Establishment of Committee, *supra* note 245, at 47,176. The BSCC has established a risk assessment subcommittee to build a data base on the environmental impacts of biotechnology products. *See Regulatory Coordination Panel to Study Risk Assessment; Comment Period Extended*, 10 CHEM. REG. REP. (BNA) 475, 475 (July 11, 1986).

248. Establishment of Committee, *supra* note 245, at 47,176. An open meeting of the BSCC was held in July 1986 to discuss scientific issues of biotechnology. Office of Science and Technology Policy, Biotechnology Science Coordinating Committee; Meeting, 51 Fed. Reg. 23,864 (1986).

249. Recombinant DNA Advisory Committee, Working Group on Biotechnology Coordination, Minutes of Mar. 1, 1985, Meeting 10 (statement of W. Gartland, Executive Secretary) (describing EPA and FDA reviews). The EPA announces reviews of proposals, including those involving proprietary data, in the *Federal Register*. *See id.* at 11 (statement of A. Goldhammer, Industrial Biotechnology Association).

The political motivation behind creation of the BSCC is suspect, appearing to stem from an effort "to unshackle industry in pursuit of biotechnology."[250] While the BSCC does not regulate,[251] the character and extent of its coordination are ambiguous.[252] Of particular concern is the extent to which regulations under different statutes are being harmonized. Agency consistency in regulating biotechnology may be good policy, but the BSCC's coordination could undermine the congressional mandates of the various statutes that are used to regulate biotechnology.[253] These policy decisions should come from Congress.

Even if BSCC intends to coordinate only scientific issues,[254] political intrusion into agency decisions will not be precluded. Risk assessment and risk management are vulnerable to subjec-

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250. Letter from W. Walsh, State Department, to G. Keyworth, Science Advisor to the President (May 27, 1983), *quoted in* Comments of the Environmental Policy Institute on OSTP Proposal for a Coordinated Framework for Regulation of Biotechnology, *supra* note 236, at 26 n.*; *see also* Withers, *supra* note 129, at 668 (Working Group was created due to concern that biotechnology would be subject to over-regulation and overlapping regulation by federal agencies).

251. Recombinant DNA Advisory Committee, Minutes of Sept. 23, 1985 Meeting 15 (statement of B. Healy, OSTP).

252. *Id.* at 16. An OSTP official stated that OSTP would not "become involved in jurisdictional 'turf battles' between agencies, [but] may help route applications . . . ." *Id.*

253. An OSTP official stated that the BSCC had "no authority to tell an agency to change its views, its review structure, or its regulatory decisions," *id.* at 17, but added that the BSCC would "identify problems . . . and can provide a forum for the agencies to resolve differences." *Id.* While OSTP recognizes that agencies may reach "very different regulatory decisions because of the statutes under which they operate," *id.*, it is unclear to what extent agencies would be persuaded to change policies. *Id. See also* FIFTEENTH ANNUAL REPORT, *supra* note 95, at 211 (quoting speech by William Ruckelshaus, former Administrator, EPA, to National Academy of Sciences (1983)) (risk management decisions include consideration of individual statutory frameworks).

For example, the laxity of USDA's biotechnology regulations has been stated to be consistent with OSTP's guidance that regulations not encumber biotechnology. *See* UNITED STATES GENERAL ACCOUNTING OFFICE, BIOTECHNOLOGY: AGRICULTURE'S REGULATORY SYSTEM NEEDS CLARIFICATION 36, 50 (Mar. 1986) [hereinafter AGRICULTURE'S REGULATORY SYSTEM]. Similarly, charges have been made that the EPA was persuaded to exempt review of certain experiments against the advice of in-house and consulted scientists. *See Summary Judgment Requested by Rifkin, FOIA Documents Cited as Compelling Evidence*, 10 CHEM. REG. REP. (BNA) 1101, 1101 (Nov. 14, 1986).

254. *See* Recombinant DNA Advisory Committee, Minutes of Sept. 23, 1985 Meeting 18 (statement of B. Healy, OSTP).

tive interpretation.[255] BSCC's "scientific" determination in the Coordinated Framework that the insertion of well-characterized intergeneric gene segments from noncoding regions requires only limited review[256] was attacked by ecologists and microbiologists.[257] This determination by the BSCC underlies the entire Coordinated Framework and determines the scope of individual agencies' review.[258] At this early stage in direct release experiments—with only limited data available—BSCC's "scientific" determination is more akin to science policy[259] based on a determination not to hinder the biotechnology industry.

OSTP's authority to coordinate biotechnology regulations by

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255. *See supra* notes 90-110 and accompanying text.

256. Coordinated Framework, *supra* note 241, at 23,307.

257. *See* SUBCOMM. ON INVESTIGATIONS AND OVERSIGHT OF THE HOUSE COMM. ON SCIENCE AND TECHNOLOGY, 99TH CONG., 2D SESS. ISSUES IN THE FEDERAL REGULATION OF BIOTECHNOLOGY: FROM RESEARCH TO RELEASE 55 (Comm. Print 1986) [hereinafter FEDERAL REGULATION OF BIOTECHNOLOGY]; *Federal Policy Could Miss Full Review of Some Harmful Products, Scientists Say*, 10 CHEM. REG. REP. (BNA) 516, 516 (July 25, 1986).

258. *See* FEDERAL REGULATION OF BIOTECHNOLOGY, *supra* note 257, at 56. Despite BSCC's assertion that it is not regulating biotechnology, the definition determining which experiments are regulated seems to be a BSCC creation. *Compare* Coordinated Framework, *supra* note 241, at 23,306 (describing "*BSCC formulated definitions*" of intergeneric and intrageneric organisms) *and id.* at 23,370 (USDA assigns direct release experiments "to one of two categories *in accordance with the definitions by the* [BSCC]") *with id.* at 23,317 ("*EPA has decided* that intergeneric combinations . . . but not intrageneric combinations . . . should be given special attention.") (emphasis added). The Foundation on Economic Trends alleged that the EPA initially indicated rejection of the exemptions for intergeneric organisms created by the addition of well-established regulatory sequences and nonpathogenic strains of pathogenic species. Apparently, the agency was later persuaded to adopt the exemptions, despite recommendations of in-house and consulted scientists to reject them. *See Summary Judgment Requested by Rifkin, FOIA Documents Cited as Compelling Evidence*, 10 CHEM. REG. Rep. (BNA) 1101, 1101 (Nov. 14, 1986).

The BSCC has established a working group to revise the definitions of "intergeneric organism," "pathogen," and "release into the environment" because of the ambiguity of those definitions in the preamble to the Coordinated Framework. *See USDA Confirms Dropping Research Rules; January Meeting to Address New Amendments*, 10 CHEM. REG. Rep. (BNA) 1195, 1195 (Dec. 15, 1986).

259. The first chairman of the BSCC described the committee as a "scientific policy and implementation committee and not a broad policy committee for the Administration." *Biotechnology Development: Hearings Before the Subcomm. on Oversight and Investigations of the House Committee on Energy and Commerce*, 99th Cong., 1st Sess. 127 (1985) [hereinafter *Biotechnology Development Hearings*] (statement of D. Kingsbury, Chairman, BSCC).