5 Va. J.L. & Tech. 5 (2000) <http://www.vjolt.net>
1522-1687 / © 2000 Virginia Journal of Law and Technology Association

VIRGINIA JOURNAL *of* LAW *and* TECHNOLOGY

UNIVERSITY OF VIRGINIA	SPRING 2000	5 VA. J.L. & TECH. 5

Biotechnology Through the Eyes of an Opponent: The Resistance of Activist Jeremy Rifkin

by Paul S. Naik[*]

I. Introduction

II. Biography of Jeremy Rifkin

A. Early Years

B. Rifkin's Motivation for Opposing Biotechnology

III. Rifkin's Efforts Against Recombinant DNA Research

A. At the RAC - Rule and Policy Making

1. The Proposal

2. Response to Proposal

3. Rifkin's Response

4. RAC's Counter-Response

5. Outcome

B. Lawsuit

1. Other Litigation Against Biotechnology Research

2. Cases Involving "Deliberate Release of Genetically Engineered Organisms"

3. Cases Involving Other Biotechnology Research Experiments

C. Efforts Against Biotech Through Opposing Biotechnology Patents

1. Litigation

2. Out-of-Court Opposition

IV. Rifkin's Efforts Against Biotechnology Products

V. Rifkin's Activities

A. Media Publicity

B. Lawsuits

C. FlavrSavr Tomato

D. Public Efforts

E. Lawsuits

VI. Conclusion - Impact and Implications

I. Introduction

"The biotech revolution will affect every aspect of our lives. The way we eat; the way we date and marry; the way we have our babies, the way our children are raised and educated; the way we work; the way we engage in politics; the way we express our faith; the way we perceive the world around us and our place in it . . . each of us [will be forced] to put a mirror to our most deeply held values, making us ponder the ultimate question of the purpose and meaning of existence."[1]

1. In this declaration we see both the tremendous awe with which the promises and power of biotechnology are greeted, and the fear, even trepidation, with which the potential changes it could wrought on human existence is viewed. Therein lies the problem.

2. "Biotechnology" is broadly defined as "the application of biological systems and organisms to technical and industrial processes."[2] This broad category includes the use of cell fusion technology to produce biological entities such as antibodies and the process of genetic engineering. The latter process involves the manipulation of the genetic code of living organisms, primarily through the method of recombinant DNA. It is primarily this ability to control the genetic blueprint that has given rise to the controversies surrounding biotechnology. However, because genetic engineering is so intimately associated with biotechnology generally, and its power is so overwhelming that it has largely supplanted traditional biotechnology methods much of the opposition against genetic engineering has been directed to biotechnology as a whole.

3. It would be no exaggeration to say that since its advent about two decades ago, genetic engineering has revolutionized the life sciences and the pharmaceutical industry. The technology, in its various conceptions and applications, is now manifested in a wide range of applications in the agricultural and food industry, in unprecedented medical and healthcare innovations, and in the functional structure of the workplace. The recent report of a breakthrough in cloning of a sheep from an adult cell is a representative discovery that illustrates the wondrous possibilities of this technology.

4. It is really no wonder that biotechnology in the form of genetic engineering would not be accorded unequivocal acceptance. In the early days of the technique, even some molecular biologists were uncomfortable with the implications of recombining genetic material (DNA). This wariness lead to a worldwide moratorium on recombinant DNA experiments in 1973 and 1974. The moratorium was followed in 1975 by a gathering of scientists at the Asilomar Conference Center in Pacific Grove, California, where a set of recombinant DNA research guidelines were produced. At the same time, the public, provoked by anti-biotech activists abetted by an uncritical media, was whipped into a frenzy by claims of accidental outbreaks of infectious cancer and possible release of genetically-modified bacteria from university laboratories.[3]

5. The hysteria eventually subsided when it soon became obvious that biotechnology was not about to lead to the apocalypse. However, the same controversies and concerns re-surfaced to dog the biotechnology industry during the 1980's, albeit in less outlandish incarnations, when the first industrial fruits of genetic engineering arrived in the marketplace. At this point, the Food and Drug Administration (the agency charged with regulating the foods and drugs sold to the American public) was faced with a difficult task. It had to promulgate rules and policies relating to biotechnology that were to be at once fair to the industry and true to the agency's mission of protecting the health and safety of the people and the environment. This task was confounded by the activities of citizen-activists who disagreed with the agency at every step of the way. The challenges the FDA faced in dealing with the first genetically engineered commercial products have not abated, and are expected to intensify as we enter a new era of biotechnology.

6. The capability to clone a viable mammal from an adult cell, and the specter of imminent cloning of human individuals that accompanies it, illustrates how future biotechnology products will likely extend beyond mere genetically engineered versions of presently existing molecules (for instance, genetically engineered versions of the naturally-existing hormone insulin). Potential products include germline gene alterations, laboratory-grown body parts, genetically-designed babies and human cloning. As a new wave of biotechnology products is set to enter the marketplace, we will see the re-emergence of the many questions about how much, and whether at all, to permit the development of this technology. And, undoubtedly, the FDA will once again be at the forefront of the battle over how to regulate these products.[4]

7. This paper attempts to retrospectively examine the impact of the efforts of Jeremy Rifkin on the rules and regulation, and ultimately the mission, of the Food and Drug Administration (FDA) pertaining to biotechnology. Rifkin arguably single-handedly raised the consciousness of the American public, and indeed the world, to the potential risks of the technology, at least as he saw them. In this way, he positioned himself as a biotechnology gadfly who became the bane of the biotechnology industry and federal agencies regulating biotechnology. It seems fitting, therefore, to study the impact of anti-biotechnology activism on federal regulation of biotechnology by focusing on Rifkin's efforts.

8. In the course of examining Rifkin's activities that were targeted specifically at the FDA, this paper also discusses his efforts aimed at curbing recombinant DNA research regulated by the National Institutes of Health (NIH) and genetic engineering activities that fell under the jurisdiction of the United States Department of Agriculture (USDA) and Environmental Protection Agency (EPA). The reasons for this are several-fold.

9. First, regulatory changes in non-FDA federal agencies that have jurisdiction over biotechnology can have a direct impact upon FDA regulations. The FDA, USDA, EPA, NIH, Occupational Safety and Health Administration (OSHA) and National Science Foundation (NSF) are federal agencies that are collectively charged with insuring the safety of biotechnology research and products within a coordinated framework for the regulation of biotechnology.[5] One of the basic principles of the coordinated framework of regulation is the promulgation of consistent regulatory policies among the agencies.[6] In this regard, the FDA has demonstrated its adherence to this principle. In some instances, it has adopted the relevant regulations from other agencies within the Coordinated Framework instead of promulgating its own regulations.[7] Thus, the impact of Rifkin's activities on non-FDA agencies has, on occasion, extended to the FDA as well.

10. Second, the FDA's function in ensuring the safety of biotechnology products is dependent on the proper flow of biotechnology products through the research pipeline. The vibrancy of biotechnology research is at least partly dependent on how much regulation is imposed on it by regulatory agencies such as the EPA (e.g., regulation of bio-pesticides) and USDA (e.g., field testing of genetically-modified organisms). Thus, any obstruction of research through increased regulation forced by activists such as Rifkin would impede flow of biotechnology products to the FDA review stage, thus, ultimately affecting the FDA's function by limiting the number and variety of products that it gets to assess.

II. Biography Of Jeremy Rifkin

A. Early years

11. Jeremy Rifkin graduated from the Wharton School of Finance at the University of Pennsylvania with a bachelor degree in economics and the Fletcher School of Law and Diplomacy at Tufts University with a master's degree in international affairs. His social activism began in the 1960s. Among his self-proclaimed accomplishments are helping to organize student opposition to germ-warfare projects at the University of Pennsylvania in 1966 and sponsoring the first national anti-Vietnam War rally in 1967. He later served as national coordinator for the National Committee for a Citizens Commission of Inquiry on U.S. War Crimes in Vietnam. In 1971, he co-founded the radical New American Movement (NAM), which was a leftist

political group. Through this movement, Rifkin pushed for the formation of a forum for mass media exposure as a mechanism for raising political awareness and to promote NAM and other radical activities and demands, thus, foreshadowing his subsequent skillful engagement of the mass media in his crusade against biotechnology. In 1972, the Peoples Bicentennial Commission (PBC) was born. Through this forum Rifkin engaged in activities that he characterized as a new American Revolution aimed at creating fundamental changes in social, economic and political institutions. These changes were to include indictment of economic freedoms and the accompanying prosperity. He believed in the elevation of human rights above property values, identifying personal rights with the collective interest. In his view, health care was a human right instead of a market commodity to be sold to the highest bidder--technology was made to serve rather than to exploit man and the environment, and production for profit was to be replaced by production based on human need and peace.[8]

12. Rifkin exhibited his attention-garnering talent early in his career. His PBC once sent tape recordings to 8,000 wives of America's top corporate executives urging the women to question their husbands about corporate wrongdoing and corruption. It also announced a $25,000 reward offer to over 10,000 secretaries for information leading directly to the arrest, prosecution, conviction, and imprisonment of chief officials of Fortune 500 corporations for criminal corporate activities.[9]

13. Following a conspicuous lack of success through the PBC's activities, Rifkin turned his attention to the pharmaceutical industry's experiments with DNA. This switch was accompanied by a change of name for the PBC (which had earlier been changed from the Peoples Bicentennial Commission to the Peoples Business Commission) to the Foundation on Economic Trends (FET). He believed that there should be public control over the prospects of formation of "new forms of life" through this technique. It turned out that this concern signified the germination of a subsequent headlong plunge into the anti-biotechnology crusade that was to catapult him into national prominence.[10]

14. At a meeting of molecular biologists at the National Academy of Sciences in 1977, Rifkin made his debut as a high-profile anti-genetic engineering activist by leading a protest that included protesters surrounding the audience during a conference session and the singing of "We shall not be cloned." Interestingly, the aggressive protest had only an equivocal impact on the conference participants. One of the scientist participants characterized it as "more amusing than threatening."[11] This protest, and the equivocal, almost dismissive, response it received, was to parallel Rifkin's subsequent activities and the reception of most biotechnology proponents.

15. In the 1980's, as a result of his unique brand of anti-biotechnology crusading activities, Rifkin received wide media attention. The media took to viewing him as "the biotechnology revolution's leading counterrevolutionary"[12] and "biotechnology's most outspoken critic."[13]

16. The substantial amount of attention Rifkin received belied the size of the organization through which Rifkin engaged his gadfly activities, the FET. The FET, at the height of its prominence, consisted of Rifkin, one assistant, one secretary and two lawyers. It did not have members, and ran on a small budget of a couple of hundred thousand dollars annually generated from Rifkin's speaking fees and the sale of his books.[14] Its stated purpose was, and continues to be, to engage in activities centered around the environmental, ethical and economic concerns raised by the development of emerging technologies.[15]

17. Jeremy Rifkin has been a prolific writer. He is the author of about a dozen books that cover a wide range of topics.[16] In a number of his books, he espouses his conception of the world, and, relatedly, how technological changes would affect it. In "Entropy," he discusses the synthesis of environmental and economic theory while seeking to lay the groundwork for notions of sustainable development.[17] In "Who Should Play God?", he (and co-author Ted Howard) plainly voices his opposition to genetic engineering, claiming the technology would be as deadly as a nuclear holocaust. He suggests that the crucial question human beings are faced with in dealing with the technology is whether to preserve human species and other life forms as they exist or to forge ahead on a mass program of biological reengineering.[18] In "Algeny," Rifkin attempts to elucidate the social underpinnings of Darwin's theory of evolution, arguing that the theory is more an attempt to make sense of the social changes resulting from the advent of the Industrial Age than a reflection of scientific truth. In this book, Rifkin draws parallels between Darwinism and what he perceives

to be a new view of the world as proposed by scientists of the genetic engineering era.[19] In "Biosphere Politics," he explores how the last five centuries of human history have shaped our relationship to the natural world.[20] In "The Biotech Century," he attempts to draw parallels between the bioscientific and informational technologies. He predicted that the next century will see the emergence of technological advances that combine computer technology and biological properties; Rifkin views this as portending an era of unprecedented changes to how humans view themselves and the world around them. While the views he expounds in his books are not without their detractors[21], it is clear that through his books he has sought to reach the public with the philosophical underpinnings of his objection to technology, specifically biotechnology.[22]

B. Rifkin's Motivation for Opposing Biotechnology

18. The unifying principle in the vast and diverse philosophical motivations driving Jeremy Rifkin's opposition to biotechnology seems to be "fear" of unknown risks. Rifkin has been opposed to biotechnology for at least 20 years. Over this period, biotechnology has seen unprecedented and rapid development. Because of this, it is difficult to pinpoint precisely what motivated Rifkin at each of the time points when he was most publicly and vigorously opposed to particular biotechnology events. Moreover, he has expressed conflicting expectations from his efforts, and his views and concerns have likely evolved over time. Nonetheless, broadly speaking, his motivations appear to be premised in fear of several distinct consequences he expects to result from the technology of genetic engineering.

19. First, Rifkin seems motivated by fears of the technology itself. He believes the new genetic science to be unlike any other technology the history of humankind has ever seen, in that it is capable of raising more troubling issues than previous technologies ever did. This belief evidently arises from his conviction that genetic engineering technology is uniquely capable of altering life, and indeed provides a tool for creating life itself.[23] No other previous technology portends this power.

20. Second, following from the all-powerful capability provided by this technology, Rifkin fears that one particularly costly price of utilizing this technology is the evisceration of human self-definition. He believes that the ability to manipulate our own genetic code represents the "ultimate expression of human control" in that it enables human beings to determine how they want to be.[24] It appears that his main concern is the erosion of the precision of the definition of the term "human," because if humans can cause deliberate alteration to how they are constituted, it would no longer be clear what a human actually is.

21. Third, driving Rifkin's fear of the loss of human self-definition is his rather negative view of human nature. In his view, all humans have an innate desire to change themselves from their existing manifestation. In this regard, he views genetic engineering as a representation of "our fondest hopes and aspirations as well as our darkest fears and misgivings." Indeed, genetic engineering are "dream tools" that grant us the power to transform our vision of ourselves and our descendants.[25] It is not clear, however, how he can be confident in this particular conclusion about humanity. It may be that he is driven by a particularly pessimistic view of human self-conception. A more cynical interpretation is that he believes he is endowed with a prescient insight into the human psyche, and consequently bears the responsibility to protect humanity from itself.

22. Fourth, beyond alarm over the prospects of the loss of human self-definition, Rifkin is interested in the preservation of "species integrity" in general. He expresses great concern over the loss of boundaries of separation between species, and has promoted the notion of species integrity, which he defines as the right to exist as a separate, identifiable creature.[26] Rifkin argues that "each creature has a fundamental identity as a member of a particular species . . . [and] animal breeding, without due regard and respect for the nature or 'telos' of an animal, may violate the animal's fundamental nature and convert it into something quite different."[27] Genetic engineering poses a threat never seen before, because, despite the more than ten millennia of domesticating, breeding and hybridizing animals, we have always been constrained by the natural biological limitations imposed by "species borders." Genetic engineering, by transcending the species level to the genetic level, bypasses these species constraints entirely.[28] Thus, there are no longer any built-in biological limits to our ability to alter the genetic blueprint of a species. This, in Rifkin's view, violates the moral and ethical canons of civilization.[29]

23. Sixth, Rifkin fears the loss of genetic variety as a result of genetic engineering. According to him, while biotechnology has significant value to agriculture and pharmaceuticals in the short run, the long term consequence is negative because there will be depletion of certain genetic stock, leading to a loss of genetic variety.[30] This would apparently result from the tendency to preserve certain gene stock through recombination into a desired target strain while eliminating strains with "bad" genes. Because "variety is an essential factor in the gene pool," he worries that the world will become "a monoculture" that is not sustainable.[31]

24. Seventh, Rifkin fears that human life would be devalued by the process of genetic engineering. He predicts that in the age of biotechnology, separate species will no longer be identified by separate names, but rather will be categorized as systems of information "that can be reprogrammed into an infinite number of biological combinations." He anticipates that the biotechnology age will see living beings described as "a very specific pattern of information unfolding over a period of time."[32] He suggests that reduction of human life to a mere bundle of genetic information will make engineering of human life more palatable by virtue of the latter being viewed as simply the engineering of a system of information. Moreover, the notion that life will be viewed merely as information further supports his argument that genetic engineering inevitably desanctifies human life.[33]

25. Eighth, Rifkin worries that society is embracing biotechnology without fully realizing the consequences of doing so. He cautions against assuming genetic engineering technology is a done deal, and implores us--more than two decades after the discovery of recombinant DNA technology--to engage in public discourse about the costs and benefits of embracing this technology. In his view, the question of how high of a price we want to pay for allowing this technology to enter our lives is one that continually haunts us. Thus, he believes the most important issue is to make the technology an issue of public attention.[34]

26. Ninth, compounding his concern that society is blindly accepting genetic engineering technology is his fear that the people who should know better are also blindly doing so. He accuses scientists, corporate leaders and politicians of being seduced by the short-term benefits of the extraordinary power offered by the new technology. Indeed, he believes that these individuals promote the virtues of the technology too enthusiastically, so that even doubters are swept up in momentary excitement. Rifkin suggests that these people should be more mindful of history's lessons in relation to past technological advances. He questions the reasonableness of these individuals' action, because he wonders how any reasonable person could believe the unprecedented power of genetic engineering would be without substantial risk.[35]

27. Tenth, not only does he fear naivete on the part of scientists, he suspects they cannot be depended upon to make the right decisions in adopting the technology. He believes that scientists have a selfish interest in adhering to a purely scientifically-detached view of the notion of "speciesness" and "beingness." Because genetic engineering deals with changing the "natural" state of living entities, he concludes that scientists have a vested interest in not acknowledging any intrinsic value or identity in the species.[36] He expects scientists to count among the special interest groups who have much to gain from the speedy introduction and acceptance of their inventions.[37] It follows, then, that Rifkin does not trust scientists to be the arbiter of what technology is appropriate and what risks it entails.

28. Eleventh, not only does Rifkin not trust scientists to be neutral judges of the appropriateness and costs of their invention, he is concerned that molecular biologists have a critically-flawed value system regarding the world around them. He realizes that many scientists have, and continue to, soundly reject his notion of intrinsic value and speciesness, relegating such thoughts to the realm of "mysticism" that doesn't belong in a scientific debate. Yet, to this day, he insists that it is these scientists who should change how they perceive the natural world; on this point he cites the support of "a growing number" of environmental scientists.[38] Moreover, he asserts that these molecular biologists' value system is completely out of synch with the opinion of the American public.[39]

29. Twelfth, he fears that scientists are repeating the mistakes of Darwinism. Darwinism, according to Rifkin's analysis, is not so much a theory for scientific truth, but rather a view of nature that is "heavily influenced by the prevailing social gestalt of the times," namely the changes resulting from the Industrial Revolution of Charles Darwin's time.[40] Similarly, he fears that present-day molecular biologists are repeating this mistake. They are justifying their intrusion into the genetic code by redefining "an organism as [not] a discrete entity but rather as a temporary set of relationships existing in a fluid context, on the way to becoming something else."[41] Thus, under this new cosmology (view of the world), scientists are able to transform and re-define genetic blueprints of existing organisms without any compunction, because the new cosmology allows them to believe their actions are consistent with the natural order.

30. Thirteenth, Rifkin fears that a specie-less cosmology will be accompanied by a significant philosophical transformation. He expects humanity to reshape its view of existence to coincide with the new conception of how species relationships are organized. In the process, he believes humanity will strive to improve existing organisms and to design wholly new ones that would be more perfect versions of itself.[42] Rifkin's disapproval of this view is implicit in his choice of name for the new cosmology. In naming it "Algeny," he draws a parallel to the ancient belief of alchemy, which was the belief that every metal was continually seeking to transform itself, specifically to become gold.[43] It is not clear, however, why Rifkin seems certain that the new conception of humanity's relationship with the nature around it is necessarily bad. What is obvious, though, is that he prefers humanity to forsake a view that seeks to *dominate* nature for one that endeavors to *work with* nature.[44]

31. Fourteenth, beyond teleological concerns, Rifkin seems also to be fearful of the more tangible consequences of genetic engineering. He argues that the new genetic engineering technologies raise "one of the most troubling political questions in all of human history." That is, who should be entrusted with the authority to decide what is a bad gene that should be eliminated and what is a good one that should be propagated.[45] Extrapolating from this question, he arrives at one of his biggest concerns, that of eugenics.[46] He wonders whether there is anyone who could be entrusted to make genetic determinations for us, and concludes that most of us would not be willing to relinquish control in this regard. He worries, however, that our desire to increase our own personal choices and options in a biological marketplace that is dominated with choices of choosing and enhancing our genetic environment would ultimately result in our placing too much control in the hands of "others."[47] In our eagerness to take advantage of the benefits of genetic engineering, we may end up surrendering our personhood in the marketplace to "others," namely wily entities[48] that possess control of the genetic technologies. What is more fearsome, he evidently thinks, is that biotechnology seems to have a distinct beginning, marked by consumers choosing from among many choices of genetic engineering products and services on the market, but no real ending, in that the end is reached only when every bit of our personhood has been exchanged and we no longer possess "the very thing we were so anxious to enrich – our humanity."[49] Furthermore, he opines that "concepts of nature [can] also serve as essential political instruments for eliciting unequivocal deference and resignation" because authorities can justify their unjust, exploitative or repressive commands by claiming them to be in accord with the natural order.[50] In this regard, it appears that Rifkin is concerned about state utilization of genetic technologies to construct and control the public. For instance, he has argued that gene therapy applications will stigmatize culturally deviant individuals,[51] that genetic information obtained by the tools of biotechnology can be used to discriminate based on genetic profile,[52] and that genetic engineering could lead to eugenics as manifested in creation of a people with selected and desirable traits.[53]

III. Rifkins Efforts Against Recombinant DNA Research

A. At The RAC – Rule And Policy Making

32. In 1984, Jeremy Rifkin submitted a groundbreaking proposal to the Recombinant DNA Advisory Committee (RAC) of the National Institutes of Health.[54] This proposal was subsequently debated at a RAC meeting on October 29, 1984. At this meeting, Rifkin had the opportunity to debate his proposal with RAC members.[55] The juxtaposition of his position against that of scientists as elaborated in letter comments and statements made by RAC members provided an illuminating glimpse into Rifkin's rationale for opposing genetic engineering. This proposal represented one his earliest significant efforts to thwart the progress of genetic engineering technology.

1. The Proposal

33. In response to NIH and NSF-funded experiments (performed by Ralph Brinster at the University of Pennsylvania) in which human genes regulating the growth hormone were being injected into sheep and pig embryos for the express purpose of incorporating the human genes permanently into the germ line of these mammalian animals, Rifkin proposed an amendment to the NIH guidelines for recombinant DNA experiment. He claimed that the germline transfer experiments represented only the second time in history that a portion of the genetic complement of humans was being transferred into the genetic code of another species.[56] He proposed that the NIH prohibit any experimentation involving the transfer of a genetic trait from one mammalian species into the germ line of another unrelated mammalian species; "unrelated" was to be defined as any two species that cannot mate and produce one generation of offspring either in the wild or under pre-existing domestic breeding programs. The guideline was to encompass all mammalian species, including homo sapiens. The agency was immediately to discontinue funding all experimental research involving the transfer of genetic traits from one mammalian species into the germ line of another unrelated mammalian species and instruct all institutions receiving NIH grants that any such experimentation using private funds would be grounds for the immediate suspension of all NIH research grants to the institution. In addition, all private companies signatory to license agreements with NIH-funded institutions were to be bound by the NIH prohibition as well.[57]

34. Rifkin's stated purpose for the prohibition was the protection of the biological integrity of every mammalian species, which, in his opinion, was a goal already reflected in the policy underlying many then-existing federal statutes.[58] He argued that crossing of species borders and incorporating genetic traits from one species directly into the germ line of another represent a fundamental assault on principles of species integrity and constitute a violation of every species' right to exist as a distinct creature.[59]

35. Rifkin further argued for symmetrical treatment of human and non-human species. He claimed that since most human beings would condemn attempts to introduce animal genes permanently into the germ line of humans as a "gross and unconscionable" breach of our telos as a species, his proposal would establish the counterpart principle that experiments involving transfer of foreign genes into non-human species would violate the telos of the transferee species, and would therefore be "morally reprehensible."[60]

36. Not wishing to stop at mammalian species, he wanted the same principle of species integrity to apply to non-mammalian species as well. Therefore he asked that the RAC establish a working sub-group to propose additional protocols or guidelines necessary to ensure compliance with "the spirit" of his proposal in regard to the protection of the germ line of *all* species.[61]

37. In a subsequent letter (following the first letter describing his proposal) to the NIH, Rifkin submitted an additional item for placement on the agenda of the RAC to be debated in conjunction with his original proposal. The amendment proposed NIH prohibition of germline genetic transfer between *human beings* specifically and other mammalian species. It is not clear why Rifkin thought it necessary to emphasize experiments involving human beings in particular when his original proposal relating to mammalian species generally by definition included humans.[62]

38. Interestingly, the proposed amendment ended by having the NIH declare experimentation involving the transfer of genetic traits between animal and human germ lines to be "morally and ethically unacceptable." This injected an explicit non-scientific, non-objective consideration into the debate about genetic transfer experiments.[63]

39. At the RAC meeting on October 29, 1984, Rifkin further explained the reasoning behind his proposal. He stated that while closely related species may be bred by traditional breeding means, nature limited what could be accomplished, because "species walls [and] mating boundaries establish some limits as to the kind of recombination that may occur through natural methods." He argued that gene transfer from one mammalian species into another species is qualitatively different from these traditional breeding programs.[64]

40. In Rifkin's view, the unit of manipulation in genetic engineering experiments is the gene itself, whereas the biological unit in the past was the organism. Thus, with genetic transfer, the unit of importance has ceased to be the species itself. He saw this as society's long and protracted journey towards a reshaping of its concept of life so that increasingly the importance of life is viewed at the genetic, rather than species, level.[65]

41. Rifkin accused scientists who argued that the gene transfer experiments were not unique, but rather were simply a chemical transfer, of engaging in a form of scientific reductionism. He reasoned that if a gene is viewed simply as a chemical, then every other gene that makes up the human species would also simply be a chemical. He worried that this would be a slippery slope approach that could lead to a point when it is too late (he suggested this to be the point when the animal takes on human characteristics) to ask the necessary and appropriate questions about these experiments.[66]

42. Contradicting his own demand for prohibition against gene transfer between human and non-human species, he also implored the RAC to develop criteria for determining what human genes should or should not be transferred into other species. He warned that if the RAC failed to do so, all human genes could potentially be transferred to other species for short-term medical or economic benefit. This possibility, he contended, would pose a major ethical and policy question. In support of his contention, he noted that several scientists, such as the noted then-director of the Whitehead Institute at the Massachusetts Institute of Technology, Dr. David Baltimore, agreed that some ethical questions could arise in experiments involving gene transfer from other species into the human germ line. Rifkin reasoned that if such experiments posed ethical problems, transfers from humans to other species should similarly be ethically problematic.[67]

43. Rifkin concluded his presentation to the committee by chastising scientists for thinking that the American public was not educated and that they could not possibly understand all the complex questions raised by the technology and for claiming that any fears were unfounded. He reminded them that genetic engineering is the most powerful instrument capable of changing the biology of the planet humankind had ever had, and so the American public has every right to believe there would be ethical and social questions at each stage of the development of the technology. In his view, the experiments he was addressing represented a fundamental precedent stage. Thus, a committee vote against his proposal would be tantamount to a declaration that there was no ethical problem with proceeding with genetic trait transfer between species, and that that would be the accepted policy of the United States Government.[68]

2. Response to Proposal

44. Prior to the RAC meeting, a total of 359 letters with 433 signatures opposing Rifkin's proposal were received from the general public, scientists and organizations. One letter with 1 signature supported it. These letter comments and the comments of RAC members in response to the proposal were directed at several distinct issues.[69]

45. There was great concern that important medical research should not be impeded. Commenters suggested that the proposal would cause the discontinuance of important medical research relating to genetic disorders, cancer and other diseases, and thus limit the search for a cure for genetic problems. Some pointed out that there was a need for people born with good health to help those less blessed than they were, and one way to help would be through research. Others pointed out that the proposal would prevent patients with autoimmune and genetic diseases from availing themselves of treatment (presumable involving gene therapy) down the line when future understanding showed safe ways to prevent such sufferings and loss of life.[70] Still others noted that since knowledge from medical research is valuable to society, any prohibition required substantial justification, which was deemed lacking in the proposal.[71] It was pointed out that animal experimentation necessarily precedes human trials for any kind of gene therapy treatments.[72] One even went so far as to declare that the practical benefits of the type of research covered by the proposal were so unquestionable and irrefutable that it was absurd even to consider that they should be outweighed by the "putative discomfort to a small number of laboratory animals."[73]

46. Interspecies genetic transfer is an important medical research tool. One commentator pointed out that only when a gene is injected into germ cells can the effect of the gene be seen in an entire organism, and only when a human gene has been injected into another mammal can the embryological actions of a human gene be elucidated. This is because such transfers are often a necessary part of protocols designed to understand how inserted genes behave in host organisms; if the gene is not foreign to the host species, its activity cannot be distinguished from that of the host.[74] Indeed, interspecies gene transfer experiments were the only means available at the time for studying gene regulation and the development of complex systems such as animals and humans.[75]

47. Critics of Rifkin asserted that the American public wanted genetic engineering research to continue. A number of RAC members pointed to the overwhelming public response to the proposal. One commentator suggested that the American public had expressed its view on the subject, calling attention to the several hundred letters from individuals opposed to the proposed prohibition.[76] One member noted the overwhelming public response to the Federal Register announcement of the proposal, which is particularly unusual in light of past difficulty in obtaining public response to any type of announcement seeking comments. She argued that this suggested that many in the country deemed the type of research in question to be extremely important.[77] Moreover, the responses were from a broad range of the society, including the general public; high officers of academic and research institutions in not just the sciences but also in the humanities and law; from private foundations dedicated to improvement of human welfare; from organizations and individuals interested in animal welfare and food production; and from individual citizens concerned about the future prospects for solving presently incurable health problems.[78]

48. Some commenters denied that inter-species genetic transfer violated species integrity. They argued that one or a few genes are not sufficient to violate the integrity of a species. This is because individuals within species possess only a portion of the gene pool of the entire species, and the gene pool is in constant dynamic evolution, with gains and losses of genetic variation. Thus, introduction of "new" genetic material into a species would actually aid in the species' survival (through genetic evolution) rather than harm it.[79]

49. Others argued that there is no basis for the notion of "species integrity." A number of individuals insisted that there was no evidence to support any inviolate principle of species integrity. They argued that there is a great commonality of genetic material among the species, and in fact inter-species genetic transfer occurs naturally, albeit rarely. Moreover, genes are merely parts of systems and the same genes from different species are often virtually identical. For example, genes of humans and dogs are not imprinted with human or canine qualities.[80] Indeed, some argued that the only "telos" (as Rifkin argued exists for every species) a species can have is "extinction." In support of this argument, they contended that genetic studies have repeatedly confirmed that the genetic makeup of organisms within a species is continually changing through natural processes and that genetic plasticity is a fundamental property of living beings.[81] One RAC member went so far as to say that it had been "utterly impossible" for the RAC even to arrive at a definition of a species, since species are constantly evolving. Another questioned whether the notion of preserving mammalian species would ultimately have to lead to a consideration of the "telos" of bacteria and viruses as well (which presumably is unreasonable since these are entities that are the common causes of diseases and, consequently, the targets of eradication efforts).[82]

50. A commentator also pointed out that gene transfer efforts were merely extensions of traditional breeding activity. He argued that genetic changes by modern methods were merely faster and more precise alternatives to conventional breeding and selection programs.[83]

51. In several *ad hominem* attacks, Jeremy Rifkin was accused of possessing a flawed character. A number of individuals attacked Rifkin's integrity. They wondered if his view of morality was "sorely limited" since he was seeking a blanket prohibition of genetic research on moral grounds, and yet did not seem to consider the morality of allowing human genetic abnormalities, some of which cause great misery, to go unstudied when the tools to study and possibly treat them were available.[84] The then-Commissioner of the FDA even went so far as to accuse Rifkin of engaging another "highly contrived" issue consistent with his character as someone "whose nuisance to substance ratio is high."[85] He was also chastised for behaving irresponsibly in ignoring all that was known about genetics and evolution, and for having engaged in obfuscation of issues. He was further accused of opposing clearly enumerated benefits of the technology with "unsupported, mythical fears of risks."[86] Finally, he was faulted for engaging in hyperbole and scaremongering through catch phrases uttered and written to engender public fear and garner media attention with "almost McCarthy-type tactics."[87]

52. The RAC committee insisted that it did not ignore public opinion. One RAC member vehemently refuted Rifkin's assertion that RAC ignored the public, noting that public members had long been part of RAC's composition and that RAC had actively sought public participation in its deliberations. On the contrary, he said, it was Rifkin who "underestimate[d] the intelligence and knowledge of the public."[88]

53. Finally, it was asserted that the existing guidelines were adequate. One committee member responded to Rifkin's accusation that RAC tended always to give permission for experiments to proceed. He pointed out that this may have seemed to be the case only because NIH procedures had previously permitted local institutional committees and review boards to approve human gene therapy protocols without RAC review and NIH approval. However, the NIH Guidelines had since been reviewed to require a much more rigorous process of *national* review.[89] Thus, the committee member seemed to be asserting that Rifkin's accusation was unfounded, since the RAC had simply not been involved in the approval of many past gene engineering experiments.

3. Rifkin's Response

54. In response to a motion for the RAC to reject the proposal, Rifkin sounded a rare conciliatory tone. He acknowledged that RAC members were well-intentioned, for they would not be part of the medical research community if they did not think they were trying to improve the welfare of humanity.[90] He empathized with the difficulty for any profession to critique itself, but asked the members to examine their world view before making any "hasty" decisions. He suggested that they re-evaluate their modern science assumptions and consider that other people may not share their world view.[91]

55. He went on to reiterate his belief that the technology at hand was so powerful that the consequences and risks had to be acknowledged, lest the costs be heaped on the ecosystem and future generations. He implied that it was either naïve or disingenuous to believe there were no risks and no costs associated with the biotechnology revolution. He felt it unreasonable that the scientific community should be given full license at every juncture to pursue any kind of research in any area. In response to RAC members' argument that impeding biotechnology research would lead to continued human suffering, he argued that such an assertion suggested a syndrome of fear. He questioned how RAC could "prematurely" conclude that the long-term benefits outweighed the risks when only a few gene transfer experiments had been carried out. He asked for a moratorium on this type of research until a time when the relevant questions were being properly addressed by the American public.[92]

56. On a final note, Rifkin suggested that the letters that had been received and quoted by the committee on his proposal were not representative of an accurate cross-section of the American public.[93] Thus, he implicitly held onto his belief that his views were the more reflective of those of the masses.

4. RAC's Counter-Response

57. The committee bristled at Rifkin's characterization of their attitude toward gene transfer experimentation. They first suggested that Rifkin had either misunderstood or miscontrued their comments. They maintained that rather than suggesting there were no problems associated with the experiments in question, they were merely following an orderly process of consistently exercising care and prudence in approaching the utilization of recombinant DNA technology. Moreover, they insisted that most of them had not spent just "one hour" considering the issues at hand, as Rifkin had suggested, but rather had been thinking about them for years. It was simply that they recognized there were risks associated with any new technology, and that a total prohibition would prevent their ever learning whether the potential risks were real or mythical.[94]

58. Moreover, they argued that total prohibition in the United States would not stop such research from being performed elsewhere. Such attempts at prohibition had not apparently ever worked, and thus the RAC should continue to evaluate such experiments, so as to allow the United States Government to maintain its control over them.[95]

59. The RAC refuted Rifkin's contention that its world view consisted only of seeing the benefits of biotechnology whereas he was singularly willing to point out the potential risks. On the contrary, one member said, the difference between Rifkin and the RAC was that, seeing both the risks and benefits, Rifkin chose to prohibit seeking the benefits whereas the RAC would prefer to continue with maximizing benefits while minimizing risks.[96] Another member wondered how a social problem (risk) could be successfully solved before the technological means was developed to address it.[97]

60. Finally, one RAC member expressed frustration with Rifkin's insatiable appetite for opposing biotechnology research. The member noted that as soon as one his concerns was allayed, another concern surfaced. He suggested that Rifkin was attempting to arrest a process that had been spectacularly successful.[98]

5. Outcome

61. The RAC voted down the proposal by a unanimous vote.

B. Lawsuit

62. Failing to persuade the NIH to change its stance on genetic transfer research, Rifkin, through FET, filed a lawsuit to enjoin research of this nature. The defendant in this suit was the USDA because of its funding and facility support for the experiments.[99]

Foundation on Economic Trends v. Block*[100] *-- The "Animal Productivity Research" Case -- District Court

63. The plaintiffs claimed that the USDA violated the NEPA by failing to prepare an environmental impact statement on its animal productivity research, which included the very genetic transfer experiments being performed by Ralph Brinster that had instigated Rifkin's proposal for prohibiting NIH support for such research.[101] They argued that the USDA's decision to focus its animal productivity research on developing faster growing, more productive, and larger animals required an analysis of the resulting environmental impacts, and thus an impact statement was necessary and should have been considered in the development of the USDA research program. The complaint alleged that the USDA's research program had or would have significant environmental, economic, and social impact through forcing dislocations in the farm economy, affecting the gene pool of farm and food animals, and polluting the air and water. The plaintiffs sought declaratory relief that the USDA had violated the NEPA[102] by preparing neither an environmental assessment nor an environmental impact statement[103] in connection with its research program (which included recombinant DNA experiments). They also sought a finding against the defendants for violation of the Administrative Procedures Act through acting arbitrarily and capriciously in not considering alternatives to its research programs for improving animal productivity.[104]

64. The Court concluded that the USDA's research activities did not constitute a "proposal for legislation or other major Federal action significantly affecting the environment," and therefore neither an environmental assessment nor impact statement was required. It granted summary judgment to the defendants.[105]

Foundation on Economic Trends v. Lyng*[106] *-- The "Animal Productivity Research" Case -- Appellate Court

65. The Appellate Court affirmed the lower court's summary judgment, but on different grounds. It found no need to determine whether the USDA program posed a significant impact to the environment because it did not even constitute a proposal for action that required an NEPA impact statement. It further noted that the plaintiffs' real objection related to the objectives of the scientific research being performed by the USDA. [107] It concluded this to be the case despite the plaintiffs' insistence that they were not objecting to selective breeding technologies per se, nor to pathbreaking research projects involving the use of recombinant DNA techniques, but rather were simply saying that an impact statement was required to evaluate the goals of animal productivity research that is focused on developing faster growing, more productive, and larger animals.[108] It is tempting to speculate that the Court was wary of the plaintiffs' real objectives in filing the lawsuit: to use procedural maneuvers to block all biotechnology research.

1. Other Litigation Against Biotechnology Research

66. From the mid-1980's to the 1990s, Rifkin filed a series of legal challenges against the USDA, NIH and EPA (and later the FDA), actions that directly or indirectly related to biotechnology.

67. The motivating factor for these lawsuits, in his own words, was that federal regulators were not interested in listening to his viewpoint until "[the] interest [was framed] by forcing public policy to deal with court decisions." Underlying this cynical view of the federal authorities was his belief that the government was simply not ready (or willing) to regulate biotechnology.[109] Relatedly, he felt that the lawsuits would serve as "educational tools to get discussions [about assumptions and intentions underlying biotechnology] going . . . before the technology [came] on line." Perhaps most importantly, as some would argue, he knew the lawsuits "[drove the] industry nuts."[110]

68. Not surprisingly, advocates of biotechnology did not have a charitable view of Rifkin's motivations for the legal challenges. They believed that Rifkin, after having failed "to intimidate" the NIH into prohibiting genetic engineering research, had decided to turn to the EPA and USDA, which are softer targets by virtue of being more politically vulnerable. They suspected that Rifkin's lawsuits (based always on procedural technicalities) were motivated by a broader purpose, namely to engage in "a war against all genetic engineering," rather than seeking merely to ensure that scientists not ignore federal biotechnology regulations.[111]

2. Cases Involving "Deliberate Release of Genetically Engineered Organisms"

Foundation on Economic Trends v. Heckler*[112] *-- District Court

69. This case arose from the NIH's decision to permit the first government-approved release of a genetically engineered organism into the environment. In the early 1980s, University of California researchers modified a bacterium that in its naturally-occurring state has the ability to nucleate ice crystals. The modification, achieved through recombinant DNA technology, resulted in deletion of the genetic code that normally confers the bacterium's ice-making trait. Upon approval of a field test of the modified bacteria involving its deliberate release into the environment, Jeremy Rifkin, through the FET, filed for an injunction against the experiment until such time as the NIH had conducted and published an environmental impact statement. [113]

70. The District Court addressed the plaintiffs' complaint that the NIH had failed to issue appropriate environmental impact statements as required by NEPA and in conformity with the regulations of the Council on Environmental Quality.[114] The gist of the plaintiffs' complaint was that a revision of NIH Guidelines in 1978 to permit deliberate release experiments and the authorization of such experiments constituted a "major federal action." It deemed NIH's failure to precede the action with a documented "hard look" at the environmental implications of that action to be tantamount to an NEPA violation.[115] In deciding whether there was a likelihood of plaintiffs succeeding on the merits, the Court concluded affirmatively on all three issues before it. It found that the NIH had not fulfilled its NEPA obligations when it failed to (1) issue an

environmental impact statement for its 1978 revision to the NIH Guidelines which provided authority to permit deliberate-release experimentation by NIH grantees;[116] (2) issue any broad, programmatic environmental impact statement[117] addressing the general environmental issues presented in NIH approval of deliberate release experiments; and (3) issue an environmental assessment or an environmental impact statement addressing the specific environmental issues associated with the first deliberate release experiment to be conducted under the 1978 revised NIH Guidelines. Consequently, the Court granted a preliminary injunction against the NIH from approving or continuing to approve experiments involving deliberate release of recombinant DNA organisms. It also enjoined the University of California from proceeding with the deliberate release experiment that the NIH had approved.[118]

Foundation on Economic Trends v. Heckler*[119] *-- Appellate Court

71. The decision of the District Court was appealed to the U. S. Court of Appeals of the District of Columbia Circuit. The Appellate Court affirmed in part and reversed in part.

72. The Court affirmed the lower court's injunction against the University of California experiment. In holding so, it went to some length to emphasize its concern about the environmental risks that may result from such experiments (although it did refrain from explicitly saying that it believed there was a likelihood of these risks materializing). It implored the NIH to attempt to evaluate seriously the risk that emigration of the genetically engineered organisms from test sites would cause ecological disruption, and suggested that until such an evaluation was completed, the questions of whether an environmental impact statement was required would remain open. It pointed out that one criterion for determining whether such a statement was required was "the degree to which possible effects on the human environment are highly uncertain or involve unique or unknown risks.[120] Thus, the Court here was quite explicitly in agreement with Rifkin's concerns.

73. On the other hand, the Court vacated the lower court's injunction against NIH's approval of *all* deliberate release experiments. It found that the district court's focus on the 1978 NIH Guidelines revision as a basis for an injunction and requiring an environmental impact statement was inappropriate. It further found that, while it thought a programmatic statement would be helpful, it was not certain as a matter of law that plaintiffs would succeed in showing that the absence of a programmatic statement was a violation of the NEPA and the Council on Environmental Quality's regulations.[121]

74. Unfortunately for Rifkin, he was excoriated in the concurring opinion. The concurring judge stated that the plaintiffs should have brought its original concerns directly to the NIH. He noted that the Court would "undoubtedly have had a better record [available to it in the case] if the Foundation on Economic Trends had not failed to raise its objections while the matter was pending before the [NIH]." He pointed out that public comments were solicited through the Federal Register, but none were forthcoming from the FET. He conjectured that had the FET voiced its objections to the NIH, it was more than likely, "given the demonstrated sensitivity of NIH and its scientists to such matters," the defendants would have responded to any objections. He further blamed the FET's conduct for delaying the vital experiments in question for "a very considerable period of time," and submitted that "the use of delaying tactics by those who fear and oppose scientific progress [was] nothing new." Furthermore, the judge worried that a "national catastrophe" would result should the development of the promising technology of genetic engineering be "crippled by the unconscionable delays . . . brought about by litigants using the [NEPA and other environmental regulations]."[122]

Foundation on Economic Trends v. Thomas*[123] *-- The "Ice-Minus Bacteria" Case

75. The plaintiffs sought an injunction against the EPA's issuance of an experimental use permit to Advanced Genetic Sciences, Inc. (AGS); the permit authorized AGS to conduct a field test of bacterial strains[124] similar to the ones used by the University of California in *Foundation on Economic Trends v. Heckler*.

76. Prior to the filing of this lawsuit, the FET had challenged the EPA's initial scientific position that the AGS experiment did not present foreseeable risk. The FET questioned the agency's conclusions about the bacteria's novelty, competitiveness, pathogenicity, and atmospheric impact.[125] After responding to the FET's concerns, the EPA proceeded with granting the permit. The plaintiffs, not satisfied with the EPA response, responded to the permit grant by filing suit the same day, alleging that the agency action violated the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and was arbitrary, capricious and an abuse of discretion.[126] Among other complaints, they contended that the EPA improperly waived certain data submission requirements for AGS in their permit application, and that the agency did not adequately consider the potential pathogenicity and toxicity of the bacteria, the likelihood of its dissemination and off-site reproduction, and the impact of release on atmospheric precipitation patterns.[127]

77. The court denied preliminary injunction. It found the plaintiffs had not made a strong showing that the EPA had acted in an arbitrary and capricious manner in arriving at its decision to grant AGS the permit.[128]

Foundation on Economic Trends v. Thomas*[129] *-- The "Financial Requirement" Case

78. In this suit, the plaintiffs (FET and Jeremy Rifkin) sought an order to require the EPA to modify its procedures for authorizing release of genetically engineered pesticides into the environment. They argued that the EPA should have promulgated regulations requiring documentation of financial capability to redress and abate any potential harms that may result from such releases on the part of the persons granted an experimental use permit (see *supra*, the "Ice-Minus Bacteria" Case) to perform such experiments.[130] The plaintiffs had previously petitioned the EPA to promulgate, through rulemaking, regulations establishing "minimum financial responsibility standards" to be required of applicants for these permits. They had argued that the risks posed by environmental releases were potentially devastating, and that the EPA did not have an adequate program for assessing, controlling, and assuring remedial actions and accountability for the environmental risks presented by the deliberate release of genetically engineered organisms.[131]

79. Without addressing the merits of the case, however, the Court dismissed the case for lack of standing on the part of the plaintiffs. For the Foundation on Economic Trends, it found that the plaintiff's alleged injury to its informational and educational functions was insufficient because the interest was not within the zone of interests to be protected or regulated by FIFRA.[132] For Jeremy Rifkin, it found his allegation of injury to his use and enjoyment of "the environmental resources of the United States," which substantially depended on "the ecological and genetic diversity and biological integrity of thousands of wild plants and animals . . . and of many domesticated plants and animals, and the stability and visibility of the biosphere which sustains them,"[133] to be "wholly abstract" and of "at most a hypothetical interest."[134]

3. Cases Involving Other Biotechnology Research Experiments

***Foundation on Economic Trends v. Lyng*[135]**

80. The plaintiffs sought to suspend and revoke the license defendants had issued permitting marketing of a pseudorabies vaccine. Prior to the lawsuit, the USDA Animal & Plant Health Inspection Service, which controls the production and marketing of veterinary medicines including vaccines through a licensing process under the Virus-Serum-Toxin Act (VSTA), had granted the license without preparing an environmental assessment or impact statement. Upon petition by the Foundation on Economic Trends (plaintiffs) to revoke or suspend the license, the agency suspended the license and prepared an environmental assessment which concluded that the licensing of the virus would not have a significant impact on the environment. The plaintiffs immediately followed this conclusion by filing this lawsuit, claiming that the defendants had violated the VSTA and NEPA (by performing an inadequate environmental assessment).[136]

81. The VSTA claim was dismissed for lack of standing on the narrow ground that the plaintiffs had failed to show specificity of resource, use, enjoyment and injury.[137] On plaintiffs' claim that the NEPA environmental assessment was inadequate, the Court ruled in the defendants' favor, finding that the agency's conclusion in the environmental assessment that the licensing of the vaccine posed no significant impact was "not arbitrary and capricious" and thus was adequate. In doing so, it noted that "some of the testing 'deficiencies' FET [had recounted] reflect[ed] the nascency of the field of genetic engineering rather than truncated examination of the [vaccine] by the agency."[138] Thus, in this case, the Court signaled its concurrence with the position of biotechnology advocates on a critical point of contention between anti and pro-biotechnology parties, namely whether the practical inability to assess unknown risks should prevent the continued engagement of genetic engineering research.

Foundation on Economic Trends v. Lyng*[139] *-- The "USDA Germplasm" Case – District Court

82. This lawsuit sought an injunction and a declaratory judgment against the USDA requiring it to prepare an environmental impact statement with respect to its germplasm preservation program.

83. The Court ruled against the plaintiffs on the ground that they had not identified any proposals for major federal action significantly affecting the quality of the human environment for which the NEPA would require an impact statement.[140]

Foundation on Economic Trends v. Lyng*[141] *-- The "USDA Germplasm" Case – Appellate Court

84. On appeal, the Court affirmed the lower court's decision on a procedural ground. Instead of deciding on the merits, as the District Court had done, it found that the plaintiffs lacked standing to sue. The plaintiffs had claimed "informational standing," which was a broadly-defined basis for standing that in some cases had been available to organizations engaged in disseminating environmental information.[142] Fearing that allowing broad availability of informational standing would eliminate any standing requirement at all in NEPA cases, the Court held that alleging "information" injury without identifying a particular agency action as the source of the injury is insufficient to gain informational standing. In this case, the Court found that the plaintiffs had failed to identify an agency action amounting to a "major federal action" in the USDA's germplasm activities.[143] Thus, while basing its holding on a procedural (standing) ground, the Court in fact also addressed the issue of merit on which the lower court had ruled against the plaintiffs. This decision was more damaging to the plaintiffs than it would initially appear, because by dismissing the case on the technical ground of standing, the Court appeared to be signaling that it wished henceforth to restrict access by such plaintiffs to the courts for litigation of similar issues on which the plaintiffs had previously been successful.[144] Indeed, there is supporting language in the opinion alluding to just such an intention; the Court noted with approval the lower court's contention that the plaintiffs were seeking "judicial involvement in day-to-day decision-making of the USDA."[145]

***Foundation on Economic Trends v. Weinberger*[146]**

85. The plaintiffs sought to enjoin the construction of a proposed "Aerosol Test Facility" and "Toxic Agent Test Support Facilities" by the Department of the Army. They contended that the defendants had failed to comply with NEPA requirements by failing to prepare an environmental impact statement. The defendants argued that such a statement was not required under the circumstances because they had made a legally adequate and factually supported finding of no significant environmental impact (in an environmental assessment).[147] The plaintiffs contended that, contrary to the defendants' disclaimers, recombinant research geared towards biological warfare would be performed at the proposed new facilities.[148] In their view, recombinant DNA research is precisely the type of "new and expanding technological advances" that concerned the drafters of the NEPA. Therefore, the scope of the proposed federal action was in fact broader than that which the Army had contemplated in its assessment finding no significant environmental impact (and hence no requirement for an impact statement).[149] The defendants countered that while testing of new types of toxins and biological agents had been contemplated, it had not actually been proposed, and thus no affirmative proposal to use recombinant DNA had been made.[150] The Court held against the defendants, finding that the Environmental Assessment[151] published by the Army was "clearly inadequate" because it was merely "an amalgam of conclusory statements and unsupported assertions of 'no impact'."[152] While agreeing with the defendants that they had not proposed the use of genetically-altered material at the facilities, the Court nonetheless believed potential risks to the environment remained, declaring, "Pathogenic agents and toxins, as well as non-pathogenic . . . microorganisms, will be used in the . . . facility . . . [and the] possibility of an accident involving personnel, or exposure to the outside environment, while low in probability, [do] exist. Clearly the risks are serious and far-reaching . . . and could produce extraordinary, potentially irreparable, consequences."[153] However, it is unclear whether, in expressing its concerns so explicitly, the Court was mainly persuaded by the extreme nature of the recombinant DNA materials involved (those of the biological warfare variety) or was influenced and convinced by the plaintiffs' contentions.

C. Efforts Against Biotech Research Through Opposing Biotechnology Patents

1. Litigation

86. Jeremy Rifkin, through the Peoples Business Commission (the precursor to the FET), filed a major amicus brief in the nation's first Supreme Court case on patenting genetically engineered forms of life.[154] Rifkin's reason for opposing patenting in this instance was probably several-fold. He correctly perceived that if scientists could patent their genetic engineering products, and thus obtain property rights to them for the patent duration, it would be a great incentive for the continued development of commercial biotechnology. Moreover, the granting of these patents would lend an aura of legitimacy to recombinant DNA work and its resultant products. Finally, granting a patent on a life form would be antithetical to his belief in species integrity and sanctity.

87. The case, *Diamond v. Chakrabarty*,[155] involved the patenting of a bacterium that had been genetically altered to break down petroleum. In his amicus brief, Rifkin presented three main arguments for opposing the grant of a patent for this bacterium.

88. First, he argued that the experience in the single area in which Congress had specifically authorized the patenting of living organisms, namely through the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970, showed that the patenting of any life form necessarily led to genetic and social impacts that were contrary to the society's best interests. In support of this contention, he stated that plant patents had led to the systematic elimination of many plant and crop varieties that were not patentable by virtue of being merely products of nature; with the loss of genetic diversity, monoculturing becomes the dominant reality. Moreover, plant breeding had become such a lucrative endeavor that there was an increasing concentration of basic plant food supply ownership in the hands of a small number of large multinational corporations.[156]

89. Second, he contended that the technology of genetic engineering, taken as a whole, was not in the public interest. Pointing to the unknown and potential risks of biotechnology, he argued that the public interest would be endangered by the "[irreversible pollution of] the planetary gene pool in radically new ways" as a result of the proliferation of genetic engineering techniques and novel life forms.[157]

90. Third, he argued that the patenting of lower organisms would invariably lead to the patenting of higher forms of life. In support of this argument, he reasoned that recombinant DNA techniques will eventually lead to genetic engineering of higher life forms (than bacteria), including humans, for which patenting will have to be allowed based on the same rationale for allowing patenting of the bacterium in this case. This, he pointed out, would raise moral and ethical issues involving a determination of "the very nature of life" itself. [158]

91. The Supreme Court ultimately held, by a 5-4 vote, to allow the patenting of the bacterium. Even so, Rifkin drew solace in the observation that the justices viewed their decision as a narrowly construed one. He noted Justice Burger's reference to "the gruesome parade of horribles" outlined in his amicus brief as the latter explained that the Court's decision was based on a logical interpretation of existing patent law and was not intended to address the larger social issues surrounding the genetic engineering of life.[159]

2. Out-of-Court Opposition

92. Besides participating in legal challenges to the patenting of genetically engineered life forms, Rifkin was also responsible for assembling major coalitions aimed at drawing attention to the issuing of such patents. In May of 1994, a coalition of hundreds of women's organizations from more than forty nations announced their collective opposition to the attempt by Myriad Genetics, a U.S. biotechnology company, to patent the discovery of a breast cancer gene. The next year, Rifkin organized a coalition of more than two hundred religious leaders, from a broad range of denominations and faiths, which announced its opposition to the granting of patents on animal and human genes, organs, tissues and organisms.[160]

IV. Rifkin's Efforts Against Biotechnology Products - Bovine Somatotropin

93. On November 5, 1993, the FDA approved the use of a genetically engineered form of a bovine growth hormone (rBST) in dairy cows. This event sparked a series of high-profile protests that eventually culminated in court challenges. By this time, Rifkin's reputation as an anti-biotechnology activist was well-established. Not surprisingly, he immediately galvanized a broad grass-roots campaign to oppose rBST. rBST represented the culmination of the technology of genetic engineering in that it was the first genetically engineered product to be commercially marketed. It thus represented the end product of the process the progress of which Rifkin had been fighting to block throughout the previous decade.

94. rBST, the acronym for recombinant bovine somatotropin, is the genetically engineered version of bovine growth hormone, which is a naturally occurring protein that cows ordinarily produce to direct nutrients toward milk production.[161] Prior to the arrival of genetic engineering techniques, the process of administering the hormone to cows to induce lactation relied on injecting growth hormone-containing tissue extracts from dead cows into live cows. The inefficiency of this method precluded large-scale commercial use of the hormone.[162] The arrival of biotechnology changed this situation; genetic engineering techniques allowed for easy and mass production of purified rBST that appeared to function similarly as natural BST.[163] Among the four major U.S. corporations that competed in the 1980s to develop recombinant BST, Monsanto was the eventual victor, after investing $800 million in product development alone.[164] Monsanto's rBST, Posilac, reportedly yielded a 15% to 25% increase in milk production.[165]

95. The FDA began its review of the safety and efficacy of rBST in 1984,[166] and finally approved its use in commercial applications on November 12, 1993, after over 120 studies had been evaluated. It declared that milk from treated cows was indistinguishable from milk from untreated cows, and therefore would not have to be labeled.[167] Congress accepted the FDA judgment in full.[168] Milk, thus, became the first food that the U.S. Government allowed to be produced using a genetically engineered drug.

96. The FDA subsequently issued interim guidelines warning producers who label milk as coming from untreated cows to ensure that those labels were neither false nor misleading. It reasoned that since all milk contains natural BST, labels that said "BST-free" would be false and potentially misleading. Whether a label would be false or misleading would largely depend on the context in which terms such as "BST-free" appeared on the label. Thus, the FDA guidelines suggested that labels indicating milk from untreated cows also include disclaimers that state, for instance, that "[n]o significant difference has been shown between milk from rBST-treated and non-rBST-treated cows."[169]

97. Jeremy Rifkin, leading an organization called the "Pure Food Campaign (PFC)," immediately denounced the use of rBST in agriculture, the commercial sale of milk from rBST-treated cows and the FDA's decision not to require labeling. Turning his attention from opposing research involving recombinant DNA, he began earnestly to oppose *products* involving the technology. He viewed rBST as a "test product" and "the key" to stopping the progress of biotechnology.[170] He predicted the fight against rBST to be a "battle that may take years"; he was "determined [that as the first genetically engineered product, rBST would] be dead on arrival."[171]

98. Rifkin demonstrated his talent at generating activist fervor by building a coalition of groups representing a broad range of concerns. His PFC was joined by the Consumers Union, the Humane Society, the New Council on Food Safety[172], organic farmers and restaurateurs,[173] among others.

99. The concerns of Rifkin and his fellow activists were wide-ranging. First, despite FDA assurances to the contrary,[174] they had health worries about rBST. The primary concern stemmed from the incidence of mastitis among rBST-treated cows, which they claimed was 79% higher than normal. This, they feared, would lead to greater usage of antibiotics, which would stay in milk that was eventually consumed by humans; they reasoned that human consumption of the antibiotic residues would lead subsequently to ineffectiveness of these antibiotics against bacteria that affect humans.[175] A second health concern was that residues of rBST would appear in milk and cause allergic reactions in humans.[176] They also contended that rBST would raise the level of IGF-1, an insulin-like growth factor, in the milk of treated cows, and feared that this factor might interfere with human metabolism and growth.[177]

100. Besides health concerns, the activists also protested the economic effects of rBST use on small dairy farmers. They claimed that the benefits of this expensive drug would accrue only to farmers with larger farms who would be the ones able to afford it.[178] Furthermore, they predicted that any further increase in milk production due to rBST would further depress the already-beleaguered dairy industry through driving down prices in a market characterized by milk surplus and government price subsidy.[179]

101. Although the health and economic concerns were important, they were probably not the only source of the antagonism of Rifkin and his fellow activists. rBST touched upon the essence of their discomfort with biotechnology. The use of an "artificial" chemical to produce something as pure, natural and wholesome as milk represented the disregard for natural boundaries that Rifkin had criticized in his long-standing opposition to biotechnology research.[180]

102. It is likely that Rifkin was further motivated by a fundamental distrust of the FDA (or any government agency, for that matter). In response to the FDA's guidelines regarding the labeling of rBST milk, he and his fellow activists accused the FDA of turning normal labeling practices on its head in an attempt to ensure that the first commercial use of a genetically engineered product was not rejected by the public. They claimed that the FDA was "hiding the technology . . . [and did] not want the public to know [about milk produced with it]."[181] In essence, they did not trust the FDA's conclusions and claims that the product was safe. They wanted consumers to be informed so they could make a decision whether or not to avoid substances such as rBST. This, of course, would not be possible without labels that identified the presence of the substance in the foods.[182] Unfortunately, their suspicions were certainly not diminished by allegations of impropriety on the part of FDA officials.[183]

103. Rifkin also realized he had a perfect product on hand to generate public support for his activities. He was a master at deciphering what the public's concerns were and how to speak to them. He correctly surmised that public suspicions about genetic engineering would be especially intense when food is involved. At one point, he reported that he was getting "hundreds and hundreds of calls, from concerned parents mostly." [184] In another adept move to focus public attention on the fact that their food supply was at issue, he successfully corralled a nationwide coalition of chefs to denounce publicly (and loudly) genetically engineered foods.[185]

V. Rifkin's Activities

A. Media Publicity

104. Rifkin and his coalition engaged in a set of activities that were clearly (and successfully) calculated to gain publicity and thus generate public awareness of rBST and it potential negative effects. They engaged constantly with the press in promoting their concerns and opposition to rBST.[186] Publicity was generated through "milk dumping" protests against retailers that sold rBST milk[187] and threats of a major boycott of all milk and dairy products from rBST-treated cows. All dairy processors were asked to sign a "BST-free" pledge, with a corresponding threat that all who refused would be listed on a national 900-number as rBST users; PFC members also handed out rBST warning leaflets at McDonald's restaurants in the United States and Canada. Finally, there were even threats, though unrealized, of a major ad campaign.[188]

B. Lawsuits

105. Adopting a now familiar tactic, Rifkin also resorted to litigation to prevent the successful development and commercialization of rBST.

Cordes v. Madigan[189]

106. This was a suit clearly aimed at halting rBST at its developmental stage. The plaintiffs recognized that rBST could soon be the first commercial application of a genetically engineered product. The suit was filed before the FDA had even approved the commercial use of rBST. At the time, the FDA had only permitted experimental injections of rBST and approved the human consumption of test rBST dairy products. The plaintiffs were dairy farmers, the FET and Jeremy Rifkin.[190] They claimed that the defendants (USDA and the National Dairy Promotion and Research Board) were promoting the use of rBST in violation of the Dairy Promotion and Research Order[191]; the Order was aimed in part at promoting the use of fluid milk and dairy products as well as projects for research and nutrition education.[192] The plaintiffs claimed that rBST may have detrimental economic and health consequences.[193]

107. Evidencing his distrust of federal agencies, Rifkin claimed, as part of his basis for standing, harm by the defendants' efforts to "disparage and discredit [him], particularly with regard to his efforts to inform the public" about rBST use.[194] The Court ruled that the FET and Rifkin lacked standing, and that the dairy farmer-plaintiffs had not exhausted their administrative remedies prior to bringing the suit.[195]

Barnes v. Shalala[196]

108. Probably chastened by the dismissal for lack of standing to sue in most of the cases he had filed previously, to ensure that this suit progressed to the point of being adjudicated on its merits, Rifkin included a large group of co-plaintiffs who represented an incredibly broad set of interests: Wisconsin dairy farmers, owners of Wisconsin dairy processors, Wisconsin grocers and distributors, a veterinarian, a nutritional educator, a nurse, the editor of a farm journal, all Wisconsinites, and the Foundation for Economic Trends, lead by Jeremy Rifkin.[197] The plaintiffs challenged the FDA's approval of rBST on three grounds: (1) that it was arbitrary and capricious because the FDA did not consider health and safety issues related to the use of rBST; (2) that the defendants did not require mandatory labeling of products from rBST-treated cows; and (3) that the defendants did not conduct an adequate environmental assessment or issue an environmental impact statement assessing the environmental effect of rBST approval. The plaintiffs requested a declaration that the defendants had failed to perform their statutory duties and further sought a permanent injunction suspending the approval of rBST until the defendants had fulfilled their statutory obligations.[198]

109. The court dismissed the claims of the plaintiff farmers, sellers of dairy products, health care professionals, and the Foundation on Economic Trends because these parties lacked the requisite "concrete and particularized" injuries to attain standing.[199] The claims of the consumers, however, were allowed to remain on all counts.[200]

110. Although the Court dealt with the case on procedural grounds, its reasoning appeared to deal a partial setback to Rifkin. In finding that only the consumer plaintiffs had standing to sue the FDA regarding its approval of rBST and that only the consumers and farmers had standing on their environmental impact challenge, the Court clearly took a position on how and what rBST issues would be considered in the legal arena.[201] It signaled that while it was ready to discuss health, safety and environmental concerns, it was not willing to entertain other concerns about the nature or mistrust of corporate power and the government, [202] which were among the main concerns motivating Rifkin and his compatriots.

Stauber v. Shalala[203]

111. Following Barnes v. Shalala, the remaining plaintiffs re-filed their claims. This time around, the Court granted the defendants' request for summary judgment, ruling that the plaintiffs had failed to put any material facts into dispute within the relevant, admissible evidence.[204]

112. In arriving at its opinion, the Court seemed to confirm the lower court's stance on what the relevant issues were in the rBST controversy: it considered only scientific evaluations of health and safety.[205] In reviewing the evidence presented, it demonstrated substantial deference to the FDA.[206] It implicitly acknowledged its deference to the FDA's expertise when it noted that the FDA had made its conclusion despite "scientists, economists, farmers and environmental and animal welfare organizations [who had] questioned the safety and quality of [rBST]-derived products, [and] the thousands of letters from consumers [FDA had received] asking it to deny approval of [rBST] or to require labeling of [rBST]-derived products." Besides assessing health and safety concerns, the Court did not discuss the other concerns of opponents of rBST.[207] Thus, the Court essentially took objections on moral (non-scientific) grounds out of its legal reasoning.

C. Flavr Savr Tomato

113. In May, 1992, the FDA published a statement of policy for foods derived from new plant varieties, which included plants developed by recombinant DNA techniques.[208] It decreed that it would not require pre-market approval of genetically altered food.[209] It also said it would not require food developed using recombinant DNA techniques to bear special labeling to reveal that fact to consumers; it believed the new techniques were merely extensions at the molecular level of traditional methods and would be used to achieve the same goals as pursued with traditional plant breeding.[210] About 3,000 letters of opposition, many from members of the Pure Food Campaign, were submitted to the FDA in response to this statement of policy.[211] Rifkin and his organization also filed a petition with the FDA to require testing and labeling of genetically engineered foods.[212] In spite of this, the FDA maintained the position it had adopted in the policy statement.

114. The FDA's approval of Calgene, Inc.'s informal request to market its Flavr Savr tomato, which had been genetically altered to achieve longer-lasting shelf life, was greeted with activist outcry. Rifkin called it "an untested potential threat to the nation's health."[213] He once again demanded the tomato be labeled to indicate that it was genetically engineered.[214]

115. Rifkin expressed several concerns regarding the commercial sale of genetically engineered *foods*, of which the Calgene tomato was the first (rBST was a *drug*, and the milk from rBST cows was not actually genetically altered). His concerns were premised upon the same environmental and ethical concerns he had expressed all along in opposing biotechnology. These concerns were not allayed by the reassurances and counterarguments of the FDA and other scientists.[215]

116. First, he argued that since genetically engineered food products are alive, they are unpredictable, being capable of reproducing, mutating and migrating once released into the environment. He feared that the long-term cumulative impact on the environment from the release of thousands of such products would be devastating.[216] Calgene's tomato would merely be the first of these products.

117. Second, the genetic transfer of genes that result in the development of products such as the Flavr Savr tomato involves the crossing of species boundaries. This, he believed, went far beyond traditional breeding techniques. To him, it represented the "ultimate offense to the dignity and integrity of the biotic community." [217]

118. Third, without labeling of genetically engineered foods, consumers would not be able to make an informed choice when purchasing their foods. In one of its handouts, the Pure Food Campaign warned consumers that unprecedented genetic combinations, including cantaloupe and yellow squash containing bacteria and virus genes, potatoes with chicken and waxmoth genes, tomatoes with flounder and tobacco genes, and fish and pork with human genes, were being introduced into their food supply. It was further argued that without mandatory labeling, and testing, food producers might scramble plant and animal genes indiscriminately without care for consumers' health and safety and the long-term impact on the global food supply. [218] Rifkin worried, for instance, that new genes that were previously not part of foods would turn out to be allergenic and be consumed inadvertently by people allergic to the allergens.[219]

119. Fourth, Rifkin was concerned about the long-term risk posed by the marker gene[220] that was inserted into the Flavr Savr tomato during the gene transfer process. In this case, the marker gene encoded an antibiotic resistance product which would neutralize the effectiveness of the antibiotic kanamycin. Rifkin speculated that this marker gene could somehow be taken up by disease-causing bacteria in a person's gut and thus render the bacteria resistant to kanamycin.[221]

D. Public Efforts

120. In opposing the Calgene tomato, Rifkin, through the PFC, again engaged in high-profile activities clearly aimed at generating media publicity to their cause. PFC members contacted about 1800 local lawmakers nationwide to urge them to introduce local ordinances requiring grocery stores and restaurants that sold or served genetically engineered foods to display signs proclaiming that fact. They also pushed the FDA to set up a registry of genetically engineered foods so that the agency could track down a food's producer if problems occurred.[222] In a massive coalition-building effort, the PFC also recruited restaurants, grocery stores, distributors and growers to join its boycott of genetically engineered foods;[223] at one stage, more than 1,500 restaurant chefs reportedly had joined with the PFC,[224] and Burger King Corporation demanded proof that the genetically-altered food (referring to the Calgene tomato) was as good as what the chain was using at the time.[225] Similar to its action in the rBST case, the PFC organized "tomato dumpings" wherever the Calgene tomato was sold.[226] In another highly unorthodox, and probably effective, move, Rifkin and his PFC asked 140,000 school teachers nationwide to discuss with their students "educational materials" listing the downsides of genetically engineered foods such as the Calgene tomato. [227] Rifkin also publicly pledged to file lawsuits against "each and every producer of . . . [genetically engineered foods] to insure . . . [that such food was] only used if it [was] proved safe."[228]

121. One of the most dramatic aspects of Rifkin's campaign involved a direct confrontation with Campbell Soup Co., which had previously signed an exclusive licensing agreement with Calgene to market fresh tomatoes in North America, with the right to use the Flavr Savr tomatoes in its processed products. Rifkin and his PFC group announced that they intended to launch an international boycott campaign against Campbell and its products. In a letter to Campbell's president and CEO, they warned the company that unless it halted its development and marketing of genetically engineered tomatoes within thirty days, its products would be the focus of a worldwide education and boycott effort.[229] Although it is unclear what effect Rifkin's threat had on Campbell (the company immediately denied Rifkin's announcement that Campbell had "bowed" to the threat), the company did announce that they had no plans to sell the tomato and noted that its right to sell fresh Flavr Savr tomatoes in North America had been sold back to Calgene. Furthermore, although it retained the right to sell fresh tomatoes elsewhere and processed tomatoes anywhere, it said it did not have plans to do so. Curiously, after applauding Campbell's apparent sensitivity to consumer concerns, Rifkin declared he would still boycott Campbell products because the company had not promised *never* to sell genetically engineered tomatoes.[230]

E. Lawsuits

122. Despite Rifkin's early public threats of suit,[231] he did not challenge the FDA's policy guidelines on the approval and labeling of the Flavr Savr tomato and other genetically engineered foods until about four years later. In May, 1998, Rifkin's PFC joined with a diverse coalition in filing a lawsuit against the FDA seeking the removal of genetically engineered foods from the market until they are tested and labeled. The suit claimed that the FDA's refusal to require testing and labeling of such foods could cause harm to American consumers. The coalition's suit is pending in the District Court of the District of Columbia.[232]

VI. Conclusion: Impact And Implications

123. After all is said and done, it is a rather surprising realization that all of Rifkin's efforts in his years of opposing biotechnology have not yielded more than a minimal measure of success procedurally or substantively in the exercise and regulation of the technology. His opposition to research did not prevent it from moving forward; on the contrary, biotechnology today is more vibrant than ever. For instance, gene therapy experimentation is proceeding rapidly[233] and the technical foundation for human cloning is being developed at breakneck speed.[234] Also, patenting of genetically engineered life forms is now commonplace. Furthermore, the FDA did not alter its initial position regarding how it would regulate genetically engineered foods and drugs. Indeed, while it is difficult to gauge what impact there was on the commercialization of rBST and Calgene's tomato, since many factors (such as product quality and marketing) affect market success, both of these products are apparently here to stay.[235] Rifkin's only obvious success came in a few lawsuits that resulted in placing procedural obstacles in federal agencies' (and thus the industry's) engagement in biotechnology-related activities. For instance, the requirement for environmental impact assessments and statements was clarified.

124. It would be myopic, however, to conclude that his opposition was fruitless simply because there were no obvious changes in research policy or government regulation directly resulting from Rifkin's efforts. His actions are likely responsible for at least two negative effects in the biotechnology industry.

125. The public opposition to pioneering biotechnology products may have resulted in the curtailment of the industry's development and introduction of similar commercial biotechnology products. Genetically engineered food products have accounted for only a tiny percentage of biotechnology products that have entered the marketplace since the Calgene tomato. In 1997, less than 5 percent of biotechnology products was food genetically engineered for desirable characteristics. Most were simply crop protection products.[236] This trend suggests that while industry interest in genetic engineering of commercial goods such as agricultural protection products has persisted, there has not been as much progress on the food product front. It is reasonable to conclude that had rBST and Flavr Savr been greeted with a more positive market response, the industry would have jumped on the bandwagon to develop and commericalize other genetically engineered foods.

126. Also, Rifkin's efforts ultimately hurt the cause of biotechnology in a manner that would result in the most damage, namely through calling into question the credibility of the FDA. The FDA, as the nation's arbiter of what foods and drugs are safe and effective for the consumption of Americans, serves as the gatekeeper for biotechnology products seeking entry into the American marketplace. Its function in this regard is tremendously dependent on the American public's confidence in its effectiveness in keeping out harmful products. The onslaught of extremely negative publicity and the accompanying public denunciation and boycott of rBST/rBST milk and the Calgene tomato, all of which had been certified safe by the FDA, tarnished the agency's image and credibility, in general, and specifically in relation to biotechnology products. Thus, Rifkin's efforts succeeded in wresting away the one legitimizing stamp of approval the industry had for its products.

127. Nonetheless, even Rifkin must realize that biotechnology is here to stay and that discrediting federal agencies entrusted with serving the public good is not the most beneficial outcome for the American public in the long run. As such, it is important to recognize that there are aspects of Rifkin and his fellow activists' activities that they could have done differently and might have led to a more constructive overall outcome in the biotechnology debate.

128. It is important that Rifkin omit hyperbole and doomsday-type sound bites from *objective* scientific debates. Officials at federal agencies like the FDA, the NIH and in the biotechnology industry are trained to make decisions based on the scientific method. Rifkin's habits were ineffective with, and apparently infuriating to, these people, all the more so because they believed that he was effectively misleading the public. Under such antagonistic circumstances, it is no wonder that neither side was willing to "listen" to the other.

129. Rifkin should have realized that his insistence on a total abolition of biotechnology was untenable. First, even if biotechnology were stopped in the U.S., it would continue elsewhere in the world. As Rifkin himself has pointed out, one of the distinctive dangers of genetically engineered entities is their potential for wreaking havoc with the environment, a parameter that recognizes no geopolitical boundaries. Second, his basis for banning the technology, the potential risks associated with it, is antithetical to the experience with and premise of all technological advances. All new technologies have inherent uncertainties, a reality that the FDA recognized when it promulgated its policy on foods derived from processes involving recombinant DNA.[237] Thus, unless Rifkin had proposed an alternative path by which society could continually better its condition without accessing new technology, it would have been impossible, arguably unconscionable, to abandon promising advances within biotechnology.

130. If Rifkin had recognized that biotechnology was here to stay, he could have chosen to *participate* in efforts to ensure the safest implementation possible of the technology, rather than continuing a vain effort to obstruct it. In this regard, Rifkin should have abandoned the strategy of engaging in procedural maneuvers aimed at blocking the technology under the guise of ensuring proper adherence to regulatory technicalities. For example, most of his lawsuits involved claims that federal agencies (e.g. FDA for rBST, USDA for deliberate release experiments) acted arbitrarily and capriciously in arriving at their decisions and that they violated the NEPA in their environmental impact considerations. While these are important issues (certainly in the case of environmental impact), it was obvious, as some courts noted, that they constituted, at best, short-term procedural obstacles against biotechnology, or, at worst, the irritating desperate acts of one who had previously lost in the battle to decide the technology's fate. Instead of engaging in these pursuits, Rifkin could have re-directed his concerns about risk assessment from one of requiring absolute certainty through exhaustive data gathering (which, of course, was impossible without first performing the research experiments in question) to a more practical demand for examination of potential risks based on the best technology and information available at the time of the experiments, and for the establishment of reasonable precautionary measures in the performance of said experiments.

131. Finally, Rifkin should have chosen more constructive avenues of opposition. Policy-making through litigation is a dubious endeavor, especially when dealing with an issue with broad-ranging implications such as biotechnology. Once the federal government made its policy choice to promote the development of biotechnology, as reflected in the establishment of a coordinated framework for the regulation of biotechnology,[238] participating agencies like the FDA were obliged to establish policies that would not impede the technology without cause.[239] Thus, the most effective, and arguably democratic, means for subsequently challenging these policies was through the political process. As he demonstrated in his success at galvanizing grassroots opposition to rBST and the Flavr Savr, Rifkin almost certainly would have been capable of promoting his cause by influencing biotechnology legislation through the normal political process.

132. On the other hand, not all the blame for the tarnishing of the image and credibility of the FDA and the biotechnology industry can be attributed to Rifkin alone. Regulatory agencies such as the FDA, research scientists and the industry could have done a few things differently as well.

133. There should have been greater recognition of the moral and ethical concerns relevant to the debate over the science and technology of genetic engineering. Instead of adhering strictly to the dogma that only scientifically-recognized concerns are relevant in assessment of risks of new technology, biotechnology proponents should have realized that biotechnology is unlike past technologies in that its power and potential derived from the very fact that it involves the uncharted territory of the blueprint of life, and, consequently, the essence of who and what human beings may think they are. Teleological and mystical as this may sound, most of the public was concerned by, or at least disturbed by the possibility of, issues arising from such an "invasion." As a corollary, they should have acknowledged the fact that people like Rifkin were merely giving voice to some common public concerns, albeit with an apocalyptic tone. Because Rifkin's concerns were ones held by at least some segment of the public, they merited debate and possibly even incorporation into policy decisions.

134. Biotechnology proponents should also have recognized that because the technology is as powerful as it is, it would be greeted with greater apprehension among the public than any other past technology. As such, it was imperative that the technology be eased onto the public consciousness through a gradual process. For instance, the FDA could have taken a compromise position in its decision on the labeling of rBST milk. Instead of relying on a seemingly convoluted interpretation of the "false or misleading" labeling requirement with regard to rBST milk, the FDA could have initially allowed such labeling. Such a move would have avoided outcry from a public that clearly felt important information was being forcibly kept from them by the FDA's restrictive labeling requirement. By allowing such labeling, market economics would have decided whether the product would be accepted by the public. Through education, marketing and effective pricing, consumers who did not have strong opinions against the product would likely buy them, or at least try them, at some point, and those who opposed them might eventually even be persuaded that their concerns were unwarranted when enough time had passed without event. By engaging in the restrictive approach it did, the FDA unnecessarily imposed "unwanted" products on the very public that had relied on it for protection, and, in the process, gave credence to biotechnology opponents' accusation that it was seeking to promote industry welfare over the people's safety. The FDA's (and the industry's) gamble that the public could be "coerced" into accepting genetically engineered food products was miscalculated. To this day, years after the introduction of rBST and Flavr Savr, opposition continues. A 1998 report states that Greenpeace has joined with Chefs Collaborative 2000 in an effort to persuade consumers to fight for labeling of genetically engineered food through a signature collection campaign to petition the FDA.[240]

135. Because of the controversy surrounding the technology and the visible industry interests involved, federal regulatory agencies such as the FDA should have taken greater efforts to insure impartiality. In this regard, mere allegations of impropriety, such as the one involving FDA officials accused of being closely allied with Monsanto and influencing rBST's approval,[241] can be disproportionately damaging indeed. Thus, federal agencies should have taken stringent measures to avoid conflicts of interest, both perceived and real.

136. The agencies should also have made a good faith effort at addressing the issue of risk assessment regarding the technology. While it is certainly true that the actual dangers of the technology could not have been assessed definitively without going forward with the experiments in question, the agencies and the industry could have made a more concerted effort to develop alternative ways to assess the potential dangers. For instance, there could have been more investment in improving existing methods of predicting risks through the use of computer modeling.

137. Finally, promulgation of new rules specific to biotechnology might have been a better approach to the regulation of biotechnology. In this regard, the FDA, instead of deciding that it could regulate under existing statutes, could have encouraged Congress to enact a new statute specific to biotechnology. The process of promulgating this regulation would have opened up a public debate over the various issues relating to the technology, thus possibly giving the eventual law a legitimacy that people like Rifkin believed the existing regulations, as promulgated by the FDA based on existing statutes, lacked. During this process, it is very likely that novel measures or frameworks of regulation would have been enacted to deal with biotechnology-specific issues. For instance, the liability scheme of risks resulting from biotechnology products could have been tailored to place the cost of remedying harm strictly on the industry; under this scheme, some of the concerns of the public might have been allayed because of the assurance that the industry had an incentive to make their products as safe as possible.

138. As we approach an era when many biotechnology products, many of a nature never seen before, are about to enter the market, it is particularly critical that all parties in the biotechnology debate assess the valuable lessons that can be culled from past battles over biotechnology. The opponents of biotechnology should recognize that the technology is here to stay and decide whether it wants to participate in making the best of it or engage in obstructive efforts that experience has shown to be of limited effect. Proponents of biotechnology, on the other hand, must recognize the legitimacy of non-scientific viewpoints and remember that the public is the ultimate arbiter of what they will accept, and thus cannot be excluded from the decision-making process.

Footnotes

[*] Associate, Morrison & Foerster, Palo Alto, Cal.; J.D., Harvard, 1999; Ph.D., Biochemistry, Univ. of Cal. San Francisco, 1996.

[1] Jeremy Rifkin, The Biotech Century: Harnessing the Gene and Remaking the World 236-237 (1998).

[2] Frank E. Young et al., *Biotechnology and The Federal Food and Drug Administration*, Forum For Applied Res. & Pub. Pol'y, 1987, at 80.

[3] Ronald Bailey, *Fear and Loathing of Biotech's Bright Future*, Reason, Nov., 1985, at 23-24.

[4] Lizette Alvarez, *Senate, 54-42, Rejects Republican bill to Ban Human Cloning*, N.Y. Times, Feb. 12, 1998, at A20 (The FDA has declared that it has jurisdiction over human cloning).

[5] Coordinated Framework for Regulation of Biotechnology: Establishment of the Biotechnology Science Coordinating Committee, 50 Fed. Reg. 47174, 47174 (1985).

[6] *Id*. at 47174-47175.

[7] Food Derived From New Plant Varieties, 57 Fed. Reg. 22984, 23004 (1992).

[8] Bailey, *supra* note 3, at 24-25.

[9]*Id*. at 25.

[10] *Id*. at 25. At the earliest stage of the inception of recombinant DNA work, Rifkin was not involved in the public debate over its safety. At the time, he was still in the process of "finding" his issue following the end of his anti-war and anti-corporate activities.

[11] *Id*. at 25.

[12] David Malakoff, *Biotech Gadfly Engineers Counterrevolution in Courts,* 17 Nat'l J. 1699, 1699 (1985).

[13] Marjorie Sun, *Biotechnology Developments,* 1 Editorial Res. Rep. 154, 155 (1987).

[14] *Id*. at 157.

[15] *Foundation on Economic Trends* (last modified Dec. 24, 1998) <http://www.tripod.com/explore/jobs_career/goodworks/jobs/389.html>.

[16] His bibliography includes: Common Sense II; Own Your Own Job; Who Should Play God?; The Emerging Order; The North Will Rise Again; Entropy; Algeny; Declaration of a Heretic; Time Wars; Biosphere Politics; Beyond Beef; Voting Green; The End of Work; and The Biotech Century.

[17] *See generally*, Jeremy Rifkin, Entropy: A New World View (1980).

[18] *See generally*, Ted Howard & Jeremy Rifkin, Who Should Play God: The Artificial Creation of Life and What It Means for the Future of the Human Race (1977).

[19] *See generally*, Jeremy Rifkin, Algeny: A New Word-A New World (1983).

[20] *See generally*, Jeremy Rifkin, Biosphere Politics: A Cultural Odyssey From the Middle Ages to the New Age (1991).

[21] *See, e.g.,* William J. Bennatta, Algeny: Book Reviews, SCIENCE, July 1985, at 97 (citing Stephen Jay Gould's DISCOVER book review that excoriated Rifkin's "Algeny" as a "cleverly constructed tract of anti-intellectual propaganda masquerading as scholarship," and quoting Gould as saying that he didn't think he had ever read "a shoddier work."); *Algeny: A New Word—A New World* (last modified June 21, 1998) <http:www.amazon.com/exec/obidos/ASIN/0140071067/qid=920963…/002-9968692-519625> (an anonymous reader wrote on the website of the internet bookseller, amazon.com, that Rifkin "shows little familiarity with the topics he discusses – the book is deeply marred by [his] apparent fundamental misunderstandings of evolutionary science and Darwinism.").

[22] In this paper, where appropriate, the views Rifkin propounds in his books are relied upon to illuminate the reasons behind his actions and his objectives in opposing biotechnology.

[23] Rifkin, *supra* note 1, at xiii.

[24] *Id*. at xii.

[25] *Id*.

[26]Notice of Proposed Actions Under NIH Guidelines for Research Involving Recombinant DNA Molecules, 49 Fed. Reg. 37016, 37017 (1984) (letter to William Gartland).

[27] Bailey, *supra* note 3, at 28.

[28] Rifkin, *supra* note 1, at 13.

[29] Bailey, *supra* note 3, at 28.

[30] Sun, *supra* note 13, at 157.

[31] *Id*.

[32] Rifkin, *supra* note 1, at 214-215.

[33] Stephen Pendorf, *Comment: Regulating The Environmental Release Of Genetically Engineered Organisms: Foundation on Economic Trends v. Heckler*, 12 FLA. ST. U.L. REV. 891, 907 (1985) (citing interview with Jeremy Rifkin on July 2, 1984).

[34] Rifkin, *supra* note 1, at xiv.

[35] *Id*. at 35-36.

[36] *Id*. at 102.

[37] *Id*. at 230.

[38] *Id*. at 102; these environmental scientists apparently deem species preservation to be both an environmental and moral imperative.

[39] *Id*. (citing two polls: (1) an Associated Press poll conducted in 1995 that found 67 percent of Americans to agree somewhat or strongly that animals have the right to pursue their own natural and essential interests and that an animal's right to live free of suffering should be as important as a person's right to live free of suffering; and (2) a USDA poll finding that a majority of Americans oppose the transfer of genes between unrelated species on ethical grounds.).

[40] Rifkin, *supra* note 1, at 202; s*ee generally*, Rifkin, *supra* note 19.

[41] Rifkin, *supra* note 1, at 34 (further interpreting these scientists' view to be that species boundaries are just convenient labels for identifying a familiar biological condition or relationship, and that they are in no way to be regarded as impenetrable walls separating various plants and animals).

[42] *Id*. at 32-33.

[43] *Id*. at 33-34 (Rifkin stating that the parallel between algeny and alchemy lies in the common principle that all beings/entities are in a fluid state of transformation).

[44] Valerie M. Fogleman, *Regulating Science: An Evaluation Of The Regulation Of Biotechnology Research*, 17 Envtl. L. 183, 197 (1987) (citing Rifkin in Algeny, *supra* note 19, at 251).

[45] Rifkin, *supra* note 1, at 172; Sun, *supra* note 13, at 157.

[46] Rifkin, *supra* note 1, at 129-147.

[47] *Id*. at 172.

[48] *Id*. (these entities -scientists, transnational companies, government agencies and other institutions- are "wily" because he suspects that they will market products and services under the guise of expanding consumers' freedom of choice.).

[49] *Id*. at 173-174.

[50] *Id*. at 200.

[51] Robert N. Proctor, *Genomics and Eugenics: How Fair is the Comparison?*, Gene Mapping: Using Law and Ethics As Guides, at 67 (George J. Annas & Sherman Elias eds., 1992).

[52] Rifkin, *supra* note 1, at 3.

[53] *Id*. at 139-144.

[54] Notice of Proposed Actions, *supra* note 26.

[55] Action Notice, 50 Fed. Reg. 9760 (1985).

[56] The first time also having been performed by the same group, but consisted of a transfer into mice.

[57] Notice of Proposed Actions, s*upra* note 26, at 37016-37017.

[58] *Id*. at 37017; He did not provide support for this assertion.

[59] *Id*.

[60] *Id*.

[61] *Id*.

[62] *Id*.

[63] *Id*.

[64] *Supra* note 55, at 9762.

[65] *Id*.

[66] *Id*.

[67] *Id*.

[68] *Id*. at 9762-9763.

[69] *Id*. at 9761.

[70] *Id*.

[71] *Id*. at 9762.

[72] *Id*. at 9763 & 9765. Note that gene therapy treatments do not necessarily involve inter-species genetic transfer, and thus would presumably not be prohibited under Rifkin's proposal. However, before the benefits of gene therapy could be realized, animals would have to be subjected to experimentation. The latter seems to be one of Rifkin's concerns.

[73] *Id*. at 9765.

[74] *Id*. at 9761 & 9764.

[75] *Id*. at 9764.

[76] *Id*.

[77] *Id*.

[78] *Id*.

[79] *Id*. at 9761.

[80] *Id*.

[81] *Id*. at 9763.

[82] *Id*. at 9765.

[83] *Id*. at 9763.

[84] *Id*. at 9761.

[85] *Id*. at 9765.

[86] *Id*. at 9764.

[87] *Id*. at 9765.

[88] *Id*. at 9764.

[89] *Id*.; it was also pointed out that transfer of genes into the human germ line would involve use of in vitro fertilization, which was then under a de facto moratorium, because national review by a then non-existent Ethics Advisory Board was required; it was also noted that animal welfare in the laboratory or animal husbandry, while a real issue, was not under the purview of the RAC.

[90] *Id*. at 9765.

[91] *Id*. at 9766.

[92] *Id*.

[93] *Id*.

[94] *Id*.

[95] *Id*.

[96] *Id*.

[97] *Id*. (Rifkin responded to this comment. He described the Iroquois nation of North America who had a civilized and advanced culture. These people followed a specific procedure whenever they considered some environmental, social, or cultural change, wherein they asked what effect the proposed change would have seven generations into the future. If they decided the costs outweighed the benefits, they would decide not to implement it. Rifkin went on to say that genetic engineering is merely one, not the only, approach to the future for solving problems. He suggested, for example, that there could instead be greater emphasis on elucidating environmental causes of diseases, since some diseases have an environmental component in addition to (or rather than) a genetic component.)

[98] *Id*.

[99] *Id*. at 9760.

[100] Foundation on Economic Trends v. Block, No. 84-3045, 1986 U.S. Dist. LEXIS 26137, at *1 (D.D.C. Apr. 29, 1986).

[101] *Id*. at *10-11 (the USDA had contributed $26,000 since 1982 in support of Dr. Brinster's work, representing 6% of the total cost of the project).

[102] National Environmental Policy Act, 42 U.S.C. § 4332(2)(C) (1982). The NEPA

[102] National Environmental Policy Act, 42 U.S.C. § 4332(2)(C) (1982). The NEPA places an affirmative obligation on the federal government to compile an Environmental Impact Statement prior to final approval of all "major Federal actions significantly affecting the quality of the human environment." The Environmental Impact Statement is the principal mechanism to implement the environmental policies articulated in NEPA.

[103]Foundation on Economic Trends v. Heckler, 587 F. Supp. 753, 768-769 (D.D.C 1984) (stating that an "environmental assessment" is a document an agency prepares to support its finding of "no significant impact" for a major federal action. If a significant impact is likely, the agency is required to prepare the more extensive labor and time-intensive "environmental impact statement").

[104] *Block*, 1986 U.S. Dist. LEXIS 26137, at *11.

[105] *Id*. at *27-28.

[106] Foundation on Economic Trends v. Lyng, 817 F.2d 882 (D.C. Cir. 1987).

[107] *Id*. at 885-886.

[108] *Id*. at 884.

[109] Malakoff, *supra* note 12.

[110] Sun, *supra* note 13, at 157.

[111] Bernard D. Davis et al., *The 'Andromeda Strain' Is Still Science Fiction*, N. Y. Times, May 31, 1986, at 26.

[112] *Heckler*, 587 F. Supp. 753.

[113] Rifkin, *supra* note 1, at 75-77.

[114] *See Heckler*, 587 F. Supp. 753.

[115] *Id*. at 756.

[116] 41 Fed. Reg. 27,914-15 (1976) (NIH Guidelines Section III-A-iv) (The original NIH Guidelines for Research Involving Recombinant DNA Molecules were issued in 1976. This set of Guidelines expressly prohibited the deliberate release of recombinant DNA molecules into the environment.). 43 Fed. Reg. 60082 (1978) (However, in the 1978 revisions to the NIH Guidelines, the Director of the NIH was given the authority to grant exceptions to certain absolute prohibitions contained in the original Guidelines, including that against deliberate release of recombinant DNA into the environment.).

[117] 40 C.F.R. § 1502.4(b)(1983). The NEPA allows federal agencies to issue either of two types of environmental impact statements, viewing environmental consequences from either a broad (programmatic) or narrow (site-specific) perspective.

[118] *Heckler*, 587 F. Supp. at 769.

[119] Foundation on Economic Trends v. Heckler, 756 F.2d 143 (D.C. Cir. 1985).

[120] *Id*. at 154-155.

[121] *Id*. at 159.

[122] *Id*. at 161.

[123] Foundation on Economic Trends v. Thomas, 637 F. Supp. 25 (D.D.C. 1986).

[124] *Id*. at 26. The EPA regulates sale and distribution of pesticides in the U.S. through a registration scheme. The scheme prohibits the registration, and thus the use and marketing, of pesticides which cause "unreasonable adverse effects on the environment. In order to test an unregistered pesticide for environmental effects, one must apply to the EPA for an experimental use permit, which sets the conditions under which the testing may take place.

[125] These are crucial factors in determining the risks of a deliberate release experiment because one of the main concerns about these experiments is the potential impact the genetically engineered organisms might have on the environment, such as through competing with non-altered versions of the modified bacteria and increased potency against preys in the open environment.

[126] *See Thomas*, 637 F. Supp. at 27.

[127] *Id*. at 28.

[128] *Id*. at 29.

[129] Foundation on Economic Trends v. Thomas, 661 F. Supp. 713 (D.D.C. 1986).

[130] *Id*. at 713.

[131] *Id*. at 715.

[132] *Id*. at 719.

[133] *Id*. at 717.

[134] *Id*. at 718.

[135] Foundation on Economic Trends v. Lyng, 680 F. Supp. 10 (D.D.C. 1988).

[136] *Id*. at 12-13.

[137] *Id*. at 14.

[138] *Id*. at 16.

[139] Foundation on Economic Trends v. Lyng, No. 87 Civ. 2909 (D.D.C. 1990).

[140] *See generally id*.

[141] Foundation on Economic Trends v. Lyng, 943 F.2d 79 (D.C. Cir. 1991).

[142] *Id*. at 83.

[143] *Id*. at 86.

[144] *See, e.g.*, *Heckler*, 756 F.2d 143. In a subsequent case that did not involve biotechnology (it involved the 'greenhouse effect'), *Foundation on Economic Trends v. Watkins*, 794 F. Supp. 395, 399 (D.D.C. 1992), the Foundation-plaintiffs attempted to argue that the Germplasm majority's criticism of informational standing was merely dicta, and that informational standing remained good law. The Court in that case did not agree and found that the Foundation did not have standing to sue. *Id*.

[145] *See* Foundation on Economic Trends v. Lyng, 943 F.2d at 86.

[146] Foundation on Economic Trends v. Weinberger, 610 F. Supp. 829 (D.D.C. 1985).

[147] *Id*. at 832.

[148] *Id*. at 835.

[149] *Id*. at 839.

[150] *Id*. at 840.

[151] *See supra* note 103 for a description of an "environmental assessment."

[152] *See Weinberger*, 610 F. Supp. at 841.

[153] *Id*. at 843.

[154] Brief on behalf of the Peoples Business Commission, Diamond v. Chakrabarty, 447 U.S. 303 (1980) (No. 79-136).

[155] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[156] Brief on behalf of the Peoples Business Commission, *supra* note 154, at 7-11.

[157] *Id*. at 11-16.

[158] *Id*. at 16-20.

[159] Rifkin, *supra* note 1, at 43.

[160] Pamphlet listing the FET's highlights from 1978-1998 (on file with author); *see*, *also*, Rifkin, *supra* note 1, at 63-65.

[161] Judith C. Juskevich & C. Greg Guyer, *Bovine Growth Hormone: Human Food Safety Evaluation*, SCIENCE, Aug. 24, 1990, at 875, 875.

[162] Sheldon Krimsky & Roger P. Wrubel, Agricultural Biotechnology and the Environment: Science, Policy, and Social Issues 166-168 (1996).

[163] Juskevich, *supra* note 161, at 875.

[164] Wade Roush, *Who Decides About Biotech?*, Tech. Rev., July 1991, at 28, 30.

[165] Krimsky, *supra* note 162, at 166.

[166] *Id*. at 183.

[167] Animal Drugs, Feeds, and Related Products: Sterile Sometribove Zinc Suspension, 58 Fed. Reg. 59,946, 59,946 (1993).

[168] 139 Cong. Rec. H6135 (daily ed. Aug. 5, 1993) (statement of Rep. Volkmer).

[169] Interim Guidance on the Voluntary Labeling of Milk and Milk Products From Cows that Have Not Been Treated With Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279 (1994).

[170] Jonathan Rauch, *Drug on the Market*, Nat'l J., Apr. 4,1987, at 818, 818-819; s*ee*, *also*, Barnaby J. Feder, *Monsanto Has Its Wonder Hormone. Can It Sell It?,* N.Y. Times, March 12, 1995, at 8.

[171] Robert Lee Hotz, *Fruits of Genetic Tinkering Are Headed for U.S. Tables*, L.A. Times, Nov. 12, 1993, at A1.

[172] Michael Garry, *The Milk Dilemma*, Progressive Grocer, May 1994, at 85, 85.

[173] Hotz, *supra* note 171.

[174] *See, e.g*., Juskevich, *supra* note 161, at 879 and 883; Hotz, *supra* note 171.

[175] Kurt Kleiner, *U.S. Bans 'Hormone Free' Milk Label*, New Scientist, Feb. 26, 1994, at 5, 5.

[176] *See*, *e.g*., Gail Feenstra, *Is BGH Sustainable? The Consumer Perspective*, *in* The Dairy Debate: Consequences of Bovine Growth Hormone and Rotational Grazing Technologies 1, 1 & 20-27 (William C. Liebhardt ed., 1993).

[177] *Id*. at 29-31.

[178] Krimsky, *supra* note 162, at 181.

[179] Roush, *supra* note 164, at 30.

[180] Tony Hiss, *How Now, Drugged Cow?: Biotechnology Comes to Rural Vermont*, HARPER'S, Oct. 1994, at 80, 85; Gail R. Doeff, *The People's Choice*, DAIRY FOODS MAGAZINE, July 1993, at 44.

[181] Kleiner, *supra* note 175.

[182] Eric F. Greenberg, *Label Clashes Are Heavyweight Bouts*, PACKAGING DIGEST, Apr. 1994, at 16.

[183] Keith Schneider, *Despite Critics, Dairy Farmers Increase Use of a Growth Hormone In Cows*, N.Y. TIMES, Oct. 30, 1994, at 26. Several Congressmen asserted that rBST's approval may have been improperly influenced by three FDA officials who were closely allied with Monsanto.

[184] Gina Kolata, *When the Geneticists' Fingers Get in the Food*, N.Y. TIMES, Feb. 20, 1994, at 14.

[185] *See*, *e.g.*, Hotz, *supra* note 171.

[186] See, e.g., *id*.

[187] Michael Garry, *Crying Over Spilt Milk*, PROGRESSIVE GROCER, Jan. 1994, at 7.

[188] Doeff, *supra* note 180.

[189] Cordes v. Madigan, No. 90 Civ. 2929, 1992 U.S. Dist. LEXIS 6250 (D.C. April 30, 1992).

[190] *Id*. at 3.

[191] *Id*. at 1.

[192] *Id*. at 2.

[193] *Id*. at 3.

[194] *Id*. at 5.

[195] *Id*. at 8-10.

[196] Barnes v. Shalala, 865 F. Supp. 550 (W.D. Wis. 1994).

[197] *Id*. at 553.

[198] *Id*. at 554.

[199] *Id*. at 558-61.

[200] *Id*. at 560.

[201] *Id*. at 560-563.

[202] *Id*. at 559-60; s*ee id*. at 553 (indicating the court was aware of the passionate controversy and hostilities engendered by rBST when it introduced its opinion by stating, "This is a case about milk, a subject near and dear to the hearts of Wisconsinites").

[203] Stauber v. Kessler, 895 F. Supp. 1178 (W.D. Wis. 1995).

[204] *Id*. at 1183.

[205] *Id*. at 1183-1186.

[206] *Id*. at 1190-92.

[207] *Id*. at 1183.

[208] *See generally,* Food Derived From New Plant Varieties, *supra* note 7.

[209] *Id*. at 22985.

[210] *Id*. at 22991.

[211] Graeme Browning, *Food Fight*, NAT'L J., Nov. 6, 1993, at 2658.

[212] *Chefs Urge Boycotting New Foods*, N.Y. TIMES, June 3, 1992, at C1.

[213] Buddy Nevins, *Dan Quayle's Science Project*, RESTAURANT BUS. MAG., July 20, 1992, at 46.

[214] Warren E. Leary, *FDA Approves Altered Tomato That Will Remain Fresh Longer*, N.Y. TIMES, May 19, 1994, at A1.

[215] For a sample of the kinds of counterarguments made by scientists and the FDA, *see* Browning, *supra* note 211; Boyce Rensberger, *Biotech Tomato Headed To Market Despite Threats*, WASH. POST, Jan. 12, 1993, at A3; Susan C. Phillips, *Genetically Engineered Foods*, CQ RES., Aug. 5, 1994, at 673, 689; and Secondary Direct Food Additives Permitted in Food for Human Consumption, 59 Fed. Reg. 26700 (1994).

[216] Phillips, *supra* note 215, at 689.

[217] *Id*.

[218] Browning, *supra* note 211.

[219] Rifkin, *supra* note 1, at 103-105.

[220] A marker gene is a gene that accompanies the gene of interest that is being transferred. Its purpose is to allow easy detection and confirmation of successful gene transfer into target cells.

[221] Rensberger, *supra* note 215.

[222] Browning, *supra* note 211.

[223] *PR Counters Activist Threat vs. Biotech Food*, O'DWYER PR SERVICES REP., Mar. 1993, at 1.

[224] Robert J. Swientek, *A Hard Cell? The Forces Shaping Public Opinion and Public Policy on Biotechnology*, FOOD PROCESSING, Jan. 1993, at 48.

[225] Nevins, *supra* note 213.

[226] Leary, *supra* note 214.

[227] Rensberger, *supra* note 215.

[228] Nevins, *supra* note 213.

[229] Swientek, *supra* note 224.

[230] Rensberger, *supra* note 215.

[231] Leary, *supra* note 214.

[232] Jim Puzzanghera, *Genetic Food Fight Boils Over in FDA Suit*, ORLANDO SENTINEL, May 28, 1998, at A1.

[233] Ronald Kotulak, *Glimmer of Hope in Gene Therapy*, CHI. TRIBUNE, Mar. 28, 1999, at C1.

[234] *See e.g.*, Nicholas Wade, *Skin Cells Bring Cloning A Step Nearer To Efficiency,* N.Y. TIMES, Jan. 5, 2000, at A14.

[235] *No US Backing for Call to Boycott Biotech Crops*, AGRA EUROPE, Oct. 11, 1996, at E5; Robert Steyer, *Monsanto Is Making Money on BST*, ST. LOUIS POST-DISPATCH, May 24, 1998, at E1..

[236] *See generally*, Sze et al., *Getting Food Output Through Genetically Engineered Crops*, CHEM. MKT. REP., June 22, 1998, at FR3.

[237] *See* Food Derived From New Plant Varieties, *supra* note 7 at 14.

[238] *See generally*, Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (proposed 1986).

[239] *See generally*, Statement of Policy for Regulating Biotechnology Products, 51 Fed. Reg. 23309 (1986).

[240] *Despite Opposition, Biotech Foods Ready For Prime Time, Experts Say*, FOOD & DRINK WEEKLY, Dec. 14, 1998, at 1.

[241] Schneider, *supra* note 183.