

ISSUES IN ENVIRONMENTAL LAW

NOTES

MOVING BEYOND RISK IN ASSESSING TECHNOLOGICAL ARTIFACTS: THE CASE OF RECOMBINANT BOVINE SOMATOTROPIN

INTRODUCTION

Due to recent advances in recombinant deoxyribonucleic acid (rDNA) technology, popularly referred to as gene splicing,¹ scientists have invented a means to mass produce a hormone found in cows known as bovine somatotropin (bST) or bovine growth hormone (bGH).² Injected into a lactating cow, rbST increases her milk production from ten to forty percent.³ Use of this new drug, which is yet to be approved by the Food and Drug Administration (FDA),⁴ has caused heated controversy. The issue has split the dairying community,⁵ and pitted consumer and environmental groups against four Fortune 500 chemical companies which have invested over ten years and hundreds of millions of dollars into research on this product.⁶

1. See, e.g., Doug Stewart, *These Germs Work Wonders*, READER'S DIG., Jan. 1991, at 83, 84; see also Keith Schneider, *Biotechnology Enters Political Race*, N.Y. TIMES, Apr. 21, 1990, at 6.

2. Keith Schneider, *Biotechnology's Cash Cow*, N.Y. TIMES, June 12, 1988, § 6 (Magazine), at 46 [hereinafter Schneider, *Cash Cow*].

3. ROBERT J. KALTER ET AL., *BIOTECHNOLOGY AND THE DAIRY INDUSTRY: PRODUCTION COST AND COMMERCIAL POTENTIAL OF THE BOVINE GROWTH HORMONE* (1984).

4. Press Office of the Food and Drug Administration, *FDA Reviewing BST for Cows, Safety Data Being Published*, Aug. 4, 1989, at 1 (Talk Paper). Talk Papers are prepared by the FDA Press Office for FDA personnel. Although not written for general distribution, Talk Papers are available from the Food and Drug Administration, Public Health Services, 5600 Fishers Lane, Rockville, Md. 20857.

5. The dairy community is divided roughly according to farm size. One survey found that 75% of dairy farmers opposed the introduction of rbST, with the smallest farms being most opposed. Laurent Belsie, *Hormone-Use Debate Heats Up*, CHRISTIAN SCI. MONITOR, Oct. 17, 1989, at 7. This split is also evident in public hearings on rbST. See *Public Hearing on H. 895 Before the Joint House & Senate Agricultural Committees*, (Feb. 15, 1990, Vt., 1989 Adj. Sess.) [hereinafter *Hearings*].

6. Keith Schneider, *Betting the Farm on Biotech*, N.Y. TIMES, June 10, 1990 (Business World Magazine), at 26 [hereinafter Schneider, *Betting the Farm*]. Monsanto has spent

Bovine somatotropin (bST) is a hormone that is produced by a cow's pituitary gland.⁷ Scientists have known since the 1930's that cows injected with bST would produce more milk.⁸ During World War II, when food supplies were low, scientists stimulated cows to produce more milk by injecting them with bST, which was obtained from the pituitary glands of slaughtered cattle.⁹ The process was never introduced commercially because it was prohibitively expensive to collect the bST.¹⁰ Genetic engineers have overcome this limitation by creating a new organism which produces a close replica of bST known as recombinant bovine somatotropin (rbST).¹¹

According to the FDA and the four chemical companies¹² that hope to market the drug, milk from rbST-treated cows is safe for human consumption.¹³ Consumers, however, remain wary,¹⁴ and a few scientists claim that more research is needed to determine whether rbST is safe.¹⁵ Consumer safety issues aside, dairy farmers are also concerned that rbST will taint milk's pure image, one of its strongest selling points, and thus drive down the demand for milk and other dairy products.¹⁶ Dairy farmers and several commentators fear that the introduction of rbST will create additional milk surpluses, lowering the price farmers receive for milk.¹⁷ This

\$300 million developing rbST and according to one estimate is spending \$50 million a year researching it. *Id.* at 27. Monsanto's field testing of the product began in 1981 after it bought rights to bST from Genentech. *Id.* at 38.

7. INDUSTRIAL BIOTECHNOLOGY ASS'N, *BIOTECHNOLOGY AT WORK: GLOSSARY OF TERMS* 2 (1988).

8. Judith C. Juskevich & C. Greg Guyer, *Bovine Growth Hormone: Human Food Safety Evaluation*, 249 *SCIENCE* 875; Schneider, *Cash Cow*, *supra* note 2, at 46.

9. Peter Gorner & Ron Kotulak, *Battle over Cow Hormone Clouds Future of Biotechnology*, *CHI TRIB.*, Apr. 10, 1990, at 14.

10. *Id.*

11. See Juskevich & Guyer, *supra* note 8, at 875.

12. The chemical companies that hope to market rbST are Monsanto, Upjohn, Eli Lilly & Company, and American Cyanamid Company. Keith Schneider, *Consumer Group Questions Milk Hormone's Safety*, *N.Y. TIMES*, Dec. 4, 1990, at A29. The four companies have invested a combined total of over \$500 million into research and development of rbST. *Id.*

13. Before approving rbST for commercial use, the FDA, in an unprecedented move, published the health and safety data that supported the agency's conclusion that the drug is safe for human consumption. Ann Gibbons, *FDA Publishes Bovine Growth Hormone Data*, 249 *SCIENCE* 852.

14. Guy Gugliotta, *A Wonder Drug or a Threat?: Bovine Growth Hormone Raises Concern on Milk Surpluses, Safety*, *WASH. POST*, June 24, 1990, at A3.

15. See Samuel S. Epstein, *BST: The Public Health Hazards*, *ECOLOGIST*, Sept./Oct. 1989, at 191 [hereinafter Epstein, *BST Health Hazards*].

16. See Beverly Corey, *Bovine Growth Hormone: Harmless for Humans*, *FDA CONSUMER*, Apr. 1990, at 16, available in LEXIS, Nexis Library, FDA File.

17. Schneider, *Cash Cow*, *supra* note 2, at 46.

negative economic impact may fall disproportionately upon small farmers.¹⁸ Animal rights activists and some dairy farmers are also concerned that rbST may have negative impacts on the health of cows regularly injected with the substance.¹⁹

The introduction of rbST technology illustrates the following issues: (1) how our society controls the introduction of commercial products resulting from new technologies; (2) why this control process is inadequate; and (3) what changes should be made to better control the introduction of new technologies. The introduction of a new drug such as rbST, which will be used in producing milk for human consumption, is governed under the Food, Drug and Cosmetic Act.²⁰ The inadequacy and limitations of the Act are demonstrated by considering legitimate concerns which it ignores—such as the likely economic impact rbST will have on small and moderate sized dairy farmers, and the associated regional shifts in milk production. Other government agencies, such as the Office of Technology Assessment, have similarly limited authority.²¹ It is, however, desirable to regulate technology for socio-economic purposes, particularly in view of the possible effects of rbST on family farms, and there are a number of possible legislative actions that could be taken in response to rbST or to new technologies in general.

Society's failure to properly control technology sometimes leads to nondemocratic, nonpluralistic, and undesirable results. New technology is currently controlled through risk assessment, which attempts to balance the known health and safety risks of a proposed new technology against its benefits. In some cases, as in the case of rbST, risk analysis is inadequate. Questions concerning the economic, social, and political effects of new technologies are

18. See Matthew H. Shulman, *Bovine Growth Hormone: Who Wins? Who Loses? What's at Stake?*, in AGRICULTURAL BIOETHICS 111, 113-14 (Steven M. Gendel et al. eds., 1990).

19. For an animal rights viewpoint see Peter Wheale & Ruth McNally, *Introduction II*, in THE BIO-REVOLUTION: CORNUCOPIA OR PANDORA'S BOX? 58-59 (1990). Animal rightists point out that the dairy industry controls several facets of a cow's life including: "where she lives, what she is fed on, which sire she breeds with, how often she is pregnant, and when she is to die." *Id.* at 58. They argue that use of rbST on cows will lead to disease and pain for the animals. *Id.* Other animal rights activists argue that "[a]n industrial, mechanistic paradigm cannot be safely imposed upon biological systems." Michael Fox, *Why BST Must Be Opposed*, in THE BIO-REVOLUTION: CORNUCOPIA OR PANDORA'S BOX?, *supra*, at 91.

For farmers' viewpoints see *Hearings*, *supra* note 5, at 10-13 (testimony of Harold Billings), 43-47 (testimony of Wes Trombley).

20. See *infra* notes 58-62 and accompanying text.

21. See *infra* notes 239-46 and accompanying text.

excluded from traditional risk analysis. Such impacts should, however, be considered because technological artifacts are not value neutral. They have social and political ramifications. A product that results from new technology, of course, is likely to have both desirable and undesirable effects. Nevertheless, when these effects are analyzed and weighed, the product should have a net benefit or overall desirable effect before it is commercially introduced.

For example, biotechnology itself may be viewed as neutral, but products that result from biotechnology (called technological artifacts or technical artifacts in philosophical literature)²² may have overall positive or negative consequences. Consider three very different applications of biotechnology whose effects range from beneficial to deplorable. Biosynthetic insulin, for example, has largely positive effects for society as a whole: it is closer to the natural human product than other commercial alternatives, and may prevent allergic reactions.²³ In contrast, the use of fetal tissue from therapeutic abortions to explore potential cures for Parkinson's disease is much more controversial, and its overall desirability is debatable.²⁴ Finally, most people would strongly disapprove of genetic engineering to create "superior" or "inferior" human beings to perform different economic functions in society.²⁵ In all three cases risk analysis is inadequate to fully evaluate the technological artifact's desirability, although the need to do so is apparent.

Because rbST is a product of rDNA technology, a brief overview of the biotechnique may demystify the topic for readers who are unfamiliar with the technology. This may not only facilitate a clearer understanding of rbST, but also demonstrate how any action taken on rbST will impact other biotechnological innovations.

22. See LANGDON WINNER, *THE WHALE AND THE REACTOR: A SEARCH FOR LIMITS IN AN AGE OF HIGH TECHNOLOGY* 20 (1986).

23. INDUSTRIAL BIOTECHNOLOGY ASS'N, *BIOTECHNOLOGY AT WORK: WHAT IS BIOTECHNOLOGY?* 16 (1989) [hereinafter *WHAT IS BIOTECHNOLOGY?*].

24. For Congress' view on this research see Alan Fram, *Legislation Would Lift Ban on Fetus-Tissue Research*, BURLINGTON FREE PRESS, July 26, 1991, at 2A. For scholarly treatment see Neal D. Ferenc, Note, *Medical Breakthroughs in Human Fetal Tissue Transplantation: Time to Reevaluate Legislative Restrictions on Fetal Research*, 13 VT. L. REV. 373 (1988).

25. See generally ALDOUS HUXLEY, *BRAVE NEW WORLD* (1932).

I. THE GENE SPLICING REVOLUTION IN BIOTECHNOLOGY AND RECOMBINANT BOVINE SOMATOTROPIN

The field of biotechnology includes both traditional and non-traditional methods of manipulating life forms for material gain.²⁶ Selective breeding programs to improve ease of harvest or disease resistance in agricultural plants or animals are an example of one kind of traditional biotechnology method.²⁷ Another example is the use of yeast to make beer: yeast is a microorganism which converts starch and sugar to alcohol.²⁸

Biotechnology also includes less traditional methods of manipulating life forms.²⁹ Microbiologists use modern genetic engineering techniques to transfer genes from a source organism into a recipient organism.³⁰ All life forms, whether they are plant or animal, contain the same basic building blocks in their DNA.³¹ Organisms differ from one another only because the genetic material for each life form is combined in different sequences and in differing amounts.³² Because all life forms are made from the same basic building blocks it is possible, in theory, to insert genetic material into any recipient organism from any source organism.³³ For example, microbiologists have discovered how to insert the human gene that controls the production of insulin into *Escherichia coli*, a bacterium.³⁴ When new genetic material is introduced into an organism, a novel or original life form is created because organisms are ultimately defined by their genetic structure.³⁵ The success of this technique has led some critics to conclude that a modern scientist has the power of a god, able to play the ultimate genetic engineer, and create new life forms according to her own ideas of what is desirable.³⁶

Recombinant DNA (rDNA), the technique used to manufacture rbST,³⁷ is the most dramatic biotechnique used to create new

26. See WHAT IS BIOTECHNOLOGY?, *supra* note 23, at iv, 1-3.

27. *Id.* at 1.

28. *Id.*

29. *Id.* at 3-10.

30. MARGARET MELLON, BIOTECHNOLOGY AND THE ENVIRONMENT 15-23 (1988).

31. See WHAT IS BIOTECHNOLOGY?, *supra* note 23, at 3.

32. See *id.* at 3-6.

33. MELLON, *supra* note 30, at 17.

34. WHAT IS BIOTECHNOLOGY?, *supra* note 23, at 6-7.

35. MELLON, *supra* note 30, at 17.

36. See generally TED HOWARD & JEREMY RIFKIN, WHO SHOULD PLAY GOD? (1980).

37. See RURAL VERMONT, BOVINE GROWTH HORMONE: WHAT'S IN IT FOR VERMONT? 1

life.³⁸ Recombinant DNA technology uses bacteria as the recipient organism. In addition to the DNA contained in their cell nuclei, bacteria commonly contain free-floating, circular pieces of DNA called plasmids.³⁹ Unlike the cell nuclei, plasmids can cross bacteria cell walls, and can be found outside the cell walls.⁴⁰ In rDNA gene splicing, these plasmids are used to carry new genes into the bacteria.⁴¹ Microbiologists can isolate the plasmids and cut out a strand of DNA from the plasmid using a restriction enzyme.⁴² The same type of enzyme is used to cut out a strand of DNA from the source organism⁴³ (e.g., a cow, a corn plant, or a firefly). Because the same enzyme is used to cut the genes from each organism, the DNA from each has matching "sticky ends."⁴⁴ Under the correct conditions, the DNA from each organism will join together, creating a whole plasmid with genetic material from both organisms.⁴⁵

The plasmid then crosses the cell wall of the host bacterium, which assimilates the new genetic structure.⁴⁶ When the new bacterium with its altered plasmid reproduces, it passes the new genetic material along to its offspring.⁴⁷ The following diagram illustrates the gene splicing technique:

(1988); see also Wade Roush, *Who Decides about Biotech: The Clash over Bovine Growth Hormone*, *TECH. REV.*, July 1991, at 28, 30.

38. JEREMY RIFKIN, *ALGENY 7* (1983). There are other modern biotechniques such as direct gene transfer techniques, cell fusion, and chimeras (chimeras are created by mixing together the cells of early embryos from different species). MELLON, *supra* note 30, at 21-23. All of these techniques have in common the ability to mix species at the cellular level instead of manipulation at the organismal level, which characterizes more traditional methods. *Id.* at 20. The first successful gene transfer occurred in 1973 when two Stanford scientists spliced genes together from unrelated organisms. RIFKIN, *supra*, at 6-7. These scientists employed an rDNA technique. See *id.*

39. MELLON, *supra* note 30, at 20-21.

40. *Id.* at 21.

41. *Id.* at 20-21. In this biotechnique the plasmids are being used as vectors. A vector is the means used to transfer genetic material from one organism to another. See *id.*

42. *Id.*

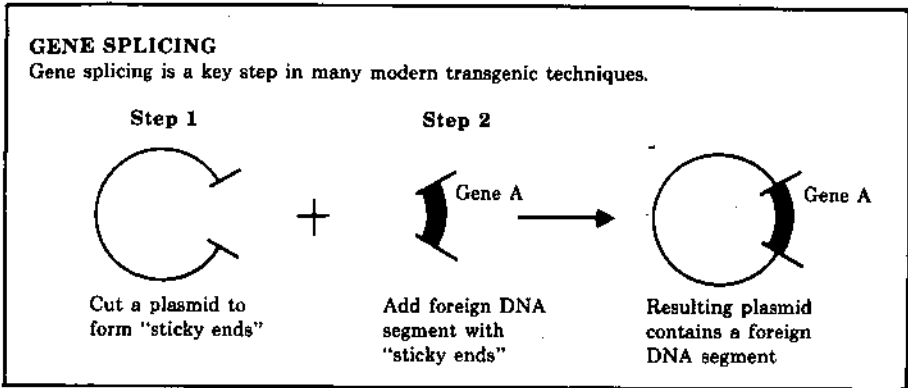
43. *Id.*

44. *Id.*

45. *Id.*

46. *Id.*

47. *Id.* at 21.



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In rbST production, the bST-controlling gene from a cow is spliced into an *Escherichia coli* bacterium plasmid.⁴⁸ The altered plasmid then crosses the recipient bacterium's cell wall. This new bacterium produces rbST.⁴⁹ It will also pass this trait onto its offspring, sparing the genetic engineer from repeating the splicing process several times over. A colony of these novel life forms is capable of producing rbST in relatively large quantities. Unlike extracting the substance from dead cows' pituitary glands, this process appears to be economically viable.⁵⁰

Recombinant DNA technology is being used to form several new products in the areas of health care, veterinary medicine, agriculture, food processing, toxic waste management, and energy.⁵¹ The FDA has approved biosynthetic products for human health care (biosynthetic insulin)⁵² and food processing (biosynthetic rennin for cheese production).⁵³ However, the FDA has not approved any agricultural product derived from rDNA technology.⁵⁴ If it is

48. See RURAL VERMONT, *supra* note 37, at 1; see also Roush, *supra* note 37, at 28, 30.

49. Roush, *supra* note 37, at 30.

50. Economic viability, of course, depends on whether the companies that developed the product are able to successfully market rbST and recover their sizeable investment in the drug.

51. WHAT IS BIOTECHNOLOGY?, *supra* note 23, at 11-23.

52. *Id.* at 16.

53. A biosynthetic form of rennin, an enzyme used in cheese production, has been approved by the FDA. Martin Tolchin, *Gene-Altered Item Approved by F.D.A.*, N.Y. TIMES, Mar. 24, 1990, § 1, at 27. Biosynthetic insulin, used to treat diabetes, was one of the first rDNA products approved by the FDA. WHAT IS BIOTECHNOLOGY?, *supra* note 23, at 16.

54. See *Wisconsin Leaders Back Curb on Sale of Growth Hormone*, N.Y. TIMES, Mar.

ultimately approved for commercial use, rbST will probably be the first such agricultural product to reach the market, because it is the furthest along in the regulatory approval process.⁵⁵ Recombinant bST is therefore a test case for rDNA technology because it is likely to be a first in the field of agriculture.⁵⁶ It has received more attention from the press, consumer groups, farms and lawmakers than have other products of biotechnology.⁵⁷ The lessons learned from the rbST approval process will have an impact on future biotechnology products.

II. THE FEDERAL GOVERNMENT'S RESPONSE TO RBST

A. *The Food and Drug Administration's Action Taken on rbST and the Public's Response*

The Food and Drug Administration regulates rbST under the Federal Food, Drug and Cosmetic Act (hereinafter the Act).⁵⁸ Under the Act, the FDA must approve any new animal drug before it can be sold or distributed in the United States.⁵⁹ To gain FDA approval, a new animal drug must meet five requirements: (1) the food products from treated animals must be safe for human consumption; (2) the manufacture and use of the drug must be safe for the environment; (3) the drug must be safe for the animal; (4) the applicant must prove that it can manufacture the drug to a consistent potency and purity; and (5) the drug must be proven effective—it must do what it is claimed to do.⁶⁰

The FDA approval process is concerned exclusively with risk. The first three requirements consider the risk that a new animal

23, 1990, at A12.

55. The FDA now expects to complete its review of rbST in early 1992. Caroline E. Mayer, *Milk Takes a Spill; An Industry Works to Clean Up Its Image*, WASH. POST, Feb. 6, 1991, at E4. Previously the FDA had hoped to rule on the drug by early 1991. *Id.* Other agricultural products are not expected to be approved until 1994 at the earliest. See Schneider, *Betting the Farm*, *supra* note 6, at 29.

56. See Schneider, *Betting the Farm*, *supra* note 6. An investment bank analyst noted, "I've contended for some time that BST [sic] is the litmus test of biotechnology products getting into the human food chain." *Id.* at 38 (quoting Paul T. Leming of Morgan Stanley & Co.).

57. See THE NEW YORK TIMES, THE NEW YORK TIMES INDEX 1990 (for example, the "dairy" heading in the New York Times Index lists 11 articles on rbST from January 1990 through December 1990, but only two articles on rennin for the same time period).

58. 21 U.S.C. § 360b (1989).

59. *Id.*

60. See 21 C.F.R. § 514 (1990); see also Press Office of the Food and Drug Administration, *supra* note 4, at 1.

drug poses to human health, animal health, and the environment. The fourth requirement also involves risk: a drug that cannot be manufactured to a consistent purity and potency is by definition too risky. Finally, the efficacy requirement ensures that society is not exposed to needless risk. In other words, any new drug necessarily presents some risk and it is illogical to expose society to that risk without some corresponding benefit.

The scientific evidence used to assess the risk posed by any new animal drug—mostly in the form of test results from extensive clinical and animal studies—is supplied to the FDA by the New Animal Drug Applicant.⁶¹ During the review process, the new drug can be used on animals in experiments approved by the FDA, but the drug may not be sold or otherwise distributed before final FDA approval.⁶² A more detailed examination of the FDA's review of rbST will demonstrate the limited nature of risk analysis.

1. Recombinant Bovine Somatotropin's Effect on Human Health

Milk or other products from animals treated with experimental drugs may be sold on the open market if the FDA determines that there is no human health risk to consumers.⁶³ In the case of rbST, the FDA concluded that there is no risk to humans from consuming milk and meat from cows injected with the drug⁶⁴ (milk from treated cows will hereinafter be referred to as "rbST milk"). Therefore, the milk and meat from experimental herds may be sold to the public.⁶⁵

A number of factors went into the FDA's determination. First, rbST is similar to bST, the hormone which occurs naturally in cows.⁶⁶ Since bST has always occurred naturally in milk, rbST is

61. 21 C.F.R. § 514.1(b).

62. 21 U.S.C. § 360b(a)(1) (1988) (deeming all animal drugs unsafe unless they have been approved); 21 C.F.R. § 511 (specifying the conditions under which an experimental drug may be used in order to investigate it).

63. Press Office of the Food and Drug Administration, *supra* note 4, at 1.

64. *Id.*

65. *Id.*

66. *See id.* at 2. Although they are supposedly biologically indistinguishable, rbST is not always identical to natural bST. *See Juskevich & Guyer, supra* note 8, at 877. Of the four pharmaceutical companies producing rbST, only Upjohn Company produces a completely identical hormone. *Id.* Eli Lilly & Company (Elanco) and American Cyanamid produce hormones which have additional proteins at the NH₂-terminus end. *Id.* Monsanto's rbST substitutes a Met amino acid for an Ala amino acid at the NH₂-terminus end. *Id.*

likely to be as safe as the natural substance.⁶⁷ Second, rbST has no significant impact on the nutritional quality of milk.⁶⁸ Third, ninety percent of rbST in milk from treated cows is destroyed when the milk is pasteurized.⁶⁹ Fourth, rbST is digested in the gastrointestinal tract of mammals and it is not absorbed into the bloodstream.⁷⁰ Finally, rbST is biologically inactive in humans.⁷¹ For these reasons the FDA determined that rbST milk could be sold to consumers,⁷² without special packaging or notification.

Information is now available that casts doubt on the FDA's findings on the safety of milk and meat from rbST treated cows. Dr. Richard Burroughs,⁷³ a former FDA employee⁷⁴ who reviewed rbST from 1985 to 1988,⁷⁵ claims that the FDA's review process for rbST has been inadequate. According to Dr. Burroughs, companies that produce rbST were not required to develop data usually required for new animal drug approval.⁷⁶ He claims that the FDA failed to properly review the product because of an overly close relationship between the FDA and the regulated industry.⁷⁷ "It

67. Press Office of the Food and Drug Administration, *supra* note 4, at 2.

68. William H. Daughaday & David M. Barbano, *Bovine Somatotropin Supplementation of Dairy Cows: Is the Milk Safe?*, 264 JAMA 1003, 1004 (1990).

69. Juskevich & Guyer, *supra* note 8, at 883.

70. Press Office of the Food and Drug Administration, *supra* note 4, at 2. No oral activity was found in laboratory rats that were administered rbST at exaggerated doses. Juskevich & Guyer, *supra* note 8, at 878, 883.

71. Juskevich & Guyer, *supra* note 8, at 877, 883. According to the FDA, studies from the early 1950's prove this point. *Id.* at 877. In an unsuccessful attempt to stimulate growth in children suffering from dwarfism, scientists injected them with bST extracted from pituitary glands of cows. Press Office of the Food and Drug Administration, *supra* note 4, at 2. The results were negative because hormones are species specific. Juskevich & Guyer, *supra* note 8, at 877. Species specific means that hormones from "lower" forms of life are inactive in "higher" forms of life. *Id.* Thus, rbST is inactive in humans. *Id.* at 883.

72. Press Office of the Food and Drug Administration, *supra* note 4.

73. Dr. Burroughs holds a degree in veterinary medicine from Cornell University, and has taught at the University of Pennsylvania. *Hearings, supra* note 5, at 4, 5 (testimony of Dr. Richard Burroughs).

74. Thomas S. Drake, *BGH Label Urged by Former FDA Researcher*, UPI, Jan. 23, 1990, at 1, available in LEXIS, Nexis Library, Wires File. Dr. Burroughs is now back at the FDA. The Federal Merit System Protection Board held that the FDA must reinstate Dr. Burroughs, because the agency neglected to follow formal rules when discharging him. Julia Flynn Siler, *All Things Right and Dutiful: A Vet Who Blew the Whistle*, Bus. Wk., Sept. 2, 1991, at 75. The FDA had alleged that Dr. Burroughs was fired for incompetence, but Burroughs argued that he was fired for publicly criticizing FDA's handling of the review process. *Id.*

75. Keith Schneider, *F.D.A. Accused of Improper Ties in Review of Drug for Milk Cows*, N.Y. TIMES, Jan. 12, 1990, at A21 [hereinafter Schneider, *Improper Ties*].

76. *Hearings, supra* note 5, at 4, 6 (testimony of Dr. Richard Burroughs).

77. *Hearings, supra* note 5, at 6-7; Schneider, *Improper Ties, supra* note 75.

used to be that we had a review process at FDA," Dr. Burroughs said.⁷⁸ "Now we have an approval process. I don't think FDA is doing good, honest reviews. They've become an extension [sic] of the drug industry."⁷⁹

Another outspoken critic of the FDA's decision to allow the sale of milk and meat from treated herds is Dr. Samuel Epstein, a physician and professor of occupational medicine at the University of Illinois College of Medicine.⁸⁰ According to Dr. Epstein, there are several unresolved public health issues which have not been addressed.⁸¹ Dr. Epstein's initial concern is that the various forms of rbST are different from natural bST.⁸² Therefore, tests performed on natural bST are inappropriate for evaluating synthetic bST.⁸³ No studies have been done to examine the effects on humans of rbST, as opposed to natural bST.⁸⁴ Despite the assumption that rbST will be broken down in the digestive tract, partially digested novel proteins might still be absorbed.⁸⁵ For these reasons, Dr. Epstein recommends a ban on the sale of milk and meat from test herds until all public health issues are resolved.⁸⁶

Dr. Epstein also fears that using rbST on dairy cattle may result in higher carcinogen levels in milk.⁸⁷ Carcinogens, such as pesticides found in cattle feed, build up in the fatty tissues of cows.⁸⁸ Cows treated with rbST burn more fat because they do not consume enough feed to meet the increased biological demands of making more milk.⁸⁹ When this fat is metabolized, carcinogens stored in the cows' fatty tissues may be released, thus increasing the carcinogen levels of their milk.⁹⁰

78. *FDA Accused by Ex-Official; Yielding to Industry Alleged*, 237 CHEMICAL MARKETING REP., Jan. 15, 1990, at 3 (quoting Dr. Richard Burroughs).

79. *Id.*

80. See, e.g., Samuel Epstein, *Growth Hormone Would Endanger Milk*, L.A. TIMES, July 27, 1989 (Metro Section), at 7.

81. Epstein, *BST Health Hazards*, *supra* note 15, at 191 (1989).

82. *Id.* at 192.

83. See *id.* at 192.

84. *Id.*

85. *Id.* This possibility was examined by the FDA, which admitted that fragments of the protein could be absorbed by the human digestive tract. See Juskevich & Guyer, *supra* note 8, at 877. The authors went on to state, however, that this is not a concern because it is unlikely that such fragments would occur in biologically significant amounts. *Id.* at 883.

86. Epstein, *BST Health Hazards*, *supra* note 15, at 195.

87. *Id.* at 194.

88. *Id.*

89. See, e.g., Schneider, *Cash Cow*, *supra* note 2, at 44.

90. Epstein, *BST Health Hazards*, *supra* note 15, at 194.

Finally, Dr. Epstein warned that sustained use of rbST derived milk could lead to premature growth in human infants and breast cancer in women.⁹¹ Both rbST and natural bST stimulate cows' livers to produce a substance called insulin-like growth factor I (IGF-I).⁹² However, cows treated with rbST may produce significantly more IGF-I in their milk.⁹³ Unlike bST, IGF-I is not species specific.⁹⁴ It is active in the human blood stream, and can be found in human milk.⁹⁵ The FDA conducted IGF-I oral toxicity tests on rats and decided that rbST milk was safe for human consumption.⁹⁶ Dr. Epstein believes that research on the human exposure to IGF-I should be given priority.⁹⁷

The heated debate between proponents and critics of rbST is characteristic of most debates over the introduction of new technological artifacts. Under the federal laws which regulate the introduction of technology, review of a technological artifact must focus on risk.⁹⁸ A direct threat to human health is a particularly compelling argument. Opponents of a new technology tend to concentrate their efforts in this area for two reasons. First, it is easier to grab headlines by claiming that human health or human lives are at risk. Second, because the regulatory process is limited to risk analysis, opponents wisely concentrate their efforts on risks because it is the only area in which regulatory agencies can respond. The opposition's decision to concentrate on the potential risk to human health is an example of this phenomenon.

Unless one is an expert in the field (in this case a doctor of veterinary medicine), one's input is limited. Although many may

91. *Id.* at 193.

92. Daughaday & Barbano, *supra* note 68, at 1005.

93. Juskevich & Guyer, *supra* note 8, at 875.

94. Daughaday & Barbano, *supra* note 68, at 1005.

95. *See id.*

96. Juskevich & Guyer, *supra* note 8, at 881-83. Because rbST-treated cows may tend to produce milk with higher levels of IGF-I, and since there was a lack of scientific literature on the subject, the FDA determined that oral toxicity tests on IGF-I were required to determine whether rbST milk is safe for human consumption. *Id.* at 879. Reports on IGF-I's oral toxicity were not published until 1989. *Id.* at nn. 66-67. These reports arrived five years after the FDA had made the determination that rbST milk was safe for human consumption. Compare *id.* at nn. 66-67 (both studies on IGF-I were published in 1989) with Roush, *supra* note 37, at 31 (the FDA approved the sale of rbST milk to consumers in 1984).

97. Epstein, *BST Health Hazards*, *supra* note 15, at 193.

98. See 21 U.S.C. § 360b (1988); see also 15 U.S.C. § 2601 (1988) (protecting against unreasonable risk to human health and the environment from toxic substances); 7 U.S.C. § 136a (1988) (protecting against unreasonable risk that pesticides may pose to human health and the environment).

desire to participate in the debate, they are likely to abstain if they lack the expertise to analyze risk. Furthermore, even experts may be discouraged from participating if they lack the funding to study and evaluate a new technology. Federal law requires industry to conduct its own research to provide evidence that the drug does not present unreasonable risk.⁹⁹ While FDA administrators have access to this information, they are required to keep it confidential in order to protect the applicant's proprietary interest.¹⁰⁰ The public has no access to the industry's research results. Although there are good public policy reasons for these rules,¹⁰¹ outside of the FDA itself, the only scientists to test new drugs have been hired by the companies producing them. The results of these tests are often kept from the public. Because only a small, elite group of scientists evaluate new technological artifacts, the review process takes on an undemocratic character.¹⁰²

2. Reaction to the FDA's Decision to Allow the Sale of rbST Milk

The Foundation on Economic Trends (the Foundation), in alliance with other environmental and consumer groups, has launched a boycott of rbST milk because of unresolved human health and safety issues.¹⁰³ The Foundation was formed to oppose rDNA technology on all fronts.¹⁰⁴ It is often associated with its

99. 21 U.S.C. § 360b(b) (1988).

100. 21 C.F.R. § 514.10-514.12 (1991).

101. The purpose of such rules is to prevent others from cheaply copying the new technology and denying the benefits to the party that invested money and time in its development. If technological innovations were not protected, people would be less willing to invest in them.

102. See Henryk Skolimowski, *Technology Assessment in a Sharp Social Focus*, in TECHNOLOGY AND HUMAN AFFAIRS 146 (Larry Hickman & Azizah Al-Hibri eds., 1981). Skolimowski argues that experts cannot independently analyze new technology because they are so engrossed in the technological aspects of civilization. *Id.* at 147. Instead, he advocates that "real expertise" in Technology Assessment is social and moral not technical." *Id.* at 148.

For a more traditional analysis of why technology assessment must rely on experts, see Joseph Coates, *Technology Assessment . . . the Benefits . . . the Cost . . . the Consequences*, in TECHNOLOGY AND HUMAN AFFAIRS, *supra*, at 156, 162. Coates too recognizes that the assessment should not mirror the prejudices of the investigators and organization sponsoring the technology, but admits that this is difficult to achieve. *Id.* at 160.

103. *Flouting FDA's Pro-BST Finding, Rifkin Says: "It's War,"* BIOTECHNOLOGY NEWSWATCH, Sept. 3, 1990, at 1.

104. See *Foundation on Economic Trends v. Lyng*, 817 F.2d 882 (D.C. Cir. 1985); *Foundation on Economic Trends v. Bowen*, 722 F. Supp. 787 (D.D.C. 1989); *Foundation on Economic Trends v. Johnson*, 661 F. Supp. 107 (D.D.C. 1986); *Foundation on Economic Trends*

president, Jeremy Rifkin, who is an outspoken opponent of rDNA technology.¹⁰⁵ Rifkin has cautioned that society should be particularly wary of any gene splicing technologies.¹⁰⁶ The technology, he argues, lessens the value of all life forms.¹⁰⁷ As human beliefs and philosophies change to accommodate the biotechnological revolution, people will begin to view all life, including humankind, as a mere cornucopia of genetic material.¹⁰⁸ Life loses its special value when it becomes the raw material for human manipulation to satisfy human needs.¹⁰⁹

The Foundation has waged war against rbST, with some success.¹¹⁰ The Foundation's campaign against rbST milk and milk products has caused five major supermarket chains to refuse to accept any such milk.¹¹¹ Several milk cooperatives and dairy food processors have also refused to accept rbST milk.¹¹² Some of these companies are acting to avoid controversy and negative publicity over milk safety.¹¹³ Most are awaiting final FDA approval of the drug in the hope that a more settled atmosphere will prevail, and negative publicity can be avoided.¹¹⁴ At least one supermarket executive has complained that he is uncomfortable with a situation where grocers regulate food instead of the government.¹¹⁵ On the other hand, Ben & Jerry's, Vermont's gourmet ice cream maker, has taken a lead in opposing rbST. The company printed phrases such as "Save Family Farms—No BGH" on millions of pints of ice cream.¹¹⁶ Included was a toll free telephone number for consumers

v. Thomas, 661 F. Supp. 713 (D.D.C. 1986).

105. Corey, *supra* note 16.

106. RIFKIN, *supra* note 38, *passim*.

107. *Id.* at 159-215.

108. *Id.*

109. *Id.*

110. See *Flouting FDA's Pro-BST Finding, Rifkin Says: "It's War," supra* note 103, at 1.

111. Belsie, *supra* note 5. Safeway, Kroger, Stop & Shop, Supermarkets General, and Vons have agreed not to market rbST. *Id.*

112. Corey, *supra* note 16. Kraft USA, Borden, Ben & Jerry's Homemade, and the country's largest dairy cooperative, Associated Milk Producers Incorporated, will not accept rbST milk for use in their products. *Id.* Several smaller dairy cooperatives in several states and Canada have also refused to accept rbST milk. Belsie, *supra* note 5.

113. See Stephen Dowdell, *Kroger: We Can't Set Food Policy: Kroger Co. Supermarket Chain Responds to Campaigns by Consumer and Environmental Groups*, SUPERMARKET NEWS, Oct. 2, 1989, at 1, available in LEXIS, Nexis Library, SupNews File.

114. *Id.*

115. *Id.*

116. Roush, *supra* note 37, at 31.

to call for more information.¹¹⁷

The companies developing rbST formed a group called the Animal Health Institute to combat the alliance formed by the Foundation.¹¹⁸ The individual companies also promoted the drug as safe and effective. The FDA, however, recently rebuked Monsanto for illegally promoting rbST as safe when the drug had not yet been approved.¹¹⁹

The media battle over the drug between these two groups has been intense because consumer perceptions of the health risks posed by rbST, rather than the actual risk itself, may determine the drug's commercial viability. Dairy farmers are sensitive to consumer's perceptions of the drug and will act accordingly. As one dairy farmer in California noted, "My only concern is what consumers think. If people won't drink it, I can't use it [rbST]."¹²⁰ If consumers are unlikely to buy rbST milk, then farmers are less likely to buy rbST in the first place.

This media blitz over rbST's safety is reminiscent of similar controversies over food safety. Consumer confidence in the FDA's risk determinations has been undermined by high profile risk determinations on other food additives. The alar "scare"¹²¹ and the saccharin debate¹²² are perhaps the most prominent examples. Because the FDA's credibility has been undermined, consumers are more willing to listen to environmental and consumer groups on issues of food safety than they used to be.¹²³

This trend has empowered citizen groups who have little or no access to the FDA approval process.¹²⁴ These groups have learned to bypass the review process, and take their case directly to the

117. *Flouting FDA's Pro-BST Finding, Rifkin Says: "It's War," supra* note 103, at 3.

118. Roush, *supra* note 37, at 30.

119. *Id.*

120. Gugliotta, *supra* note 14 (quoting Fred Machado).

121. For information on the alar "scare" see Marina M. Lolley, Comment, *Carcinogen Roulette: The Game Played under FIFRA*, 49 *Md. L. Rev.* 975, 984-88 (1990).

122. On the saccharin debate see Richard A. Merrill & Michael R. Taylor, *Saccharin: A Case Study of Government Regulation of Environmental Carcinogens*, 5 *VA. J. NAT. RESOURCES L.* 1 (1985).

123. Marian Burros, *New Urgency Fuels Effort to Improve Safety of Food*, *N.Y. TIMES*, May 7, 1990, at A1. Even the acting head of the FDA acknowledges that consumers have lost confidence. *Id.* at D11. Consumer confidence has also been eroded by the increased incidence of chemicals in food due to factory farming methods. *Id.* at A1. Salmonella poisoning has also raised concerns. *Id.* at D11.

124. See *supra* notes 58-62 and accompanying text.

people through boycotts. Although boycotts empower consumer and environmental groups to a certain extent, boycotts cannot provide full public participation. A consumer advocate put it this way: "In the U.S. system the average person has no say in the development of technology or the development of products. They can only get their say by veto power—I will buy it or I will not buy it—and that's not public participation."¹²⁵

In part, the controversy over rbST's human health effects is fueled by other concerns such as bovine health and the potential economic effects on dairy farmers. Groups opposed to rbST may concentrate on attention-getting human health risks even if their opposition springs from some other concern. For instance, some dairy groups have joined with the Foundation on Economic Trends in advocating a boycott,¹²⁶ but their interests are primarily socio-economic and not health-based. Similarly, farmers and animal rights advocates may be opposed to rbST more because of the health impacts on cows than because of the human health consequences. Nevertheless, they become involved in all facets of the debate.

3. Impact on the Health of Cows

Experts agree that rbST does have some adverse effects on bovine health, but there is disagreement over the significance of these effects. The FDA has made no determination on the safety of the drug as administered to cows, and thus has not yet approved the sale and marketing of the drug in the United States.¹²⁷

Several possible adverse effects have been reported. First, there is evidence that rbST may cause mastitis—a painful inflammation of the udder.¹²⁸ Evidence of this condition led the United

125. Roush, *supra* note 37, at 30 (quoting Michael Hansen, an analyst for Consumer's Union).

126. *Flouting FDA's Pro-BST Finding, Rifkin Says: "It's War," supra* note 103, at 1.

127. The author has arrived at this conclusion through process of elimination. The FDA has found no adverse human health effects. See *supra* notes 63-72 and accompanying text. Further, although the FDA has not announced that rbST is efficacious, several studies have shown that it does increase milk production in cows. See, e.g., KALTER, ET AL., *supra* note 3, at 3. Finally, it is unlikely that manufacturing consistency standards are blocking approval of rbST, since it was developed by four technically competent companies which invested \$500 million in the project. Daniel S. Greenberg, *Higher Milk Production Isn't Worth the Money Spent on It*, L.A. TIMES, Dec. 10, 1990, at B3. Thus, the only issue remaining is rbST's effects on bovine health.

128. *FDA Sees BST As Safe for Humans, Udderly Problematical for Bovines*, BIO-

Kingdom's Veterinary Products Committee to refuse Monsanto a license to market the drug in Great Britain.¹²⁹ The Committee was also concerned about pain and swelling at the injection site.¹³⁰ Monsanto is appealing the decision.¹³¹ The Committee is also expected to deny rbST licenses to other companies hoping to market the drug in Great Britain.¹³²

Additionally, David S. Kronfeld, a researcher at the University of Pennsylvania, concluded that high levels of rbST in cows can result in subclinical hypermetabolic ketosis.¹³³ This condition is associated with mastitis, decreased immune function, reduced reproductive capacity and other symptoms associated with early lactation.¹³⁴ Kronfeld suggested that other studies did not show similar results because some sick cows were removed from the trials.¹³⁵ Researchers assumed the cows picked up the disease before the experiment began.¹³⁶

The same concerns were voiced by Dr. Burroughs, the former¹³⁷ FDA employee mentioned earlier for his criticisms of the review process.¹³⁸ He claims that cows treated with the drug have abnormally high rates of reproductive problems.¹³⁹ Dr. Burroughs also claims that rbST causes a higher incidence of udder infection, and that the FDA has not adequately addressed this issue.¹⁴⁰ Dr. Robert J. Collier of Monsanto acknowledges these problems, but is

TECHNOLOGY NEWSWATCH, Dec. 18, 1989, at 9 [hereinafter *Udderly Problematical*].

129. Michael Hornsby, *Milk Yield Hormone for Cows Faces Ban*, TIMES (London), Sept. 15, 1990 (Home News), available in LEXIS, Nexis Library, TTimes File. The Committee for Veterinary Medical Products of the European Community has recommended that SOMATECH, Monsanto's brand name for rbST, be approved by member nations. David Brown, *Hormone to Boost Milk Yield Is Safe, Say EC Vets*, DAILY TELEGRAPH, Mar. 27, 1991, at 4, available in LEXIS, Nexis Library, Telegr File. But the decision from the EC Committee is not binding on member nations. See *Bovine Somatotropin; Going Sour*, ECONOMIST (U.K. ed.), Apr. 6, 1991, at 82 available in LEXIS, Nexis Library, Econ File. An EC moratorium on the drug is due to expire at the end of 1991. Brown, *supra*.

130. Hornsby, *supra* note 129.

131. *Id.*

132. *Id.*

133. D. S. Kronfeld, *Growth Hormone-Induced Ketosis in the Cow*, 48 J. DAIRY SCI. 342 (1965).

134. Shulman, *supra* note 18, at 121.

135. *Id.*

136. *Id.*

137. The FDA has now reinstated Dr. Burroughs after losing a hearing before the Federal Merit Systems Protection Board. See *supra* note 74.

138. See *supra* notes 73-79 and accompanying text.

139. Schneider, *Improper Ties*, *supra* note 75.

140. Drake, *supra* note 74.

confident that they can be corrected with better herd management.¹⁴¹ Larry O'Neill, a spokesperson for Monsanto, says that the infections were reported for test cows given five times the normal dose of rbST, and are not likely to occur in commercial herds.¹⁴²

As of publication, the FDA continues to review the effect of rbST injections on cows.¹⁴³ The FDA's opinion on this question is not clear because the FDA is not permitted to release test results supplied to it by new drug applicants.¹⁴⁴ However, it was reported, in an article published in *Technology Review*, that the FDA sent letters to both Monsanto and Eli Lilly in 1988 indicating that the agency was concerned about the high rate of udder infections in experimental herds.¹⁴⁵ The same article also noted that the agency was concerned about reactions at the injection site.¹⁴⁶ Furthermore, although the FDA has access to information not available to the public, experts outside the FDA seem to agree that available research indicates that rbST injections cause mastitis and reproductive problems in cows.¹⁴⁷

The controversy is over the significance of these findings. Certainly the United Kingdom's Veterinary Products Committee found these adverse effects significant when it denied Monsanto's application to distribute the product in Great Britain, since they based their decision on risks to bovine health rather than human health.¹⁴⁸ Monsanto, on the other hand, believes whatever problems do exist can be corrected or will not occur at the recommended safe dose levels.¹⁴⁹ Terry Smith, a researcher at the University of Wisconsin, stated that an effect on cows' fertility was to be expected because cows injected with rbST produce more milk

141. Schneider, *Improper Ties*, *supra* note 75.

142. Gibbons, *supra* note 13, at 853.

143. Press Office of the Food and Drug Administration, *supra* note 4, at 1.

144. The Food, Drug, and Cosmetic Act requires the FDA to keep test results confidential in order to protect an applicant's proprietary information. See *supra* notes 100-01 and accompanying text.

145. Roush, *supra* note 37, at 33.

146. *Id.*

147. This conclusion was recently controverted by a National Institutes of Health report which found that it is impossible to come to a conclusion about rbST's effect on cows from the published data. National Inst. of Health, Bovine Somatotropin 10 (Dec. 12, 1990) (revised draft, Technology Assessment Conference Statement). The report, however, noted that the incidence of clinical mastitis increased in cows treated with rbST in some trials. *Id.* The panel noted that they did not have access to several studies currently available only to the FDA. *Id.* at 11.

148. Hornsby, *supra* note 129.

149. Gibbons, *supra* note 13, at 853.

for a longer period of time, and thus it is natural for their pregnancies to be delayed.¹⁵⁰ Richard Teske, Deputy Director of the FDA's Center for Veterinary Medicine believes that the whole question comes down to a labeling issue.¹⁵¹ Milk cannot be sold from cattle infected with mastitis.¹⁵² Companies marketing rbST would not be able to put claims on the drug's label that it increases milk production, because they would not be able to show that it increases edible milk production.¹⁵³ Therefore, even at this early stage, regulators in the United Kingdom and the United States disagree over the significance of the observed increased rate of mastitis and other problems seen in experimental herds.

The controversy over the significance of rbST's risk to cows demonstrates that risk assessment is a far from purely objective activity. In fact, scientists are likely to inject their own values into risk analysis, because scientific knowledge is imperfect, uncertain, and incomplete.¹⁵⁴ Congressional directives are likely to be general, leaving room for considerable uncertainty in specific instances.¹⁵⁵ Furthermore, even in risk analysis, politics will sometimes influence appointed officials. Given the tight nexus between industry experts and FDA officials, and the practical exclusion of all others from the decision-making process, there is great reason for concern.

4. Likely Public Response if the FDA Approves the Sale of rbST in the United States

If the FDA gives final approval for the sale of rbST, the public

150. Gugliotta, *supra* note 14.

151. *Udderly Problematical*, *supra* note 128.

152. *Id.*

153. *Id.*

154. See Edward J. Woodhouse, *Sophisticated Trial and Error in Decision Making about Risk*, in *TECHNOLOGY AND POLITICS* 208 (Michael E. Kraft & Norman J. Vig eds., 1988) (discussing uncertainty in risk analysis and the infusion of political values into the analysis).

155. Congress directs the FDA to refuse approval of a new animal drug if: (1) the drug has not been "adequate[ly] test[ed]"; (2) the drug is "unsafe" or cannot be determined to be "safe"; (3) manufacturing methods are "inadequate to preserve" its quality and consistency; (4) there is no "substantial evidence" of its efficacy; (5) the proposed tolerance limit exceeds what is "reasonably required" for it to be efficacious; (6) certain patent information is not included in the application; (7) the labeling is "false or misleading"; or, with certain exceptions, (8) the drug "induces" cancer in man or animal. The Food Drug and Cosmetic Act, 21 U.S.C. § 360b(d)(1) (1988). What is or is not "safe" or "adequate" is left to the agency's judgment.

reaction is likely to be negative. First, the Foundation on Economic Trends has promised a lawsuit against the FDA if the Agency approves the drug.¹⁵⁶ Second, the Foundation boycott of rbST milk and dairy products is likely to diminish the market for the drug.¹⁵⁷ Third, consumer surveys have shown that the public is wary of rbST. One survey in Wisconsin¹⁵⁸ found that 77% of the populace would prefer to drink milk from untreated herds and 67% would be willing to pay an extra 22¢ per gallon for it.¹⁵⁹ Finally, lawmakers may involve themselves in the process, and consider additional legislation to control rbST apart from FDA review.¹⁶⁰

B. *Effects beyond the Federal Government's Scope*

1. The Economic Ramifications of rbST on Dairy Farming

The use of rbST to increase milk production in cows is likely to create larger milk supplies and at the same time decrease demand. This would aggravate a trend that already exists in the dairy industry: the industry's productive capacity has grown as technology advanced, while at the same time demand has plummeted, despite population growth, as American consumers become more aware of health issues associated with milk.¹⁶¹ This trend results in milk surpluses.¹⁶² At the same time, dairy farms have be-

156. Mark Lee, *Firm Confident Milk Hormone Is Safe*, TULSA WORLD, Jan. 27, 1990, at C1, available in LEXIS, Nexis Library, Tuls File.

157. *Flouting FDA's Pro-BST Finding, Rifkin Says: "It's War," supra* note 103, at 1.

158. People in Wisconsin are likely to be more educated on dairy issues because Wisconsin is the country's largest dairy producer, accounting for 17% of the nation's milk supply. THE 1989 INFORMATION PLEASE ALMANAC, ATLAS AND YEARBOOK 749 (Otto Johnson ed., 1989).

159. Gugliotta, *supra* note 14.

160. See *infra* notes 239-58 and accompanying text.

161. In 1950 there were 23,853,000 dairy cows producing milk for a population of 150,697,000; in 1988, however, it took only 10,307,000 dairy cattle to serve a population of 246,100,000. THE 1989 INFORMATION PLEASE ALMANAC, ATLAS AND YEARBOOK (Otto Johnson, ed., 1989) at 68, 766, 136-37. Moreover, the average annual output of American dairy herds rose from 5,842 pounds per cow in 1955 to nearly 13,000 pounds per cow in 1985. Greenberg, *supra* note 127. Some herds have reached over 20,000 pounds per cow annually without even using rbST. *Id.* These gains in efficiency are due to better feeds, selective breeding programs, and better herd management. *Id.* On dwindling consumer demand because of health concerns among consumers, see Mayer, *supra* note 55, at E1.

162. The federal government buys surplus milk. In 1988, the last year in which there were large surpluses, the federal government spent \$1.3 billion. In 1986 the federal govern-

come larger.¹⁶³ Larger farms and higher production per cow have led to fewer dairy farms. As large farms replace smaller ones, family farms are disappearing.¹⁶⁴

Against this backdrop, many dairy farmers are opposed to the introduction of rbST. John Kinsman, a dairy farmer who milks about eighty cows in Lime Ridge, Wisconsin, feels disenfranchised by the prospect of rbST being introduced into the American dairy barn: "We had this feeling that we had no power over this product, that we were going to have to accept it and it was going to put another one-third of family farmers out of business."¹⁶⁵ Wes Trombley, a dairy farmer in South Royalton, Vermont, believes that BST stands for "Big Surplus Trouble,"¹⁶⁶ and added: "I do not want to stick a needle in the cow frequently as she is my friend."¹⁶⁷

Dairy farmers, however, are not united in their opposition to rbST. Skip Hardie, for example, who milks 400 cows in North Lansing, New York, favors the new technology.¹⁶⁸ He is testing the drug on 100 of his cows to provide information for the FDA review, and is confident of the drug's safety: "I have four small children and we drink the milk from our own cows."¹⁶⁹

Dairy farmers on large farms are generally receptive to the new technology, while smaller herd managers tend to be against it.¹⁷⁰ In a hearing in Vermont discussing a potential ban on rbST

ment spent \$2.3 billion. Mayer, *supra* note 55, at E4. The 1989 drought and increased milk exports lowered surpluses and raised milk prices, but the effect was temporary. Greenberg, *supra* note 127. Currently, surpluses have forced prices lower than they have been for a decade. Meg Dennison, *Good News Is Lacking for Dairy*, RUTLAND DAILY HERALD, Feb. 11, 1991, at 1. Low milk prices, of course, have a dramatic effect on dairy farmers. For example, Jennifer Nelson, a dairy farmer in Ryegate, Vermont, said her family is losing \$1,000 per week because it costs \$13.00 per hundredweight to produce 100 pounds of milk, but they are paid only \$12.02 per hundredweight. *Id.* at 12.

163. James B. Kliebenstein & Seung Y. Shin, *Impact of Bovine Somatotropin (BST) on Dairy Producers*, in AGRICULTURAL BIOETHICS, *supra* note 18, at 194, 201.

164. Agriculture is becoming increasingly polarized. Shulman, *supra* note 18, at 116. The largest farms in the United States comprise 5% of the total number of farms, and produce 50% of the nation's agricultural output. *Id.* Smaller farms, on the other hand, make up 71% of the total number, but produce only 12% of the nation's output. *Id.* Both of these groups are growing, while the group in the middle, which represents the traditional full-time family farmer, is shrinking. *Id.*

165. Gugliotta, *supra* note 14 (quoting John Kinsman).

166. *Hearings*, *supra* note 5, at 44 (testimony of Wes Trombley).

167. *Id.* at 47.

168. Sharon Eurich, *Is Cream in Your Coffee Genetically Engineered?*, Gannett News Services, Jan. 30, 1990, available in LEXIS, Nexis Library, GNS File.

169. *Id.*

170. For a discussion of the different effects of rbST on large and small farms, see Roy

sales, smaller dairy farmers were significantly more opposed to rbST than their larger counterparts.¹⁷¹ Perhaps one small farmer in Vermont expressed the division most emphatically when he said, "If one businessman milking 5,000 cows would simply drop dead, then 100 more farm families could make a living milking 50 cows [apiece]."¹⁷²

Proponents of rbST argue that the drug is size-neutral. They maintain that the adverse impacts will not fall on farmers according to the size of their farms, but rather that the benefits will flow to the better farm managers.¹⁷³ Proponents argue that the small farmer can adopt rbST as easily as the large farmer, because rbST does not require a large initial investment for its use.¹⁷⁴ They also warn that rbST is not a "silver bullet" technology.¹⁷⁵ A farmer who simply injects the drug into her cows may not get maximum results from the input,¹⁷⁶ for it has been shown that the response of dairy herds is directly related to the quality of herd management.¹⁷⁷

This argument does not survive a more thorough analysis. Cows injected with rbST require special feeds which are highly packed with nutrients.¹⁷⁸ High nutrient feeds are more expensive.¹⁷⁹ Farmers who have relied on alternative feeds—raising their own, buying it locally, or even letting their cattle graze—will have to change their practices at considerable expense in order to adopt rbST effectively. It may even be necessary to invest in computerized feed systems to develop separate feed programs for individual cows, depending on such factors as their lineage, previous performance, and point in the lactation cycle.¹⁸⁰ Smaller, more diverse farms may need outside consultants to assess the new technology's

C. Barnes & Peter J. Nowak, *Bovine Somatotropin's Scale Neutrality and Constraints to Adoption*, in AGRICULTURAL BIOETHICS, *supra* note 18, at 143.

171. See *Hearings*, *supra* note 5.

172. *Id.* at 47 (Testimony of Wes Trombley).

173. John Mercurio, States News Service, July 13, 1990, available in LEXIS, Nexis Library, SNS File.

174. Shulman, *supra* note 18, at 125 (quoting Robert Kalter). One report had the initial investment at \$0.25 to \$0.75 per cow, per day. Mercurio, *supra* note 173.

175. Alan Levitt, *The Flap over Bovine Growth Hormone*, PREPARED FOODS, Mar. 1990, at 21, available in LEXIS, Nexis Library, PFoods File (quoting Andrew Novakovic).

176. See *id.*

177. U.S. DEP'T OF AGRIC., 1989 YEARBOOK OF AGRICULTURE, FARM MANAGEMENT: HOW TO ACHIEVE YOUR BUSINESS GOALS 304 (1989).

178. Shulman, *supra* note 18, at 125.

179. *Id.*

180. *Id.*

impact and make recommendations to insure its effective use.¹⁸¹ Successful management of an rbST-treated herd is facilitated by a larger farm's capacity to purchase sophisticated and expensive tools.¹⁸²

The problem of unequal impact is further aggravated by the fact that large farms may have earlier access to rbST than small farms.¹⁸³ A Cornell University study in New York State found that large farms are likely to adopt rbST before smaller ones. Likewise, a study by the Office of Technology Assessment concluded that larger farms were in a much better position to adopt the technology.¹⁸⁴ The first farms to successfully adopt rbST technology will be able to reap the benefits from an increase in milk production before the anticipated drop in prices from oversupply.¹⁸⁵

The argument that small farms will be at a disadvantage to larger farms in adopting rbST has been borne out by statistical analysis.¹⁸⁶ Researchers studied 270 dairy farms in Wisconsin, looking for constraints against the successful adoption of rbST.¹⁸⁷ They concluded that larger farms and farms that hire more outside labor will face the fewest constraints.¹⁸⁸ There was also a favorable correlation between a farmer's ability to adapt to rbST and the productivity of his farm, in terms of total milk sold and milk produced per cow.¹⁸⁹ The larger the herd the easier it will be to make the capital improvements required for greater feed intake and larger waste handling needs.¹⁹⁰ Thus, the extra capital, additional labor, and enhanced managerial capabilities needed to use rbST efficiently are not equally distributed within the dairy community.¹⁹¹ For these reasons, rbST will reinforce and further exacerbate the inequalities that already exist in dairying.¹⁹²

Because rbST is not scale neutral, its adverse effects on the

181. U.S. DEP'T OF AGRIC., *supra* note 177, at 303.

182. Shulman, *supra* note 18, at 125.

183. *Id.* at 126.

184. *Id.*

185. Simon Garfinckel, *Milk Hormone's Benefit Doubted*, CHRISTIAN SCI. MONITOR, Mar. 7, 1990, at 9.

186. See Barnes & Nowak, *supra* note 170.

187. *Id.* at 146.

188. *Id.* at 152.

189. *Id.* at 149-52.

190. *Id.* at 157.

191. *Id.* at 156.

192. *Id.* at 156-57.

dairy industry will fall on small and medium sized producers. Milk support prices will fall because cows injected with rbST will make the current milk surplus even larger.¹⁹³ As this happens, smaller farms will come under economic pressure to use rbST on their herds, in order to increase output to make up for losses from a falling price.¹⁹⁴ Smaller farms, however, may not have the capital and managerial capabilities to use rbST effectively, and thus they will suffer both from lower prices and from the increased costs of using the drug in their herds.¹⁹⁵ To make matters worse, they may even experience losses in productive capacity if the drug is used improperly and leads to health problems in the cows.¹⁹⁶ For smaller farms the introduction of rbST may represent a triple whammy of falling prices, increased inputs, and decreased productive capabilities.¹⁹⁷

An Office of Technology Assessment study found that regional shifts in dairy production can be anticipated from the commercial introduction of rbST.¹⁹⁸ Larger and better capitalized dairy operations tend to be located in California and the Southwest.¹⁹⁹ Smaller and medium sized family farms, on the other hand, are located in the upper Midwest and the Northeast.²⁰⁰ For example, Wisconsin produces 17% of the nation's milk, has over 36,000 dairy farms, and has an average herd size of about 50 head of cattle.²⁰¹ California, second in milk production nationwide, produces 13% of the nation's milk, but does so with only 2,400 dairy farms.²⁰² The larger farms of the South and Southwest are likely to benefit from the introduction of rbST, at the expense of smaller farms in the Midwest and Northeast.²⁰³

193. *Id.* at 157.

194. *Id.*

195. *Id.*

196. *Id.*

197. *Id.*

198. See OFFICE OF TECHNOLOGY ASSESSMENT, CONGRESSIONAL BOARD OF THE 99TH CONGRESS, TECHNOLOGY, PUBLIC POLICY, AND THE CHANGING STRUCTURE OF AMERICAN AGRICULTURE 232 (1986) (Report OTA-F-285) (hereinafter OTA).

199. COMMITTEE ON THE ROLE OF ALTERNATIVE FARMING METHODS IN MODERN PRODUCTION AGRICULTURE, BOARD ON AGRICULTURE, NATIONAL RESEARCH COUNCIL, ALTERNATIVE AGRICULTURE 57-65 (1989).

200. *Id.*

201. Donna K. H. Walters, *In Wisconsin, Battle Lines Form over Milk Hormone*, L.A. TIMES, Apr. 27, 1990, at A1, A24.

202. *Id.*

203. Barnes & Nowak, *supra* note 170, at 157.

Proponents of the drug argue that rbST need not increase the supply of milk because farmers could reduce their herd size while maintaining their previous production levels by using rbST on their remaining cows.²⁰⁴ Nick Kalm, a spokesperson for American Cyanamid, one of the four companies hoping to market rbST, said that "[f]armers wouldn't have to necessarily produce more milk BST [sic] allows them to reduce the amount of grain necessary to feed the cows" ²⁰⁵ As a result, farmers could produce the same amount of milk with fewer cows and less grain.²⁰⁶ This analysis seeks to reassure American dairy farmers, but ignores economic reality. Dairy farmers in an expansionary mode—those who are increasing both herd size and overall milk production—are in the best economic position to adopt rbST, and are also more disposed to do so.²⁰⁷ Expanding operations have the fewest constraints against adopting rbST.²⁰⁸ The likely scenario is more milk production per cow and more cows per farm, especially on larger farms.²⁰⁹ This will lead to milk surpluses, even though many farmers may choose not to increase their herds or not to use rbST.

For producers, the projected effects of rbST dairy surpluses are largely negative. A University of Wisconsin study found that if 25% of United States dairy producers use rbST milk, prices could drop by 50¢ per hundredweight.²¹⁰ This drop would represent a \$100 million loss per year for the other 75% of producers not using rbST.²¹¹ The study also concluded that rbST users themselves would benefit only initially from increased production, but once the price of milk dropped to reflect the new relationship between supply and demand, rbST users would be left in the same position they were before.²¹² In effect producers would find themselves on a technology treadmill, receiving no advantage from their increased inputs.²¹³ A similar study concluded that without federal price supports producers would eventually be earning less money than they

204. Mercurio, *supra* note 173.

205. *Id.* (quoting Nick Kalm, spokesperson for American Cyanamid).

206. *See id.*

207. Barnes & Nowak, *supra* note 170, at 154-55.

208. *Id.*

209. *See id.* at 153-55.

210. Steven H. Lee, *Controversy in Bovine Hormone's Future*, CHI TRIB. (North Sports Final ed., zone W), May 21, 1990, at 6, available in LEXIS, Nexis Library, ChTrib File.

211. *Id.*

212. *Id.*

213. *Id.*

would if they had never turned to biotechnology.²¹⁴ This study estimated a loss to producers of \$59 million a year in the absence of federal price supports.²¹⁵

During the past year the price that dairy farmers receive for milk fell through the floor, ending a period of relatively strong prices.²¹⁶ There was approximately a 27% decrease over the one year period from January 1990 to January 1991.²¹⁷ In January of 1990, New England milk prices were over \$15.00 per hundredweight.²¹⁸ By January of 1991, the average price had fallen over \$4.00 to \$11.47 per hundredweight.²¹⁹ This low price was unchanged as of August 1991, when Vermont farmers received between \$11.00 and \$12.00 per hundredweight.²²⁰

In Vermont it costs about \$14.00 to produce a hundred pounds of milk.²²¹ With the drop in prices, most dairy farmers spend more to produce their milk than they earn from sales.²²² Thus, they are operating at a financial loss.²²³

Adjusted for inflation, current prices are the lowest that dairy farmers have seen since records have been kept.²²⁴ There is so much pressure on dairy farmers that they are attempting to organ-

214. Garfinckel, *supra* note 185.

215. *Id.*

216. *Citizen Action Needed to Save Farms*, VPIRG UPDATE (Vt. Pub. Interest Research Group, Montpelier, Vt.), Spring 1991, at 12 [hereinafter VPIRG UPDATE].

217. *Id.*

218. *See id.*

219. *Id.*

220. Tena Starr, *Dairy Farmers Plan Milk Strike: Oct. 1 Action Called Last Straw*, BURLINGTON FREE PRESS, Aug. 1, 1991, at B1. A hundredweight is equal to one hundred pounds of milk, or approximately 11.6 gallons, depending on the weight of solids in the milk. *See* John Dillon, *Ag Secretary Would Veto Leahy-Jeffords Dairy Bill*, BARRE-MONTPELIER TIMES-ARGUS, July 25, 1991, at 1. Milk is sold by weight instead of volume because milk with more solids weighs more than milk without solids. Thus, milk with more solids, which is more valuable to processors, receives a higher price per gallon than milk with fewer solids.

221. Starr, *supra* note 220, at B1; *see also* VPIRG UPDATE, *supra* note 216, at 12.

222. *See* Starr, *supra* note 220, at B1. A Troy, Vermont, dairy farmer noted, "[i]t's an end-of-the-road kind of thing. But if we're going to have to live on \$11 milk, we're going to starve to death anyways." *Id.* (quoting Dexter Randall).

223. Despite the large drop in the price of milk to farmers, consumers have not seen corresponding savings in their grocers' dairy aisles. While the price that dairy farmers receive for a gallon of milk is under \$1.00, the average cost of producing milk in Vermont is \$1.20. VPIRG UPDATE, *supra* note 216, at 12. However, there is almost no correlation between the price to farmers and the price consumers see in the supermarket. While milk prices to farmers in Vermont fell 26% in 1990, consumers realized only a .09% savings. *Id.* The balance went to retailers. *See id.*

224. VPIRG UPDATE, *supra* note 216, at 12.

ize a milk strike,²²⁵ spilling their milk instead of selling it in an attempt to tighten supply so that prices will rise again.²²⁶ A milk strike has not occurred since the Great Depression.

In conclusion, barring legislative action,²²⁷ introducing rbST into the American dairy barn is likely to cause economic dislocation and suffering for many of America's small to medium sized dairy farms, which are mostly owned and operated by families. Even without rbST, there has been a movement in dairying towards larger farms and greater productive capacity per cow. Introduction of rbST will accelerate this trend. The result will be more industrial-type farms and fewer family farms. Rural economies, already depressed from a continually shrinking human resource base, will sink further into depression. The choice for policy makers is whether rural life and rural families are worthy of protection at the expense of some level of inefficiency in dairy farming.²²⁸ The fun-

225. Starr, *supra* note 220, at B1. Some farmers have applied for food stamps and other emergency relief. *VPIRG UPDATE*, *supra* note 216, at 12.

226. See Starr, *supra* note 220, at B1. The farmers also plan to use the tactic as a weapon to force Congress to enact legislation which is pending before both houses. *Id.* at 9B.

227. The current milk crisis came about without the introduction of rbST, and has spurred federal legislation. Although the proposed legislation is not directed at rbST, it would considerably alleviate the negative effects rbST could have on dairy farmers. The legislation would create a supply management system and stabilize both production and milk prices for farmers. S. 1527, 102d Cong., 1st Sess. (1991). The Senate Bill's short title is "Family Dairy Farm Protection Act of 1991." *Id.* at § 1. If such legislation were passed, rbST might not cause such wild fluctuations in the dairy market, and its negative impacts on dairy farmers could be greatly mitigated. See *infra* notes 303-15 and accompanying text.

228. Free market economists would argue that society chooses what it values through the operation of the free market. Technologies which are more efficient allow for lower production cost. Consumers are likely to choose such products over substitutes that are produced through less efficient methods. Thus, conservative economists argue that wealth maximization through efficiency in a free market best addresses society's needs.

But negative spillovers from uncontrolled technology create a need for technology assessment. For a history of the negative consequences of uncontrolled technology see Azizah al-Hibri, *Introduction to Some Salient Views on Technology*, in *TECHNOLOGY AND HUMAN AFFAIRS* 173-90, *supra* note 102. There seems to be a consensus that some state regulation is necessary to control developing technology. David Kiefer, *Assessing Technology Assessment*, in *TECHNOLOGY AND HUMAN AFFAIRS* 165, *supra*. However, there is much disagreement as to how much regulation is required. One commentator has argued that a "gross national happiness index" is needed to precisely measure all the effects that technology has on society, so that the overall desirability of any new technological artifact could be determined. *Id.* at 168. The problem, of course, is coming up with values everyone can agree on. *Id.*

Others take the approach that efficiency is not the only value that society should foster. See *WINNER*, *supra* note 22. Again though, it is difficult to identify standards that all of society agrees on for the assessment of new technology. Generally, Congress has dealt with this problem by creating broad nebulous standards, abdicating power to the executive branch. See, e.g., *Ethyl Corp. v. EPA*, 541 F.2d 1 (D.C. Cir. 1976), *cert. denied*, 426 U.S. 941 (1976). This debate is illustrated by the controversy over controlling dairy production:

damental issue underlying this choice is the question of prohibiting or restraining new technological artifacts for social reasons: not because they present an undesirable risk to the health and safety of people or the environment, but because they prove to be socially unworthy.

2. The Effects That rbST Will Have on Taxpayers

Not only will rbST have adverse social and economic impacts on dairy farmers, but it is also likely to increase the burden on taxpayers. Taxpayers may have to buy the excess milk surplus that will result from the commercial introduction of rbST. From 1980 to 1986 the government paid an average of slightly more than \$2 billion per year to buy and store surplus milk and milk products.²²⁹ The whopping price tag led to pressure to cut back on tax-based support programs.²³⁰ In response, the whole-herd buyout program was implemented to alleviate the strain on taxpayers by encouraging dairy farmers to decrease production.²³¹ This program paid

Some argue that dairy farmers do not need our help. Let the strongest survive, they say. . . .

In our society, we judge few things solely in dollars and cents. Some things simply cost [more] because of the benefits received. Our automobiles cost more because of seatbelts and other safety standards. Our electricity costs more because the American public wants clean air. Our municipal water costs more, because of the efforts we must take to keep it clean.

There is also a cost in failing to pass supply management legislation—we will lose our family farmer. They are a hardworking and industrious people, but they face the constant threats of rising prices, declining profits and dramatic boom-or-bust swings in the market place. The giant, corporate farms can make it through the lean times but our small, family farms struggle to survive.

When our country was founded, we were an agrarian nation made up of small farms. In the past 200 years, large corporate farms have come to dominate our landscape, but some of our past—the family farmer—still survives. Committee on Agriculture, Nutrition, and Forestry, Senator Patrick Leahy, Leahy & Jeffords Introduce Dairy Bill: Three-Tier Supply Management Plan Is Focus 2-3 (July 23, 1991) (Press Release) (statement of Sen. Patrick Leahy).

The Bush Administration, however, favors the free market approach. The Secretary of Agriculture, Edward Madigan, has urged President Bush to veto bills which would interfere with the operation of the "free market." Dillon, *supra* note 220. Other commentators have insisted that the federal government not regulate milk prices: "[milk] producers who survive the present hard times will be better off in the long run." James Kilpatrick, *Hands Off Milk Prices, Let the Market Work*, BURLINGTON FREE PRESS, Aug. 9, 1991, at 10A.

229. Shulman, *supra* note 18, at 118.

230. *Id.*

231. *Id.*

farmers to stop farming by buying out their dairy herds.²³² The introduction of rbST would work against the federal government's goal of reducing milk surpluses.

One study concluded that, with federal price supports in place, the introduction of rbST would increase producers' income by \$3 billion, while saving consumers \$1.7 billion.²³³ However, the federal government would spend an additional \$23 billion in price supports.²³⁴ Thus, "[f]or every dollar you expend, you get back 20 cents."²³⁵

The Bush Administration seems to agree that the use of rbST on America's dairy farms will cost the taxpayer. Gambling that rbST will probably not be introduced in 1992, the Administration recently reduced its budget for dairy support prices by \$205 million.²³⁶ This \$205 million represents the value of rbST milk and dairy products the government would have bought were the drug to be introduced commercially in 1992.²³⁷

The benefits of the federal government's surplus purchases go to a relatively diffuse group of people—dairy farmers. Profits from efficiency gains are not concentrated in any one sector of the economy because improvements in feed, management, reproductive technology, and selective breeding techniques usually go to a diffuse group of people. On the other hand, rbST production and profits lie in the hands of four chemical and pharmaceutical giants: Monsanto, American Cyanamid, Elanco (a subsidiary of Eli Lilly), and Upjohn.²³⁸ With the commercial introduction of rbST, the increase in government expenditures for surplus milk would go to an oligopoly of four chemical companies and would encourage even higher milk surpluses. A possible solution to this problem would be to cut federal payments to producers who use the drug.

232. *Id.*

233. Garfinckel, *supra* note 185.

234. *Id.*

235. *Id.* (quoting Russel Gum).

236. Memorandum from Ralph Chite, Analyst in Agricultural Policy, Congressional Research Service of the Library of Congress, to the Honorable David R. Obey, United States House of Representatives, 1 (Feb. 13, 1991) (on file with *Vermont Law Review*). Representative Obey is a Democrat from Wisconsin.

237. *Id.* Originally, the total predicted cost of the program was \$815 million. *Id.* Thus, the \$205 million price tag for rbST milk represented almost 25% of the total. The \$205 million would buy 1.8 billion pounds of surplus rbST milk. *Id.*

238. See *supra* note 12 and accompanying text.

C. *The Role of Congress and the Office of Technology Assessment in the Introduction of New Technology*

The federal government is not limited to assessing risk in analyzing new technologies. Both the Office of Technology Assessment (OTA) and Congress may consider factors other than risk in responding to scientific advances. However, there are limits on the ability of OTA and Congress to act in the area of new technologies. Congress is a relatively small body with large responsibilities, and has limited resources to deal with specific problems such as rbST. The OTA has only the authority to study technology and report on ramifications that may result from its introduction into society.²³⁹ The OTA does not have authority to take action on any one technology or even to propose legislation to deal with it.²⁴⁰

The OTA is housed within Congress,²⁴¹ rather than the executive branch. The OTA was created to provide impartial information on new technology to Congress and to Americans in general.²⁴² In the 1960's and early 1970's, Congress was required to make several policy decisions regarding technology.²⁴³ As Congress was not competent to make scientific assessments of new technology, it was forced to rely on the testimony of experts. However, these experts often disagreed.²⁴⁴ Moreover, the experts were often partisan, representing different political ideologies or political interest groups.²⁴⁵ In response to these problems, the OTA was designed to give Congress impartial information and reports on technology.²⁴⁶

The OTA has analyzed the potential effects of biotechnology on agriculture.²⁴⁷ Part of its report concerned the introduction of rbST and the effects it could have on the dairy industry.²⁴⁸ More recently the OTA has published a report focused solely on rbST.²⁴⁹ The report confirmed the FDA's conclusions that rbST is safe for

239. 2 U.S.C. § 472(c) (1988).

240. *Id.*

241. 2 U.S.C. § 472(a) (1988).

242. 2 U.S.C. § 471 (1988).

243. See John H. Gibbons & Holly L. Gwin, *Technology and Governance: The Development of the Office of Technology Assessment*, in *TECHNOLOGY AND POLITICS* 98, 99 (Michael E. Kraft & Norman J. Vig, eds., 1988).

244. *Id.* at 100.

245. *Id.*

246. 2 U.S.C. § 472(c) (1988).

247. OTA, *supra* note 198, at 75-85.

248. *Id.* at 81, 85.

249. See Roush, *supra* note 37, at 32.

human consumption.²⁵⁰ The report went on to criticize the chemical companies' decision to pursue the development of rbST as the first agricultural product derived from recombinant genetics.²⁵¹ The report suggests that industry and government should reevaluate priorities in research and development in this field.²⁵²

The information, of course, is helpful, but Congress has taken no action to specifically regulate biotechnology. A Biotechnology Omnibus Bill was introduced in Congress in 1990, but no action was taken. Similar legislation is not likely to be introduced in 1991.²⁵³ Furthermore, Representative Peter Smith of Vermont introduced a bill that would have placed a temporary moratorium on rbST.²⁵⁴ The bill was introduced in 1990, but has not been reintroduced in the 102nd Congress.²⁵⁵ Representative Smith was defeated in the fall of 1991, and his replacement, Representative Bernard Sanders, has no plans to reintroduce this bill.²⁵⁶ Moreover, the Smith bill had few sponsors and Representative Smith himself did not hold hearings on the matter.²⁵⁷

Although rbST has caused considerable controversy at the state level, the Office of Technology Assessment and Congress have barely participated in the debate. Technology proceeds at such a rapid pace that Congress does not have the ability to keep up with every new individual technological artifact. Indeed, Congress has yet to produce legislation regulating modern biotechnology in any way.²⁵⁸ Congress lacks the time and political consensus to make

250. *Id.*

251. *Id.* at 34.

252. *Id.* at 34-36.

253. See *For 102nd Congress, New Year Rings in Renewed Debate on Old Bills*, BIOTECHNOLOGY NEWSWATCH, Jan. 7, 1991; see also *Chemicals: Control Efforts to Focus on Existing Substances*, BUREAU OF NAT'L AFF.: DAILY REP. FOR EXECUTIVES, Jan. 17, 1991, at S-27.

254. *Bovine Growth Hormone Faces Renewed Congressional Criticism*, BIOTECHNOLOGY NEWSWATCH, Feb. 5, 1990, at 3.

255. Telephone Interview with Anthony Pollina, Aide to United States Representative Bernard Sanders of Vermont (Feb. 27, 1991) [hereinafter Pollina Interview].

256. *Id.*

257. *Id.*

258. The federal bureaucracy has attempted to regulate new products of biotechnology through already existing regulation. Laws that were designed to regulate chemicals such as the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§ 136-136y (1988), and the Toxic Substances Control Act, 15 U.S.C. §§ 2601-2671 (1988), are being used to regulate novel life forms. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (1986) (notice of federal regulatory policy, Office of Science and Technology Policy); see also ENVIRONMENTAL LAW INSTITUTE, 2 LAW OF ENVIRONMENTAL PROTECTION § 18.03, at 18-19 to 18-56 (Sheldon M. Novick et. al. eds., release #6, July 1991).

intelligent decisions on each technological artifact to emerge from humankind's endeavors. Thus, if we are going to take control of our technological destiny, we must rely on mechanisms other than the Congress or the OTA.

III. GOVERNMENT SHOULD REGULATE TECHNOLOGY BEYOND RISK

Society should regulate new technological artifacts not just on a risk basis, but also on a socio-economic basis.²⁵⁹ Five hundred million dollars have been spent on a drug which will create more surplus milk so that the federal government can buy it and store it in a cave.²⁶⁰ This irrational result can occur because it makes economic sense at the individual level. The four companies which have invested heavily in developing rbST may profit, if the drug is approved for general use by enough governments worldwide.²⁶¹ Some individual farmers may gain from reduced feed cost per unit of milk.²⁶² There may also be a benefit to milk consumers from lower prices on the supermarket shelf.

Society as a whole, however, may suffer significant detriments from the introduction of rbST. Among these effects are increased subsidy payments for milk surpluses,²⁶³ dislocation costs for family dairy farmers,²⁶⁴ changes in rural land use patterns, and the continued disintegration of rural communities.²⁶⁵ There will also be less palpable social and cultural effects: the continued proletarianization of the American work force by concentrating agricultural power into large farms relying on outside labor,²⁶⁶ an undermining

259. There are also strong ethical arguments for the regulation of biotechnology. For example, society may deem it immoral to use rDNA techniques to alter a human embryo's genetic makeup. See, e.g., HOWARD & RIFKIN, *supra* note 36. These types of questions, however, are beyond the scope of this note.

260. This is not simply a figure of speech. The federal government stores "mountains" of butter in cool storage caves. Greenberg, *supra* note 127.

261. Sales of the drug could exceed \$1 billion per year. *Bad Moos for BST*, *ECONOMIST*, Aug. 11, 1990, at 66.

262. Using rbST makes a cow more efficient; she requires less feed per gallon of milk produced as long as rbST is properly used. See Juskevich & Guyer, *supra* note 8, at 875.

263. See *supra* notes 229-38 and accompanying text.

264. For every 1% increase in production resulting from gains in efficiency, 1,700 dairy farmers are eliminated. Shulman, *supra* note 18, at 118-19.

265. Chuck Hassebrook, *Democracy in Technological Research: Planning a Future for Family Farming*, in *AGRICULTURAL BIOETHICS*, *supra* note 18, at 251, 252. Rural communities where farms are too large to be operated by a single family tend to have a small wealthy elite, many poor laborers, and no middle class. *Id.* The lack of a middle class has an impact on the quality of social and community services, education, and local government. *Id.*

266. See *id.*

of the value of self-reliance,²⁶⁷ and increased disempowerment and desolation of America's middle class.²⁶⁸ In sum, rbST conflicts with the republican values our nation was founded on: liberty, restraints on power, and public virtue.²⁶⁹

At the time of the American Revolution farmers made up a large middle class.²⁷⁰ The middle-class farmer became "a revolutionary symbol of republican virtue"²⁷¹ and was viewed as an essential "defender[] of freedom against corruption and tyranny."²⁷² American farmers, unlike their European counterparts, were freeholders; thus, not being enslaved or indentured to an aristocratic class, they acted as a natural counterweight to tyranny.²⁷³ Independent middle-class farmers were capable of defending free men's²⁷⁴ rights against the oppression of the crown. "A republican society was a society of freeholders, and praise of husbandry amounted to a national faith."²⁷⁵

Perhaps Thomas Jefferson expressed this "national faith" in its purest form:

Those who labour in the earth are the chosen people of God, if ever he had a chosen people Corruption of morals in the mass of cultivators is a [phen]omenon of which no age nor nation has furnished an example. [Corruption of morals] is the mark set on those, who . . . depend for [their subsistence] on the casualties and caprice of customers. Depend[e]nce begets subservience and venality, suffocates the germ of virtue, and prepares fit tools for the designs of ambition.²⁷⁶

267. *See id.*

268. *See id.*

269. *See* JOHN F. KASSON, *CIVILIZING THE MACHINE: TECHNOLOGY AND REPUBLICAN VALUES IN AMERICA, 1776-1900* 4 (1976). In the eighteenth century, public virtue meant social restraint, putting the good of the whole above individual personal desires. In practice this meant social service, industriousness, and self-restraint. *Id.*

270. *Id.* at 6-7.

271. *Id.* at 7.

272. *Id.*

273. *Id.*

274. The masculine gender is used here, because American women of the eighteenth century did not enjoy comparable rights and status with men.

275. KASSON, *supra* note 269, at 8.

276. THOMAS JEFFERSON, *NOTES ON THE STATE OF VIRGINIA* 164-65 (William Peden, ed., Institute of Early American History and Culture ed. 1955) (1785). The full text of this quotation reads:

Those who labour in the earth are the chosen people of God, if ever he had a chosen people, whose breasts he has made his peculiar deposit for substantial and genuine virtue. It is the focus in which he keeps alive that sacred fire, which otherwise might escape from the face of the earth. Corruption of

The case of rbST illustrates that government should consider other values besides risk avoidance and economic efficiency when assessing technology for its worthiness. Philosophers, such as Langdon Winner, have advocated the same position.²⁷⁷ Winner argues that technological artifacts have political qualities because of the socio-economic effects that follow from their use.²⁷⁸ Technology, Winner argues, offers a way of ordering and creating our world:

Consciously or unconsciously . . . societies choose structures for technologies that influence how people are going to work, communicate, travel, [or] consume In the process[] [of making] structuring decisions[,] . . . different people are situated differently and possess unequal degrees of power By far the greatest latitude of choice exists the very first time a particular . . . system . . . is introduced. Because choices tend

morals in the mass of cultivators is a phaenomenon of which no age nor nation has furnished an example. It is the mark set on those, who not looking up to heaven, to their own soil and industry, as does the husbandman, for their subsistence, depend for it on the casualties and caprice of customers. Dependance begets subservience and venality, suffocates the germ of virtue, and prepares fit tools for the designs of ambition.

Id.

In Vermont, at least, these values have endured—there is still strong public support for family farmers. Support for family farmers in the state has been expressed in various ways. Most recently, legislation for an agricultural efficiency program, called Vermont Farms, Inc., was proposed by the late Governor Richard Snelling. Elizabeth Cote, *Plan Could Save \$23 Million*, BURLINGTON FREE PRESS, Aug. 8, 1991, at 1A. The five year program would save participating Vermont farmers one dollar from the cost of every one hundred pounds of milk produced. *Id.* The goal of the program is to make Vermont's dairy farmers more competitive. *See id.* at 2A.

A citizen's group has started a similar program called Adopt-A-Cow. Maura Griffin, *Adopt-A-Cow Program Promotes Dairy Farming*, BARRE-MONTPELIER TIMES-ARGUS, July 16, 1991, at 9. The program raises funds through donations and disburses it to dairy farmers in the form of grants designed to increase efficiency and marketing opportunities. *Id.*

A Vermont ice cream maker, Ben & Jerry's Homemade, Inc., has vigorously supported family farms in Vermont. The company has agreed to pay its supplier, a dairy cooperative, a fair price for milk, instead of the current price, which is below the farmers' cost of production. *Ben & Jerry's Will Subsidize Dairy Farms*, BURLINGTON FREE PRESS, Apr. 23, 1991, at 2B. This amounts to \$500,000 over eight months, which is equivalent to \$1,040 for each of the cooperative's family farms. *Id.* The ice cream maker also publishes its support for family farms on its ice cream containers. One pint of Ben & Jerry's Chocolate Chip Cookie Dough Ice Cream (on file with *Vermont Law Review*).

Even the Vermont Supreme Court has done what it can for the state's dairy farmers. It recently held for family farmers in a dispute over the size of a cowpass. In *re Agency of Transportation*, No. 90-299 (Vt. July 12, 1991). The farmers needed the larger cowpass to get machinery and cows from their barn to their pasture, which was to be cut off by a proposed highway improvement. *Id.*

277. *See, e.g.,* WINNER, *supra* note 22.

278. *Id.* at 16-39.

to become strongly fixed[,] . . . the original flexibility vanishes for all practical purposes once the initial commitments are made. In that sense technological innovations are similar to legislative acts . . . that will endure over many generations. For that reason the same careful attention one would give to the rules, roles, and relationships of politics must also be given to such things as the building of highways, [or] the creation of television networks²⁷⁹

Winner argues that technological artifacts are of two types. The first type of technological artifact is malleable in its design and use. The political and social relations which flow from such technology are not predetermined, but rather indeterminate until conscious or unconscious decisions are made regarding its design and implementation.²⁸⁰ The second type of technological artifact can be classed as inherently political technology. Inherently political technology is strongly compatible with certain social and political relationships. This type of technology offers few choices in its design and use. The consequences of using an inherently political technology tend to be fixed.²⁸¹ Therefore, when society assesses technological artifacts with intractable political qualities, the choice is merely whether or not to adopt the technology.²⁸²

Recombinant bST is a technological artifact of the second type. Because rbST must be nearly identical to its natural counterpart, scientists had little choice in its design. At least at the design stage, rbST's creators could not control the technology's political qualities. Nevertheless, rbST has inextricable political qualities. If, as a society, we plan on using rbST, then the requirements for better herd management, high-nutrient feeds, and capital-intensive farming methods necessarily flow from its structure and nature. The demise of the family dairy farmer and healthy rural communities will also flow directly from the introduction of rbST, at least in dairy farming's current economic context.²⁸³

279. *Id.* at 28-29.

280. *Id.* at 22-29.

281. *Id.* at 29-38.

282. *Id.* at 38.

283. If rbST is introduced into a different economic context, then the negative consequences for family farmers will be strongly mitigated. See *infra* notes 286-302 and accompanying text. Inherently political technologies are strongly compatible with certain social and political outcomes. WINNER, *supra* note 22, at 32-33. However, even inherently political technologies may have different effects on society if they are used in sufficiently different contexts. *Id.* at 39.

Since technological artifacts present consequences for society which go beyond the pros and cons of traditional risk analysis, government should not concentrate solely on risk in regulating new technology. The undermining of rural economies and traditional American values surely deserves as much debate and as much attention as the human health risks presented by rbST. There are several possible legislative actions which would address the problems posed by rbST. Those which would change the review process to permit consideration of the socio-economic effects of new technological artifacts are preferable, because they increase public participation and reinforce our democratic values and control over our destiny.

IV. RECOMMENDED LEGISLATIVE ACTION

Congress could respond to the problems identified in this note in several ways. This note concentrates on four possible solutions. First, Congress can enact a moratorium on the commercial use of rbST. Second, a federal supply-side management program can be created to address the long-term problems associated with advancing technology in the dairy industry, the tendency towards ever-increasing surpluses, and the periodic crises that result. Third, the Office of Technology Assessment can be directed to recommend specific legislation with respect to specific technological artifacts. Finally, the Federal Food, Drug and Cosmetic Act can be amended to require manufacturers to show that their product has a net beneficial socio-economic effect.

These proposals should be evaluated in light of their effectiveness in dealing with the various problems described above. In addition, because these legislative actions aim to institutionalize economic decisionmaking, any evaluation of them should have an ethical dimension. The proposals should be measured against ethical standards for economic decisions, such as those offered in a pastoral letter by the National Conference of Catholic Bishops.²⁸⁴ The Bishops suggest three questions to be used in judging the ethics of economic decisions: "What does the decision . . . do to people?"; What does it do "for people?"; and "How does it allow them

284. NATIONAL CONFERENCE OF CATHOLIC BISHOPS, ECONOMIC JUSTICE FOR ALL: CATHOLIC SOCIAL TEACHING AND THE U.S. ECONOMY (June 4, 1986), quoted in Brian Buhr et al., *Economic Issues and Analyses in Biotechnology*, in *AGRICULTURAL BIOETHICS*, *supra* note 18, at 161.

to participate?"²⁸⁵ These three questions can be used to test the strength of each legislative proposal.

A. Congressional Moratorium on the Use of rbST

A moratorium on rbST is the narrowest and most straightforward policy option of the four proposals. It would attempt to settle only the conflict over rbST, and would not address the issues raised by new technologies in general.

Similar legislation has been proposed in several states, and has resulted in heated debate.²⁸⁶ Wisconsin and Minnesota both passed temporary bans on the use of rbST.²⁸⁷ The Minnesota ban is effective as long as there is a similar ban in Wisconsin or in states whose aggregate milk production represents forty percent of the United States' total.²⁸⁸ The Wisconsin statute prohibited the commercial use of bovine somatotropin until June 1, 1991.²⁸⁹ In the interim, the Wisconsin legislature directed the Board of Regents of the University of Wisconsin to study rbST's efficacy and effects on animal health.²⁹⁰ The first report from this group was due to be delivered to the Wisconsin legislature on March 1, 1991,²⁹¹ in order to give the legislature time to consider the Board's findings, and

285. *Id.*

286. See *Hearings*, *supra* note 5; see also Maine House Bill No. 1163 (1991) (prohibits the sale of rbST milk and meat); New Hampshire House Concurrent Resolution No. 19 (1990); New York Assembly Bill No. 123 (1991) (milk containing rbST must be labeled as such); Pennsylvania House Resolution No. 190 (1989) (calling for Congress to enact a temporary moratorium on rbST until its effects on consumers and dairy farmers are fully studied); South Dakota House Bill No. 1259 (1991) (regulating the use of rbST); Washington House Bill 2105 (1991) (authorizing temporary restrictions on the use of rbST until further study); Virginia Senate Joint Resolution No. 5 (1990) (requesting the Virginia Department of Agriculture to study the impact of rbST on Virginia's dairy industry); Vermont House Bill No. 895 (1990) (placing a temporary moratorium on commercial introduction of rbST, and directing further study by state institutions).

287. WIS. STAT. ANN. § 97.235 (West Supp. 1991); MINN. STAT. ANN. § 151.15(3) (West Supp. 1991).

288. Act approved Apr. 26, 1990, 1990 Minn. Sess. Law Serv. ch. 526, § 15 (West) (this section was never codified). The Minnesota ban would have expired after one year in any event, MINN. STAT. ANN. § 15.15(3) (West Supp. 1991), which would have been June 12, 1991. See *id.* note. This final expiration date has been extended to June 12, 1992. Act filed as law June 21, 1991, 1991 Minn. Sess. Law Serv. ch. 213, § 2 (West) (to be codified at MINN. STAT. § 151.15(3)).

289. WIS. STAT. ANN. § 97.235 (West Supp. 1991). The ban has expired without any action taken by the Wisconsin Legislature. Search of WESTLAW, Wi-Legis and Wi-St-Ann databases (Oct. 20, 1991) (search for statutes containing "bovine somatotropin").

290. WIS. STAT. ANN. § 36.25(32) (West Supp. 1991).

291. *Id.* § 36.25(32)(f).

take whatever further action they deem necessary, before the moratorium expired in June. The Wisconsin law also funded a study to consider labeling rbST milk,²⁹² created an institute²⁹³ to evaluate the effects of new agricultural technologies on family farmers,²⁹⁴ and set up extension programs to educate consumers about biotechnology.²⁹⁵

The Wisconsin measure was well thought out. Temporary moratoriums are justified where material information is absent and can be revealed only through further study.²⁹⁶ Because the Wisconsin law actively sought information on all issues related to rbST, the state was placed in a good position to act on the drug when the moratorium expired. The Wisconsin law is preferable to one which would have done nothing further than place a temporary ban on rbST use. Furthermore, Wisconsin's bill meets the Bishops' criteria above. Before making a permanent economic decision, the Wisconsin legislature set up an apparatus to find out what such a decision would do to people and what it would do for people. The bill also allowed those affected by the decision to be involved in making it. The biotechnology educational program will allow Wisconsin's citizenry to participate in the democratic process in a more meaningful way. Moreover, under the bill, active dairy farmers were given the opportunity to advise the Board of Regents on design of their study, and to oversee research conducted under the statute.²⁹⁷

The Wisconsin law has been severely criticized.²⁹⁸ Opponents felt that the law would jeopardize the Wisconsin dairy industry because it would put Wisconsin farmers at a competitive disadvan-

292. Act of Apr. 27, 1990, 1990 Wis. Legis. Serv. 353, § 1g(3) (this section was never codified).

293. The institute is called the Agricultural Technology and Family Farm Institute. *Id.* § 36.25(30m) (West Supp. 1991).

294. *Id.*

295. *Id.* § 36.25(31).

296. A permanent moratorium on rbST use, for which there are no legislative blueprints, need not be absolutist either. Such a moratorium could be lifted in times of dairy shortages, or feed shortages due to drought, or if international competition or competition from other beverages seemed to require it. In general, if the economic decision were made not to use rbST to avoid harm to dairy farmers, the moratorium should not remain in place during periods when rbST could be used to benefit the majority of American dairy farmers. Such a flexible response could be administered through a government agency such as the Department of Agriculture with clear guidance from Congress.

297. WIS. STAT. ANN. § 36.25(32)(e) (West Supp. 1991).

298. *Crying Wolf about Milk*, N.Y. TIMES, May 1, 1990, at A22 (editorial); *Keeping Biotech Out of the Dairy Barn*, CHI. TRIB., Oct. 22, 1989, § 4, at 2 (editorial); see also Rogers Worthington, *To Dairy Industry, Hormone Top Issue*, CHI. TRIB., Jan. 7, 1990, at 21.

tage with respect to farmers in other states where rbST could be used.²⁹⁹ Since the ban ended June 1, 1991, and the FDA has not yet approved rbST, this concern did not materialize. Nevertheless, the bill's critics were correct in that the state level is not the proper level for regulating rbST, because dairy farmers from the several states are in economic competition with one another.³⁰⁰

Although the Wisconsin law should be lauded for the intelligent way it attempted to deal with the problems of rbST, there is only so much the people of the State of Wisconsin can do. The Wisconsin legislation is well considered and ethically designed, but necessarily flawed because it had to be enacted at the state level. Similar legislation should be adopted at the federal level. Federal legislation avoids the competitive problems associated with nonuniform state regulation. As mentioned earlier, a three year federal moratorium was introduced by Representative Peter Smith of Vermont in 1990,³⁰¹ but the bill died and no comparable legislation has been introduced in 1991.³⁰² A federal bill comparable to Wisconsin's would be highly desirable.

B. Federally Imposed Supply-Side Dairy Management

In response to the current economic crisis in the dairy industry, legislation has been introduced in Congress which would create a supply-side management scheme.³⁰³ The purpose of the legislation is to balance production and consumption and to reduce government expenditures, while stabilizing farm income.³⁰⁴

At the beginning of each year, the Secretary of Agriculture and a board of dairy farmers would estimate the excess milk that would be produced during the year in the absence of supply-side

299. See *Keeping Biotech Out of the Dairy Barn*, *supra* note 298; Worthington, *supra* note 298, at 26.

300. See *Keeping Biotech Out of the Dairy Barn*, *supra* note 298; Worthington, *supra* note 298, at 26.

301. Nancy Walser, States News Service, Feb. 7, 1990, available in LEXIS, Nexis Library, SNS File.

302. Pollina Interview, *supra* note 255.

303. See S. 1527, 102d Cong., 1st Sess. § 4 (1991). The bill in the Senate is titled "Family Dairy Farm Protection Act of 1991." *Id.* at § 1(a). For a similar bill in the House see H.R. 2628, 102d Cong., 1st Sess. (1991). This note concentrates on the Senate bill although there are important differences between the two versions.

304. S. 1527, 102d Cong., 1st Sess., § 3(a) (1991). The bill also is designed to guarantee consumers a pure and wholesome milk supply for the future. *Id.* § 3(b).

management.³⁰⁵ Depending on the estimated level of excess production, certain policies would be followed. If the estimate of surplus milk is below five billion pounds, the Secretary is to treat all producers alike.³⁰⁶ If there will be an excess of five to seven billion pounds, producers are, in effect, assessed a uniform fee for each hundredweight they produce.³⁰⁷ This assessment is refunded to producers who do not increase production in that year.³⁰⁸

When production creates an excess of over seven billion pounds, a two-tier price system kicks in.³⁰⁹ Producers will be given a quota based upon their past production history.³¹⁰ Farmers who exceed their quota will receive a lower price for their milk.³¹¹ Generally, the bill creates a disincentive for individual farmers to produce more milk every year, and creates incentives to reduce production levels. This scheme should dampen the wild fluctuations that may occur if rbST is commercially introduced. Farmers are not likely to spend money on a production enhancement drug, if greater production may cost them money. Also, because the goal of the program is to achieve market stability, the introduction of rbST into such a regulated atmosphere may not put downward pressure on milk prices—the Senate bill would be working to counteract the effects of rbST.

This analysis assumes that the Senate bill will pass in its current form. But this is unlikely for two reasons. First, the House version has significant differences. Even if the Senate votes favorably on the bill in its current form, there is a good chance it could be changed in a conference committee. Second, and more importantly, the Bush Administration is likely to veto the bill if it is passed.³¹² In a five page letter sent to Senator Patrick Leahy of Vermont, the Secretary of Agriculture, Edward Madigan, made specific objections to nearly every provision in the Senate bill.³¹³ Madigan claims that the bill will increase the cost of federal food assistance programs for the poor, will lower prices paid to beef cattle producers, will conflict with the Constitution, and reduce “eco-

305. *Id.* § 4(e)(1).

306. *See id.* § 4.

307. *Id.* § 4(f)(1).

308. *Id.* § 4(f)(4).

309. *Id.* § 4(g).

310. *Id.* § 4(g)(6).

311. *Id.* § 4(g)(3)-(4).

312. Dillon, *supra* note 220, at 1.

313. *Id.*

conomic activity."³¹⁴ He also claims that farmers oppose the bill.³¹⁵ Thus, although the bill would greatly mitigate the socio-economic harm that would otherwise result if rbST were introduced, it is likely that it will be vetoed by President Bush.

C. *Changes in the Authority of the Office of Technology Assessment*

Obviously, a moratorium on rbST is limited in that it only addresses one particular technological artifact. In contrast, Congress could use the OTA to obtain a comprehensive review of all new technologies extending beyond risk analysis. It is sensible to use the OTA because Congress does not have the time to adequately evaluate each new technological artifact before it is commercially introduced.

The OTA is not authorized to write legislation—it merely studies and evaluates technology and leaves the rest for Congress.³¹⁶ This proposal would change the OTA's responsibilities by requiring the OTA to draft and propose legislation prohibiting the introduction of new technologies which have no net social value. After the OTA proposed the legislation and explained the need for it, the OTA would hold hearings and respond to public comment, making changes in its draft or withdrawing it completely if the public response warranted. If and when the OTA submitted the proposed legislation to Congress, Congress would have the advantage of a record created by skilled, neutral policy makers.

This proposal is a compromise between the need for controls on technology, and the need for democratic processes in making decisions which will greatly affect people for generations to come. By putting the responsibility for initiating legislative proposals in the hands of the OTA, the proposal overcomes congressional inertia. However, by leaving final authority over technology in the hands of Congress, the proposal minimizes the possibility that such decisions will be made by the scientific elite.

The proposal also meets the Bishops' guidelines for making economic decisions. As discussed earlier, new technology is like a

314. *Id.* at 1, 10.

315. Phillip Brasher, *Madigan Says Farmers Oppose Quotas in Bills*, BURLINGTON FREE PRESS, Aug. 9, 1991, at 7A.

316. 2 U.S.C. § 472(c) (1988).

statute or a constitution—once it is in place it is difficult to change, and it controls people's and society's destiny. Before new technologies become rooted in our everyday lives, it is important to have a process or mechanism to ask what the technology will do to people, and what it will do for them. This proposal would allow those who will be affected by new technologies to participate at two levels. At the bureaucratic level, the OTA would be required to listen to people concerned over a new technology or a proposed law. At the congressional level, citizens could urge their congresspersons to accept or refuse the OTA's recommendations. In this way the proposal advances the notions of ethical economic decision making.

*D. Incorporating Socio-Economic Concerns into
Risk Cost-Benefit Analysis*

The final proposal would amend the Food, Drug and Cosmetic Act³¹⁷ to require companies wishing to introduce a new technological artifact to show that it would have a net beneficial socio-economic impact. The socio-economic benefits that would result from the use of a new technical artifact, such as a new animal drug, would have to outweigh the socio-economic costs that would flow from it. Such an amendment to the new animal drug provisions of the Act, for example, would require the FDA to weigh the socio-economic costs of a drug, in addition to the risk it poses to human health, animal health, and the environment. Clearly, this would require the FDA to develop expertise in the area of agricultural economics.

A similar bill was proposed in the European Parliament as an amendment to the European Community's Veterinary Bill,³¹⁸ in response to the anticipated impacts of rbST on Europe's dairy barns.³¹⁹ Although the amendment was not acted upon, the European Commission's Farms Directorate is drafting new legislation along similar lines.³²⁰

The major advantage of this proposal over the others is that

317. In so far as new technologies are regulated under statutes other than the Food, Drug and Cosmetic Act, it would be necessary to make similar amendments to those statutes. See *supra* note 258 and accompanying text.

318. *Bad Moos for BST*, *supra* note 261, at 70.

319. See *id.* at 66.

320. *Id.* at 70.

one integrated decision could be made in respect to each technological artifact. The drawback is that the decision-making process would be solely in the hands of bureaucrats. Those affected by the decision would not have a direct voice in making it, although they would be able to participate through the public hearing process.³²¹ Consequently, this option is not as democratic as the others which have been discussed.

The proposal does, however, meet the criteria of the two questions: "What does it do for people?" and "What does it do to people?" The requirement of a net socio-economic benefit means that these questions must be precisely balanced. According to one economist these are standard questions that economists are qualified to address.³²² Requiring proponents of new technology to prove the socio-economic worth of their products will create an incentive for companies to make more socially responsible investments than they do now.

CONCLUSION

Examining the issues that surround a unique and controversial new technology, recombinant bovine somatotropin, demonstrates that the current system used by the federal government to evaluate new technologies is inadequate. The review process should address the socio-economic impacts of new technological artifacts. As our society is now ordered, the power of technological decision making is in the hands of science, private enterprise, and to a limited extent government bureaucrats. The power of technology to transform our society, culture, and values is similar to the power of government to shape society through law. Yet, despite the profound influence technology has upon us, we allow a relatively small, insulated group to make technological decisions and provide them with little or no criteria upon which to base those decisions. The recommendations proposed here are intended to allow for a small degree of control in requiring that new technologies have a net socio-economic benefit before they are introduced. The propos-

321. Under this proposal, socio-economic data supplied by companies seeking approval of new products would not be confidential, although technical research results and composition would continue to be protected. Companies are less likely to consider socio-economic data sensitive; furthermore, because socio-economic data would be derived from the "soft" sciences, input from the public would be necessary to act as a check against information supplied by the advocate of the technology, who is likely to be biased.

322. Buhr et al., *supra* note 284, at 161.

als are also aimed at making the decision-making processes more democratic.

These proposals came about as a reaction to one new technology, rbST, and as such they may be limited because rbST may be a unique product.³²³ They may raise more questions than they answer, and further study and argument is needed in this newly emerging field. Nevertheless, these proposals represent a starting point for continued discussion. The discussion must recognize that technology, like law, is a value-laden concept which deserves control beyond risk and beyond the marketplace.

John Beiswenger

323. Frederick H. Buttel, *Biotechnology, Agriculture, and Rural America: Socioeconomic and Ethical Issues*, in *AGRICULTURAL BIOETHICS*, *supra* note 18, at 227, 238.