Recombinant Bovine Growth Hormone and the Courts: In Search of Justice

by

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The implications of [rBGH] are broad. They may affect millions of people who are waiting for cures for cancer, for AIDS, and for a variety of other fatal diseases. Biotechnology holds the best hope for conquering these monumental human afflictions. If the progress of biotechnology was slowed or stopped, many people would never have the chance to benefit from the efforts of our scientists.[1]

At our mother's breast, we taste our first food, milk.
Prepared by her body, the food and the feeding
rebind the newly separated. . . .
And cows, the most likely substitute for the human
mother, are wrapped in this mystique. "Mother"
Elsie and her family sold milk for Borden.
Carnation's claim to "contented cows" assured us

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* M. Phil., 1990, Cambridge University; M.A., 1992, Harvard University; J.D., 1998, New York University Law School. The author wishes to thank the New York University School of Law Fellowship for Legal Scholarship, Dorothy Nelkin for her constructive insights, and Roger Frie for his encouragement.

1. Donald W. Hecht, *Bovine Somatotropin Safety and Effectiveness: An Industry Perspective*, FOOD TECH., Apr. 1991, at 118, 124.

that in exchange for their milk, a pleasant lifestyle was provided for the animals who produced it.[2]

I. INTRODUCTION

Biotechnology is revolutionizing the life sciences and our traditional views of nature. New technological possibilities in genetics have already created new expectations for diagnosis and treatment and threaten the possibility of exploitation and eugenics. In agriculture, scientists have applied biotechnology to custom design plants for resistance to natural pests, alter to bacteria to bypass growth-limiting natural soil cycles, and to create transgenic animals for purposes ranging from improved food production to the creation of human-like organs for transplant purposes.[3] In this manner, the concept that each life form has a fixed, unalterable essence has already been rendered obsolete.

The impact of this technological revolution for all aspects of society will be enormous. Scientists are already planning new ways to make biotechnology serve the human interest from preconception genetic planning to the production of new, highly specific psychoactive drug therapies. While adding new possibilities, these innovations fundamentally overthrow age-old precepts that the human body and the reproductive system are essentially static and inalterable. In the legal sense, these new conceptions of the body mean that familiar quantities, such as property, privacy, and individual rights will be challenged and must be redefined.[4]

With biotechnology disputes now entering the courts, the judiciary is already being challenged to re-evaluate traditional legal concepts and to redefine a public approach to technology and nature.[5] The pursuit of justice would require the courts to recognize and balance all the legitimate interests being affected by the new technology. Unfortunately, the courts are not uniformly adhering to this standard. Instead, the myth of scientific progress often seems to overwhelm other interests, concerns, and issues. Thus, many decisions simply bow to science and do not explore further implications. The failure of justice in such situations is serious and needs further attention.

The approach of the American court system to biotechnology is vividly illustrated by the controversial agricultural product, recombinant bovine growth hormone (rBGH), alternatively called bovine somatotropin (BST).[6] First synthe-

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2. William C. Liebhardt, *Preface* of THE DAIRY DEBATE CONSEQUENCES OF BOVINE GROWTH HORMONE AND ROTATIONAL GRAZING TECHNOLOGIES at xv, xv (William C. Liebhardt ed., 1993) [hereinafter DAIRY DEBATE].

3. *See* SHELDON KRIMSKY & ROGER P. WRUBEL, AGRICULTURAL BIOTECHNOLOGY AND THE ENVIRONMENT: SCIENCE, POLICY, AND SOCIAL ISSUES 166-68 (1996); *see also From Present to Future—Where Is Genetic Engineering Leading Us?*, THE GRASS ROOTS & PUBLIC POLICY (Found. on Econ. Trends, Wash. D.C.), Fall 1995, at 6.

4. *See* SHEILA JASANOFF, SCIENCE AT THE BAR: LAW, SCIENCE, AND TECHNOLOGY IN AMERICA 24-41 (1995). This section of Jasanoff's book examines the legal system's adaptation of traditional doctrines to rapid changes in knowledge and technological capacity. *Id.*

5. *Id.* at 140.

6. KRIMSKY & WRUBEL, *supra* note 3, at 166. "Bovine Somatotropin" (BST) is the scientific name of this veterinary growth promoter, and "Bovine Growth Hormone," (BGH) is its

sized in 1982, rBGH was intended as the symbol of the biotechnology revolution in agriculture.[7] But even before its approval by the Food and Drug Administration (FDA) in 1993,[8] rBGH came under attack. Minnesota and Wisconsin placed temporary moratoria on the use of rBGH.[9] Vermont passed labeling laws so that consumers could elect to avoid rBGH treated milk products.[10] Grocery stores and milk producers were inundated with worried inquiries about the drug.[11] And public milk dumpings were staged around the nation.[12]

Ultimately, the dispute over rBGH reached the courts. Cases involving the hormone were filed in 1992 in the District of Columbia,[13] in 1994 in Wisconsin,[14] in 1995 in Vermont,[15] and in 1996 in Illinois.[16] These cases are the forerunners of challenges to human biotechnology innovations and have placed the courts in the center of the debate over what interests will be recognized in the new world of biotechnology. In the Washington D.C. case, the court was asked to declare that the FDA safety review of rBGH was inadequate.[17] In Wisconsin, the plaintiffs demanded a similar re-evaluation of the safety review, as well as damages for a number of other injuries caused by the hormone.[18] In Vermont, the court considered whether the State of Vermont's rBGH-labeling requirement violated milk producers' constitutional liberties.[19] And conversely, in Illinois, the court was to consider whether the state's ban on rBGH labeling violates dairy producers' constitutional rights.[20] Taken together, these challenges ask the courts

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popular designation. *Id.* I will use the latter term, using the prefix "r" to denote the hormone's recombinant state.

7. Wade Roush, *Who Decides About Biotech?*, TECH. REV., July 1991, at 28, 30; *see also* TERRY D. ETHERTON, AMERICAN COUNCIL ON SCIENCE & HEALTH, THE EFFICACY, SAFETY AND BENEFITS OF BOVINE SOMATOTROPIN AND PORCINE SOMATOTROPIN 2-3 (1994) (claiming that rBGH is representative of the new agricultural biotechnology that can help meet world nutritional needs).

8. Susan M. Cruzan, U.S. Dep't of Health & Human Servs. 1 (1993) (press release) (on file with author) (approving the use of BST).

9. Keith Schneider, *U.S. Approves Use of Drug to Raise Milk Production*, N.Y. TIMES, Nov. 6, 1993, at A1.

10. VT. STAT. ANN. tit. 6, § 2754 (1993) (repealed 1997).

11. *See, e.g.*, Tony Hiss, *How Now, Drugged Cow?: Biotechnology Comes to Rural Vermont*, HARPER'S MAGAZINE, Oct. 1994, at 80, 82-83; Molly O'Neill, *The Debate over Milk and an Artificial Hormone*, N.Y. TIMES, May 18, 1994, at C1.

12. *See, e.g.*, Neil Steinberg, *Protesters Dump on Use of Hormone for Milk*, CHI. SUN-TIMES, Feb. 4, 1994, at 8; *Milk Wars: Goliath is Losing*, THE GRASS ROOTS ANDPUBLIC POLICY (Found. on Econ. Trends, Wash. D.C.), Fall 1995, at 1 [hereinafter *Milk Wars*].

13. *See* Cordes v. Madigan, No. 90-2929, 1992 U.S. Dist. LEXIS 6250 (D.D.C. Apr. 30, 1992).

14. Stauber v. Shalala, 895 F. Supp. 1178 (W.D. Wis. 1995); Barnes v. Shalala, 865 F. Supp. 550 (W.D. Wis. 1994). For a discussion of the Wisconsin litigation see *infra* Part III.A.

15. International Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996). For a discussion of the Vermont litigation see *infra* Part III.B.

16. *See* Ben & Jerry's Homemade, Inc. v. Lumpkin, No. 96-C-2748, 1996 U.S. Dist. LEXIS 12469 (N.D. Ill. Aug. 28, 1996).

17. Cordes v. Madigan, 1992 U.S. Dist. LEXIS 6250, at *2.

18. Stauber v. Shalala, 895 F. Supp. at 1182.

19. International Dairy Foods Ass'n v. Amestoy, 92 F.3d at 70-71.

20. Ben & Jerry's Homemade, Inc. v. Lumpkin, 1996 U.S. Dist. LEXIS 12469, at *2.

to evaluate the FDA's recommendations enacted by Congress.[21] It is worth noting that the FDA essentially functions as an extension of Congress on issues involving new food and drug products. Thus, challenges to FDA rules are analogous to court challenges under other federal laws.[22]

The courts have not risen to the challenge posed by rBGH. The cases involving rBGH raise questions about the importance of continued technological progress, issues of human health and safety, long term economic impacts, and the value of nature. For the most part, however, courts have failed to recognize either the scale or scope of the issue. Instead, an underlying adherence to scientific progress seems to guide the courts. In the cases thus far, they have focused exclusively on health and safety issues, excluding the wider social concerns; or alternatively, the courts have focused only on nebulous social issues, but have not raised them in the context of biotechnology. This failure bodes ill for a reasoned resolution of the rBGH controversy and for future biotechnology issues. Without authoritative intervention, the rBGH dispute may continue to simmer until it explodes in public. In addition, the apparent lack of judicial strategies raises concern that the courts will be unprepared to address the even more ethically-fraught human biotechnology as it arrives.

Very few suggestions have been offered in the realm of legal scholarship to help the courts out of this current predicament. Indeed, much of the commentary focuses only on the phenomenon of science in the courts.[23] These writers argue that courts should more systematically defer to scientific truths in order to render a better kind of justice.[24] This kind of approach fails, however, to adhere to the norms of justice and to respond to the totality of issues surrounding rBGH. Instead, what is needed is a balancing strategy, in which the court acknowledges the legitimate technological, health and safety, economic, and moral interests at stake, and then reconciles the factors in light of policy and social interests. Only by airing and weighing the interests can courts hope to offer a permanent resolution.

Using the case of rBGH, I hope to add a new dimension to the discussion of how science and technology should be approached in the courts. In Part II of this Article, the history and the controversy surrounding rBGH is explained. Part III, discusses the cases that have addressed rBGH. It will become apparent that the courts have not yet found a way to render just solutions regarding the hormone. While the courts have variously discussed certain aspects of the controversy in depth, no coherent approach has been developed. Part IV, discusses the different suggestions that have been made to help courts deal more competently with "science" cases. In rejecting these solutions, I will suggest that

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21. *See infra* Part III.

22. In this sense, the courts are being asked to supplement the congressionally mandated FDA safety review. The FDA is obliged to evaluate the safety and efficacy of a new product and to make recommendations to Congress. Congress can then, as here, turn the recommendations into law. To find fault with any aspect of the FDA recommendation then lies, as with other laws, with the courts. For an additional discussion about the judicial link to agencies, see SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS 49-57 (1990) [hereinafter FIFTH BRANCH].

23. *See infra* notes 217-34 and accompanying text.

24. *See infra* notes 217-34 and accompanying text.

the courts must instead recognize interests and then engage in functional balancing tests.

II. RECOMBINANT BOVINE GROWTH HORMONE

A. *Background*

BGH itself is a naturally occurring protein that cows ordinarily produce in their pituitary glands and then secrete throughout their bodies.[25] In cows, BGH acts to direct nutrients toward milk production and is, thus, critical in regulating the lactation cycle.[26] Researchers have been aware of the role of BGH since the 1930s.[27] In fact, during World War II, British scientists sought to increase milk production by injecting pituitary extract from dead cows into live cows.[28] The inefficiencies of this process, however, made any such effort difficult and precluded large-scale development of the hormone for commercial purposes.[29]

The advent of biotechnology in the 1980s changed this situation dramatically. Recombinant DNA techniques allowed for the cheap production of mass quantities of a purified form of rBGH.[30] Using this technology, four major United States corporations, Monsanto, American Cyanamid, Upjohn, and Eli Lilly raced throughout the 1980s to develop a marketable rBGH product.[31] Monsanto, the ultimate victor in this competition, is said to have invested over $800 million alone in developing this product.[32] Monsanto's rBGH product, called "Posilac," is injected into the bloodstream of a cow to supplement the amount of BGH occurring naturally.[33] With elevated quantities of BGH and rBGH present, the cows begin directing virtually all their metabolic energies toward milk pro-

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

26. *Id.*

27. KRIMSKY & WRUBEL, *supra* note 3, at 167-68.

28. *Id.*

29. *Id.* at 168; *see also* LOVELL S. JARVIS, THE POTENTIAL EFFECT OF TWONEW BIOTECHNOLOGIES ON THE WORLD DAIRY INDUSTRY 5 (1996) ("Although [BGH] was identified over a century ago, the high cost of its production restricted research and practical applications until recently."); Juskevich & Guyer, *supra* note 25, at 875 (stating that commercial use of BGH was precluded because of limited supply and impurity of pituitary-derived BGH).

30. Juskevich & Guyer, *supra* note 25, at 875. *See, e.g.*, ETHERTON, *supra* note 7, at 3-8. To create mass quantities of the rBGH using recombinant techniques, scientists isolate the genes responsible for the natural hormone, insert them into the gnomes of rapidly reproducing bacteria, provide the bacteria with the necessary factors for protein production, and then harvest the resulting hormone. *Id.*

31. KRIMSKY & WRUBEL, *supra* note 3, at 168; Roush, *supra* note 7, at 30.

32. Roush, *supra* note 7, at 30.

33. *See* KRIMSKY & WRUBEL, *supra* note 3, at 172-73.

duction.[34] Studies report that rBGH yields a 15% to 25% increase in milk production.[35]

The FDA began to review the safety and efficacy of rBGH in 1984.[36] FDA regulations require that an applicant for approval of a new product provide: (1) a method of assaying its presence, or absence, in food and (2) the proposed residual level that shall be permitted to remain in the food.[37] Also, an application for marketing a new animal biologic must be supported by data that addresses the safety, efficacy, and tolerance issues with the burden of proof on the manufacturer.[38] On November 12, 1993, after over 120 studies had been evaluated, rBGH was officially approved for use in commercial applications beginning in 1994.[39] With remarkable consensus among medical and veterinary groups, the FDA concluded that the use of rBGH on cows had resulted in no direct health risks for humans.[40] Dr. David A. Kessler, the Commissioner of the FDA, declared, "There is virtually no difference in milk from treated and untreated cows . . . . We have looked carefully at every single question raised, and we are confident this product is safe for consumers, for cows and for the environment."[41] Congress accepted the FDA judgment in full[42] and refused to make concessions to the dissenting voices of Senators from Wisconsin and Vermont, who worried about the potential effect of the hormone on already beleaguered dairy farmers.[43] Milk, thus, became the first food that the Government would allow to be produced using a genetically engineered drug.

B. *The Controversy*

The approval of rBGH in 1993 sparked a highly public and contentious debate that continues today. There have been boycotts and protests, and there is even a rBGH hotline offering consumers an outlet for their concerns and providing information on rBGH.[44] Underlying the debate is a deep-seated public distrust of growing corporate power. Agribusiness has been portrayed as the evil

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34. *See, e.g.*, David S. Kronfeld, *Recombinant Bovine Growth Hormone: Cow Responses Delay Drug Approval and Impact Public Health*, *in* DAIRY DEBATE, *supra* note 2, at 65, 70-74.

35. KRIMSKY & WRUBEL, *supra* note 3, at 166; *see also* Dale E. Bauman, *Bovine Somatotropin: Review of an Emerging Animal Technology*, 11 NEW TECHNOLOGICAL ERA FOR AMERICAN AGRICULTURE 71, 72 (1990).

36. KRIMSKY & WRUBEL, *supra* note 3, at 183.

37. 21 U.S.C. § 360b(I)(G)-(H) (1994).

38. *Id.* § 360b.

39. Animal Drugs, Feeds, and Related Products: Sterile Sometribove Zinc Suspension, 58 Fed. Reg. 59,946, 59,946 (1993); *see also* KRIMSKY & WRUBEL, *supra* note 3, at 183.

40. KRIMSKY & WRUBEL, *supra* note 3, at 173; *see also* Juskevich & Guyer, *supra* note 25, at 877-83 (providing the actual results of the FDA review).

41. Schneider, *supra* note 9, at A1.

42. *See* 139 CONG. REC. H6135 (daily ed. Aug. 5, 1993) (statement of Rep. Volkmer).

43. *See* 139 CONG. REC. S7913 (daily ed. June 24, 1993) (statement of Sen. Hatch).

44. This "hotline" (1-800-PRO-COWS) is part of the "Just Say Moo" campaign organized by Stoneyfield Farm Yogurt of New Hampshire to galvanize support. For an example of the "Just Say Moo" campaign see the advertisement that Stoneyfield Farm Yogurt placed in *The Grass Roots & Public Policy*. *See* THE GRASS ROOTS AND PUBLIC POLICY (Found. on Econ. Trends, Wash. D.C.), Fall 1995, at 18.

force destroying the family farm and traditional lifestyles. In a sense then, the battle over rBGH is just the latest installment in the larger struggle against agribusiness' continuing dominance. To opponents, Monsanto's promotion of rBGH is simply a plot to make dairy farmers, and indeed, all milk drinking Americans, dependent on the faceless corporate power. Opponents of rBGH warn that this latest "technology trap" will further undermine the individual's control over his or her life.[45] The view is encapsulated in the lobbying newsletter of the anti-rBGH group, the Pure Foods Campaign:

> [T]he rBGH and biotech food fight represents a societal turning point, a defining battle over who will set the table—biotech, agribusiness and chemical companies such as Monsanto, or the family farmers using sustainable agricultural practices.
>
> Ultimately, the is a battle over who will exercise sovereignty over the genetic blueprints of animals, plants and all life forms . . . .[46]

Monsanto's search for profits are ultimately perceived as the antithetical to the interests of farmers and the public.[47]

1. *Safety Concerns*

On a more explicit level, the rBGH controversy revolves around two issues of safety of the product and the threat posed to small dairy farms. A number of scientists, environmentalists, and activists claim that the FDA review of rBGH was flawed and fails to recognize the importance of data indicating serious health threats.[48] These vocal advocates, who include Jeremy Rifkin, a biotechnology gadfly, and Consumer's Union, insist that residues of rBGH appear in milk and may cause allergic reactions in humans.[49] In addition, they note that rBGH raises the level of IGF-1, an insulin-like growth factor, in the milk of treated cows. This factor, they worry, will interfere with human metabolism and growth.[50] Critics also claim that the increased incidence of mastitis (udder infections) experienced by treated cows, which the FDA dismissed as "manageable," is actually a

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45. *See* Hiss, *supra* note 11, at 85-90.

46. *Milk Wars*, *supra* note 12, at 1.

47. *Id.*; *see also* MICHAEL W. FOX, SUPERPIGS AND WONDERCORN 19 (1992). In addition, a number of commentators point out that rBGH will increase the milk surplus and thus cause milk prices to decline further. As a result, the government price supports and surplus buying program will have to increase, costing the taxpayers money. On this line of reasoning, Monsanto is the *only* party that stands to gain from rBGH. *See* Roush, *supra* note 7, at 30; *see also* L.J. Butler & Gerry Cohn, *The Economics of New Technologies in Dairying: BGH vs. Rotational Grazing*, *in* DAIRY DEBATE, *supra* note 2, at 189, at 222-27.

48. KRIMSKY & WRUBEL, *supra* note 3, at 187-90. There is a lot of public discussion of these issues. *See, e.g.*, James Ridgeway, *Robocow: How Tomorrow's Farming Is Poisoning Today's Milk*, THE VILLAGE VOICE, March 14, 1995, at 27; *rBGH Sickens Cows, Ruins Farmers*, THE GRASS ROOTS AND PUBLIC POLICY (Found. on Econ. Trends, Wash. D.C.), Fall 1995, at 9. *See generally* Kronfeld, *supra* note 34, at 65.

49. *See, e.g.*, Gail Feenstra, *Is BGH Sustainable? The Consumer Perspective*, *in* DAIRY DEBATE, *supra* note 2, at 1, 20-27.

50. *Id.* at 29-31; *see also* JARVIS, *supra* note 29, at 6.

matter for grave concern.[51] Potential indirect effects include increased antibiotic use on cows and a resulting dangerous level of antibiotic residue in milk, as well as, an increased pus content in the milk.[52] Finally, these dissenters warn that the increased protein needs of treated cows will proportionately increase the use of high protein feed and this, in turn, will raise the risk of cows being infected with bovine spongiform encephalopathy—"mad cow disease."[53]

To be fair, the FDA openly addressed these issues during the approval process.[54] Thus, in published research, FDA scientists have reviewed numerous studies and have concluded that rBGH is biologically inactive in humans and therefore, "residues of BGH in food products would have no physiological effect even if absorbed intact from the gastrointestinal tract."[55] Similarly, the FDA report dismissed concerns over the potential health effects of elevated levels of IGF-1 in treated milk.[56] FDA scientists note that the injection of rBGH into animals could temporarily increase quantities of IGF-1 in milk;[57] however, they note that even these increased levels are within the naturally occurring range of IGF-1 found in untreated milk or human breast milk.[58]

In the same vein, an FDA press release admits that the use of rBGH may result in greater incidence of mastitis and use of antibiotics on cows.[59] The agency, however, dismisses any resulting health risk on grounds that an existing regulatory regimen requires that every truckload of milk shipped by the dairy farmer pass a test for antibiotic residue.[60] This inspection will protect the public from unsafe levels of antibiotic residue in the milk.[61]

The FDA has not actually addressed critics' concerns over the possible connections between rBGH and mad cow disease. The agency's lack of apparent concern over this issue is not wholly surprising. The United States Department of Agriculture has made clear that it does not regard mad cow disease as a risk in this country, noting time and time again that thus far there have been no reported cases of the disease in the United States.[62] The federal agencies only recently

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51. JARVIS, *supra* note 29, at 7.

52. *Id.*; Feenstra, *supra* note 49 at 34-41.

53. KRIMSKY & WRUBEL, *supra* note 3, at 174-80. Scientists have postulated that bovine spongiform encephalopathy, or "mad cow disease," can be transmitted through animals eating rendered protein from infected animals. For further discussion on this point see John Lanchester, *A New Kind of Contagion*, NEW YORKER, Dec. 2, 1996, at 70.

54. *See* Juskevich & Guyer, *supra* note 25, at 875.

55. *Id.* at 883.

56. *Id.* at 879.

57. *Id.* at 883.

58. *Id.* at 879.

59. Cruzan, *supra* note 8, at 1.

60. Council for Agricultural Science & Technology, CAST Presents Scientific Information on Bovine Somatotropin (BST) 3 (May 27, 1993) (press release) (on file with author).

61. Cruzan, *supra* note 8, at 1. As an additional precaution, the FDA announced a monitoring system to track the relationship between rBGH use and increased antibiotic residues. *Id.*

62. *See, e.g.*, Lawrence K. Altman, *U.S. Officials Confident That Mad Cow Disease of Britain Has Not Occurred Here*, N.Y. TIMES, Mar. 27, 1996, at A12. Recently, the FDA has begun to talk about implementing new regulations as a precautionary measure after a disturbing mad cow-like disease outbreak in mink. *See* Sandra Blakeslee, *Fear of Disease Prompts New Look at Rendering*, N.Y. TIMES, Mar. 11, 1997, at C1.

have begun expressing concern that the United States food supply could become tainted.[63] Despite official reassurances, a steady trickle of conflicting safety studies has given opponents reasons to continue their attack on economic grounds.[64]

2. *Economic Concerns*

Opponents to rBGH also protest that the economic effects on small dairy farmers will be devastating.[65] They claim that the benefits of this expensive technology will only accrue to those with sizable farms.[66] Thus, the 300 cow farms of Wisconsin and Vermont will be pushed out of the way by the 4,000 cow farms of Texas and New Mexico.[67] In addition, opponents to rBGH fear that any further increase in milk production will drive milk prices too low to sustain many independent dairy farms.[68] Because of an already existing milk surplus, prices already depend on government surpluses.[69]

Though important, the issues of rBGH's safety and potential economic effects do not by themselves explain the intensity of the controversy. Indeed, the safety review of the product was relatively uncontroversial by FDA standards.[70] Numerous studies were done, and groups ranging from the American Medical Association to the National Academy of Scientists endorsed the findings.[71] In addition, the economic instability of small dairy farms is nothing new.[72] These farms began their steep decline after World War II, when the pasteurization of milk became universal.[73] Increased productivity and price variations have driven dairy farmers out of business every year, and the move toward greater industrialization was established long before the introduction of biotechnology.[74]

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63. Blakeslee, *supra* note 62, at C1.

64. KRIMSKY & WRUBEL, *supra* note 3, at 187-90.

65. *Id.* at 180-81; Hiss, *supra* note 11, at 84.

66. KRIMSKY & WRUBEL, *supra* note 3, at 181.

67. *Id.* at 181-82.

68. Butler & Cohn, *supra* note 47, at 204. For a discussion specifically in terms of Vermont, see Hiss, *supra* note 11, at 83.

69. Roush, *supra* note 7, at 30 ("From 1987 to 1989, the government spent between $600 million and $1.3 billion a year to purchase surplus milk under price-support legislation. In 1986, the year after field tests of rBGH began, the government paid dairy farmers to slaughter 1 million cows to reduce milk subsidy payments then costing taxpayers more than $1 billion annually.").

70. For examples of truly contentious debates following FDA approval, see FIFTH BRANCH, *supra* note 22, at 152-79.

71. *See* ETHERTON, *supra* note 7, at 10-15; KRIMSKY & WRUBEL, *supra* note 3, at 172-73.

72. *See* KRIMSKY & WRUBEL, *supra* note 3, at 180-81; *see also* Hiss, *supra* note 11, at 84-85. It is difficult to sustain a critique of the hormone as a technology that will single-handedly cause the death of small dairy farms. Dairy farms are already highly dependent on technology because mechanical milking, bulk storage and transfer tanks, artificial insemination, and embryo transfer have turned dairy farming into an operation fixated on efficient production.

73. Sally Johnson, *In Vermont, Milkmen Are Leaving the Scene*, N.Y. TIMES, Nov. 10, 1996, at A23.

74. *See* KRIMSKY & WRUBEL, *supra* note 3, at 180.

3. *Conflicting Views of Nature*

The force of the rBGH controversy must also be understood in the context of a more fundamental opposition to biotechnology. Biotechnology and indeed rBGH sets forth a view of nature that conflicts with the vision of nature pervasive throughout this Judeo-Christian based society.[75] Indeed, for a large portion of society, "nature" refers to life, or living systems, in a state untouched by humans.[76] As such, nature has an intrinsic moral authority either as an evolved state of perfection or as a symbol of divine perfection.[77] The thriving environmental movement is testament to the power and pervasiveness of this understanding,[78] biotechnology threatens this view directly. As one commentator observes, molecular biologists are "[m]aking an end run around nature's restrictions . . . produc[ing] progeny that nature would never allow."[79] Biotechnology posits life and nature as systems that can be rewritten for human advantage, and where no life form is sacred in itself.[80] The conflict is, thus, clear—to accept biotechnology wholly would be to discard the view of an untouched nature as sacred. This essential conflict has been with biotechnology since the early debates over recombinant DNA in the 1970s.[81]

rBGH is emblematic of the overarching discomfort with biotechnology.[82] rBGH challenges the traditional perception of what is "natural" and raises questions about the morality of intervention in "nature." Milk and cows perhaps are consummate symbols of what is natural and pure: "At our mother's breast, we

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75. *See* Dorothy Nelkin, *Living Inventions: Animal Patenting in the United States and Europe*, 4 STAN. L. POL'Y REV. 203, 206 (1992).

76. *See id.*

77. In reality, these views are completely intermingled. *See* RACHEL CARSON, SILENT SPRING (1962); KIRKPATRICK SALE, THE GREEN REVOLUTION: THE AMERICAN ENVIRONMENTAL MOVEMENT, 1962-1992 (1993); *see also* Mario Giampietro, *Sustainability and Technological Development in Agriculture: A Critical Appraisal of Genetic Engineering*, 44 BIOSCIENCE 677, 691 (1994); *Religions Condemn Patenting of Life: Historical Coalition Formed*, THE GRASS ROOTS & Public Policy (Found. on Econ. Trends, Wash. D.C.), Fall 1995, at 1.

78. For a history of the environmental movement, see SALE, *supra* note 77.

79. Kathy Collmer, *Brave New Pigs: Part Human, Part Machine*, 39 THE LAND REPORT 19, 19 (1990). For further discussion on this point, see FOX, *supra* note 47. According to Fox, there is a larger ethical concern about this approach to animals and nature. *Id.* at 101. Biotechnology without holism, he argues, threatens to undermine the integrity of the earth and life. *Id.* at 163.

80. *See* FOX *supra* note 47, at 101.

81. *See, e.g.*, Stuart Auchincloss, *Does Genetic Engineering Need Genetic Engineers?: Should the Regulation of Genetic Engineering Include a New Professional Discipline?*, 20 B.C. ENVTL. AFF. L. REV. 37, 47-50 (1993). For a general history, see SHELDON KRIMSKY, BIOTECHNICS AND SOCIETY: THE RISE OF INDUSTRIAL GENETICS (1991). *See also* ROBERT BUD, THE USES OF LIFE: A HISTORY OF BIOTECHNOLOGY (1993); HORACE FREELAND JUDSON, THE EIGHTH DAY OF CREATION: MAKERS OF THE REVOLUTION IN BIOLOGY (1979) (giving a more general and thorough description of the emergence of genetics and recombinant techniques).

82. My assumption here is that the debate operates on both a substantive and a symbolic level. Following anthropologist Clifford Geertz and historian Robert Darnton, I present the "meanings" implicit in the discussion. *See* CLIFFORD GEERTZ, THE INTERPRETATION OF CULTURES (1973); ROBERT DARNTON, THE GREAT CAT MASSACRE AND OTHER EPISODES IN FRENCH CULTURAL HISTORY (1984).

taste our first food, milk. Prepared by her body, the food and the feeding rebind the newly separated. . . . And cows, the most likely substitute for the human mother are wrapped in this mystique."[83] Articles about the rBGH controversy constantly play on this symbolic relationship. For example, a March 9, 1994, *New York Times* article about rBGH links the issue of milk with a young mother, her infants, and her desire to choose the most nurturing option to feed these offspring.[84] Similarly, another controversy explores our sentimentalization of the dairy cow. As the author reflects: "Like most 2,000-pound Holsteins, they'd never imagined anything other than a reasonably long life of familiar green pasture, a predictable milking schedule and the steady twang of the country-and-western music that is played in their barn."[85] Even Monsanto, in its efforts to build support for rBGH plays on this imagery. In their national advertising campaign featuring small children dunking their mother's cookies, Monsanto urges the public that rBGH in milk is itself *natural* with the caption: "You've had BST and cookies all your life."[86]

Much of the opposition to rBGH is directed at this perceived corruption of "the pure." To a large swath of the population, biotechnology violates the sanctity of milk with its vision that, "'a dairy cow is, metabolically, an appendage to the mammary gland.'"[87] rBGH leaves the cow as an unkempt prisoner of technology, as illustrated by an anti-rBGH lobby's picture of a cow boxed into a metal cage and hooked to a series of milking hoses.[88] Rejecting this violation of nature, many voice their concern. A letter to the New York Times chides promoters of rBGH for failing to consider the health of the cows: "excessive milk production reportedly makes them suffer continuously from bruised udders and brings on an early death from metabolic stress. This is a cruel way to treat a gentle creature."[89] Another letter despairs the day when, "daily chores on Wisconsin and Minnesota dairy farms . . . [will] include disposing of hypodermic needles in addition to sterilizing milking machines."[90] Instead, they seek a respect for life, and hope for farms where one might find a "dappled Holstein . . . curled up in a pen under a maple tree."[91] Ultimately, as one observer concludes: "From the broader perspective of genetically engineered food products, the milk hormone is one of the worst products the industry could have started with . . . . Milk is something people consider natural and sacred. They don't want to see it

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83. Liebhardt, *supra* note 2, at xv.

84. Keith Schneider, *Lines Drawn in a War over a Milk Hormone*, N.Y. TIMES, Mar. 9, 1994, at A12.

85. O'Neill, *supra* note 11, at C1.

86. KRIMSKY & WRUBEL, *supra* note 3, at 184.

87. Hiss, *supra* note 11, at 85 (quoting Bob Collier, Monsanto's Dairy Research Director).

88. *Antibiotics: A Medical Disaster in the Making*, THE GRASSROOTS & PUBLIC POLICY (Found. on Econ. Trends, Wash. D.C.), Fall 1995, at 16.

89. Letter to Editor, *The Health of Cows*, N.Y. TIMES, Mar. 7, 1994, at A16.

90. Letter to Editor, *Milk Hormone Poses Health and Welfare Risks*, N.Y. TIMES, May 19, 1994, at A22.

91. Hiss, *supra* note 11, at 85.

manipulated."[92] According to this view, rBGH is too much of a violation of the natural order to be accepted.

It is clear that the discussion of rBGH has multiple levels. Underlying the controversy is a strong mistrust of corporate power and agribusiness in particular. To many, these increasingly dominant institutions symbolize nothing more than greed and the sacrifice of individual independence. On explicit terms, many oppose rBGH because it is unsafe for cows and humans. These critics argue that the FDA review failed to address the evidence indicating direct and indirect dangers to health. Others complain that not enough consideration was taken of the potential economic effects of rBGH. They claim that small dairy farms are already struggling, and that this product may just be the death blow. The rBGH debate is also infused by general opposition to biotechnology and its corruption of "nature." For rBGH's opponents, milk, cows, and farms are symbols of purity and perfection, and the new technology is entirely unwelcome.

III. rBGH IN THE COURTS

As rBGH evolved into a full scale public debate in the early 1990s, a number of cases made their way into the courts. These cases have translated the wide-ranging public debate into legal disputes and brought the matter before the judiciary. In Wisconsin the plaintiffs asked the court to consider possible damage to dairy farmers, consumers, producers, and others caused by FDA approval of rBGH.[93] In Vermont, a challenge to the state's rBGH labeling law presented the court with an even broader range of concerns about rBGH and the desirability of biotechnology.[94] In both cases, however, the courts refused to take up the complex challenges presented to them.[95] Instead, they seemed to defer to technological determinism, implicitly endorsing the idea that scientific development must be allowed to continue unchecked.[96] Thus, the courts divert their attention to subsidiary or procedural issues and fail to devise a strategy for approaching rBGH.

I will analyze the two major challenges to rBGH approval in depth, parsing out the courts' approach to the issues and their ultimate outcomes. In doing so, I hope to illustrate the current judicial approach to biotechnology. Although I will

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92. Robert Lee Hotz, *Fruits of Genetic Tinkering Are Headed for U.S. Tables*, L.A. TIMES, Nov. 12, 1993, at A1 (quoting Nachama Wilker, Executive Director, Committee for Responsible Genetics) (internal quotations omitted).

93. Stauber v. Shalala, 895 F. Supp. 1178 (W.D. Wis. 1995); Barnes v. Shalala, 865 F. Supp. 550, 553 (W.D. Wis. 1994).

94. International Dairy Foods Ass'n v. Amestoy, 898 F. Supp 246, 247 (D. Vt. 1995), *rev'd*, 92 F.3d 67 (2d Cir. 1996).

95. *See id.*; Barnes v. Shalala, 865 F. Supp. at 559-64.

96. This view has been pervasive in judicial consideration of biotechnology issues. For example, in *Moore v. Regents of the Univ. of Cal.*, the California Supreme Court declined to reconceptualize property rights to include a patient's property interest in his own cells because preserving the incentives of research were deemed more important. Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 494-95 (1990). One commentator notes that this kind of technological determinism is pervasive in the courts. JASANOFF, *supra* note 4, at 12.

not discuss the case, *Cordes v. Madigan*,[97] in depth, as it was dismissed for lack of jurisdiction without discussion,[98] the fact that the case was filed is representative of the widespread concern about rBGH. The plaintiffs in *Cordes* charged that the United States Department of Agriculture's (USDA) Dairy Promotion Program was promoting the use of rBGH in violation of limitations written in the Dairy Tobacco Adjustment Act,[99] the Federal Food, Drug and Cosmetic Act,[100] and the Administrative Procedure Act.[101] The court found that the plaintiffs, who included Jeremy Rifkin and his lobbying group, the Foundation on Economic Trends, had not suffered a justiciable injury.[102] The court also dismissed the other plaintiffs, dairy farmers, for lack of standing and a failure to exhaust administrative remedies.[103]

In addition, I will not speculate on the impact of the recently settled *Ben & Jerry's Homemade, Inc. v. Lumpkin*,[104] although its presence is again significant in itself. In this case, Ben & Jerry's and a number of other dairy manufacturers sued officials of the state of Illinois and the city of Chicago for effectively barring them from labeling their products as rBGH-free, and thus violating its First Amendment right to commercial free speech.[105] The state claimed that rBGH-free labels would violate an Illinois law requiring any statement on a food label to be proven.[106] Because there is no test for the presence rBGH, the state barred the rBGH-free label as misleading.[107] In August 1997, the parties settled the case out of court, agreeing that compromise language can be placed on the labels.[108] Labels can now contain statements such as, "'[w]e oppose [rBGH]. The family farmers who supply our milk pledge not to treat their cows,'" as long as they also note that the FDA has found no significant difference between treated and untreated milk.[109] If this agreement leads other states to loosen similar labeling restrictions, as some expect, labels on a number of nationally

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97. Cordes v. Madigan, No. 90-2929, 1992 U.S. Dist. LEXIS 6250 (D.D.C. Apr. 30, 1992).

98. *Id.* at *10-11.

99. Dairy Tobacco Adjustment Act of 1983, 7 U.S.C. § 4504d (1994).

100. Federal Food, Drug and Cosmetic Act of 1938, 21 U.S.C. §§ 301-393.

101. Administrative Procedure Act of 1966, 5 U.S.C. §§ 500-706.

102. Cordes v. Madigan, 1992 U.S. Dist. LEXIS 6250, at *4-8.

103. *Id.* at *8-10.

104. Ben & Jerry's Homemade, Inc. v. Lumpkin, No. 96-C-2748, 1996 U.S. Dist. LEXIS 12469 (N.D. Ill. Aug. 28, 1996). The settlement was announced in a Ben & Jerry's press release. *See* Ben & Jerry's Homemade, Inc., Legal Settlement Clears Way for National Anti-rBGH Label (Aug. 14, 1997) (press release) (on file with author).

105. Ben & Jerry's Homemade, Inc. v. Lumpkin, 1996 U.S. Dist. LEXIS 12469, at *2.

106. Illinois Food, Drug and Cosmetic Act of 1967, 410 ILL. COMP. STAT. ANN. 62/1 (West 1993).

107. Robert Steyer, *Ben & Jerry's Caught in Middle of BST Label Confusion*, ST. LOUIS POST-DISPATCH, Mar. 16, 1997, at 9E.

108. *Ben & Jerry's, State in Accord on Growth Hormone Statement*, CHI. TRIB., Aug. 14, 1997, at 4.

109. *Ben & Jerry's Label to State Opposition to Growth Hormone*, STAR-TRIB. (Minneapolis-St. Paul), Aug. 23, 1997, at 2E.

distributed products will soon carry the anti-rBGH message.[110] At the very least, then, the settlement assures that the rBGH issue will continue to be in the public eye.

A. *Wisconsin: Challenging FDA Approval*

The two motions in the Wisconsin case illustrate the courts' inadequate response to the issues raised by rBGH.[111] The complaint challenged the FDA's approval of rBGH on grounds that the FDA failed to meet standards set by the Federal Food, Drug and Cosmetic Act,[112] the National Environmental Policy Act,[113] and the Administrative Procedure Act.[114] The case was ultimately dismissed on the defendant's motion for summary judgment.[115] In the two opinions issued by Chief Judge Crabb, the court's approach to rBGH is made clear.[116] The plaintiffs in the case present a range of opposition to rBGH, including concerns of tainted milk and frightened consumers.[117] While the court seemed to recognize the kinds of concerns underling the opposition to rBGH, it acknowledged only the health and safety issues in the opinions.[118] In this manner, the Wisconsin court implicitly endorses a form of technological determinism and ultimately fails to engage the many levels of issues raised by rBGH.

In the first Wisconsin decision, *Barnes v. Shalala*,[119] the court granted the defendants' motion to dismiss for lack of subject matter in part, and denied it, in part.[120] The plaintiffs included Wisconsin dairy farmers, owners of Wisconsin dairy processors, Wisconsin grocers and distributors, a veterinarian, a nutritional educator, a nurse, the editor of a farm journal, all Wisconsinites, and the Foundation for Economic Trends, led by activist Jeremy Rifkin.[121] The defendants were Donna Shalala, the Secretary of Health and Human Services, and David A. Kessler, the Commissioner of the FDA.[122] The plaintiffs the challenged defendants' approval of rBGH under 21 U.S.C. § 360b(d)(1) and (2), on three grounds:

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110. *Company Allowed to Denounce Hormone*, THE PLAIN DEALER (Cleveland), Aug. 15, 1997, at 2C (noting that states having similar bans, such as Hawaii, Nevada, and Oklahoma, are expected to lift their bans as a result of the Ben & Jerry's settlement).

111. *See* Stauber v. Shalala, 895 F. Supp. 1178 (W.D. Wis. 1995); Barnes v. Shalala, 865 F. Supp. 550 (W.D. Wis. 1994).

112. Federal Food, Drug and Cosmetic Act of 1938, 21 U.S.C. §§ 301-394 (1994).

113. National Environmental Policy Act of 1970, 42 U.S.C. §§ 4321-4370(d).

114. Administrative Procedure Act of 1966, 5 U.S.C. §§ 500-706.

115. Stauber v. Shalala, 895 F. Supp. at 1197.

116. *See id.* at 1187-97; Barnes v. Shalala, 865 F. Supp. at 559-64.

117. Stauber v. Shalala, 895 F. Supp. at 1182; Barnes v. Shalala, 865 F. Supp. at 554.

118. Stauber v. Shalala, 895 F. Supp. at 1183-85; Barnes v. Shalala, 865 F. Supp. at 558-59.

119. Barnes v. Shalala, 865 F. Supp. 550 (W.D. Wis. 1994).

120. *Id.* at 564.

121. *Id.* at 553.

122. *Id.* at 554.

> 1) the approval was arbitrary and capricious because the FDA failed to consider health and safety issues related to the use of [rBGH]; 2) the defendants failed to require mandatory labeling of products from cows treated with [rBGH]; and 3) the defendants failed to conduct an adequate environmental assessment or issue an environmental impact statement assessing the environmental effect of [rBGH] approval.[123]

The plaintiffs requested a declaration, under 28 U.S.C. § 2201 and Federal Rule of Civil Procedure 57, that the defendants failed to perform their statutory duties in approving rBGH.[124] They also asked that a permanent injunction suspending the approval of rBGH be granted until the defendants complied with their statutory obligations.[125]

On the defendants' motion to dismiss for lack of subject matter jurisdiction, the court considered the levels of jurisdictional issues and concluded that the Wisconsin district court could consider the challenges to the FDA.[126] Further, the court ruled that the defendants' decision not to require mandatory labeling of milk and milk products *was* a reviewable action in the district court.[127] The court granted, however, the defendants motion in part.[128] The court held that the plaintiff farmers, sellers of dairy products, health care professionals, and the Foundation on Economic Trends lacked the requisite "concrete and particularized" injuries to attain standing as plaintiffs before the court.[129] On the same evaluation, the claims of the consumers were allowed to remain on all counts.[130]

While this motion was at heart a procedural matter, this court clearly took a position on how rBGH will be treated and what issues will be considered. Discussions of standing are illustrative of the court's approach. The court signaled that it was willing to discuss the health and safety issues by retaining the consumers' complaints for consideration.[131] The court stated, "that the consumer plaintiffs have standing to pursue this action because the purpose of the Food, Drug and Cosmetic Act is to protect consumers from unsafe food, drugs and cosmetics."[132] The court further maintained that both the farmers and the consumers had standing on their environmental impact challenge.[133] In that regard, the court stated that the environmental assessment accompanying the FDA approval of rBGH failed to address "environmental impacts associated with rBGH including, *inter alia*, health impacts on dairy cows, . . . potential health

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123. *Id.*
124. *Id.*
125. *Id.*
126. *Id.* at 557.
127. *Id.* at 557-58.
128. *Id.* at 564.
129. *Id.* at 558-61 (citing Family & Children's Ctr., Inc. v. School City, 13 F.3d 1052, 1058 (7th Cir. 1994)).
130. *Id.* at 560.
131. *See id.*
132. *Id.* at 561.
133. *Id.* at 563.

risks to consumers caused by increased IGF-1 and antibiotic residue and the economic impacts on family dairy farms."[134]

At the same time, the court stopped short of allowing deeper concerns about nature or the mistrust of corporate power to come into the discussion. The court gestured at its awareness of the passionate controversy and hostilities stirred by rBGH.[135] The *Barnes* opinion began with the statement: "This is a case about milk, a subject near and dear to the hearts of Wisconsinites."[136] In addition, the court acknowledged that diffuse fears might be behind the dislike of rBGH.[137] Consumers "are being harmed by their inability to consume milk products that they know are free of milk from [rBGH] treated cows."[138] The court flatly refused, however, to consider the injuries of the other parties as substantive enough to maintain standing.[139] The *Barnes* opinion gave no explanation for this approach. One can only speculate that concern about corporate health and scientific progress, embraced in other decisions, played some part. Thus, the nurse's worry about advising consumption of tainted dairy products is categorized as "speculative," as is the veterinarians' concern about over-prescribing antibiotics to the detriment of disease at large.[140] Similarly, the farmers' interest in providing the "customers with safe and wholesome products" is deemed too far from the intent of the Food, Drug and Cosmetic Act to maintain their standing.[141] Nowhere in the opinion did the court actually discuss the motivations behind these various groups' vocal opposition to rBGH. The court made no explicit statements to discount the opponents' arguments; however, the purview of the court is clearly shut to a discussion of concerns about nature or agribusiness.

In its decision on the second motion, *Stauber v. Shalala,*[142] the court replicated this approach. The plaintiffs in the case were the American consumers of commercially sold dairy products.[143] The defendants were again Donna Shalala and David A. Kessler, with Monsanto also present as an intervenor.[144] The claims brought were the same as above.[145] On this motion, the court granted the defendants' request for summary judgment, ruling that the plaintiffs did not put any material facts into dispute within the relevant, admissible evidence.[146] In making the judgment, Chief Judge Crabb again considered only scientific evaluations of health and safety.[147] After reviewing the evidence presented, the court ultimately deferred to the FDA, in a manner that is well established by

134. *Id.* at 562.
135. *Id.* at 559-60.
136. *Id.* at 553.
137. *Id.* at 560.
138. *Id.*
139. *Id.* at 562.
140. *Id.* at 560-61.
141. *Id.* at 562.
142. Stauber v. Shalala, 895 F. Supp. 1178 (W.D. Wis. 1995).
143. *Id.* at 1182.
144. *Id.*
145. *See supra* note 122 and accompanying text.
146. Stauber v. Shalala, 895 F. Supp. at 1183.
147 *Id.* at 1183-86.

precedent.[148] Though the court again seemed to acknowledge that there are other concerns, it declined to address them.[149]

The *Stauber* court very clearly recognizes the various and divergent positions on safety.[150] For example, the opinion noted the concern raised both by the FDA and by others about: (1) rBGH residues in milk; (2) the potential link between mastitis and increased antibiotic residue in milk; (3) the increased somatic cell count—pus—found in milk from rBGH treated cows; and (4) the threat of increased IGF-1, the insulin-like growth factor, due to increased BGH levels in the cow.[151] The court's recognition of these safety issues does not, however, mean that the FDA assessment will be overturned. Recent precedent has mandated against the judiciary re-evaluating the actual data presented to regulatory agencies.[152] Courts are only to review agency abuses and factors falling outside the regulatory scope.[153] According to this line of precedent, the *Stauber* court discarded the safety issues raised by the plaintiffs by applying the narrow strictures of judicial review.[154] The court stated, "when a decision goes to the core of an agency's expertise, generally the court must defer to the agency's more informed judgment."[155] In the end, the court recognized that the plaintiffs raised "valid concerns" but concluded that the FDA review was adequate, and therefore, cannot be overruled.[156]

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148. *Id.* at 1190-92.

149. *Id.*

150. *Id.* at 1183-85.

151. *Id.* at 1184-85.

152. *See* Camp v. Pitts, 411 U.S. 138, 142 (1973) (holding that a reviewing court should not create a new record, but should review the record created by the agency and determine whether the agency acted in an arbitrary and capricious manner); Edwards v. United States Dep't of Justice, 43 F.3d 312, 314-15 (7th Cir. 1994) (stating that the reviewing court should determine if the agency acted properly in its adjudication); Cronin v. United States Dep't of Justice, 919 F.2d 439, 443-44 (7th Cir. 1990) (stating that a district court is also a reviewing court of an administrative agency's decision and as such should not conduct new evidentiary hearings, except in emergency situations).

153. *See, e.g.*, Camp v. Pitts, 411 U.S. at 142; Edwards v. United States Dep't of Justice, 43 F.3d at 314-15; Cronin v. United States Dep't of Justice, 919 F.2d at 443-44. *See also* JASANOFF *supra* note 4, at 69. Court deference to these kind of expert reviews has been sharply defined over the past decade. For a detailed analysis of this change, see JASANOFF, *supra* note 4, at 75-92. In the judicially active 1970s, courts applied the "hard look" doctrine in reviewing agency decisions. *Id.* at 75. This approach permitted a court to re-evaluate agency decisions if they seemed particularly egregious. *Id.* This activism was firmly rejected by the Supreme Court in *Baltimore Gas and Electric Co. v. Natural Resources Defense Council, Inc.*, 462 U.S. 87 (1983). In *Baltimore Gas*, the Supreme Court mandated that with regard to "scientific determination . . . a reviewing court must generally be at its most deferential." *Id.* at 103. This approach was reaffirmed in numerous other cases, and now is generally taken as the rule. *See, e.g.*, Chevron U.S.C. Inc. v. Natural Resource Defense Council, Inc., 467 U.S. 837, 843-44 (1984) (stating that courts should be deferential to administrative interpretations).

154. Stauber v. Shalala 895 F. Supp. 1189.

155. *Id.* "'[I]n evaluating scientific evidence in the drug field, the FDA possesses a expertise entitled to respectful consideration by th[e] court.'" *Id.* (quoting Tri-Bio Lab., Inc. v. United States, 836 F.2d 135, 142 (3d Cir. 1987)) (alterations in original).

156. *Id.* at 1191. This ruling is again consistent with an underlying desire not to interfere with technological "progress," as expressed in *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 494-95 (Cal. 1990). *See supra* note 96 and accompanying text.

No discussion was offered on the deeper levels of opposition to the hormone. The court noted, "Scientists, economists, farmers, and environmental and animal welfare organizations have questioned the safety and quality of [rBGH]-derived products. In addition, the FDA received thousands of letters from consumers asking it to deny approval of [rBGH] or to require labeling of [rBGH]-derived products."[157] The court also acknowledged that the lack of an environmental review of the product might cause concern.[158] The court, however, pointedly refused to delve into any of these issues further. Using the precedent that disallows courts to consider any evidence that was not a part of the FDA record, the court declined to consider any of the plaintiffs' complaints.[159] In a sense, this move is disingenuous. The line of precedent cited specifically bars judicial review of the *same data* presented to the reviewing agency.[160] The *Stauber* court, however, expanded the scope of the rule to bar consideration of any kind of nonagency reviewed data, whether or not it could have been a part of the agency record.[161] In one powerful move, then, the court eliminates any opportunity for opposition on moral grounds to become part of the discussion. The court effectively defers to technological determinism and corporate expansion.[162] Thus, the biotechnological product is to be accepted as just another scientific inevitability to be absorbed, however painfully, by society at large.

The Wisconsin court thus refuses to engage rBGH in its totality. By focusing on scientific evaluations of health and safety, this court recognized only part of the debate. Even more, its narrow interpretation of precedent eliminates the need to consider underlying moral and social issues.

B. *Vermont: Challenging Labeling Laws*

The Vermont case and its appeal presented a different question to the courts. *International Dairy Foods Ass'n v. Amestoy*,[163] centers on the legitimacy of a Vermont law requiring that products from rBGH treated cows be so labeled.[164] As a law stemming from consumer discomfort with rBGH, the Vermont case puts social and moral issues squarely before the court. Ultimately, however, the *International Dairy Foods Ass'n* courts also failed to devise a strategy for confronting the rBGH controversy. Initially, the Judge effectively

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157. Stauber v. Shalala, 895 F. Supp. at 1183.

158. *Id.* at 1186.

159. *Id.* at 1189.

160. *See* Camp v. Pitts, 411 U.S. 138, 142 (1973); Edwards v. United States Dep't of Justice, 43 F.3d 312, 314-15 (7th Cir. 1994); Cronin v. United States Dep't of Justice, 919 F.2d 439, 443-44 (7th Cir. 1990).

161. Stauber v. Shalala, 895 F. Supp at 1190. The *Stauber* court's expansion on this case law is significant because there is no provision in the Food and Drug Acts for evaluating the social, ethical, or economic impacts of the veterinary hormone. Thus, if Congress does not act on legitimate social, ethical, and economic impacts, the public's only recourse on these issues, is in the courts. *See* KRIMSKY & WRUBEL, *supra* note 3, at 188.

162. Stauber v. Shalala, 895 F. Supp. at 1189.

163. International Dairy Foods Ass'n v. Amestoy, 898 F. Supp. 246 (D. Vt. 1995), *rev'd*, 92 F.3d 67 (2d Cir. 1996).

164. *Id.* at 249.

legitimized the concerns about the nonnaturalness of rBGH.[165] His opinion, however, is sharply censured and reversed by the court of appeals.[166] Only circuit court Judge Leval's opinion, written in dissent, begins to give a picture of how courts could more comprehensively discuss an issue like rBGH.[167]

In the initial phase of the case, *International Dairy Foods Ass'n* (*IDFA I*), the United States District Court for the District of Vermont denied the plaintiffs' request for a preliminary injunction.[168] The plaintiffs in the case were a group of food and dairy industry associations.[169] The defendants were the Attorney General of Vermont and the Commissioner of the Vermont Department of Agriculture.[170] The plaintiffs challenged the Vermont labeling law,[171] which provides, inter alia, that "[i]f [rBGH] has been used in the production of milk or a milk product for retail sale in this state, the retail milk or milk product shall be labeled as such."[172] The plaintiffs charged that the law is unconstitutional violating the First Amendment, the Supremacy Clause,[173] and the Commerce Clause of the United States Constitution.[174] The plaintiffs asked for a preliminary injunction prohibiting the defendants from enforcing the law.[175]

The *IDFA I* court denied this request.[176] In its review of the issues, the court found that the plaintiffs did not provide concrete evidence that they would be irreparably damaged by the labeling requirement.[177] Further, the court denied that the labeling requirement violated the Commerce Clause because both in-state and out-of-state producers would have to follow the law, and both in-state and out-of-state producers could choose to refrain from using rBGH.[178] Finally, the court found that the plaintiffs' First Amendment freedom not to speak on rBGH use was offset by a legitimate state interest: "Vermont has determined that its

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165. *Id.* at 248-50.

166. International Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 74 (2d Cir. 1996).

167. *Id.* at 74 (Leval, J., dissenting).

168. International Dairy Foods Ass'n v. Amestoy, 898 F. Supp. at 249.

169. *Id.* at 248. The plaintiffs included the IDFA, the Milk Industry Foundation, the International Ice Cream Association, the National Cheese Institute, Grocery Manufacturers of America, Inc., and the National Food Processors Association. *Id.*

170. *Id.*

171. VT. STAT. ANN. tit. 6, § 2754 (1997).

172. International Dairy Foods Ass'n v. Amestoy, 898 F. Supp. at 249. The law mandates that rBGH products will be marked with a blue dot. *Id.* A sign near each dairy case will identify those marked products as being from rBGH treated cows, with the additional statement: "The United States Food and Drug Administration has determined that there is no significant difference between milk from treated and untreated cows. It is the law of Vermont that products made from the milk of [rBGH] treated cows be labeled to help consumers make informed shopping decisions." *Id.* at 250.

173. U.S. CONST. art. VI, cl. 2. The Plaintiffs subsequently agreed not to pursue the Supremacy Clause claim. International Dairy Foods Ass'n v. Amestoy, 898 F. Supp. at 247.

174. U.S. CONST. art. I, § 8, cl. 3.

175. International Dairy Foods Ass'n v. Amestoy, 898 F. Supp. at 247.

176. *Id.* at 254.

177. *Id.* at 250-52.

178. *Id.* at 253.

citizens are entitled to have information which assists them in making purchases consistent with their beliefs on the appropriateness of [rBGH] use."[179]

The court here groped toward exploring the issues surrounding rBGH, but did so only in a tentative manner. The court recognized the Vermont citizens' broader concerns about biotechnology that underlie the labeling law stating:

> (1) They consider the use of a genetically-engineered hormone in the production unnatural; (2) they believe that use of the hormone will result in increased milk production and lower milk prices, thereby hurting small dairy farmers; (3) they believe that the use of [rBGH] is harmful to cows and potentially harmful to humans; and, (4) they feel that there is a lack of knowledge regarding the long-term effects of [rBGH].[180]

The court, however, failed to consider the other positions that were also represented in the case. As the representative of food and dairy groups, the plaintiffs' interest was in rBGH being fully accepted into the food chain; for them, the hormone promises greater efficiencies and profit. The plaintiffs also had an interest in promoting the success of the hormone—technology, biotechnology in particular, promises advances in food variety, availability, and salability.[181] These plaintiffs opposed labeling precisely because the label marks the milk as different or unnatural.[182] The FDA *itself* took a stand on this position when it decided that any sort of labels would be unnecessary.[183] The FDA has repeatedly backed the statement that milk from treated and untreated cows is the same.[184] The court, however, diminished the weight of plaintiffs' interests. The court stated, "without intending to disparage the importance of such injury, we observe that all that is lost [to the plaintiffs] is profits."[185] For the *IDFA I* court, the resulting First Amendment issue balanced Vermonters' deep anxiety about this "unnatural" product against the plaintiffs' mundane monetary interests in this very small market.[186] In this sense, the court appeared to agree that agribusiness is to be distrusted. The profit motive was marked as a suspect interest, and the defendants' fears were legitimated.[187] Ultimately, however, this decision does not do much to deepen the judicial discourse on rBGH. The *IDFA I* court's consideration of the issues was incomplete.

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179. *Id.* at 252.

180. *Id.* at 250.

181. *See, e.g.*, ETHERTON, *supra* note 7, at 2.

182. International Dairy Foods Ass'n v. Amestoy, 898 F. Supp. at 250-51.

183. *Id.* at 248-49.

184. Interim Guidelines on the Voluntary Labeling of Milk and Milk Products from Cows That Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6,279, 6,280 (1994). The FDA recommended an interim guideline that labeling would be voluntary, and that any labeling should include the caveat that the FDA has determined milk from treated and untreated cows to be indistinguishable. *Id.* This interim guideline is unenforceable.

185. International Dairy Foods Ass'n v. Amestoy, 898 F. Supp. at 251.

186. *Id.* at 253-54.

187. *See id.*

On appeal to the Second Circuit, the circuit court in *International Dairy Foods Ass'n v. Amestoy*[188] (*IDFA II*) retreated further from addressing the totality of the issues raised by rBGH. The majority opinion followed the same general line of reasoning as found in *IDFA I*, using a First Amendment balancing test to resolve the challenge.[189] On reviewing the case, the circuit court rejected the district court's opinion that Vermont's interest was substantial, and instead dismissed the labeling law as merely an effort to satisfy "consumer curiosity."[190] This, the court concluded, is not enough of a "substantial issue" to justify the injury done by intruding on the plaintiffs' First Amendment rights.[191] In this sense, the circuit court followed the line of technological determinism, refusing to allow individual interests to move scientific progress off line.[192] The decision of the district court was thus reversed and remanded for the entry of an appropriate injunction.[193]

In *IDFA II*, Judge Leval's dissent is actually the more significant opinion because it offers the first example of how issues like rBGH might fruitfully be evaluated. Judge Leval began by attempting to explain the labeling controversy in its larger context.[194] He explained that "[g]enetic and biotechnological manipulation of basic food products is new and controversial."[195] To illustrate this point, Judge Leval described a newspaper cartoon included as evidence:

> [I]n frame 1, a man declares his confidence in the safety of [rBGH] milk; in frame 2, he drinks the milk; in frame 3, he turns into a werewolf. Plaintiffs cite this cartoon as a demonstration that the concerns of Vermonters are fantastical. They overlook the fact that the cartoon is a joke. But like most jokes it has a basis in reality. . . . What it reflects is that . . . consumers are worried about the effects of [rBGH].[196]

Judge Leval explored the interests involved, including the underlying distrust of agribusiness.[197] Going over the evidence, he reiterated the district court's determination that Vermont citizens are concerned that rBGH is unnatural, unsafe for humans and cows, likely to harm small dairy farms, and understudied with respect to long term health and safety effects.[198]

At the same time, Judge Leval expanded on the district court's consideration of the case by developing the plaintiffs' counterpoised interests

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188. International Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996).

189. *Id.* at 72-74.

190. *Id.* at 73 & n.1.

191. *Id.* at 73-74.

192. Again this move is analogous to the decision in *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990). *See supra* note 96 and accompanying text.

193. International Dairy Foods Ass'n v. Amestoy, 92 F.3d. at 74.

194. *Id.* at 74 (Leval, J., dissenting). Judge Leval voiced his dissent from the First Amendment framework overall. *Id.* Reviewing precedent, he argued that the benefit of the First Amendment in commercial speech has never been applied for the purpose of *withholding* information from interested parties. *Id.* at 80-81.

195. *Id.* at 76.

196. *Id.* at 79 n.4.

197. *Id.* at 77.

198. *Id.* at 75-76.

more fully. In this regard, he rejected the plaintiffs' free speech argument.[199] Judge Leval reasoned that in reality the text of the label is innocuous because it states prominently that the FDA "has determined that there is no difference between [products] from treated and untreated cows."[200] Instead, the Judge Leval identified the plaintiffs' interest in biotechnology as part of scientific progress and profit.[201] He concluded that the plaintiffs "do not wish consumers to know that their milk products were produced by use of [rBGH] because there are consumers who, for various reasons, prefer to avoid [rBGH]."[202] Balancing these interests against the Vermont interest, he thus reasoned that: "the majority's ruling deprives Vermont of the right to protect its consumers by requiring truthful disclosure on a subject of legitimate public concern."[203] Concerns about nature, economics, safety, and even corporate intentions are all considered in Judge Leval's dissenting opinion.[204] Ultimately, the Judge balanced the parties' interests in the larger context of biotechnology.[205] His opinion stands as an example of the kind of breadth and consideration necessary to decide an issue like rBGH.[206]

IDFA I and *IDFA II* are thus significant not only for illustrating the courts' reluctance to consider biotechnology issues, but also for Judge Leval's thoughtful exposition of an alternative approach. In *IDFA I*, the district court raised the possibility that important cultural issues are challenged by rBGH, but it does not adequately balance these interests. The circuit court majority retreated further in *IDFA II* reversing the district court's opinion while refusing to recognize *any* of the surrounding issues. Only Judge Leval, dissenting in *IDFA II*, attempts to navigate a course that can recognize the weight and context of all the issues. In his dissenting opinion, he measures the concerns driving the Vermont law against those of the manufacturers, and on balance, finds for the State of Vermont. In another case, however, this balancing might have yielded opposite results.

IV. BIOTECHNOLOGY AND THE COURTS

A. *Present Frustrations*

Ultimately, the courts have not settled on an approach to the new biotechnology concerning rBGH. No court has given an explicit explanation for its reluctance. It is likely, however, that the courts are reluctant to impede scientific "progress."[207] While the Wisconsin district court reduced the controversy to a

199. *Id.* at 81.
200. *Id.* at 79.
201. *Id.* at 80.
202. *Id.*
203. *Id.* at 81.
204. *Id.* at 74-81.
205. *Id.* at 78-81.
206. My intent is not to endorse Judge Leval's result, but to hold up his process of reasoning as exemplary.
207. *See* Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 494-95 (Cal. 1990) (finding that a physician's use of a patient's cells for research purposes without the patient's consent did not amount to conversion). In *Moore*, the court refused to apply the law of conversion to the case

deferential review of the FDA's scientific assessment, the Second Circuit dismissed all opposition to rBGH as irrational.[208] The fact remains, however, that legitimate interests are represented in the rBGH controversy. Some involved in the controversy doubt the adequacy of the FDA safety review and have raised credible opposition based on indirect risks.[209] Others claim that rBGH is illegitimate on economic grounds—they document that rBGH will be expensive for the American taxpayer and will mean final extinction for small dairy farmers.[210] Still another group bases their opposition on a less quantitative interest, calling the hormone a violation of nature and the natural order.[211] Proponents of the hormone meet all these challenges by referring to the FDA finding that rBGH is safe.[212] In addition, they maintain that the hormone is an important step on the road to a healthier and more productive planet.[213] Thus, the proponents hold rBGH as representative of the fruits that scientific progress can continue to yield.

Courts need to find a way to engage and address these various interests in order to settle the conflicts. Congress has not provided any guidance on the issue. Congress simply accepted the FDA evaluation and set a date for the start of rBGH use.[214] A few senators, notably from Wisconsin and Vermont, voiced concern about the hormone.[215] In the wake of pressured debate about the 1993 Omnibus Budget Resolution, these concerns were muted and eventually dropped from discussion.[216] With this absence of Congressional discussion, the weight of resolving problems following FDA approval has fallen to the courts.[217]

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because to do so would hinder scientific research. *Id.* at 494; *see also supra* note 96 and accompanying text.

208. International Dairy Food Ass'n v. Amestoy, 898 F. Supp. 246, 250-51 (D. Vt. 1995), *rev'd*, 92 F.3d 67, 74 (2d Cir. 1996).

209. *See supra* Part II.B.1.

210. *See supra* Part II.B.2.

211. *See supra* Part II.B.3.

212. Animal Drugs, Feeds, and Related Products: Sterile Sometribove Zinc Suspension, 58 Fed. Reg. 59,946, 59,946 (1993); *see also* KRIMSKY & WRUBEL, *supra* note 3, at 173; Schneider, *supra* note 9, at A1.

213. *See* ETHERTON, *supra* note 7, at 2.

214. *See* 139 CONG. REC. E2081 (daily ed. Aug. 6, 1993) (statement of Rep. Gephardt) (advocating the approval of bovine hormone to help farmers).

215. 139 CONG. REC. H6135-44 (daily ed. Aug. 5, 1993).

216. 139 CONG. REC. E2081 (daily ed. Aug. 6, 1993) (statement of Rep. Gephardt); *see also* 139 CONG. REC. S7974 (daily ed. June 24, 1993); 139 CONG. REC. H6135-44 (daily ed. Aug. 5, 1993) (raising arguments in opposition to rBGH by Vermont and Wisconsin Congress people).

217. This is a common pattern for new scientific developments. Congress has not enacted a new body of law to deal with biotechnology, thus the courts are left to resolve how the new technology fits with the existing law. *See generally* Al Gore, *Planning a New Biotechnology Policy*, 5 HARV. J.L. & TECH. 19 (1991). A similar situation appears in the failure of Congress to enact a new body of law dealing with software technologies. *See* Gary M. Hoffman & Geoffrey M. Karny, *Can Justice Keep Pace with Science?*, WASH. POST, Apr. 10, 1988, at B3 ("Because Congress has failed to enact a new body of law to adequately protect software technologies, courts have been obligated to fill the gap."). Again rulemaking has largely been left to the courts.

B. *Possibilities for the Future*

In her book on the intersection of science and law, Professor Sheila Jasanoff provides a sense of how the adversarial approach can succeed with respect to rBGH and science issues more generally.[218] Professor Jasanoff calls the open forum of the court "an essential part of the process by which American society comes to grips with the moral, material and institutional dimensions of technological change."[219] For her, the judicial system actually serves as a socially useful check on potent scientific determinism.[220] Thus, the procedures underlying the adversarial system allow the courts to actually get behind claims and controversies, in order to reveal various legitimate or illegitimate interests.[221] According to Professor Jasanoff, it is only by exposing scientific claims that they can be made accountable to public values and expectations.[222] Thus, Professor Jasanoff concludes that an effective legal system must allow the conflicting interests to be aired, in order to produce appropriate context-specific resolution.[223] Ultimately, she concludes, "The law's dominion rests . . . on its power to rebuild order and stability from uncertainty and chaos . . . ."[224] According to Professor Jasanoff, all of the legitimate positions on rBGH should be considered.

Other writers on science and law fall short of making a useful contribution. Instead, they are preoccupied with epistemological issues and the differences between science and law. As such, the literature is rich with superficial comparisons between the science and law.[225] Aside from making broad suggestions that the judiciary become more comfortable evaluating scientific issues, these commentators have not developed potential approaches for deciding biotechnology cases.

Steven Goldberg, Professor of Law at Georgetown University, and Peter Schuck, Professor at Yale Law School, focus their relevant works on the need to ease the translation of scientific developments into legal terms.[226] Both scholars contrast the truth-seeking nature of science with the justice-seeking aims of the

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218. JASANOFF, *supra* note 4, at 206.

219. *Id.*

220. *See id.* at 5-7, 140.

221. *Id.* at 20-21. What *is* "legitimate" requires, of course, further study and consideration.

222. *Id.* at 214.

223. *Id.* at 222.

224. *Id.* at 224. Jasanoff further resolves that technological determinism should not be allowed to control the courts. "[T]he involvement of the courts in [biotechnology] often reinforces dominant beliefs and institutional arrangements, which, in this society, include a well-entrenched faith in the progressive force of science and technology." *Id.* at 140.

225. STEVEN GOLDBERG, CULTURE CLASH: LAW AND SCIENCE IN AMERICA 6-20 (1994); Peter H. Schuck, *Multi-Culturalism Redux: Science, Law, and Politics*, 11 YALE L. & POL'Y REV. 1, 4-5 (1993) ("Science appeals to the capacity of technical rationality . . . . Law appeals to the capacity of universal, abstract, binding principles . . . .").

226. GOLDBERG, *supra* note 225; Steven Goldberg, *The Reluctant Embrace: Law and Science in America*, 75 GEO. L.J. 1341 (1987); *see also* Schuck, *supra* note 225. Justice Stephen Breyer also entered the debate arguing that a more rational regulatory system based on better science would eliminate many legal challenges. *See generally* STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION (1993).

courts.[227] For both, undesirable "culture clashes" occur between the disciplines when courts adjudicate scientific issues. The "culture clash" puts obstacles in the way of both scientific progress and legal procedure. For Goldberg and Schuck, a "clash" between science and law has the potentially hazardous result of disrupting scientific progress and creating mountains of litigation.[228] To avoid such situations, Goldberg advocates attaching "science counselors" to new technology projects, such as rBGH, to respond to public concern and eliminate the need for judicial intervention at all.[229] Similarly, Peter Schuck concludes that interference in science must be avoided at all costs.[230] Toward this end, he urges courts and politicians to become conversant in scientific and technological developments; that way, regulation will create fewer bottlenecks and the threat to progress will be eliminated.[231]

This vision is taken one step further by Marcia Angell, the Executive Editor of the New England Journal of Medicine, and Peter Huber of the conservative Manhattan Institute for Policy Research.[232] These commentators argue that legal decisions involving science and technology *must* comport with scientific progress.[233] According to Angell and Huber, science and law are alike in that each seeks the truthful resolution of a problem.[234] In comparing the two disciplines, however, these writers conclude that science offers a better form of truth because it is verifiable and objective.[235] Angell and Huber, thus, maintain that when considering science, justice would be better served if courts adhered strictly to scientific determinations.[236] Angell deplores the results of the silicon breast implant trials as runaway "anti-science" based on hysteria rather than truth.[237] Huber extends these principles to include technology. Huber argues that if science develops a workable product and it is deemed safe by the scientific establishment, courts should have nothing further to add.[238] To do otherwise, he claims, would denigrate scientific progress and give baseless fears a platform.[239]

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227. GOLDBERG, *supra* note 225, at 8-20; *see also* Schuck, *supra* note 225, at 23-24 ("The canons of science, after all, dictate that if research uncovers a new truth, scientists must not suppress it but should instead let the chips fall where they may.").

228. GOLDBERG, *supra* note 225, at 94-103; Schuck, *supra* note 225, at 7-14.

229. GOLDBERG, *supra* note 225, at 103-04.

230. Schuck, *supra* note 225, at 36-38.

231. *Id.*

232. MARCIA ANGELL, SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE 188-90 (1996) (discussing the necessity of testing science and the usefulness of the scientific method); PETER W. HUBER, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM 148-50, 192-200 (1991) (distinguishing between scientific fact and legal fact).

233. *See* ANGELL, *supra* note 232, at 188-89; HUBER, *supra* note 232, at 197-204.

234. *See* ANGELL, *supra* note 232, at 208-09; HUBER, *supra* note 232, at 197.

235. ANGELL, *supra* note 232, at 209; HUBER, *supra* note 232, at 197.

236. ANGELL, *supra* note 232, at 209 ("Only by relying on scientific evidence can we hope to curb the greed, fear and self-indulgence that too often govern such disputes."); HUBER, *supra* note 232, at 197 ("The methods of science are so fundamentally different from those of litigation that scientific anarchy in court is inevitable if rules of evidence are not strictly maintained.").

237. ANGELL, *supra* note 232, at 177-91.

238. HUBER, *supra* note 232, at 226-28.

239. *See id.* 214-28.

According to Huber, any judicial intervention with scientific developments is as repugnant as social engineering.[240]

Neither of these approaches recognize that "justice" is, in fact, quite a different goal than the pursuit of "truth." The goal of justice never presupposes one right answer, as science does with "truth." Rather, as King Solomon stated in the Old Testament, just solutions weigh the interests of the parties and from there attempt to produce the solution that best comports with social mores and the interests of the parties.[241] As scholars John Thibaut and Laurens Walker stated:

> [T]he ultimate test of any particular solution is the character of the distribution of outcomes among the interested parties, and no solution will ultimately be recognized as "correct" by all of them. Hence the objective of resolving conflicts of interest must frankly be seen as something other than finding the "true" or scientifically valid result. [From] the time of Aristotle the objective in resolving this kind of dispute has been characterized as "justice."[242]

The answer for a court seeking to render justice on an issue like rBGH, is thus not simply to understand the science better, as suggested by Goldberg and Schuck; rather, it is to understand the issue as it impinges on all parties with legitimate interests. Complete deference to rBGH as a product of scientific progress, cannot resolve the conflicts brought before the courts. This approach will only elevate scientific reasoning to a position of total dominance for solving all types of societal problems at the expense of legal justice.[243]

V. CONCLUSION

The judicial system is well designed to admit and address the full range of interests presented by rBGH. Indeed, some even claim that this is an essential function of the courts. As Jasanoff writes: "[l]itigation . . . is an especially potent resource for making transparent the values, biases, and social assumptions that are embedded in many expert claims about physical and natural phenomena."[244] When he was Chief Judge of the United States Court of Appeals for the

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240. *See id.* at 11.

241. 1 *Kings* 3:23. Admittedly, an entire field of philosophy is devoted to defining "justice." It is not my intent here to enter that discussion. My point is only that "justice" and "truth" are two quite different quantities.

242. John Thibaut & Laurens Walker, *A Theory of Procedure*, 66 CAL. L. REV. 541, 544 (1978) (citations omitted).

243. Scientific reasoning can be dangerous when applied to social problems because it fails to value phenomena that are not measured or quantified by science. *See, e.g.*, Rochelle Cooper Dreyfuss & Dorothy Nelkin, *The Jurisprudence of Genetics*, 45 VAND. L. REV. 313, 339-40 (1992). This problem is, of course, most starkly evident in German social policies under the Nazi regime. *Id.* at 340.

This elevation of science above all social considerations also fails to recognize the degree to which science, like law, is shaped by subjective considerations. *See generally* THOMAS S. KUHN, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS (1962); BRUNO LATOUR & STEVE WOOLGAR, LABORATORY LIFE: THE SOCIAL CONSTRUCTION OF SCIENTIFIC FACTS (1979).

244. JASANOFF, *supra* note 4, at 20.

District of Columbia, Judge Bazelon took precisely this position on cases involving science and technology issues. He reflected that:

> [O]penness is in everyone's bests interests, including the decision makers' . . . . When the issues are controversial, any decision may fail to satisfy large portions of the community. But those who are dissatisfied with a particular decision will be more likely to acquiesce in it if they perceive that their views and interests were given a fair hearing.[245]

This kind of considered adversarial approach helps to reveal the whole range of issues and assumptions at stake.[246] Ultimately, it can help quell dispute by assuring that all parties understand the potential and problems of the new technology.

In order to properly address rBGH, courts need to air the interests underlying the debate—to sort the legitimate from the illegitimate. Like Judge Leval, courts need to note Monsanto's interests, the FDA position, the worries about economic effects, and the interests of consumers and producers.[247] These factors must be counterbalanced and considered in order to provide an ultimate solution. It is important that the judicial system avoid falling prey to the technological determinism buoying rBGH and actually take up the task of rendering justice. Only then will they satisfy the goal of open dispute resolution and begin to bring closure to this contentious social issue.

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245. David L. Bazelon, *Coping with Technology Through the Legal Process*, 62 CORNELL L. REV. 817, 825 (1977).

246. *See* EDWARD YOXEN, THE GENE BUSINESS: WHO SHOULD CONTROL BIOTECHNOLOGY? 181-82 (1983). Yoxen compares the way that early debates over biotechnology played out in the United States and Great Britain. *Id.* In his opinion, the American system of highly adversarial legal debate ultimately serves to conclusively resolve problems; in Great Britain, the dissent is never so publicly aired and thus continues to simmer. *Id.*

247. Much debate could also be avoided by considering these factors at the initial policy making stage. For an argument in this vein, see Nelkin, *supra* note 75, at 209 (arguing that an evaluation of new biotechnology needs to include all related social and economic consequences).