Pace Environmental Law Review

Volume 15
Issue 2 *Summer 1998*

Article 9

June 1998

Pushing RBST: How the Law and the Political Process Were Used to Sell Recombinant Bovine Somatotropin to America

David Aboulafia

Pushing RBST: How the Law and the Political Process Were Used to Sell Recombinant Bovine Somatotropin to America

DAVID ABOULAFIA*

Table of Contents

I. Introduction 604
II. The Regulation of Biotechnology 607
  A. Generally 607
  B. The Scope Document 609
  C. The Food, Drug & Cosmetic Act 611
    1. Generally 611
    2. Residue Testing 613
  D. The Role of the Food & Drug Administration 614
    1. Generally 614
    2. Labeling Guidelines 616
      a. Constitutional Implications 618
    3. Post Approval Reaction & Controversy .. 621
III. The Adverse Effects of rbST on Cows 626
IV. Potential Effects on Human Health 628
  A. Antibiotics 628
  B. IGF-1 632
V. BST's Potential Effects on the Dairy Industry .. 636
VI. Analysis 640

---

* This article is dedicated to Pace University Professors Suzan M. Porto, M. Stuart Madden and Joseph Olivenbaum, with sincere appreciation for their interest, dedication, and instruction. Also, dedicated to Andrea and the kids, who let me work.

A. The Limitations of Risk Assessment Methodology 640
B. Known Risk and the Inherent Difference of Biotechnology 642
C. Socioeconomic Effects 646
D. The Promotion of Biotechnology 647
E. The Failings of the Food, Drug, and Cosmetic Act 650
F. Labeling 652
VII. Conclusion 653

> I deem it important that . . . you meet some counterweight against the snobbery of social institutions: against the bland assumption that because things social are, therefore they must be; against the touching faith that the current rationalizations of an institution, first, fit the facts, second, exhaust the subject, third, negate other, negate better possibilities.[1]

I. Introduction

Bovine Somatotropin (bST), otherwise known as Bovine Growth Hormone (BGH), is a hormone which occurs naturally in cattle.[2] It is known to increase appetite, weight, and milk production in cows.[3] Recombinant Bovine Somatotropin (rbST) is a genetically engineered, synthetic bST created through recombinant deoxyribonucleic acid (rDNA) technology.[4]

All life forms have deoxyribonucleic acid (DNA) composed of what is principally the same genetic material.[5] A

1. *See* KARL N. LLEWELLYN, THE BRAMBLEBUSH 1, 42 (1930).

2. *See* Marianna Kulka and Susan Semenak, *MILK SHAKE-UP; A Production-Boosting Hormone is Raising Safety and Public Relations Concerns for the Dairy Industry; MILKING: THE ISSUE*, EDMONTON J., May 28, 1995, at C7 [hereinafter Kulka & Semenak].

3. *Id.*

4. *See* John Beiswenger, *Moving Beyond Risk in Assessing Technological Artifacts: The Case of Recombinant Bovine Somatotropin*, 16 VT. L. REV. 667, 667 (1992).

5. *Id.* at 670 (citing INDUSTRIAL BIOTECHNOLOGY ASS'N, BIOTECHNOLOGY AT WORK: WHAT IS BIOTECHNOLOGY? 3 (1989)).

bird is different from a bear, for instance, because the genetic material making up each creature's DNA is arranged in different sequences and appears in varying amounts.[6] Genes known to produce certain traits can be spliced from a host organism and transplanted into a recipient organism; the recipient then inherits that trait and ultimately passes it along to its offspring.[7] Genetic material is interchangeable between many organisms.[8] For instance, researchers have already successfully spliced a gene from a flounder into a tomato to increase the latter's resistance to freezing.[9]

In the case of rbST, a cow's bST-producing gene is spliced onto a plasmid of an E. coli bacteria.[10] A plasmid is a free-floating piece of DNA which is able to pass through another bacteria's outer cell wall.[11] The recipient bacteria chosen by the genetic scientist assimilates the plasmid and inherits the ability to produce the hormone, which it immediately begins to do.[12] Once placed into a fermentation tank the bacteria reproduces,[13] passing the bST-producing trait along to the 16 billion bacteria it may reproduce each day.[14] The resulting synthetic hormone is collected and administered in the form of an injection to cows.[15] Treated cows may produce up to forty percent more milk each day.[16] Synthetic bST was origi-

---

6. *Id.*

7. *Id.* at 672 (citing MARGARET MELLON, BIOTECHNOLOGY AND THE ENVIRONMENT, at 21 (1988)).

8. *Id.* at 671 (citing MELLON, at 23).

9. *See* Andrew K. Weegar, *Fishy Tomatoes and Hot Potatoes; The Tomato in Your Supermarket May Have Genes in it From a Flounder. Wouldn't You Like to Know That?* MAINE TIMES, Mar. 31, 1995, at 11.

10. *See* Beiswenger, *supra* note 4, at 673 (citing RURAL VERMONT, BOVINE GROWTH HORMONE: WHAT'S IN IT FOR VERMONT? 1 (1988)).

11. *See id.*

12. *Id.*

13. *See* Tony Hiss, *How Now Drugged Cow: Biotechnology Comes to Rural Vermont*, HARPER'S MAGAZINE, Oct. 1, 1994, available in 1994 WL 1330636, at *7.

14. *See* Jack Challem, *Defend Yourself Against Supergerms, Antibiotic Resistant Bacteria*, NATURAL HEALTH, Mar. 1995, at 56.

15. *See* Beiswenger, *supra* note 4, at 667.

16. *See* Reid G. Adler, *Controlling the Applications of Biotechnology*, 1 HARV. J. L. & TECH. 1 (1988), *available in* LEXIS, Allrev Database, at *17 (citing Debra Schwarz of the Wisconsin Family Farm Defense Fund, Inc.).

nally developed by Genentech, Incorporated, and licensed to the Monsanto Corporation[17] in the early 1980s.[18] Monsanto is the only company producing the drug and which has received approval to market it to the public.[19]

With a testing and approval process that lasted well over a decade, rbST has been more extensively studied than perhaps any other animal drug in the United States.[20] Monsanto has invested one-half billion dollars towards its development over that time.[21] The hormone rbST carries with it an impressive list of approvals and endorsements, including those from the U.S. Food and Drug Administration (FDA), U.S. Department of Health and Human Services (DHHS), American Medical Association (AMA), National Institutes of Health (NIH), World Health Organization (WHO), United Kingdom Medicines Commission, American Council on Health and Science (ACHS), Office of Technology Assess-

17. Monsanto, the company that brought us PCB's and Agent Orange, was recently named among the100 most socially responsible corporations in America by Business Ethics magazine. *See* Marjorie Kelly, *Chemical Company Can Be Good Citizen, Monsanto Proves Greatly Improved Environmental Record Stands Out*, STAR-TRIBUNE NEWSPAPER (Mpls.-St.Paul), June 17, 1996, at 3D.

18. *See* Alex Barnum, *Battle Over Milk Hormone Hits Marketplace, Dairies In No Hurry To Use Controversial Bovine Growth Drug*, SAN FRANCISCO CHRON., February 3, 1994, at D1.

19. *See* International Dairy Foods Association v. Amestoy, 92 F.3d 67, 75 (2d Cir. 1996). American Cyanamid and Upjohn were also rbST developers. *See* Symposium, *Biotechnology and Tort Liability*, 55 U. PITT. L. REV. 791 (1994) (citing Daniel S. Greenberg, *Higher Milk Production Isn't Worth the Money Spent on It*, L.A. TIMES, Dec. 1990, at B3). Eli Lilly and Co. and Dow Chemical, through a joint venture, researched rbST through Eli Lilly's animal health division, but abandoned further development of the drug. *See* Telephone Interview with Ron Cooper, Manager of New Products Planning and Development, Eli Lilly & Co., Elanco Animal Health Division, Indianapolis, Ind. (Nov. 13, 1996) [hereinafter Telephone Interview with Ron Cooper]; Telephone Interview with Amy Alvis, Business Analyst, Dow Chemical Corp. (Nov. 19, 1996) [Telephone Interview with Amy Alvis].

20. *See* Dale D. Buss, *Bovine Growth Hormone Approval Sparks Controversy*, FOOD PROCESSING, Jan. 1, 1994, available in 1994 WL 12765297.

21. *See FDA Approval for the Use of the Hormone BST*, Federal News Service, Aug. 3, 1993, *available in* LEXIS, News Library, at *3 [hereinafter *FDA Approval for the Use of the Hormone BST*].

ment (OTA),[22] the American Dietetic Association (ADA)[23] and former U.S. Surgeon General C. Everett Koop.[24]

However, a sustained controversy has surrounded rbST, one that is not fully explained simply by the fact that it is the first agricultural product developed through biotechnology.[25] The magnitude and scope of the controversy surrounding rbST is due to several factors. These factors include: 1) the nature of the laws regulating rbST; 2) the debilitating effects the drug may have on animals; 3) the unknown and long term impact that use of the drug might have on human health; 4) the questionable nature and character of the FDA approval process; and 5) the drug's potential to affect the socioeconomic foundation of the dairy industry.

Section II of this Article represents an overview of the laws governing biotechnology and how these laws were applied in the case of rbST. The section also describes some of the controversies surrounding the FDA's approval of rbST. Section III describes the adverse effects the drug may have on animals. Section IV discusses the drug's potential to affect human health. Section V details how the use of rbST may impact upon the dairy industry.

II. The Regulation of Biotechnology

A. Generally

The field of biotechnology is governed primarily by statutory law.[26] The statutes governing this area are found within the Toxic Substance Control Act (TSCA),[27] the Federal Insec-

22. *See BST Report Continued*, INDUSTRIAL ENV'T., June 1, 1995, available in 1995 WL 8110452.

23. *See generally* Buss, *supra* note 20.

24. C. Everett Koop, M.D., *Statement of C. Everett Koop on the Introduction of Supplemental BST*, (photo. reprint) Feb. 6, 1994.

25. *See FDA Approval for the Use of the Hormone BST*, *supra* note 21, at *3.

26. The "Scope" document outlines the applicable laws governing biotechnology. *See* Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment, 57 Fed. Reg. 6753, 6754 (1992) [hereinafter Exercise of Federal Oversight].

27. Toxic Substances Control Act of 1977 (TSCA) §§ 1-412, 15 U.S.C. §§ 2601 -2692 (1997).

ticide, Fungicide and Rodenticide Act (FIFRA),[28] the Virus, Serum, and Toxin Act (VSTA),[29] Federal Plant Pest Act (FPPA),[30] Federal Food, Drug, and Cosmetic Act (FDCA)[31] and the National Environmental Policy Act (NEPA).[32] Agencies with applicable regulatory authority include the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Environmental Protection Agency (EPA) and the United States Department of Agriculture (USDA).[33]

The "Coordinated Framework,"[34] published by the Council on Natural Resources and the Environment[35] in 1986, serves as a technical guide to the coordination of regulatory authority among the various federal agencies with jurisdiction over biotechnology, and directs which agencies have jurisdiction over which products.[36] The Framework's view is that existing statutes are generally able to effectively regulate biotechnology.[37] Regulations, however, can be permitted to evolve based upon scientific revelations as to the potentials for risk,[38] presumably for those risks inherent in products al-

28. Federal Insecticide, Fungicide, and Rodenticide Act of 1972 (FIFRA) §§ 2-34, 7 U.S.C. §§ 136-136y (1997).

29. Virus, Serum, Toxin Act of 1913 (VSTA), 21 U.S.C. §§ 151-159 (1997).

30. Federal Plant Pest Act (FPPA), 7 U.S.C. §§ 150aa -150jj (1997).

31. Federal Food, Drug and Cosmetic Act of 1938 (FDCA), 21 U.S.C. §§ 301-395 (1997).

32. National Environment Policy Act of 1969 (NEPA) §§ 2-209, 42 U.S.C. §§ 4321 -4370d (1997).

33. *See* Linda Maher, *The Environment and the Domestic Regulatory Framework for Biotechnology*, 8 J. ENVTL. L. & LITIG. 133, 139 (1993) (citing Office of Science & Technology, Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,303 (1986)).

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

35. In April of 1994, an interagency "Working Group" was formed under the White House Cabinet Council on Natural Resources and the Environment for the purpose of researching and coordinating government's regulatory policies for biotechnological products. *See* Proposal For A Coordinated Framework Regulation of Biotechnology, 49 Fed. Reg. 50,856 (1984) [hereinafter Proposal For A Coordinated Framework]. This document was the proposed version of the Framework document which was then refined and introduced as the ultimate Coordinated Framework document.

36. *See generally* Exercise of Federal Oversight, 57 Fed. Reg. at 6753.

37. *See* Coordinated Framework, 51 Fed. Reg. at 23,302.

38. *See id.* at 23,303.

ready approved and in use.[39] Risk assessment can be approached in much the same way as for "traditionally modified organisms."[40] The authors of the Framework did not appropriately describe how oversight powers might be applied.[41] Nor did they define what the scope of these powers might be.[42]

B. The Scope Document

In July of 1990, the Office of Science and Technology Policy, working in conjunction with the President's Council on Competitiveness, filled this gap with the publication of its so-called "Scope" policy document.[43] Finalized on February 27, 1992, this document contains critical guidelines which limit the discretionary authority of these agencies in regulating biotechnology.[44]

First, the Scope document provides that oversight is to be exercised by an agency only when there is evidence indicating that there is an unreasonable risk associated with the bio-engineered product or organism.[45] Oversight is not to be exercised simply because a product is bio-engineered.[46] The risk assessment is to focus upon the characteristics of the

---

39. *See* Nitrofurans; Withdrawal of Approval of New Animal Drug Applications, 56 Fed. Reg. 41,902, 41,903 (1991) [hereinafter Nitrofurans] (indicating that "approval [of a new animal drug] may be withdrawn if 'new evidence,' evaluated together with previously existing evidence, shows that the drug is not shown to be safe").

40. *See* Coordinated Framework, 51 Fed. Reg. at 23,308.

41. *See id.*

42. *Id.*

43. *See* EXERCISE OF FEDERAL OVERSIGHT WITHIN SCOPE OF STATUTORY AUTHORITY: Planned Introductions of Biotechnology Products Into the Environment, 57 Fed. Reg. at 6753, 6753, 6754 [hereinafter Exercise of Federal Oversight].

44. *See id.*

45. A risk is "unreasonable" when the value of the reduction in risk obtained by additional oversight is greater than the cost thereby imposed. *See id.* at 6756. *But cf.* Lake v. FDA, Civil Action No. 88-6275, 1989 U.S. Dist. Lexis 7179, at *9 (E. D. Pa. June 26, 1989) (referring to medical devices, the court stated that "[w]hen there is no valid scientific evidence of efficacy, and the risks are unknown, the risk is unreasonable").

46. *See* Exercise of Federal Oversight, 57 Fed. Reg. at 6756.

product, not the process by which it was created.[47] A process-focused oversight would work to discourage use of emerging technology.[48] A cost element is imposed whereby the benefits achieved by oversight must exceed the cost of the oversight.[49] However, agencies are given broad discretion in initiating a range of oversight options, including the labeling of products.[50] Second, agencies are allowed to exercise their discretion and permit companies to skirt the regulatory process entirely by determining that a genetically manipulated product is so similar to its "natural" counterpart that it is not "new," therefore, requiring no new oversight.[51] Third, the "costs of testing to meet regulatory requirements" are described as barriers to the development of the industry.[52] Finally, the Scope document asserts that industry can generally be trusted to act responsibly because it knows that harsher oversight might follow irresponsible actions.[53] The document states that there are only limited instances where the private market will not provide adequate safeguards, on

---

47. *Id.* This approach was in fact mandated by the first Principle of Regulatory Review for Biotechnology in 1990. *Id.* at 6755. The four principles as approved by the Bush Administration in short are: 1) Oversight is not to be focused on the biotechnological process *per se*; 2) regulations should present a minimal burden to industry while adequately protecting the public; 3) regulations should adapt to swift changes in technology; and 4) in order to "create opportunities for the application of. . .new biotechnology products," performance-based, not design-based standards should be employed. *Id.* at 6760.

48. *Id.* at 6756.

49. *See* at 6756. *But cf.* Nitrofurans, 56 Fed. Reg. at 41,903 (indicating that the "cost benefit considerations" do not apply to the Delaney and general safety clauses of the Food Drug and Cosmetic Act).

50. *See* Exercise of Federal Oversight, 57 Fed. Reg. at 6757-58.

51. *Id.* at 6759.

52. *Id.* at 6761.

53. *See id.* at 6757.

> (In applying the risk-based approach there will of course be areas in which regulatory interventions are frequent, and areas in which such interventions are legally authorized but are less common because the industry operates safely and the occasions for regulation and enforcement are fewer. Such safety could be the result of long-standing industry practices, and of industry's pragmatic understanding that government intervention - whether through federal or state law or otherwise - would occur if safety rules were violated).

Id.

its own, to protect the public and the environment from the potential dangers of biotechnology.[54] It is suggested that regulation be used as a shield to protect industry "from avoidable incidents that could tarnish its image and development."[55] The Scope document represents the views of the Reagan, Bush, and Clinton Administrations, that a principal government role is to support and nurture biotechnology, and create the least restrictive regulatory environment possible.[56]

C. The Food, Drug, and Cosmetic Act (FDCA)

1. Generally

RbST is regulated by the FDA under the FDCA.[57] The FDCA requires that a new animal drug be safe for the animal,[58] that an end product from an animal treated with

---

54. *Id.* at 6761.

55. *See id. But cf.* Barr Laboratories, Inc. v. Harris, Food Drug Cosm. L. Rep. (CCH) § 38,012 (D.D.C. 1979), *as cited in* PETER BARTON HUTT & RICHARD C. MERRILL, FOOD AND DRUG LAW 1050 (2d ed. 1991) [hereinafter HUTT & MERRILL] ("The [Food, Drug, and Cosmetic] Act's purpose is to protect public health, not ensure or enhance equitable economic circumstances."); Barr Laboratories, Inc. v. Harris, 482 F. Supp. 1183, 1185 (D.D.C. 1980) (stating that "[n]either the legislative language [of the Food, Drug, and Cosmetic Act] nor the [committee] reports suggest any intention to safeguard competitive positions within the industry . . .").

56. *See generally* Maher, *supra* note 33. *Cf.* WILLIAM F. FUNK ET. AL., ADMINISTRATIVE PROCEDURE AND PRACTICE 1, 122 (1997) [hereinafter FUNK] ("Presidents Bush and Clinton continued and expanded the approach of the Reagan administration to regulatory oversight"). *See also* A STUDY CONDUCTED BY THE EXECUTIVE BRANCH OF THE FEDERAL GOVERNMENT, USE OF BOVINE SOMATOTROPIN (BST) IN THE UNITED STATES: ITS POTENTIAL EFFECTS (photo. reprint 1995) Jan. 1994.

57. *See* FDCA, 21 U.S.C. §§ 301-395.

58. *See id.* 21 U.S.C. at § 360b (e)(1)(A) ("[t]he Secretary shall . . . issue an order withdrawing approval of an application . . . with respect to any new animal drug if the Secretary finds. . .that experience or scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved . . ."); *id.* at § 360b (e)(1)(F) ("If the Secretary . . . finds that there is an imminent hazard to the health of man or of the animals for which such drug is intended, he may suspend the approval of such application immediately . . ."); *id.* at § 360b (d)(2)(B) ("[i]n determining whether such drug is safe for use . . . the Secretary shall consider . . . the cumulative effect on man or animal of such drug . . ."); *id.* at § 360b (c)(2)(A)(viii) (the Secretary shall approve an abbreviated application for a drug unless . . . the inactive ingredi-

the drug be safe for human consumption, and that the drug can be as effective as it is claimed to be.[59] The manufacturer must be able to produce the drug with a constant level of potency and purity.[60]

Additionally, the Act mandates consideration of the new animal drug's "cumulative effect on man or animal,"[61] and a determination as to whether the conditions under which the drug will be employed will be "reasonably certain to be followed in practice."[62] Approval of a drug may be immediately withdrawn if it is found that the product represents an "imminent hazard to health of man or animals."[63] A profound exception to the strictness of the statute is that a drug, proven carcinogenic in man or animal, may nevertheless be used if it will not harm the recipient animal and if residues of the drug do not appear in "any food yielded by or derived from" the animal.[64] This exception permitted DES, a synthetic hormone, to be used in cattle feed at least five years after it was demonstrated to be carcinogen in laboratory animals.[65]

---

ents of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed . . . [or] the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included . . .").

59. *See generally id.* at § 360b. Effectiveness must be demonstrated by "substantial evidence." *See* New Animal Drug Applications, 21 C.F.R. § 514.1 (b)(8)(ii) (1997).

60. *See* 21 C.F.R. at § 514.1 (b)(5).

61. FDCA, 21 U.S.C. at § 360b (d)(2)(B).

62. *Id.* at § 360b (d)(2)(D).

63. *Id.* at § 360b (e)(1). An imminent hazard may be found where new evidence shows that the drug is not "safe for use under the conditions of use upon the basis of which the application was approved."*Id. See also* Food and Drugs, General Administrative Rulings and Decisions, 21 C.F.R. § 2.5(a) (1997) (stating that the "[t]he 'imminent hazard' may be declared at any point in the chain of events which may ultimately result in harm to the public health. The occurrence of the final anticipated injury is not essential . . .").

64. *See* FDCA, 21 U.S.C. at § 360b (d)(1)(I).

65. *See* Fred Kuchler, et. al, *Regulating Food Safety: The Case of Animal Growth Hormones*, FOOD REVIEW, July 1, 1989, at 25, *available in* 1989 WL 2508076, at *6. DES was an FDA approved drug administered to pregnant woman in order to decrease their risks of miscarriage. *See also* GERALD W. BOSTON * M. STUART MADDEN, LAW OF ENVIRONMENTAL AND TOXIC TORTS 1, at 405-08 (1994) [hereinafter BOSTON & MADDEN]. Years later, DES was linked to in-

2. Residue Testing

Under the Food, Drug, and Cosmetic Act, anyone who files an application for a new animal drug is required to describe testing methods for determining whether residues of the drug, if any, exist in the end product provided for human consumption.[66] These methods must include ways for detecting substances which may be created in food because of the drug's use.[67] However, when the agency is provided with "adequate information" reasonably establishing that the drug will not appear in food "in concentrations considered unsafe," then there is no requirement for residue analysis.[68]

The FDA stated it did not require Monsanto to develop such a test because it had judged rbST to be safe for human consumption, and because "developing such a test . . . would be useless for regulatory purposes."[69]

---

juries to the reproductive systems of females whose grandmothers had consumed the drug. *Id.*

66. *See* FDCA, 21 U.S.C. § 360b (b)(1)(G). *See also* Nitrofurans, 56 Fed. Reg. at 41,902 (approval of two new drugs withdrawn where drugs were proven animal carcinogens and no test capable of detecting residues in animal tissues was provided by manufacturer); Ivy-Reed Co., Inc.: Steer-oid; Opportunity For Hearing, 44 Fed. Reg. 1,462 (1979) (New Animal Drug Application found incomplete where sponsor failed to submit data demonstrating that unsafe residues of the drug would not be present in human food).

67. *See* FDCA, 21 U.S.C. § 360b (b)(1)(G).

68. *See* New Animal Drug Applications, 21 C.F.R. at § 514.1 (b)(7). *But cf.* United States v. Anderson Seafoods, Inc., 622 F.2d 157, 161-62 (5th Cir. 1980) (indicating that the FDA acted within its discretion in finding that mercury present in swordfish, as a result of environmental pollution, is an "added substance" which may be injurious to health under the Food, Drug, and Cosmetic Act, even though the amount attributable to the actions of man are unknown or unquantifiable, and even though the amount may present only a minute potential for harm.); United States v. An Article of Food, Inc., 752 F.2d 11, 15 (1st Cir. 1985) (claimant's evidence that potassium nitrate is naturally present in foods, that a Puerto Rico Health Department study had determined it safe for human consumption, and that there was an absence of conclusive evidence showing that the substance was unsafe, were insufficient to rebut an FDA finding that the substance was an unsafe food additive under the Food, Drug, and Cosmetic Act).

69. U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, FOOD & DRUG ADMINISTRATION, FDA VETERINARIAN, QUESTIONS AND ANSWERS ABOUT BST, (photo. reprint 1995) May/June 1994, at 8 [hereinafter USDHHS, FDA VETERINARIAN]. The AMA's Scientific Advisory Council had stated that the development of such a test was feasible. *See Why Milk With RBGH Needs To Be Labeled*, 140 CONG.

D. The Role of the Food and Drug Administration

1. Generally

Federal review of rbST began in 1985,[70] but years before the drug's approval, legislators began to express their concerns.[71] Many of these concerns were focused on the FDA, the agency with primary oversight responsibility for rbST.[72]

In September of 1989, the chairman of the Senate Agriculture Committee, Senator Patrick J. Leahy, wrote to the FDA Commissioner regarding the FDA's rbST testing procedures.[73] Among the Senator's concerns were the methods the FDA employed to assess the product's potential risks.[74] Three months later, having received no reply to his inquiry, the Senator wrote again.[75] Leahy, with his correspondence still unanswered, in a formal request also signed by seven congressmen, asked the General Accounting Office (GAO) to conduct a thorough study of the FDA's rbST review process.[76]

REC. H2159 (daily ed. Mar. 24, 1995) (statement of Rep. Bernie Sanders). In April of 1997 it was reported that a sixteen year old boy, with the help of his chemistry teacher, invented a test to detect the presence of rbST. *See* Linda Stewart Ball, *Students Have Ideas Down To A Science,* DALLAS MORNING NEWS, Apr. 6, 1997, *available in* 1997 WL 2659583. Several months later, however, FDA's position still appeared to be that no such test existed. *See* Nancy Millman, *Gene Flap Spawning Food Fight,* CHIC. TRIB., Aug. 18, 1997, *available in* 1997 WL 3579419. Meanwhile, the General Accounting Office has formally advised the FDA to "develop a comprehensive strategy to address animal drug residues in milk." *See* Advisory Committee; Notice of Meeting, 61 Fed. Reg 20,831, 20,832 (1996).

70. *See* Keith Schneider, *FDA. Accused of Improper Ties In Review of Drug for Milk Cows,* N.Y. TIMES, Jan. 12, 1990, at A21.

71. *See Bovine Growth Hormone Faces Renewed Congressional Criticism,* BIOTECHNOLOGY NEWSWATCH, February 5, 1990, at 3 [hereinafter *BGH Faces Renewed Criticism*] (indicating that in February of 1990 Representative Peter Smith introduced a bill that would have prohibited the consumption of milk products produced with rbST for three years and which would have allowed the product to be used for research purposes only); *see also Providing Time To Learn The Economic and Health Effects of BST,* 136 CONG. REC. H310 (daily ed. Feb. 7, 1990) (statement of Rep. Smith).

72. *See* Robert A. Bohrer, Symposium, *Food Products Affected by Biotechnology,* 55 U. PITT. L. REV. 653, 675 (1994).

73. *See BGH Faces Renewed Criticism, supra* note 71. at 3.

74. *See id.*

75. *See id.*

76. *See id.*

Two months later, Dr. Richard J. Burroughs, an FDA veterinarian who participated in the review of rbST, was fired after disputing the agency's interpretation of industry studies, and after being accused of "slowing down the approval process . . . ."[77] He claimed that some FDA reviewers were not competent, and that the agency was covering up animal health problems stemming from the drug's use.[78] He charged that the agency had become "an extension of the drug industry."[79]

Meanwhile, by March of 1993, the GAO had formally recommended to the U.S. Department of Health and Human Services (USDHHS), which oversees the FDA, that the agency be made accountable "to answer specific questions" about the safety of rbST.[80] Five months later, the controversy climbed further up Capitol Hill, as was evidenced in a news conference pertaining to the impending approval of the drug.[81] The conference was attended by six senators, five of whom supported the product.[82] Senator Russell Feingold, the lone dissenter, characterized rbST as "the Edsel of the biotechnology industry," and stated that "it's not by chance that the first and last speakers here [Senators John Danforth and Kit Bond] happen to be from Missouri, the headquarters of the Monsanto corporation."[83] In November of 1993, the FDA, after thorough testing, concluded that milk from rbST treated cows was essentially the same as milk from untreated cows, and after seeking a second opinion from the NIH regarding

77. *See* Schneider, *supra* note 70. On August 2, 1991 the Federal Merits Protection Board ordered the FDA to reinstate Dr. Burroughs to his former position. *See also* Jon Sawyer, *FDA Loses Decision on Firing . . . Cow Hormone Case is Focus of Dispute*, ST. LOUIS POST-DISPATCH, Aug. 11, 1991, at 7C.

78. *See* Schneider, *supra* note 70.

79. *Id.*

80. James Ridgeway, *Robocow: How Tomorrow's Farming is Poisoning Today's Milk*, VILLAGE VOICE, Mar. 14, 1995, *available in* LEXIS, News Library, at *8.

81. *See generally FDA Approval for the Use of the Hormone BST*, *supra* note 21, at *7.

82. *See id.*

83. *Id.*

the safety of the product,[84] the FDA approved the drug for use.[85]

2. Labeling Guidelines

The FDA expressed earlier the view that most bio-engineered products needed no more regulation than did other products.[86] The agency did not believe that bio-engineered food end-products were materially different from their non-engineered counterparts.[87] If anything, genetically modified foods were actually safer than foods modified by conventional breeding methods.[88] In February of 1994, the FDA published its "interim" guidelines on rbST product labeling.[89] The guidelines did not pertain to products from rbST-treated cows, but sought to regulate, albeit "voluntarily," the labeling of products that did not come from treated cattle.[90] Having decided that there was no material difference between rbST-treated products and those untreated,[91] the agency deter-

84. *See* 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. J. 37, 44 (1993) (citing Guy Gugliotta, *A Wonder Drug or a Threat?*, WASH. POST, June 24, 1990, at A3).

85. *See* Animal Drugs, Feeds, and Related Products; Sterile Sometribove Zinc Suspension, 58 Fed. Reg. 59,946 (1993). *See also* U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PRESS RELEASE #P93-40, Nov. 5, 1993 [hereinafter U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES].

86. *See* Maher, *supra* note 33, at 149.

87. *See generally* Alex Barnum, *FDA Rules Raise Questions*, SAN FRAN. CHRON., June 15, 1992, at B1. The USDA has expressed a similar view. *See* Final Policy Statement for Research and Regulation of Biotechnology Processes and Products, 51 Fed. Reg. 23,336, 23,337 (1986).

88. *See* Barnum, at B1.

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

90. Interim Guidance, 59 Fed. Reg. at 6280.

91. *But cf.* Genentech, Inc. v. Bowen, 676 F. Supp. 301, 311 (D. D.C. 1987) (indicating that human growth hormone (hGH) derived from human pituitary glands, and synthetic human growth hormone produced through recombinant DNA technology (r-hGH), although identical in chemical structure, are *not* the same for the purposes of the Orphan Drug Act). *See also* Letter from Samuel S. Epstein, M.D. to the Editors of *The Journal of the American Medical Association*, JAMA, Mar. 20, 1991, at 1389 *available in* 1991 WL 4860198 [hereinafter JAMA] (rbST's molecular structure is up to 3% different from natural bST, containing as many as nine additional amino acids).

mined that not only did it lack the authority to mandate the labeling of treated products,[92] but that labels such as "rbST-free," if not put in a "proper" context, would be viewed as false, misleading, and a violation of the FDCA.[93] Such a "proper context" might be achieved if a company either included a statement that no significant difference has been shown between milk derived from rbST-treated cows and non-rbST-treated cows, or detailed its reasons for not treating cows with rbST.[94] The proffered reasons could not, however, mention any safety or quality issues, which the agency considered fully resolved.[95]

In addition, a substantial record-keeping and "certification" burden was placed on companies making a "rbST-free" claim.[96] This burden was accompanied by the assertion that a firm might find itself defenseless "in the face of circumstantial evidence that it is using rbST or selling milk from treated cows [despite claims to the contrary]."[97]

Critics charged that the guidelines contained language "strikingly similar" to that found in a legal memorandum Monsanto previously distributed,[98] which warned companies not to label their products as BGH- free.[99] In any event, following the publication of the guidelines, Monsanto proceeded

---

92. *But see* Anne Miller, *Time for Government to Get Mooo-ving: Facing Up to the BST Labeling Problem*, 18 HAMLINE. L. REV. 503, 516 (1995) (arguing that the FDA has "broad discretion when regulating food standards . . . is not limited to regulating labels solely for health and safety reasons . . ." and therefore does have the authority to mandate rbST labeling).

93. *See* Interim Guidance, 59 Fed. Reg. at 6280. *But see* FDCA, 21 U.S.C. at § 321(n) (stating that "in determining whether the labeling . . . is misleading, there *shall* be taken into account . . . the extent to which the labeling . . . fails to reveal facts material . . . with respect to consequences which may result from the use of the article to which the labeling . . . relates . . . ") (emphasis added).

94. *See id.*

95. *See id.*

96. *Id.*

97. *Id.*

98. It has been noted that the FDA will routinely incorporate language provided by the manufacturer into its product labeling regulations. *See* Telephone Interview with Ron Cooper, *supra* note 19.

99. *See* XII THE HUMANE FARMING ASSOCIATION SPECIAL REPORT, THE BATTLE AGAINST BGH TAINTED MILK RAGES ON 14, at 7, n.d. [hereinafter THE BATTLE AGAINST BGH].

to levy suit against two dairies, which did just that,[100] and the company wrote to over two thousand other firms, threatening them with legal action if they dared to do the same.[101]

a. Constitutional Implications

The FDA guidelines basically permitted the states to set their own, more specific, labeling restrictions, as long as they set regulations falling within the agency's parameters.[102] Thereafter, a company distributing its products nationwide, along with "rbST-free" claims, could theoretically encounter fifty different sets of restrictive standards, raising fears that varying state guidelines might not only inhibit free speech,[103] but carry with them the potential to unconstitutionally restrict interstate commerce.[104] For instance, when Illinois passed its 1994 law prohibiting the labeling of products as

100. *See id.* Suits against Swiss Valley Farms and the Pure Milk and Ice Cream Company of Texas were both settled out of court. *See also Growth Hormone for Cows Raises Health Questions*, BUFFALO NEWS, Apr. 30, 1996, at B2 (indicating that under the terms of the settlement for the Texas company it was reported that their practice of promoting their dairy products as BGH-free will continue).

101. *See* THE HUMANE FARMING ASSOCIATION SPECIAL REPORT, THE BATTLE AGAINST BGH, *supra* note 99, at 10.

102. Illinois, Hawaii, Nevada and Oklahoma passed laws *prohibiting* the labeling of products as "rbST-free." *See* Beth Berselli, *Settlement Reached In Hormone Labeling Case; Ben & Jerry's, States Agree Food Makers Can Indicate Absence of Added Product*, WASH. POST, Aug. 15, 1997, at A22, *available in* 1997 WL 12881480. Vermont passed a law *mandating* that products from cows treated with rbST be labeled as such. *See* International Dairy Foods Ass'n v. Amestoy, 898 F. Supp. 246 (D. Vt. 1995) *rev'd*, 92 F.3d 67 (2d Cir. 1996).

103. For commercial speech to be protected under the First Amendment, it must at least concern an activity that is lawful, must not be misleading, and the governmental interest asserted as a rationale for restricting the speech must be substantial. *See* Central Hudson Gas & Electric Corp. v. Public Service Comm'n of New York, 447 U.S. 557, 566 (1980). If these inquiries yield positive responses, it must then be determined "whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest." *Id.*

104. The general rule governing such Commerce Clause inquiries has been stated as follows: "Where the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." *See* Pike v. Bruce Church, 397 U.S. 137, 142 (1970) (citing Huron Portland Cement Co. v. City of Detroit, 362 U.S. 440, 443 (1960)).

"rBGH-free," Ben & Jerry's Ice Cream dropped all of its rBGH-free labeling, because it was financially infeasible for the company to label its products differently for different markets.[105]

Vermont's regulations, which mandated the labeling of products from treated animals, were challenged by trade groups as unconstitutional in *International Dairy Foods Ass'n v. Amestoy*.[106] Plaintiffs, relying upon the First Amendment and the Commerce Clause, moved for a preliminary injunction to enjoin Vermont from enacting section 2754 of Title 6 of the Vermont statutes which would have required retailers to label milk products produced with rbST.[107] The court denied the motion, explaining that the plaintiffs had not demonstrated that they would suffer irreparable harm without the injunction.[108] Nor had they shown that it was likely that their action could succeed upon its merits.[109]

As to the First Amendment, the court ruled that the labeling required by the Vermont law was commercial speech, which could be regulated because Vermont had narrowly tailored the law and demonstrated that it had a "substantial interest in informing consumers of the use of rbST."[110] The court also noted that the law did not prohibit speech, but rather mandated truthful disclosure.[111] The court rejected

105. *See* Ben & Jerry's Homemade, Inc. v. Lumpkin, No. 96-C-2748, 1996 U.S. Dist. LEXIS 12469 (D. Ill. Aug. 27, 1996). Claiming violation of their First Amendment rights, Ben and Jerry's brought suit against Illinois and the city of Chicago when they were officially informed that marketing their products in the state as "rBGH-free" would violate the Illinois Food, Drug, and Cosmetic Act. *See id.* at *4. In August of 1997 a settlement was reached between Illinois and the ice cream manufacturer and a coalition of organic food companies. *See* Berselli, *supra* note 102, at A22. Under the terms of the settlement, the company will be permitted to advertise its products as "rBGH-free," but specific compromise language was adopted by the parties. *See id.*

106. International Dairy Foods Ass'n v. Amestoy, 898 F. Supp. 246 (D. Vt. 1995) [hereinafter *International Dairy Foods Ass'n I*].

107. *See International Dairy Foods Ass'n I*, 898 F. Supp. at 247. *See also* VT. STAT. ANN. tit. vi § 2754 (1997) (this section was terminated on June 30, 1997, because it caused irreparable harm to dairy manufacturers).

108. *See id.* at 251.

109. *See id.* at 251.

110. *Id.* at 253-54.

111. *See id.* at 251.

the Commerce Clause argument, stating that the labeling law represented a legitimate local interest; it was not preferential to in-state milk producers; and that it would have only an incidental effect upon interstate commerce.[112]

On appeal, the Second Circuit reversed the district court, granting the injunction on First Amendment grounds.[113] The court noted that the First Amendment protects not only free speech, but the right not to speak, and that the labeling law required the appellants to make an "involuntary statement" about their products.[114] The loss of such a right would amount to an irreparable injury, therefore an injunction was warranted.[115] The court also found it likely that the appellants would succeed on the merits.[116] Vermont did not have a "legitimate interest" in providing such information to its consumers.[117] The court ruled that "consumer curiosity alone is not a strong enough state interest to sustain the compulsion of even . . . [a] factual statement . . . ."[118]

In a ringing dissent, Judge Leval stated that Vermont's concern over rbST's potential effects upon milk prices, local farmers, and human/animal health was a legitimate state interest not to be dismissed as mere "curiosity."[119] Noting that the Vermont law enforced compliance upon retailers and not the plaintiff milk producers,[120] the Judge stated that the First Amendment should not protect commercial speech

112. *See id.* at 251-52. *Cf.* Hunt v. Washington State Apple Advertising Comm'n, 432 U.S. 333 (1977) (North Carolina statute prohibiting interstate shipments of apples from Washington State displaying that state's product grades struck down as violating the Commerce Clause).

113. *See* International Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996) [hereinafter *Int'l Dairy Foods Ass'n II*].

114. *See Int'l Dairy Foods Ass'n II*, 92 F.3d at 71.

115. *See* 92 F.3d at 71.

116. *See id.* at 72.

117. *See id.* at 74.

118. *Id.*

119. *Id.* at 75-78. *Cf.* Grocery Manufacturers of America, Inc. v. Gerace, 755 F.2d 993, 1003-04 (2d Cir. 1985) (New York law requiring imitation cheese products to be appropriately labeled as such on restaurant signs, menus and containers is "intended to prevent deception and unfair competition [and] to promote honesty and fair dealing," is a legitimate local interest, and constitutional under the Commerce Clause).

120. *See Int'l Dairy Foods Ass'n II*, 92 F.3d at 79.

where "[t]he objective of the plaintiff . . . is to conceal their use of rbST from consumers . . . ."[121] He added, "[t]he majority's invocation of the First Amendment . . . stands the Amendment on its ear."[122]

3. Post-Approval Reaction and Controversy

The approval of rbST prompted action from many quarters. Pathmark, ShopRite, Kroger and 7-Eleven food store chains avoided selling milk with rbST,[123] as did an estimated 300 grocery chains and dairies.[124] Over seventy school districts nationwide adopted formal policies rejecting milk from cows treated with rbST.[125] Canada enacted a one year moratorium on the sale and use of the product,[126] while Denmark, Sweden, Norway, the Netherlands,[127] Australia,[128] New Zealand and Argentina banned rbST.[129] The fifteen nations of the European Union banned the drug until the year 2000.[130] The attorney generals from New York, Wisconsin,

121. *Id.* at 74.

122. *Id.*

123. *See* Hiss, *supra* note 13, at *2.

124. *See* Ian Jones, *Farmer, Consumer Coalition to Develop Test for rBGH,* FOOD & DRINK DAILY, June 6, 1995, *available in* LEXIS, News Library, at *1.

125. THE BATTLE AGAINST BGH, *supra* note 99, at 10.

126. *See* Roberta Histed, *Concerned Citizen's View: Worrisome Data on BST Use Emerging,* OTTAWA CITIZEN, July 2, 1995, at A11 [hereinafter Histed, *Concerned Citizens*]. *See also OECD Predicts Large Increase in U.S. BST Use,* AGRA EUROPE, Mar. 3, 1995, at E5 (indicating that the Canadian ban apparently did not affect imports from countries where BGH use is permitted).

127. *See* Pratap Chatterjee, *Environment: New Butter Faces Fears of Cancer, Gigantism,* INTER PRESS SERVICE, August 18, 1995.

128. *See FDA Says It Has No Authority to Ban BST Labeling,* FOOD LABELING NEWS, Aug. 3, 1995 *available in* 1995 WL 8214442 [hereinafter *FDA Says It Has No Authority to Ban BST Labeling*].

129. *See* Mark Thompson, *The Earth Goes Global,* 15 CA. LAW. 41 (1995) (citing Margaret Mellon of the Union of Concerned Scientists); *see also* Susan Semenak, *Stirring Up Fears of Spiked Milk; Nothing Wholesome About BST: Critics,* MONTREAL GAZETTE, May 13, 1995, at A1.

130. *See* Thompson, *supra* note 129, at 44. The European Commission later agreed to permit U.S. dairy imports from treated cattle while continuing to forbid rBGH use in the EU. *See* Alison Maitland, *Trade Row Looms Over Maize,* FIN. TIMES (LONDON), Sept. 4, 1996, at 3. However, in June of 1997, despite intense lobbying by Monsanto, a European Union (EU) proposal to defer worldwide approval of rBGH for another two years was accepted by the Codex Alimentarius Commission, the United Nations food standards committee. *See*

and Texas called for mandatory labeling of rbST-related products.[131] A ninety-day moratorium on use of the product in the U.S. passed through Congress right after FDA approval.[132]

The controversy was, in part, focused directly on the FDA itself, which has been criticized for treating the bio-tech industry preferentially.[133] Some view the agency "as little more than an 'industry cheerleader.'"[134] Others have described the FDA as a drug *approval* agency, as opposed to a drug *review* agency,[135] and an organization with a "moral weakness" at its top,[136] "more interested in protecting the interests of Monsanto than the interests of consumers."[137]

EU/Codex Alimentarius: EU Stands Its Ground on Milk Hormones, AGRI-INDUSTRY EUROPE, July 4, 1997.

131. *See Anonymous FDA Whistleblowers Spark Congressional Probe of BST*, FOOD LABELING NEWS, Apr. 21, 1994, *available in* 1994 WL 2550919, at *1 [hereinafter *Anonymous FDA Whistleblowers*].

132. *See* Buss, *supra* note 20, at *2.

133. *See* Maher, *supra* note 33, at 147. *See also* FDCA, 21 U.S.C. at § 335a (f)(1) (indicating that "the Secretary . . . may . . . refuse by order . . . to approve any abbreviated drug application . . . if a significant question has been raised regarding the integrity of the approval process. . . ").

134. *See* Maher, *supra* note 33, at 195.

135. *See* Beiswenger, *supra* note 4, at 676-77 (citing *FDA Accused by Ex-Official; Yielding to Industry Alleged*, CHEM. MARKETING REP., Jan. 15, 1990, at 3 (quoting Dr. Richard Burroughs)).

136. *See* John Schwartz, *Probe of 3 FDA Officials Sought; Industry Ties Before Approval of Bovine Growth Hormone Are at Issue*, WASH. POST, Apr. 19, 1994, at A3.

137. *See Anonymous FDA Whistleblowers*, *supra* note 131, at *3 (quoting U.S. Representative Bernie Sanders).

Commentators have described situations where an administrative agency is in effect "captured" by the industry it regulates. *See* Allan Kanner, *Environmental and Toxic Tort Issues*, 127 ALI-ABA 775, 797, and n.50 (1995) (citing Ziem & Castleman, *Threshold Limit Values: Historical Perspectives and Current Practice*, J. OCCUP. MED., Nov. 1989, 910 (referring to Occupational Safety and Health Act (OSHA)). This "phenomena" has been noted to occur in situations where the agency has the simultaneous objectives of both promoting and regulating the industry. *See* Marshall v. Consumers Power Co., 237 N.W.2d 266, 279-80 (1975) (referring to the Atomic Energy Commission as being formed to "fulfill the often conflicting goals of both regulating and promoting nuclear energy"). *See also* Richard H. Fallon, Jr., *Of Legislative Courts, Administrative Agencies, and Article III*, 101 HARV. L. REV. 916, 978 (1988) ("empirical worries arise about the susceptibility of various agencies to influence by powerful private groups").

In March of 1994, four months after rbST had been approved, an anonymous letter, circulated by FDA employees, once again raised the issue of bias in the FDA approval process.[138] In response, three congressmen once again requested the GAO to investigate.[139] The employee letter specifically implicated three former Monsanto employees-turned FDA employees, all of whom were involved in various aspects of the FDA's rbST approval process.[140] The employees included Margaret Miller, Michael Taylor and Susan Sechen. Ms. Miller, deputy director of the FDA's Office of New Animal Drugs,[141] participated in the rbST review process while con-

---

The potential problem of agency "capture" is exacerbated by three general factors in the case of the FDA and rbST. First, a decision by the FDA *not* to take enforcement action with respect to a presumed violation of the Food, Drug, and Cosmetic Act would be presumptively unreviewable by a court under the Administrative Procedure Act. *See* Heckler v. Chaney, 470 U.S. 821, 837-38 (1985).

Second, even if an FDA action with respect to rbST was reviewable, the court would be highly deferential to the agency. *See* Baltimore Gas & Electric Co. v. National Resources Defense Council, 462 U.S. 87, 103 (1983) (explaining that when an agency makes a scientific prediction "within its area of special expertise, at the frontiers of science . . . a reviewing court must generally be at its most deferential").

Third, it is the formal policy of the United States to promote the use and increased use of dairy products. *See* Dairy Promotion Program, 7 C.F.R. § 1150.139 (1996) (authorizing the National Dairy Promotion Board to "promote the use of fluid milk and dairy products"); *see also* Agricultural Act of 1959, 7 U.S.C. § 1446b (1997) (providing that "it is the policy of Congress . . . to promote the increased use of [dairy products]"). Note, however, that the latter statute states that it is also Congressional policy to encourage "farmers to develop . . . disease-free cattle . . . and to stabilize the economy of dairy farmers." *Id.*

Admittedly, the FDA is particularly susceptible to criticism from both sides of the regulatory aisle. On the one hand, the agency may be viewed as being composed of "slow, unimaginative bureaucrats who are intent on disapproving drugs so as to avoid criticism by Congressional committees," while on the other hand, the agency may be criticized for its "personal allegiance to the medical profession and the drug industry . . . quick to approve new drugs without adequate evidence for safety. . .slow and inept in withdrawing drugs from the market." *See* Richard J. Crout, *The Nature of Regulatory Choices*, 33 FOOD, DRUG & COSM. L.J. 413 (1978) *cited in* HUTT & MERRILL, *supra* note 55, at 586.

138. *See Anonymous FDA Whistleblowers*, *supra* note 131, at *1.

139. *See id.*

140. *See id.* at *1-2.

141. *See id.*

currently publishing papers with Monsanto scientists.[142] Mr. Taylor, a former Monsanto attorney who advised the company on food labeling issues, became the FDA's deputy commissioner for policy.[143] Later, according to the congressional letter to the GAO, he "approved and signed the FDA's labeling guidelines thereby justifying the FDA's policy prohibiting the labeling of milk produced with rBGH."[144] Ms. Sechen, also implicated, worked as a graduate research assistant for bST pioneer and Monsanto consultant, Dale E. Bauman.[145] Ms. Sechen reviewed rbST data for the FDA while simultaneously participating in BST research projects reportedly sponsored by Monsanto at Cornell University.[146]

But, in October of 1994, the GAO vindicated the three FDA officials.[147] At the same time, a USDHHS inspector general report expressed disapproval towards Monsanto for illegally promoting the drug prior to its approval.[148] The FDA has been accused of not only *allowing*, but also *participating*

142. *See id.* at *3. It was also reported that Ms. Miller, while with the FDA, "increased the antibiotic protocol for milk to permit an increase of 10,000 percent." *MONSANTO: Dr. Virginia Weldon "Top Candidate" to Become Commissioner of the FDA*, M2 PRESSWIRE, May 27, 1997, *available in* 1997 WL 10370482.

143. *See Anonymous FDA Whistleblowers*, *supra* note 131, at *1.

144. *Id.* Around the end of 1995, Mr. Taylor left his job at the FDA and assumed a position with the USDA. *See id; see also* Telephone Interview with Mary Cottone, Administrative Assistant, Policy, Food and Drug Administration (Jan. 8, 1997). Soon after he reportedly returned to employment in the private sector. *See id.*

145. *See* Letter from Bernie Sanders, U.S. Representative, to Charles Bowsher, Comptroller General, U.S. General Accounting Office (Apr. 15, 1994) (on file with the Federal Document Clearing House), *available in* 1994 WL 14179415; *see also* Elizabeth Doran, *GAO Probes Allegations of Tainted BST Review*, POST-STANDARD, Oct. 17, 1994 at A1.

146. *See Anonymous FDA Whistleblowers*, *supra* note 131, at *3. *But see* Doran, *supra* note 145 (quoting Dale E. Bauman stating that the USDA, not Monsanto, funded all of Sechen's research).

147. The General Accounting Office report, while noting certain "institutional failings" on the part of the FDA, found no conflicts of interest. *See GAO Says Taylor Had No Conflict of Interest in BST Approval*, FOOD LABELING NEWS, Nov. 3, 1994 *available in* 1994 WL 2727976. Because of time limitations the report did not address whether the FDA's approval process was biased. *See id.*

148. *See* Ridgeway, *supra* note 80, at 29.

in the process.[149] Just one month later, an official within Canada's Bureau of Veterinary Drugs charged that Monsanto had offered the Canadian government up to two million dollars if it would approve rbST "without being required to submit data from any further studies or trials."[150]

Additionally, some rbST endorsements contained unusually strong partisan tenors. Some were curiously, perhaps more than coincidentally, similar. For instance, the Journal of the American Medical Association suggested the following: "health professionals can play an important role in reassuring the public about the safety of milk and refuting misstatements or misconceptions about bST."[151]

---

149. *See* BRADLEY MILLER & JOHN C. STAUBER, THE HUMANE FARMING ASSOCIATION, COMMENTS ON THE VOLUNTARY LABELING OF MILK AND MILK PRODUCTS FROM COWS NOT TREATED WITH RECOMBINANT BOVINE GROWTH HORMONE 1, 2 (Mar. 10, 1994). The USDA has also been accused of unlawfully promoting rbST prior to its approval. *See generally* Cordes v. Madigan, No. 90-2929, 1992 U.S. Dist. LEXIS 6250 (D. D.C. Apr. 30, 1992).

150. Ridgeway, *supra* note 80, at 29. *See also* FDCA, 21 U.S.C. at § 335c (a)(1) ("[t]he Secretary shall withdraw approval of an abbreviated drug application if the Secretary finds that the approval was obtained, expedited or otherwise facilitated through bribery [or] payment of an illegal gratuity . . .").

151. William H. Daughaday, M.D. & David M. Barbano, Ph.D., *Bovine Somatotropin Supplementation of Dairy Cows . . . Is the Milk Safe?*, JAMA, Aug. 22/29, 1990, at 1005 [hereinafter Daughaday & Barbano]. The AMA's support of rbST, while inexplicable in the respect that there were no health-related reasons to do so, may be partially explained by the fact that the association received a grant from Monsanto for television education programs promoting its use. *See* Neal D. Barnard, *AMA Endorsements Raise Questions About Ethics and the Medical Profession,* SACRAMENTO BEE, Sept. 19, 1997, at B9. The AMA has also received educational grants from the Beef Board and the National Livestock and Meat Board. *See id.*

Interestingly enough, the FDA has formally expressed its concern that "companies may influence the content of educational programs not only directly . . . but indirectly through the nature of the relationship between the company and also the provider (e.g., if the provider believes that future financial support from the company depends upon producing programs that promote the company's products) . . . . [T]he goal of the agency [is] to ensure that scientific and educational activities that are not intended to be promotional are designed to be truly independent from promotional influence by the marketers . . . ." *See* Draft Policy Statement on Industry-Supported Scientific and Educational Activities, 57 Fed. Reg. 56,412, 56,412-413 (1992) [hereinafter Draft Policy Statement]. Perhaps more interesting still is that this policy statement was drafted by none other than Michael R. Taylor. *See* Draft Policy Statement, 57 Fed. Reg. at 56,414. *See also supra* text accompanying notes 143-44.

C. Everett Koop issued a statement suggesting: "Supermarkets and dairy processors can play an important role by assuring consumers of the safety of the milk supply, by providing facts on BST to interested customers, or by referring them to credible health and nutrition authorities."[152] The American Dietetic Association, while generally approving of biotechnology, appeared to issue a more neutral opinion: "Biotechnology needs only to be explained, not to be promoted. Because of consumer apprehensions about biotechnology, explanations of the risks and benefits of biotechnology should include assurances of regulatory control."[153]

III. The Adverse Effects of rbST on Cows

Monsanto states that the health of rbST treated cows will be similar to that of other high milk producing animals.[154] The USDHHS reported that the FDA found evidence of only "slightly increased incidence of mastisis" in treated cows.[155] The NIH reported that

> well managed, rbST-treated cows . . . probably experience no greater health problems than untreated cows producing the same amounts of milk . . . . [Any] additional effects of rbST on health of the dairy cow appear to be minimal . . . . There is no compelling evidence of increased incidence of foot and leg problems or metabolic disease.[156]

---

152. C. Everett Koop, *supra* note 24.

153. THE AMERICAN DIETETIC ASSOCIATION, Position of The American Dietetic Association: "Biotechnology and the Future of Food, J. Am. Dietetic Ass'n (1992). It is to be noted that the association has come under fire for pursuing contributions from groups like the National Livestock and Meat Board. *See* Marian Burros, *Dietetic Association Risks Image by Cuddling Up to Food Groups*, N.Y. TIMES NEWS SERVICE, *reported in* PORTLAND OREGONIAN, Nov. 28, 1995. Also questionable is its relationship with Monsanto, which hired the group to respond to consumer questions about rbST. *See id.*

154. MONSANTO COMPANY, QUESTIONS MOST ASKED BY PRODUCERS, Promotional Pamphlet, n.d. .

155. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *supra* note 85.

156. National Institutes of Health, Technology Assessment Conference Statement, Bovine Somatotropin 8 (Dec. 5-7, 1990) [hereinafter NATIONAL INSTITUTES OF HEALTH].

Yet, a variety of other sources disagree, including the GAO, which found a "much higher incidence of mastisis occurring in cows treated with rBGH."[157] Consumers Union, reportedly using the FDA's own data, cited a seventy-nine percent increase in mastisis attributable to the drug's use.[158] Another study, using Monsanto's data, found a nineteen percent increase in mastisis.[159]

An insert Monsanto provides to veterinarians, describes twenty-one potential side effects which might be expected.[160] It has been reported that rbST use in cows increases the likelihood of cystic ovaries, reproductive disorders, weight loss, fever, twisted stomachs, digestive disorders, lesions, lacerations of knees and feet, spontaneous abortions and even death.[161] Cows may experience decreased immune functions,[162] higher rates of stress[163] internal bleeding,[164] swelling at the injection site,[165] enlargement of internal organs, increased intolerance to heat, higher rates of metabolic disease.[166] The use of rbST double the likelihood of hoof rot and uterine infections, and treated cows experience retained placentas and ketosis at three or four times the normal rate.[167] Presumably, these ailments are present in "untreated cows producing the same amounts of milk."[168] The FDA, in ap-

157. Ridgeway, *supra* note 80, at 28.

158. *See id.* at 31.

159. *See id.*

160. *See id.* at 30.

161. *See* Andrea Maenza, *Bovine Growth Hormone Unwanted, But May Be Approved in Canada*, TAKE ACTION, Spring, 1995, at 1.

162. *See* Beiswenger, *supra* note 4, at 683 (citing Matthew H. Shulman, *Bovine Growth Hormone: Who Wins? Who Loses? What's at Stake?*, AGRICULTURAL BIOETHICS 111, at 121 (Steven M. Glendel, et. al, eds. 1990)).

163. *See* Paul McKeague, *Whelan Lobbies to Ban Hormone*, WINDSOR STAR, Apr. 6, 1995, at F6.

164. *See* Robert Gavin, *New Hormone Dangerous to Cows, Farmers Charge FDA Says Few Problems Reported Among 3 Million Cows Injected*, SYRACUSE HERALD AM., Mar. 26, 1995, at G1.

165. *See Int'l Dairy Foods Ass'n II*, 92 F.3d at 78.

166. *See* THE HUMANE FARMING ASSOCIATION, SPECIAL REPORT, BOVINE GROWTH HORMONE 1 (1991) [hereinafter THE HUMANE FARMING ASSOCIATION, BOVINE GROWTH HORMONE].

167. *See* Hiss, *supra* note 13, at 10.

168. NATIONAL INSTITUTES OF HEALTH, *supra* note 156, at 8.

proving rbST, had determined that the risks to cattle were "manageable."[169] During the first year of rbST use, the FDA compiled 806 adverse reaction reports.[170] While statistically this is but a tiny percentage of the number of cows injected with the drug, there is reason to believe this number may not be a true indicator of the number of adverse reactions.[171]

IV. Potential Effects on Human Health

A. Antibiotics

The primary concern of some rbST opponents regarding the potential impact of the drug upon human health is, coincidentally, relative to its primary impact upon animal health. This impact is the drug's potential to spur higher rates of mastisis in cows. Mastisis is a painful bacterial infection of the udder which is related to the increased demand placed on the cow to produce milk.[172] It causes the cows to excrete pus

169. Stauber v. Kessler, 895 F. Supp. 1178, 1183 (W.D. Wis. 1995).

170. *See* U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, FOOD & DRUG ADMINISTRATION, FDA TALK PAPER NO. T95-14, BST UPDATE: FIRST YEAR EXPERIENCE REPORTS 2 (1995) [hereinafter USDHHS, BST UPDATE]. The FDA later explained that only 496 of the 806 adverse reactions were related to rbST. *See* Robert Steyer, *FDA Says Cow Drug is Safe*, ST. LOUIS POST-DISPATCH, Oct. 22, 1995, at 1E. A follow-up survey covering the period between February 1 to August 25, 1995 revealed 509 reports of adverse reactions, 392 of which the agency claimed were "possibly associated" with rbST use. *See id.* A twenty-four month summary of adverse reactions to rbST, covering the period from February 4, 1994 through February 4, 1996, reported 1,438 reactions, 918 of which the agency states were "possibly" associated with rbST use. *See* FOOD & DRUG ADMINISTRATION, CENTER FOR VETERINARY MEDICINE, CVM UPDATE, TWO YEAR REPORT ON BST 1 (1996). RbST use accounted for nearly half of all reported cattle deaths, but less than five percent of the reported incidents of mastisis due to overall animal drug administration. *See id.*

171. The FDA encourages users to report such reactions to Monsanto or to their veterinarians, as well as the agency. *See* USDHHS- FDA, BST UPDATE, *supra* note 170, at 2. It may be unrealistic, or even unfair, to assume that a rural vet will regularly make reports to the FDA, or that a company like Monsanto can be asked to voluntarily and accurately report data that could jeopardize a $1/2 billion investment. *See also Wisconsin Democrats Ask FDA to Address Alleged BGH Inconsistencies*, FOOD LABELING NEWS, Dec. 7, 1995, *available in* 1995 WL 11335046 (citing examples where Monsanto did not report adverse reactions to the FDA); Steyer, *supra* note 170, at 1E (quoting Dr. Stephen Sundlof, director of the FDA's Center for Veterinary Medicine, confirming that adverse reactions are under-reported).

172. *See* Kulka & Semenak, *supra* note 2, at 10.

into the milk, making the milk unusable.[173] Because cows with mastisis do not produce sellable milk, the infection must be treated with antibiotics.[174] Opponents of rbST fear that higher levels of antibiotics can therefore be expected to appear in milk.

An animal's constant exposure to antibiotics[175] can cause certain bacteria to develop a resistance which they are able to pass on, not only to their offspring, but to any bacteria with which they may come into contact.[176] If exposed to still more antibiotics, these bacteria may be generated into "supergerms" resistant to some of medicine's most potent antibiotic cures.[177] Furthermore, humans can assimilate these resistant bacteria by eating contaminated animal foods or even by eating foods grown from soil fertilized with manure from antibiotic-treated animals.[178] The problem is compounded by the fact that in some cases humans and animals are administered the same general types of antibiotics.[179] As early as 1984, the Centers for Disease Control (CDC) estab-

---

173. *See* McKeague, *supra* note 163, at F6.

174. *See FDA Sees BST as Safe for Humans, Udderly Problematical for Bovines*, BIOTECHNOLOGY NEWSWATCH, Dec. 18, 1989, at 9. Mastisis primarily occurs because today's dairy cows are bred and fed to produce as much as seven times more milk than they did half a century ago. *See* Histed, *Concerned Citizens*, *supra* note 126, at A11. In effect, the cows' systems are already stressed to the point that they become sick, and rbST promises to magnify this problem. *Id.* It is to be noted that while beyond the scope of this article, the animal rights issues presented by rbST use are significant.

175. It is estimated that during the early 1980's over 12 million pounds of antibiotics were fed to poultry and livestock, amounting to approximately forty percent of the total amount of antibiotics produced in the United States during that period. *See* Susan Okie, *Experts Urge Steps to Stem Antibiotic Resistance*, WASH. POST, Aug. 26, 1997, at 207 (quoting Morton N. Swartz, professor of medicine, Harvard Medical School). *See also* N. Rehmatullah, M.D., *Antibiotics Give Profits, Cures and the Unkillable*, PLAIN DEALER, June 10, 1997, at 8B (indicating that antibiotics are placed in animal feed in order to "eliminate low-level bacterial colonies in animal intestines, allowing less food to be absorbed more efficiently," thereby promoting growth).

176. *See* Challem, *supra* note 14, at 56.

177. *Id.*

178. *See* Barbara O' Brien, *Animal Welfare Reform and the Magic Bullet: The Use and Abuse of Subtherapeutic Doses of Antibiotics in Livestock*, 67 U. COLO. L. REV. 407, 426 (1996).

179. *See* Rehmatullah, *supra* note 175, at 8B (stating that the "research shows that cross-resistance in animals and humans is dramatic and startling.").

lished a link between antibiotic administration to animals and antibiotic resistance in humans.[180] The CDC has stated that the development of human resistance to antibiotics represents "a major public health crisis."[181]

In the United States, about 19,000 people die each year from infections which are resistant to antibiotic therapy.[182] The problem, however, is by no means confined to America,[183] and the costs of treating patients with multidrug-resistant

---

180. *See* O'Brien, *supra* note 178, at 425. *See also Drug Resistance: Multi-Drug Resistant Salmonella Typhimurium,* DISEASE WEEKLY PLUS, Feb. 10 1997, at 1 (Information Access Co., Charles W. Henderson) (indicating antibiotic resistant strains of Salmonella have developed, possibly due to "intensive animal husbandry"); *What's The Worst That Could Happen*, GENESIS REPORT-RX, Aug.1, 1996, *available in* 1996 WL 10364806 [hereinafter GENESIS REPORT] (antibiotic resistant strains of E. coli and Shigella bacteria are believed to be associated with antibiotic administration to poultry and animals).

181. *See* Hiss, *supra* note 13, at 10. *Accord* Challem, *supra* note 14 (quoting Stephen Sundlof, D.V.M, Ph.D., of the FDA's Center for Veterinary Medicine, stating that resistance to antibiotics is "one of the most significant problems facing human and veterinary medicine"); *BMA Reveals New Guidelines for Antibiotics,* MARKETLETTER , Nov. 10, 1997 (Information Access Co., Industry Express, United Kingdom) [hereinafter *BMA Reveals New Guidelines*]. The British Medical Association warned that increasing resistance to antibiotics is a major public threat. *See id.*

182. *See* Challem, *supra* note 14, at 56. *See e.g.,* Okie, *supra* note 175, at 206 (twenty-five percent of Streptococcus pheumoniae bacteria, which cause meningitus, pneumonia and ear infections, are penicillin-resistant); *BMA Reveals New Guidelines*, *supra* note 181 ("cases of multidrug-resistant salmonella have increased ten-fold in the past six years"); GENESIS REPORT, *supra* note 180 (E. coli bacteria now resistant to up to six different antibiotics); *Old Killer May Inspire New Fears*, SACRAMENTO BEE, Oct. 23, 1997, at A1 (twelve percent of patients with tuberculosis are resistant to at least one drug); *Drug Resistance: Resistance Increasing in Gram-Positive Bacteria*, Disease Weekly Plus (Charles W. Henderson) Sept. 30, 1996, *available in* 1996 WL 10364195 (Vancomycin-resistant enterococci now resistant to almost all available antibiotics); *The National Science and Technology Council on Emerging and Re-Emerging Infectious Diseases*, 22 POPULATION & DEV. REV. 175 (1996), *available in* 1996 WL 13524573 (staphylococcal infections now respond consistently to only one antibiotic).

183. *See e.g., Incurable TB May Hit Epidemic,* Reuters, *reported in* CHIC. TRIB., Oct. 23, 1997, at 17 ("the U.S. Centers for Disease Control and Prevention and the International Union Against Tuberculosis and Lung Disease found multi-drug resistant TB in one-third of 35 countries surveyed."); Rehmatullah, *supra* note 175, at 8B (European use of Avoparcin in animals linked to human resistance to Vancomycin); *Drug Resistance: Antibiotic Misuse Causing Frightening New Bugs,* DISEASE WEEKLY PLUS, Sept. 8, 1997 (Information Access Co.) *available in* 1997 WL 13677678. European doctors report multidrug resistant

infections can be staggering.[184] Furthermore, it is estimated that the development of one new antibiotic can cost upwards of $300 million, while there may be less than a dozen individuals worldwide considered to be true experts on antibiotic resistance.[185]

However, the FDA concluded that the existing system gauging milk purity, as far as antibiotics were concerned, was sufficient to ensure that any increase in the use of antibiotics would present no dangers to human health.[186] The FDA based its conclusion on the fact that every tanker of milk produced in the United States is currently tested by industry for the most common drugs used to treat mastisis, beta-lactum drugs.[187] In addition, ninety percent of all producers voluntarily submit to additional milk safety standards.[188] The FDA also conducts random drug residue tests, but leaves primary control of milk product safety to the states,[189] whose regulators routinely test for four different antibiotic residues.[190]

However, some feel that the FDA has traditionally demonstrated a certain laxness in regards to industry's use of antibiotics. For instance, antibiotic-resistant "marker"

---

strain of S. aureus and a resistant strain of a fungus, Aspergillus, which can cause fatal lung congestion. *See id.*

184. *See* Barbara Benson, *Resistant Bugs Cost Big Bucks at N.Y.C. Hospitals: $500 Million a Year Spent to Fight Staph; Study May Mobilize Health Care Payers,* CRAIN'S N.Y. BUS., June 9, 1997, at 3 (pointing out that "[t]he direct cost of fighting antibiotic-resistant infections" in New York City hospitals amounted to $435.5 million in 1995 alone); Tim Zimmermann, *Fighting TB: A Second Chance To Do It Right,* U.S. NEWS & WORLD REP., Mar. 31, 1997, at 45 (treating one case of multidrug-resistant tuberculosis, likened to "Ebola with wings," can cost $250,000) (quoting Richard Bumgarner, deputy director of the World Health Organization's Global TB Program).

185. *See* Rehmatullah, *supra* note 175, at 8B. Half of these experts are reported to be nearing retirement. *See id.*

186. *See* U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, FOOD & DRUG ADMINISTRATION, FDA BACKGROUNDER, NEW ANIMAL DRUG FOR INCREASING MILK PRODUCTION, at 2.

187. *See id.*

188. *See id.*

189. *See* NATIONAL INSTITUTES OF HEALTH, *supra* note 156, at 5.

190. *See* Challem, supra note 14, at 56. *Accord* Stauber v. Kessler, 895 F. Supp. 1178, 1184 (W.D. Wisc. 1995). *See also* Ridgeway, *supra* note 80, at 32 (FDA spot checks for twelve different antibiotic residues).

genes[191] had already been used in dozens of genetically engineered crops by the time the FDA began a review to determine whether the genes could increase a human's resistance to the beneficial effects of antibiotics.[192] Of much greater concern is the fact that milk products may permissibly contain any one of eighty antibiotics currently used by the industry.[193] In 1989, a Wall Street Journal study found antibiotic residues in thirty-eight percent of the milk samples it tested.[194]

B. IGF-1

Another major concern is the effect rbST may have on another hormone, Insulin-like Growth Factor-1 (IGF-1), and the potential impact this substance may have on humans. Both natural human growth hormone and natural bovine growth hormone stimulate and regulate the production of (natural) IGF-1, a hormone bound to proteins, which is present (and virtually identical) in both human and bovine milk.[195] IGF-1 regulates cell growth in adults and infants[196] and in turn may mediate the actions of growth hormone.[197]

The FDA reported "that rbST does not increase the IGF-1 content above levels normally found in milk of non-treated animals."[198] The NIH stated, "[m]ilk from rbST-treated cows contains higher concentrations of IGF-1."[199] Researchers who

191. Typically, the DNA of a desired trait is linked with an antibiotic gene (the "marker") and transferred to a group of recipient cells. *See* Bohrer, *supra* note 72, at 671-73 (1994). Cells which are not transformed by the genetic process are destroyed by the antibiotic, while cells successfully transformed express the DNA of both the desired trait and its antibiotic marker. *See id.* This enables the genetic scientist to isolate these cells, extract them, and use them to create organisms which will assume not only the desired characteristics of the transferred gene, but resistance to the antibiotic marker as well. *See id.*

192. *See* Barnum, *supra* note 18, at D1.

193. *See* Challem, *supra* note 14, at 57.

194. *See* Hiss, *supra* note 13, at 10.

195. *See* Samuel S. Epstein, *A Needless New Risk of Breast Cancer*, L.A. TIMES, Mar. 20, 1994, at 5, *available in* 1994 WL 2146663.

196. *Id.*

197. *See* USDHHS, FDA VETERINARIAN, *supra* note 69, at 7.

198. *Id.* at 8.

199. NATIONAL INSTITUTES OF HEALTH, *supra* note 156, at 9.

seem to have the respect of both proponents and opponents report that "[m]ean amounts of IGF-1 in the milk of treated cows were always higher than those found in the controls."[200] Still others point to Monsanto's own data as quantifying an eight-fold increase in IGF-1, attributable to rbST injections.[201]

After conducting a study, the FDA concluded that rbST's possible effect on IGF-1, and IGF-1's potential to affect human health,[202] was not an issue for several reasons. First, the amount of IGF-1 found in untreated cows normally varies greatly, and the amount found in treated cows was within the range of that found in human milk.[203] Second, there was no evidence that IGF-1 is biologically active in man.[204] Third, studies in animals indicated that IGF-1 had no oral toxic-

200. *See* Judith C. Juskevich & C. Greg Guyer, *Bovine Growth Hormone: Human Food Safety Evaluation*, 249 SCIENCE 875, 882 (Aug. 24, 1990).

201. *See* Roberta Histed, *Synthetic Hormones in Milk Haven't Been Proven Safe*, OTTAWA CITIZEN, June 23, 1995, at A10 [hereinafter Histed, *Synthetic Hormones*].

202. The conclusion that FDA approval can be equated with product safety was questioned by the GAO, who conducted a study of 198 drugs approved by the agency over a ten year period. *See Int'l Dairy Foods Ass'n*, 92 F.3d at 77 (Leval, J., dissenting). It was found that over half of these drugs had "serious post approval risks" requiring either "labeling changes or withdrawal from the market." *Id.* Judge Leval writing in dissent concluded: "[A] government agency's conclusion regarding a product's safety, reached after limited study, is not a guarantee and does not invalidate public concern for unknown side effects." *Id.* (citing GAO REPORT: FDA DRUG REVIEW: POSTAPPROVAL RISKS, 1976-1985, Apr. 1990, at 2-3).

203. *See* Juskevich & Guyer, *supra* note 200, at 882-883.

204. *See* Daughaday & Barbano, *supra* note 151, at 1003. *See also* Letter from Linda A. Grassie, Communications and Education Branch, Center for Veterinary Medicine, Food and Drug Administration, to the author (Oct. 25, 1995) (indicating that the FDA based its conclusion in part on studies done in the 1950's where BST was injected into humans).

ity.[205] Finally, IGF-1 is destroyed by the heat process used to prepare infant formula made with milk.[206]

Despite significant scientific evidence which indicates that IGF-1 is harmless to humans,[207] a small group of scientists and researchers claim there is a link between cancer[208] and ingesting the milk from rbST treated cows,[209] and that female fetuses and infants may be particularly at risk.[210]

---

205. *See* Juskevich & Guyer, *supra* note 200, at 883. The FDA's findings were based on a Monsanto study conducted with rats which lasted two weeks and found no oral toxicity. *See* Stauber v. Kessler, 895 F. Supp. 1178, 1192 (W.D. Wis. 1995). *Cf.* Barry Commoner, *The Hazards of Risk Assessment*, 14 COLUM. J. ENVTL. L. 365, 371-72 (1989). Mr. Commoner's views of the use of animal studies to assess risk are instructive. The author cites as an example the potent carcinogen aminoacetyl fluorene which, when fed to rats, produces cancer. *See id.* When fed to guinea pigs, however, no cancer is produced. *Id.* If the chemical is fed to people, will they react like rats or like guinea pigs? The answer is disturbing: Because of the vast inherent differences between the human population and a controlled animal population, some people may react like rats, others like guinea pigs. *Id.* This at least suggests the potential for dangerous inaccuracies in toxicity studies based upon animal experiments. *But cf.* Prop. Rules, Sponsored Compounds in Food Producing Animals, 50 Fed. Reg. 45530, 45542 (1985) (citing the reliability of animal bioassays despite their "inherent limitations and uncertainties"). *See also* Nitrofurans, 56 Fed. Reg. at 41,905 (factors such as "age, hormonal status, physical stress and immunologic competence" may affect cancer rates and "cannot be controlled in either the target animal population fed (a drug) or in the human population that eats food products derived from these animals."); *See* also FUNK, *supra* note 56, at 486. "Animal studies are subject to conflicting interpretations particularly concerning how the results should be extrapolated to determine human consequences." *Id.*

206. *See* Daughaday & Barbano, *supra* note 151, at 1005. The American Medical Association seems to agree with the FDA, that the heat process used to prepare baby formula destroys all IGF-1. *Id.* However, the NIH did not concur with these findings and reported that as much as ten percent of the hormone might remain after treatment. *See* NATIONAL INSTITUTES OF HEALTH, *supra* note 156, at 7.

207. Reportedly as many as 2,000 studies have concluded that rbST is not harmful to human beings. *See FDA Says It Has No Authority to Ban BST Labeling*, *supra* note 128 (referring to statements made by Richard Durbin, U.S. Representative).

208. IGF-1 may have a direct stimulating affect upon cancer cells. *See* Linda Gasparello, *Is . . . BST Alarm a Tempest in a Milk Glass*, FOOD & DRINK DAILY, Aug. 9, 1995 (citing former cancer researcher George Tritsch).

209. *See generally* Histed, *Synthetic Hormones, supra* note 201, A10. *See also* Epstein, *supra* note 195, at 5.

210. *See* Amy O'Connor, *BGH Linked to Cancer in Humans*, VEGETARIAN TIMES, Mar. 1, 1995, at 18 (citing Samuel Epstein) (intestinal walls of children

One scientist warns that IGF-1 could engender premature growth in infants.[211] Another demonstrated that IGF-1 has "a direct growth-promoting action on fetal cells."[212] Researchers are worried about cell division in the bowel and rbST's role in promoting colon cancer in humans.[213] Still others cite IGF-1's "wide spectrum of physiological and renal effects,"[214] and the roles it plays in diseases and conditions such as acromegaly (a disease which enlarges the human extremities),[215] glucose intolerance and hypertension,[216] thyroid tumors,[217] diabetic kidney disease (nephropathy),[218] and polycystic ovary syndrome.[219]

While it has been argued that IGF-1, as a "protein hormone," is harmlessly digested in the gut,[220] some feel the hor-

---

or infants may be more permeable than those of adults, and may more readily absorb IGF-1). *Accord* Bonnie Liebman, *Crying Over Milk*, 19 NUTRITION ACTION HEALTH LETTER 10 (1992), at 7. *See also* Frank Murray, *Hormone For Cows May Cause Human Cancer*, BETTER NUTRITION FOR TODAY'S LIVING, Nov. 1995, at 8 [hereinafter Murray] (citing former cancer researcher George Tritsch as claiming that IGF-1 levels can affect the progress of leukemia in children).

211. *See* Epstein, *supra* note 195, at 5 ("breast tissues of female fetuses and infants are sensitive to hormonal influences").

212. *See* Sara V.R. Carlsson-Skwirut, Abstract, *The Biosynthesis of Somatomedins and Their Role in the Fetus*, 279 ACTA ENDOCRINOL SUPPLEMENT 82-85 (Copenhagen, 1986) *available in* LEXIS, Medline Database.

213. *See* McKeague, *supra* note 163, at F6.

214. *See* G.D. Ogle, et al., Abstract, *Renal Effects of Growth Hormone*, PEDIATR. NEPHROL. (Austl.) Sep. 1992; 6 (5): 483-9, *available in* LEXIS, Medline Database.

215. *See generally* S. Ezzat, Abstract, *Hepatobiliary and Gastrointestinal Manifestations of Acromegaly*, DIG. DIS. (Switz.) 1992; 10 (3): 173-80, *available in* LEXIS, Medline Database.

216. *See* THE HUMANE FARMING ASSOCIATION, BOVINE GROWTH HORMONE, *supra* note 166, at 3.

217. *See* G.A. Thomas, E.D. Williams, Abstract, *Evidence for and Possible Mechanisms of Non-Genotoxic Carcinogenesis in the Rodent Thyroid*, MUTAT. RES. (Wales) June 1991; 248 (2): 357-70, *available in* LEXIS, Medline Database.

218. *See* M. Krawczuk-Rybak, M. Urban, Abstract, *The Role of Growth Hormone in the Development of Complications in Insulin-Dependent Diabetes*, PADIATR. GRENZGEB (Germany)1991; 30 (3): 237-43, *available in* LEXIS, Medline Database.

219. *See* R. Kazar, Abstract, *The Etiology of Polycystic Ovary Syndrome*, MED. HYPOTHESES, (Eng.) Nov. 1989; 30 (3): 151-5, *available in* LEXIS, Medline Database.

220. *See* Bohrer, *supra* note 191, at 677-79.

mone can survive the digestive process.[221] Milk treated with rbST may contain IGF-1 not bound to casein-carrier proteins, possibly making the hormone more potent, and more biologically active in humans.[222] The FDA unequivocally denies that there is any link between the consumption of IGF-1 and cancer, or any other human disease.[223]

Another barely discernable issue is that it appears that the FDA merely selected IGF-1 for study from a number of hormones affected by rbST.[224] One source reports that milk from rbST injected cows was found to contain other hormones "in amounts up to 1,000 times greater than normal levels."[225] In short, significant questions regarding the possible effects of IGF-1 may remain unanswered.[226]

V. RbST's Potential Effect on the Dairy Industry

No small issue is the potential for rbST's introduction to create havoc in the dairy industry, speeding up a process which is currently putting small and mid-size farmers out of business and devastating rural economies.[227] There is an

221. *See* Murray, *supra* note 210. *See also* Chatterjee, *supra* note 127 (citing C. Xian, BRIT. J. ENDOCRINOLOGY, Aug. 1995) (IGF-I may not be harmlessly digested when combined with casein, the principle protein in cow's milk); O'Connor, *supra* note 210, at 18.

222. *See* Histed, *Synthetic Hormones*, *supra* note 201, at A10.

223. *See* USDHHS, FDA VETERINARIAN, *supra* note 69, at 7.

224. *See* Juskevich & Guyer, *supra* note 200, at 883.

225. *See* THE HUMANE FARMING ASSOCIATION, BOVINE GROWTH HORMONE *supra* note 166, at 3. *See also* JAMA, *supra* note 91, at 1389 ("blood hormone levels in cows are increased up to 1200-fold by rbST").

226. RbST proponents are among those citing the lack of knowledge regarding the drug's potential affects upon humans over the long term. *See* NATIONAL INSTITUTES OF HEALTH, *supra* note 156, at 9 ("[t]he importance of the increased amounts of IGF-1 in milk from rbST-treated cows is uncertain . . . . Whether the small additional amount of IGF-1 from rbST-treated cows has a significant local effect on the esophagus, stomach, or intestine is unknown."); Alex Boston, *More Research Needed Into BST*, MONTREAL GAZETTE, June 3, 1995, at B3 (indicating that "[f]urther studies will be required to determine whether the ingestion of higher-than-normal concentrations of (IGF from cows) is safe for children, adolescents and adults") (quoting the AMERICAN MEDICAL ASSOCIATION COUNCIL ON SCIENTIFIC AFFAIRS (1991)).

227. *See* Beiswenger, *supra* note 4, at 689-93. *See also Hearings before the House Agric. Subcomm. on Livestock, Dairy, and Poultry*, 104th Cong. (1995), *available in* 1995 WL 10384795 [hereinafter *Hearings on Milk Price Supports*]

oversupply of milk and milk products in the United States. Each year, farmers produce three percent more than the public can use,[228] while breeding animals that produce up to two percent more than the year before.[229] Overproduction has traditionally been discouraged by the federal government which, for instance, spent $158 million in 1994 buying surplus dairy products in order to stabilize prices.[230]

Large farms or those increasing herd size are better prepared to institute the strict "factory" farming practices, and absorb the much higher costs for labor, feed,[231] waste han-

---

(prepared statement of Keith Collins, Acting Chief Economist, U.S.D.A.) (indicating that in 1993 approximately thirty percent of the nation's dairy farmer lost money).

The regional shifting currently taking place and the effects of this shifting upon the dairy industry in various states have been well documented. *See, e.g., Meanwhile, In Maryland*, YORK DAILY REC., Oct. 23, 1996 (one out of five dairy farms in Maryland have disappeared since 1992); Hiss, *supra* note 13, at *1 (Vermont has 80% less farms than it had forty years ago); Jerry Jackson, *Despite Demand, Dairies Dwindling*, ORLANDO SENTINEL, Oct. 6, 1996, at H1 (Florida lost ten percent of its farms in 1995, and has lost fifty percent since 1960); Nita McCann, *Milk Prices Rising But Not Soon Enough For Farmers*, MISS. BUS. J., Jul. 22, 1996, at 1 (Mississippi has lost about twenty percent of its dairy farms in the last two years).

228. *Compare* Hiss, *supra* note 13, at 2, *and Hearings on Milk Price Supports*, *supra* note 227 (from 1985 through 1995 milk production increased an average of 1.5% annually while commercial consumption increased 1.8% per year) *with* Wendy Lin, *Makeover for Milk: Decline in Consumption Leads to Major Shakeup*, PLAIN DEALER, Mar. 26, 1997, at 1E (milk consumption was up 0.8% in 1996, capping a thirty year decline).

229. *See* Hiss, *supra* note 13, at 6.

230. *See* Steve Prestegard, *Industry Report: Ag and Food Processing*, MARKETPLACE MAGAZINE, Apr. 25, 1995. The federal government subsidizes the dairy industry in two principal ways; through "marketing orders" which set milk prices by region throughout the nation, *see U.S. Congress Conferees Set to Finalize Farm Bill Thursday*, CAPITAL MARKETS REP., Mar. 21, 1996, and "price supports" whereby the Commodity Credit Corporation (CCC) purchases surplus dairy products in order to stabilize prices. *See* Jennifer A. Galloway, *Milk Price Supports to Increase as Supply, Demand Near Balance*, WIS. ST. J., November 21, 1995, at 8B. CCC dairy program expenditures averaged $350 million annually between 1991-1995. *See Hearings on Milk Price Supports*, *supra* note 227, at *8.

231. It has been argued that the use of rbST would increase the nutritional efficiency of cows, inferring that animals would require less feed. This, in fact, may not be the case. *Compare* Jim Chen, *The American Ideology*, 48 VAND. L. REV. 809, 869 (May 1995) (citing NATIONAL RESEARCH COUNCIL, METABOLIC MODIFIERS: EFFECTS ON THE NUTRIENT REQUIREMENTS OF FOOD-PRODUCING ANI-

dling and specialized equipment which successful use of rbST demands.[232] If milk production increases,[233] the disparity between supply and demand may increase.[234] If the prices milk producers receive for their products then drop, as many as thirty percent of American dairy farmers may be forced out of business,[235] with others forced to adopt rbST and its accom-

---

MALS 26 (National Academy Press 1994)), *with* Miller, *supra* note 92, at 508 (cows treated with rbST have "increased feed requirements") (citing Roy C. Barnes & Peter J. Nowak, *Bovine Somatatropin's Scale Neutrality and Constraints to Adoption*, AGRIC. BIOETHICS 143, 147 (Steven M. Gendel, et. al. eds., 1990)).

Note also that the marked increase in the cost of dairy products, which American consumers experienced in the Fall of 1996, was caused in part by bad weather which affected the quality, price and availability of feed. *See* Shaun Schafer, *Dairy Demand / Prices for Dairy Products at Record Levels: Little Relief Seen*, TULSA WORLD, Oct. 13, 1996. Lower-quality feed causes cows to produce less milk, a result which may be magnified in cows treated with rbST. *See id.*

232. *See* Beiswenger, *supra* note 4, at 689. *But see* Jennifer A. Galloway, *Monsanto Losing Money With rBGH, Company Blames Production; Experts Say Farmers Have Been Slow To Accept Drug*, WIS. ST. J., Apr. 14, 1996, at 1E, *available in* 1996 WL 9913823 (farmers with smaller herds are able to monitor their animals more closely, therefore allowing them to be more successful rBGH users).

233. *Compare* A STUDY CONDUCTED BY THE EXECUTIVE BRANCH OF THE FEDERAL GOVERNMENT, USE OF BOVINE SOMATOTROPIN (BST) IN THE UNITED STATES: ITS POTENTIAL EFFECTS (photo. reprint 1995) Jan. 1994, at iii (a 1% annual increase in milk production is anticipated from the introduction of rbST) *and* Kuchler, *supra* note 65, at *4 (earlier studies had predicted increases of from 8% to 25%), *with FY 98 Agric. Appropriations: Hearings before the Senate Comm. on Appropriations, Subcomm. on Agric., Rural Dev., and Related Agencies*, 105th Cong. (1997) , *available in* 1997 WL 8220631 [hereinafter *Hearings on FY 98 Agriculture Appropriations]* (statement of Dan Glickman, Secretary of Agriculture) (indicating that milk production was expected to increase less than 1% in 1997).

234. *See* Lin, *supra* note 228, at 1E (indicating that milk consumption increased 0.8% in 1996, capping a thirty year decline); *Trade With European Union: Hearings Before the House Comm. on Agric., Subcommittee on Livestock, Dairy and Poultry*, 105th Cong. (1997) *available in* 1997 WL 10571041 (prepared statement of Paul Drazek, Special Assistant to the Secretary for Trade) (indicating that "U.S. dairy product exports declined about 7% in 1996 . . . ").

235. *See* THE HUMANE FARMING ASSOCIATION, BOVINE GROWTH HORMONE, *supra* note 166 (citing studies by the Office of Technology Assessment and Cornell University). Another view of this situation is that with less dairy farmers we may have fewer cows, with this eventuality translating into less pollution and a cleaner environment. *See* Jim Chen, *Get Green or Get Out: Decoupling Environmental From Economic Objectives in Agricultural Regulation*, 48 OKLA. L. REV. 333, 348 (1995) (describing dairy cows as "cud-chewing emitters of manure, urine and methane"). *See also Hearings on FY 98 Agriculture Appro-*

panying technology in order to increase output and income.[236] An economic burden would fall disproportionally on small and mid-sized farmers.[237]

Some studies have concluded that after experiencing an initial benefit, those who adopt rbST might eventually find themselves in the same financial position they were in before they started to use the drug.[238] In the absence of federal price supports, which are planned to be phased out by the year 2000, farmers might find that their financial position has worsened.[239] Much of what may occur to the industry is

---

priations, supra note 233 ("cow numbers will continue their long term decline" in 1997).

236. *See* Beiswenger, *supra* note 4, at 690.

237. *Id. Accord* Adler, *supra* note 16, at *17. *See also* Mike Ivey, *BGH Sales Up, But U.N. Retains Ban*, CAP. TIMES, July 31, 1997, at 1B (explaining that rbST "is more scale biased than anyone had thought") (quoting Brad Barham, assistant professor of agriculture at the University of Wisconsin at Madison).

238. *See* Beiswenger, *supra* note 4, at 691 (citing Steven H. Lee, *Controversy in Bovine Hormone's Future*, CHIC. TRIB., May 21, 1990, at 6).

239. *See U.S. Congress Conferees Set to Finalize Farm Bill Thursday*, CAP. MARKETS REP., Mar. 21, 1996. Price supports will be incrementally decreased from 1996 through 1999. *See* 7 U.S.C. § 7251(b) (1996). Note that when milk prices are higher than the support price the latter have little net effect or purpose. *See* John Tucker, *Dairies Love New Farm Bill*, IDAHO STATESMAN, Mar. 30, 1996. However, when market prices fall below the support price, the supports may provide a critical safety net particularly beneficial to small producers. *Cf. Hearings on Milk Price Supports, supra* note 227, at *8.

In 1997, milk prices fell to a low of $10.70 per hundred pounds of milk, the lowest in six years. *See Dairy Farmers Up Pressure For Higher Minimum Milk Price,* DOW JONES NEWS SERV. Sept. 9, 1997. In response, 150 farmers rallied outside the Capital with petitions signed by 9,000 milk producers asking the government to set a temporary minimum price support level of $14.50. *See id.* Dan Glickman, Secretary of Agriculture, citing 7 U.S.C. § 7251(b), stated that he was prevented from complying with the petitions by the mandates of the statute which set the minimum support level at $10.20 per hundredweight for 1997. *See* Mark Glover, *Pressure's on for Milk Prices*, SACRAMENTO BEE, Sept. 15, 1997, at B3.

Furthermore, critics have charged that the antiquated milk marketing order system, *see supra*, note 230, artificially raises the prices paid to some producers while artifically lowering prices for others. *See Judge Delays Order Striking Down Rules on Pricing of Milk,* WALL ST. J., Dec. 8, 1997, at B10. To further complicate the issue and compound the problem of volatile milk prices, a Federal District Court Judge recently enjoined the Secretary of Agriculture from enforcing milk marketing orders in 28 regions throughout the country, finding that the orders were unlawful under the Agricultural Marketing Agreement Act, 7 U.S.C. § 608(c)(18). *See* Minnesota Milk Producers v. Glickman,

still speculative, depending upon many factors including the demand for milk and the number of farms actually adopting rbST.[240]

VI. Analysis

A. The Limitations of Risk Assessment Methodology

The "risk-based approach" to regulatory oversight, as applied to biotechnology, is limited in its ability to adequately regulate rbST. This is because of the assumptions from which it operates, created by the regulatory scheme.

First, the assessment of a product does not focus on the process of biotechnology, but on the products produced by biotechnology.[241] Biotechnology, as a means by which to physiologically alter organisms to produce certain desired traits or characteristics, is not viewed as being inherently different

---

No. CIV. 4-90-31, 1997 WL 684863, at *5 (D. Minn. Nov. 3, 1997). Faced with the prospect of pandemonium in the nation's milk markets, and the reality that farmers in some regions might stand to lose as much as ten to fifteen percent of their income, *see* Charles H. Taylor, *Taylor Taking Lead On Dairy Issue,* GOV'T PRESS RELEASES, Nov. 17, 1997, *available in* 1997 WL 12104910 (press release from the office of U.S. Rep. Charles H. Taylor, on file with the Federal Document Clearing House), U.S. District Judge David S. Doty delayed his order until February 15, 1998. *See Judge Delays Order Striking Down Rules on Pricing of Milk, supra* note 239, at B10.

240. The actual number of farms currently using rbST and the number of animals affected appears disputed, or is at least subject to rapid change. Monsanto had stated that fifteen percent of dairy farms and cows had used rbST between 1994 and 1996. *See* Robert Steyer, *Backers and Critics Both Wrong on BST,* ST. LOUIS POST-DISPATCH, Aug. 11, 1996, at O1E. According to a USDA report, in 1995, "9.4% of farmers used BST on 10.1%" of the nation's cows. *Id. See also Int'l Dairy Foods Ass'n I,* 898 F. Supp. at 253 (stating that "[d]epending on which statistics one accepts, nationwide . . . about one-third of lactating cows presently are being treated with rbST"); Ivey, *supra* note 237, at 1B (Monsanto has recently estimated that twenty-five percent of dairy farmers have tried rbST, while a University of Wisconsin survey of approximately 1,200 producers showed adoption rates of 50% for large farms and 4% for small farms).

It is important to note that these statistics do not represent the percentage of milk products which may be "affected" by rbST. Industry practice is to "pool" milk provided by farmers. *See* Letter from Lisa Ward, Consumer Response Representative, *The Dannon Co., Inc.* to the author, August 7, 1995. Therefore, without special precautions being taken, milk from farms using rbST will be routinely combined with milk from farms not using the drug. *See id.*

241. *See supra* text accompanying notes 46-47.

from the selective breeding methods through which mankind has traditionally modified animals or plants.[242]

Second, oversight will probably not be exerted where there is no "known" risk associated with the product at hand.[243] Risks to human or animal health which are merely possible, or those which may be unknown at present, are not considered because they are speculative or remote. Because cost is an issue,[244] and because regulation implies cost, there is no room in the regulatory equation to account for such risks.[245]

Third, risk assessment does not seek to analyze the possible social, economic or political effects which might follow the introduction of a particular bio-tech product,[246] such as rbST's potential to affect the dairy industry. These factors are merely collateral to the risk analysis. In essence, risk assessment cannot always evaluate whether it is generally desirable to have a certain product introduced.[247]

Finally, regulation is generally viewed as an interference or a barrier to development of the biotechnology industry.[248] The biotechnology industry is to be supported and encouraged,[249] and the increased use of dairy products is be promoted.[250] Regulation may be used as necessary to defend the

---

242. *See supra* text accompanying note 40.

243. *See* Exercise of Federal Oversight, 57 Fed. Reg. at 6762 (quoting PRESIDENT'S COUNCIL ON COMPETITIVENESS, FACT SHEET ON CRITICAL TECHNOLOGIES (April 1991), stating that "[r]egulations . . . should address risks that are real and significant rather than hypothetical or remote").

244. The "risk-based approach" to regulatory oversight endorsed by and described in the Scope document is viewed as critical if the "heavy costs" associated with regulation are to be avoided. *See* Exercise of Federal Oversight, 57 Fed. Reg. at 6760.

245. *See supra* note 49 and accompanying text.

246. *See* Beiswenger, *supra* note 4, at 669-70. *But cf.* Jim Chen, *Get Green or Get Out: Decoupling Environmental From Economic Objectives in Agricultural Regulation*, 48 OKLA. L. REV. 333, 348 (1995). The author argues that by *ignoring* the socioeconomic impact of rbST the FDA merely continued an established policy, fulfilled its obligations under the National Environmental Policy Act and acted in a way that was environmentally sound.

247. *See* Beiswenger, *supra* note 4, at 670.

248. *See supra* text accompanying note 52.

249. *See supra* text accompanying notes 47 and 55.

250. *See supra* note 137.

industry's image and protect its development.[251] Industry is to be generally trusted with the responsibility for developing safe biotechnological products,[252] the reporting of adverse reactions[253] and, in certain instances, for voluntarily determining whether drug residues may be consumed by humans.[254]

These assumptions work together collectively, and can be likened to a person who is crossing a street. The pedestrian assumes there are no inherent risks to crossing. He assumes there are no cars in the area, therefore no unexpected or otherwise unknown dangers. He observes the immediate area and finds no cars, and therefore no apparent dangers. He concludes that there is no danger and that it is safe to cross. He balances probabilities and assumes it will continue to be safe from the time he starts to cross until he reaches the other side.

The regulatory decision maker also acts upon certain assumptions. Unlike the pedestrian, however, he is aware that there may be unknown risks in crossing this particular street. He also knows there are remote chances of serious injury, and that a great number of individuals will cross. Yet, he makes an economic decision not to construct a stop light, rationalizing that he has no evidence that the risk of being hit by a car justifies such an expense.

Furthermore, he has two conflicting mandates. The ability of people to cross must not be interfered with. Yet, he must keep pedestrians reasonably safe, at least to the point where safety becomes an interference. If he turns out to be wrong, and people are injured at this particular corner, remedial action will be taken, which will prevent further injury.

B. Known Risk and the Inherent Difference of Biotechnology

The obvious problem with this risk assessment reasoning, in short, lies in the nature of the assumptions which form

251. *See supra* text accompanying note 55.
252. *See supra* notes 53-54 and accompanying text.
253. *See supra* note 171.
254. *See supra* text accompanying note 188.

its foundation. Biotechnology, with a power to broadly affect the way we live, or even how long we live,[255] is a technology fundamentally different in scope than any other. In the case of rbST, it is different because of the nature, scope and magnitude of the potential impact of the unknown and otherwise remote risks which accompany its use.

The introduction of genetically modified organisms generally carries with it unknown risks,[256] the consequences of which may not be evident until several generations have passed, or until a unique environmental agent is presented.[257] Although rbST has been thoroughly tested for risks,[258] these very same tests have identified the potential for unknown or remote hazards[259] which may not make themselves fully known until after several generations of Americans have used the product.

For instance, there remain questions of fact as to the amount of IGF-1 which may be found in milk from treated

---

255. *See* Maher, *supra*, note 33, at 178-79.

256. *See supra* note 226. Generally speaking, there are many examples of the potential unknown dangers of releasing certain organisms into the environment without understanding or appreciating the possible long term implications and consequences of such releases. For instance, by cross-pollinating certain strains of corn, agriculturalists created a hybrid seed that produced a greater yield, but that was less resistent to a certain type of fungus which wiped out 15% of the American corn crop in 1970, causing an estimated $1 billion in losses. *Cf.* Auchincloss, *supra* note 84, at 42-43. There is dire speculation as to the potential of genetically modified organisms to produce harm after introduction. *See also* Maher, *supra* note 33, at 152-53 (potential to disrupt the food chain); *see id.* at 142 (potential to alter the balances among species) (citing BUREAU OF NATIONAL AFFAIRS, UNITED STATES BIOTECHNOLOGY: A LEGISLATIVE AND REGULATORY ROADMAP, BNA SPECIAL REPORT ON BIOTECHNOLOGY #27, at 5 (Aug. 1989)). *Cf.* Gil Lamont, *Banking on Animal Organs*, MAINSTREAM, Summer, 1995, at 11 (the European house sparrow, South American nutria, starling and zebra mussel are examples of non-native species introduced into America which had damaging effects on the environment or native animal populations).

257. *See* Maher, *supra* note 33, at 186. *Cf.* Auchincloss, *supra* note 84, at 42 *citing* BARRY COMMONER, MAKING PEACE WITH THE PLANET 1, 14 (1990) (explaining that "[e]very action having an impact on an ecosystem has consequences which are inevitable and governed by the laws of nature . . . . To the extent that the laws of nature are not known, the-consequences of an intrusion will come as a surprise").

258. *See supra* note 207.

259. *See supra* note 226.

cows, its composition, and its potential effect.[260] The FDA relied in part on the opinion of the NIH, which approved rbST while unsure as to whether IGF-1 could affect the human digestive system.[261] The AMA similarly approves of the use of rbST, yet does not know whether "higher than normal" ingestion of IGF-1 is safe.[262] The effect rbST has on other hormones in our bodies is unknown.[263]

Also unknown is the extent to which use of rbST increases mastisis in cows[264] and the possible ramifications this may have upon human health. First, sophisticated husbandry techniques must accompany rbST use in order to limit its detrimental effects.[265] Yet, while rbST must be prescribed by a veterinarian,[266] ultimately, farmers may use the drug in any manner they wish, or under any conditions as they may exist on their farms. Given the expense rbST use inevitably entails, and the sophistication proper use requires, the "conditions of use" are not necessarily "reasonably certain to be followed in practice" as required by the FDCA.[267]

Second, the methods by which adverse animal reactions are reported and gauged are inadequate. A system of voluntary reporting to scattered sources, including the manufacturer, cannot reasonably be expected to provide adequate information regarding the seriousness or true rates of mastisis in treated herds.[268] Even this reporting may not provide the FDA with accurate information, as the FDA appears to have trouble identifying when mastisis occurs as a result of rbST use.[269] Furthermore, it is unknown for sure how many farmers have even used the drug, or how many of the nation's cows have been treated.[270] Additionally, the percentage of

260. *See supra* notes 198 through 226 and accompanying text.
261. *See supra* note 226.
262. *See id.*
263. *See supra* text accompanying note 225.
264. *See supra* text accompanying notes 154 through 159.
265. *See supra* notes 231, 232 and accompanying text.
266. *See supra* text accompanying note 160.
267. FDCA, 21 U.S.C. at § 360b (d)(2)(D).
268. *See supra* note 171 and accompanying text.
269. *See supra* note 170.
270. *See supra* note 240.

the Nation's consumers who have ingested products from treated animals is unknown.[271]

If mastisis increases, so may use of the antibiotics used to treat the infection. This will compound the disturbing and dangerous prevalence of antibiotic administration to farm animals in the United States today.[272] Treated cows developing a resistance to these antibiotics due to excessive exposure may pass this resistance on to humans who consume their milk.[273] The FDA has acknowledged the seriousness of human overexposure to antibiotics,[274] but is satisfied that antibiotic residues which may appear in milk can be adequately monitored.[275] Yet, the current mechanisms gauging the antibiotics in our food supply are inadequate. This is true not only because they have to some extent been proven so,[276] but simply because more types of antibiotics are used than are tested for.[277] In short, the probability that rbST use may cause indirect injury to humans may be remote. Dangers may be supposed, or presently incapable of measurement or analysis. However, the nature of the injury, if it occurs, has the potential to be widespread and extremely serious.

The premise of the Coordinated Framework and the Scope document, that biotechnology is like any other technology, is inaccurate. The one-dimensional focus on known risk is short-sighted. Appropriate risk assessment methodology should recognize the uniqueness of biotechnology. When the introduction of a genetically modified organism or product carries with it an unknown risk with a potential to have a substantial impact upon human health, a balancing test should be engaged in to weigh the value of and need for the product against the magnitude, not the probability, of the potential risk.

---

271. *Id.*

272. *See supra* notes 175 through 185 and accompanying text.

273. *See supra* notes 178 through 180 and accompanying text.

274. *See supra* note 181.

275. *See supra* text accompanying note 186.

276. *See supra* text accompanying note 194.

277. *See supra* text accompanying notes187-189 and 193; *see also supra* note 190 and accompanying text.

In this way, products vital to human health or well-being will survive the analysis, while products less vital may not. Put simply, the passion and force we employ when we propel our bodies across the avenue, and the care and precaution we take when we do, should be relative to the need we have to cross. When there is no urgent need, greater care should be taken because of the deadly consequences, however remote, of not doing so.

The exercise of a higher standard of care to guard against remote and harmful events is not a surrender to paranoia or irrational fear. It is merely a conservative undertaking which an agency, charged with the protection of human health, should routinely engage in.

C. Socioeconomic Effects

The risk assessment methodology applicable to rbST, because of its inherent limitations and emphasis on cost and quantifiable and "unreasonable" risk,[278] is insufficient to adequately measure a biotechnological product's total impact upon society. The FDA was not required, nor perhaps is even permitted, to consider the potential impact of rbST upon the dairy industry.[279] This is so, in part, because biotechnological products are to be regulated like any other product,[280] and socioeconomic factors are not requisite to the analysis. Yet, rbST use may accelerate regional shifts in dairy production, and perhaps engender the virtual disappearance of the family farm.[281] This may not only quicken the further depression of rural economies,[282] but herald a new age in animal drug use and factory dairy farming techniques.[283]

---

278. *See supra* notes 45 and 49 and accompanying text.

279. *See supra* note 246 and accompanying text. *Cf.* Nitrofurans, 56 Fed. Reg. at 41,903 *quoting* 44 Fed. Reg. 54,883 (stating that "[t]he law is clear that FDA may not consider socioeconomic *benefits* in the determination of the safety to human beings of a new animal drug . . . ") (emphasis added).

280. *See supra* text accompanying notes 37, 40 and 46.

281. *See supra* notes 227 through 240 and accompanying text.

282. The applicable statute states that it is Congressional policy to "stabilize the economy of dairy farmers." *See* Agricultural Act, 7 U.S.C. at § 1446b (1997).

283. *See supra* text accompanying notes 231 and 232.

Furthermore, the cumulative cost of the drug to the economy may very well outweigh any of its potential benefits. Small farmers may be forced to adopt the drug in order to compete with larger concerns.[284] If they do, they must also adopt the expensive methods, equipment and increased feed requirements that successful rbST use demands.[285] While this may provide some with short term economic benefits, the long term benefits, because of the many factors which affect dairy prices, such as government intervention, the lack of it,[286] or increases in feed prices,[287] are less certain to follow. Furthermore, if oversupply due to increased production results, or if demand decreases, prices will fall. In the absence of federal price supports, the smaller farmers may find themselves with increased costs and falling prices.[288] Farmers may inevitably experience what those who abuse addictive drugs experience: a viscous cycle of dependency that leaves one with an expensive habit and an unfulfilled need.

Therefore, it is imperative, for the foregoing reasons, that the review of biotechnological products include non-scientific, social and economic factors. An appropriate balancing test, as discussed, which weighs the value of and need for the product against the magnitude of the potential risk presented by the product, will afford regulatory agencies the ability to determine whether a biotechnological product is truly desireable or beneficial.

D. The Promotion of Biotechnology

The biotechnological regulatory scheme appears to be designed in such a way that safety measures will not be permitted to interfere with the developing technology. Monsanto's influence on the drug's approval process has been questionable, as has the FDA's seeming acquiecence to this influence.[289] The company is accused of engaging in certain

284. *See supra* text accompanying note 236.
285. *See supra* notes 231-32 and accompanying text.
286. *See supra* note 239 and accompanying text.
287. *See supra* note 231 and accompanying text.
288. *See supra* notes 238-239 and accompanying text.
289. *See supra* notes 138-149, 151 and 153 and accompanying text.

activities, in Canada, which, had they occurred in America, would have been sufficient grounds to deny approval of the drug.[290] The FDA's decision to permit three of its employees, with close ties to the company, to participate in the drug's approval and review process was either an act of blatent bias, or one of utter foolishness because of the likelihood that charges of bias would result.[291] It does not take a GAO investigation for even an uniformed layperson to reach one of these two, rather obvious conclusions, either one of which also provided the Secretary of the USDHHS with the necessary grounds to deny approval of rbST.[292] The company's seeming influence on the political process[293] and on public health organizations and individuals[294] upon which the public relies for objective information and analysis is unsettling.

The impression is one of undue industry influence and agency bias[295] operating under color of law, where the primary objective is to sell a technology, and get people to cross the biotechnological street. Indeed, risk assessment methodology may, by its very nature, be particularly vulnerable to bias. Critics have asserted it is often employed "to defend a decision which has already been made."[296] The reaction of the American and world communities to rbST approval[297] is stark evidence of the public's perception of the approval process and its result.

It is vital to the credibility and effectiveness of regulatory agencies, such as the FDA, that they maintain a neutral, nonpartisan posture. The laws governing biotechnology which

290. *See supra* note 133, 150 and accompanying text.
291. *See supra* notes140-146 and accompanying text.
292. *See supra* note 133.
293. *See supra* note 83 and accompanying text.
294. *See supra* notes 151 through 153 and accompanying text.
295. *See supra* notes 133 through137 and accompanying text.
296. *See* Commoner, *supra* note 205, at 365-66. The author explains that "the new technology is chosen in advance of the risk assessment . . . [which] is not used to decide which technology to use, but rather how to best defend the choice already made." *Id. Cf.* E. Donald Elliott, *The Future of Toxic Torts*, 25 HOUS. L. R. 781, 795 (1988) (stating that "[a]dministrators reach their decisions on political grounds, then instruct their lawyers to write opinions rationalizing them in terms of the relevant scientific and technical facts").
297. *See supra* notes123-132 and accompanying text.

mandate that the industry be supported, shielded or encouraged,[298] are incompatible with those seeking to protect the public. It is inappropriate for a regulatory agency to operate under a mandate which demands that the agency performs a protective function for the industry it is charged with regulating. While regulatory agencies can never be immune from political pressure, they must be free from overtly prejudicial mandates, which define the scope of their authority in favor of certain industries and at the potential expense of animal and human health and well-being.

It may be a legitimate function of government to offer incentives to the private sector to invest in emerging technologies, or to generally support their efforts to do so, if government views the new technology as potentially beneficial to the country as a whole. It is somewhat of a different matter for government to essentially guard and promote, through its offices and by its finances, an unnecessary, perhaps detrimental product, simply because that product happens to be produced through a potentially beneficial technology. The private sector is often best left to its own devices and resources to produce and promote products which should ultimately be allowed to face the free market system without the assistance of government.[299] Here, it may be fairly judged as either beneficial or not beneficial, worthwhile or not worthwhile.

When a government agency with regulatory responsibility is mandated to perform a cheerleading function of any kind for the very industry it is supposed to regulate, an obvious conflict of interest is created. This speeds the deterioration of the public's faith in the regulatory system as a whole. The success of biotechnology as an industry depends in part on a positive public perception. This presupposes the public's faith in the willingness and ability of the government to properly regulate the technology, thereby protecting the public against any potential dangers. It may actually be antithetical to the objectives of government to jeopardize that faith by

298. *See supra* notes 52-56 and accompanying text.
299. *See generally Anonymous FDA Whistleblowers*, *supra* note 131.

requiring regulatory agencies to act as public relations officers for the very same industries over which they are required to perform watchdog functions.

If one believes, however, that a function of government should be to actively promote an industry, then perhaps this function is better performed by an independent office with this as its sole function. In this way, the American people may at least receive what they are ultimately asked to pay for: publicity from press agents, and regulatory protection from regulators.

E. The Failings of the Food, Drug, and Cosmetic Act

The approval of rbST illustrates that the FDCA as currently written may be inadequate to properly regulate biotechnological products. For instance, the Act required that rbST be assessed for its "cumulative effects."[300] However, short term animal studies[301] and the available scientific information[302] may have been inadequate to determine such effects. Where the cumulative effects of an animal drug upon man or the animal cannot be adequately determined, caution requires that the potential value of the drug be weighed against the magnitude of the potential detriments of its cumulative effects prior to its approval. The FDCA should be amended to reflect this sober view of regulatory scope.

The Act appears to require that the manufacturer describe methods for detecting drug residues in animal end-products.[303] However, under the FDCA, it appears the FDA was permitted to rely on "adequate information" as a substitute for an assay test.[304] The FDA did not require Monsanto to develop such a test, despite the feasibility of doing so,[305] and in stark contrast to actions previously taken by the agency when faced with similar scenarios.[306] Despite concern

300. *See* FDCA, 21 U.S.C. at § 360b (d)(2)(B).
301. *See supra* note 205.
302. *See supra* note 226 and accompanying text.
303. *See supra* notes 66, 67 and accompanying text.
304. *See supra* note 68 and accompanying text.
305. *See supra* note 69 and accompanying text.
306. *See supra* note 66.

over the potential effects upon human health from consuming products from animals treated with rbST,[307] American consumers drank milk from treated cattle for over two years before the GAO stepped in to advise the FDA to address the problem of drug residues.[308]

The FDCA should be amended to ensure that new animal drug applicants develop a test for residues of the new drug in the animal-end product used for human consumption if no such testing methodology exists. The FDA should have absolutely no discretion to accept other information as a substitute for this requirement.

Additionally, the Act requires that the animal drug be safe for the animal.[309] Despite the serious potential side-effects of the drug,[310] the FDA determined that the risks to animals were "manageable."[311] This could only be because the agency felt that the side-effects could be avoided through proper use, or because the ailments resulting from rbST use could be controlled or cured through the use of drugs or other management techniques. Yet, the conditions under which the drug will be used are not totally controlled by the agency. Furthermore, the fact that side effects resulting from rbST use may be treated by still other drugs, does not necessarily mean that the product is safe for the animal it is used upon. The approval of an animal drug with serious side effects and with no potential to benefit the animal is contrary to the statutory policy encouraging the raising of cattle free from disease.[312]

Thus, if a goal of the FDCA is to protect animals from drugs with serious deliterious effects, the Act must be amended to specify that such a drug cannot be used unless its potential benefit to the animal outweighs the risks of its use. Furthermore, in light of the unknown risks inherent in the use of rbST and because the drug may in fact represent an

307. *See supra* Part IV(A).
308. *See supra* note 69.
309. *See supra* note 58.
310. *See supra* text accompanying notes 160 through167.
311. *See supra* note 169 and accompanying text.
312. *See* Agricultural Act, 7 U.S.C. at § 1446b.

"imminent hazard"[313] to the health of man and animals, there would be little lost and possibly much gained by placing a moratorium on rbST use until some of these questions surrounding the drug have definitive answers.

F. Labeling

Should existing regulations prove inadequate to protect human health, labeling regulations which mandate that consumers be informed when dairy products are produced from rbST treated animals, would at least provide consumers with a choice whether or not to be exposed to such products in the first place. Appropriate labeling regulations will ensure that consumers are provided with the choice whether to trust the conclusions of a profit-motivated industry, and a government with a mandate to support the industry, that there is no danger in crossing the biotechnological street. The alternative is to simply rely on government to construct a regulatory stop light designed to prevent future injury once some harm has already occurred. This assumes, of course, that any prospective injury could even be traced to rbST use. In this event, and in the absence of labeling giving the public a choice, harm may occur not to a lone individual making a voluntary decision to cross a byway, but to a population that has been compelled to trust the conclusions of government and industry that rbST is safe.

The FDA is somewhat handcuffed by the language of the Scope and Framework documents which does not recognize biotechnological products as "different" from others.[314] Because mandatory labeling would denote just such a difference, it would therefore be misleading and a violation of the FDCA require same.[315] However, the Scope document also affords agencies the authority to label biotechnological products[316] and the FDA has traditionally been afforded broad discretion in labeling decisions.[317] Furthermore, it is the

313. *See* FDCA, 21 U.S.C. at § 360b (e)(1).
314. *See supra* text accompanying notes 86 and 87.
315. *See supra* note 93 and accompanying text.
316. *See supra* note 50 and accompanying text.
317. *See supra* note 92.

agency's own interpretation of the law which binds it, and which has led it to create a policy which interferes with the consumer's statutory right to know by discouraging truthful labeling.[318] Specific labeling guidelines which mandate that products from rbST treated animals be labeled as such would provide consumers this right. They would also eliminate the varying state interpretations of the "Interim" guidelines.[319] Some of these guidelines have prevented manufacturers which insist on rbST-free labeling from freely availing themselves of the benefits of interstate commerce.[320] Some may, in fact, be unconstitutional.[321]

VII. Conclusion

Biotechnology holds tremendous potential benefits for mankind, and more potential to drastically alter the way we live than any other previous technology. It is an emerging science well worth encouraging. However, current regulatory methodology is inadequate in that it fails to take into account the social and economic factors which may be directly affected by biotechnology. As well, existing regulation does not seek to analyze the balance between the overall potential benefit versus the overall potential detriment of introducing a biotechnological product.

Furthermore, the industry is regulated by laws which, on the one hand, are overly concerned with the development and protection of industry, and on the other hand exclude from analysis or consideration the unknown, yet wholly probable consequences, most notably the human safety and health consequences, of introducing certain biotechnological products into the mainstream. For instance, while the evidence indicates that rbST is safe, considerable questions remain about

318. *See supra* note 93. Furthermore, the guidelines have contributed to results which are anomalous, at best. For instance, in Illinois, Ben and Jerry's was prohibited from advertising their products as BGH-free, *see supra* note 105, while in New York, The Dannon Company, which uses milk from rbST treated cattle, is permitted to label its products as containing *no artificial anything*. *See supra* note 240.

319. *See supra* note 102 and accompanying.

320. *See supra* notes 102, 104 and 105 and accompanying text.

321. *See supra* Part II(D)(2)(a).

the long term impact it may have on human health. For this reason alone, rbST use should be immediately suspended until all questions regarding its possible long term impact on human health have been answered.

It would be wholly unwise to turn a blind eye to factors which, although not readily quantifiable, may be quite real. Because of what is at stake, our fervor to develop the biotechnological arena must yield to a cautious and more sober analysis of the possible ramifications of our actions. It may be of no small importance to our children and grandchildren that we repeatedly ask ourselves the question: If we're *wrong*, what will the consequences be?

Given the state of the dairy industry, rbST was a poor product to choose as the first agricultural biotechnological product, primarily because it is an unnecessary, and perhaps even counterproductive product. Here, the singular pursuit of profit by a company which sensed an economic windfall, combined with a blind urgency on the part of government to encourage a new technology, has produced an apparent willingness on the parts of both to engage in questionable, improper or simply overtly partisan activities on behalf of the new technology. This has not only tainted the drug's review process, but has jeopardized the very goals both government and industry were attempting to achieve. Viewed from one extreme, it would not be totally speculative nor would it be unwarranted to conclude that industry and government have employed a regulatory, economic and political system that forces the American public to accept a product which it currently does not need, which it may never truly benefit from and which it may, in fact, be harmed by.