
CITIZEN PETITION BEFORE THE UNITED STATES

FOOD AND DRUG ADMINISTRATION

Dockets Management Branch

Food and Drug Administration

Department of Health and Human Services

Room 1-23, 12420 Parklawn Drive

Rockville, MD 20857

CENTER FOR FOOD SAFETY,

a project of the

INTERNATIONAL CENTER FOR

TECHNOLOGY ASSESSMENT,

310 D Street, N.E.

Washington, DC 20002,

et al.

Petitioners,

vs.

JANE HENNEY,

in her official capacity as,

Commissioner

Food and Drug Administration

Parklawn Building, Room 1471

5600 Fishers Lane

Rockville, MD 20857

Defendants.

**PETITION SEEKING THE WITHDRAWAL OF THE NEW ANIMAL DRUG
APPLICATION APPROVAL FOR POSILAC® - RECOMBINANT BOVINE
GROWTH HORMONE (rBGH)**

Pursuant to the Right to Petition Government Clause contained in the First Amendment of the United States Constitution,⁽¹⁾ the Administrative Procedure Act,⁽²⁾ and the Food and Drug Administration's (FDA) implementing regulations,⁽³⁾ the undersigned submits this citizen petition for rulemaking and collateral relief under §360b of the Federal Food Drug and Cosmetic Act to respectfully request the Commissioner to undertake the following actions:

(1). Immediately suspend the approval of the new animal drug application for Posilac® - recombinant bovine growth hormone (rBGH);

(2). Immediately publish a Notice of Opportunity for an Evidentiary Hearing concerning "new evidence" related to the new animal drug application approval of Posilac® (rBGH) in the Federal Register;

(3). Upon completion of the hearing, issue an order withdrawing the approval of the new animal drug application for Posilac® (rBGH); *and*

(4). Revoke all regulations associated with the approval of Posilac® (rBGH) including those found at 21 C.F.R. § 522.2112.

PETITIONERS

Petitioner **Center for Food Safety (CFS)**, a project of the International Center for Technology Assessment, is located at 310 D Street, N.E., Washington, DC 20002. CFS was established in 1997 to address the increasing concerns about the impacts of our food production system on human health, animal welfare and the environment.

Petitioner **American Humane Association (AHA)** is located at 236 Massachusetts Ave., NE, Suite 203, Washington, DC 20002. Headquartered in Denver, CO, AHA is the national is a national, non-profit organization dedicated to protecting children and animals from cruelty, neglect and exploitation. It has 6500 organizational members and 160,000 individual members nationwide.

Petitioner **Breast Cancer Action Montreal** is located at 5890 Monkland Ave., Montreal, PQ H4A 1G2, Canada. It is a grassroots advocacy group run by women with breast cancer. It seeks to educate women about breast cancer prevention.

Petitioner **Community Nutrition Institute (CNI)** is located at 910 17th Street, N.W., #413, Washington, D.C. 20006. CNI is a non-profit organization founded in 1969 with a special focus on food policy. From the beginning, CNI has been a leading advocate for consumer protection, food program development and management, and sound federal diet and health policies. The Institute provides policy analysis, information, and education to consumers, program managers, federal agencies, and lawmakers.

Petitioner **Corporate Agribusiness Research Project** is located at P.O. Box 2201, Everett, Washington 98203-020. Petitioner monitors corporate agribusiness from a public interest perspective.

Petitioner **Family Farm Defenders** is located at Box 581 Hillsboro, WI 54634. A coalition of organizations and individuals committed to the creation of farmer-controlled and consumer-oriented food and fiber production. We adhere to the principle of democracy by empowering farmers to speak for and represent themselves in the quest of economic justice and responsible sustainable agricultural policies.

Petitioner **Gateway Green Alliance** is located at PO Box 8094, St. Louis, MO 63156.

Petitioner advances environmental justice and economic equity, eliminates toxic hazards such as landfills and incinerators, and promotes political empowerment and fairness.

Petitioner **Greenpeace International** is located at Keizersgracht 176, 1016 DM Amsterdam, The Netherlands. It is one of the world's major environmental organizations with offices in 33 countries, including the United States, and over 3 million donating supporters worldwide. Greenpeace is a non-profit organization devoted to the protection of the environment with an emphasis on global environmental problems such as climate change and protection of the ozone layer, prevention of nuclear, chemical and biological pollution and the defense of biodiversity.

Petitioner **Humane Society of the United States (HSUS)** is located at 2100 L Street, NW, Washington, DC 20037. The Humane Society of the United States is the nation's largest animal-protection organization, with more than 5 million constituents. The HSUS was founded in 1954 to promote the humane treatment of animals and to foster respect, understanding, and compassion for all creatures.

Petitioner **Institute for Agricultural and Trade Policy (IATP)** is located at 2105 1st Avenue South, Minneapolis, MN 55404-2505. IATP was established in 1986 as a nonprofit and tax exempt research and education organization. Our mission is to create environmentally and economically sustainable communities and regions through sound agriculture and trade policy. The Institute assists public interest organizations in effectively influencing both domestic and international policymaking.

Petitioner **Institute for Food and Development Policy (Food First)** is located at 398 60th Street, Oakland, CA 94618. Food First is a member-supported, non-profit "peoples" think tank and education-for-action center. Its work highlights root causes and value-based solutions to hunger and poverty around the world, with a commitment to establishing food as a fundamental human right.

Petitioner **LaMontanita Co-op** is located at 3500 Central Ave. SE, Albuquerque, NM 87106.

Petitioner **Mothers & Others for a Liveable Planet** is located at 40 West 20th Street, 11th Floor, New York, NY 10011-4211. Mothers & Others, a national nonprofit education organization, works to promote consumer choices which are safe and ecologically sustainable for this generation and the next. By providing strategies that can reduce individual and community consumption of natural resources, and by mobilizing consumers to seek sustainable choices, we aim to effect lasting protection of public health and the environment.

Petitioner **North American Farm Alliance** is located at P.O. Box 747, Covert, MI 49038.

Petitioner **Organic Trade Association** is located at P.O. Box 1078, Greenfield, MA 01302. The Organic Trade Association is the membership-based business association representing all sectors of the organic industry in North America. OTA's goal is to encourage global sustainability through promoting and protecting the growth of diverse organic trade. Petitioner **Rural Vermont** is located at 15 Barre Street, Montpelier, VT 05602. Founded in 1985, Rural Vermont is a farm and rural advocacy organization. One of its primary goals is to join the interests of farmers and consumers in order to support a healthy food supply, sustainable agriculture and strong rural economy.

Petitioner **Sierra Club, Virginia Chapter** is located at route 1, Box 1890, Palmyra, VA 22963. The Virginia Chapter of the Sierra Club is Virginia's branch of the nation's foremost grassroots environmental organization. With 11,000 members statewide, Chapter volunteers work to pass pro-environment legislation in the Virginia General Assembly, to advocate sound environmental policy at the state and local levels, and to assist the National Sierra Club in its work on federal issues.

Petitioner **Vermont Public Interest Research Group (VPIRG)** is located at 64 Main Street, Montpelier, VT 05602. Established in 1972, VPIRG has grown into Vermont's largest consumer and environmental organization with over 20,000 members. The Vermont Public Interest Research Group is a statewide nonprofit organization dedicated to education, lobbying and advocacy on fundamental issues affecting Vermonters. They have prioritized the issues of environmental health, energy conservation and consumer protection.

Petitioner **Wisconsin Organic Crop Improvement Association**, Chapter #1 is located at RR 1, Box 1198, Soldiers Grove, WI 54655-9717.

Petitioner **Cissy Bowman** is located at 8364 S SR 39, Clayton, IN 46118. Petitioner is Vice President of the Organic Farmers Marketing Association and owner of Center Valley Organic Farm. Petitioner represents the following organizations: Hoosier Organic Marketing Education (HOME) (a non-profit organization dedicating to providing educational information to the public about organic farming and food); Indiana Certified Organic, Inc. (ICO) (a certifier of organic operations); Organic Farmers Information and Education Foundation (OFIEF) (a non-profit foundation whose purpose is to provide public information and education on organic farming to enhance food security and the environment); the Indiana Organic Peer Review Panel and the Indiana Farmers Union.

Petitioner **Judy Brady** resides at 62 Sussex Street, San Francisco 94131. She is a writer and political trainer for the Women's Cancer Resource Center in Berkeley, CA. She is also a board member of Green Action, an environmental justice organization.

STATEMENT OF GROUNDS

I. Statement of the Law

A. 21 U.S.C. § 360b, in pertinent part, states:

(e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to health of man or animals.

(1) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application filed pursuant to subsection (b) with respect to any new animal drug if the Secretary finds--

(A) 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 or the condition of use authorized under subsection (a)(4)(A);

(B) that new evidence not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved or that subparagraph (I) of paragraph (1) of subsection (d) applies to such drug;

(C) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that such drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(D) the patent information prescribed by subsection (c)(3) was not filed within 30 days after the receipt of written notice from the Secretary specifying the failure to file such information;

(E) that the application contains any untrue statement of a material fact; or

(F) that the applicant has made any changes from the standpoint of safety or effectiveness beyond the variations provided for in the application unless he has supplemented the application by filing with the Secretary adequate information respecting all such changes and unless there is in effect an approval of the supplemental application. The supplemental application shall be treated in the same manner as the original application.

If the Secretary (or in his absence the officer acting as 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, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited

hearing under this subsection; but the authority conferred by this sentence to suspend the approval of an application shall not be delegated.

(2) The Secretary may also, after due notice and opportunity for hearing to the applicant, issue an order withdrawing the approval of an application with respect to any new animal drug under this section if the Secretary finds--

(A) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under subsection (1), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection;

(B) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or

(C) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

(3) Any order under this subsection shall state the findings upon which it is based.

B. Administrative Procedure Act, 5 U.S.C. Section 706, Scope of Review.

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning and applicability of the terms of an agency action. The reviewing court shall --

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings and conclusions found to be -- (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

II. Statement of Fact

A. Background Information Concerning rBGH.

Bovine Growth Hormone is a natural protein produced by the pituitary gland of cattle. The hormone has a variety of effects including the stimulation of milk production. Scientists are now able to genetically engineer large quantities of synthetic Bovine Growth Hormone. The gene responsible for natural production of Bovine Growth Hormone in cattle was isolated, genetically modified through the substitution of an amino terminal methionine and transferred into bacterial cells. These bacteria are then "programmed" to mass produce modified or recombinant Bovine Growth Hormone (rBGH). This version of rBGH differs in molecular structure from naturally occurring Bovine Growth Hormone by the substitution of methionine for alanine on the NH₂ terminus end.⁽⁴⁾

Synthetic Bovine Growth Hormone (rBGH) (also referred to as bovine somatotropin (rBST)) produced through genetic engineering is injected into cattle to increase milk production. The current consensus is that cows given rBGH increase their milk production by an average of between 10 and 25 percent. The hormone is not used for any therapeutic purpose in animals or to treat any negative animal health indication.

In the early and mid-1980's, the FDA granted the four companies Investigative New Animal Drug (INAD) approvals for rBGH, which allowed for research use of rBGH on cows, and approved the human consumption of test rBGH-derived dairy products. Currently, rBGH is being manufactured by Monsanto Co. and sold in the United States under the brand name Posilac®.

Despite increasing evidence that rBGH had significant health impacts on animals and humans, on November 5, 1993, the FDA approved the new animal drug application (NADA) for Monsanto Co.'s Posilac®. 58 Federal Register 59946 (November 12, 1993). This initial approval was reviewed by the United States District Court. See Stauber v. Shalala, 895 F. Supp. 1178 (E.D Wis.1994).

B. New Evidence of Imminent Human Health Hazard.

1. New Evidence of Oral Activity and Absorption of rBGH.

In 1990, the FDA published a justification for its determination that milk and dairy products derived from rBGH-treated cows was "safe for human consumption."⁽⁵⁾ The article contained seven tables of data supporting its conclusion, including two tables of data taken from an unpublished Monsanto study of rats orally fed rBGH at high levels. Attach. 1, at App. VI. In its 1990 conclusion, FDA officials state that the this ninety (90) day rat feeding study showed that rBGH "is not orally active in rats"⁽⁶⁾ and found that, "No oral activity was found when rBGH was administered to rats at exaggerate doses."⁽⁷⁾ The FDA officials summarized this by stating, "No toxicologically significant changes were noted in the clinical chemistry, hematology, or urinalysis parameters determined in rats administered rbGH orally."⁽⁸⁾

On April 21, 1998, however, health officials from Health Canada issued a comprehensive report finding, *inter alia*, gaps in the scientific data used in FDA's review of human health risks associated with rBGH use.⁽⁹⁾ Attach. 1. This Health Canada review included a thorough analysis of the comprehensive data reviewed by the FDA during its decisionmaking process. Attach. 1, at 7.

Contrary to FDA's conclusions, the Health Canada data review found evidence that laboratory rats orally fed high doses of rBGH were absorbing the substance. More specifically, the report details that a Monsanto ninety (90) day rat feeding study actually found that between twenty (20%) and thirty (30%) of the rats in the study developed primary antibody response to rBGH - an indication that orally administered rBGH was absorbed into the blood stream and it produced a distinct immunological effect. Attach. 1, at 28. Additionally, the data showed that in the male rats cysts formed in the thyroid and an increase infiltration of rBGH into the prostate.⁽¹⁰⁾ Attach. 2, at 3.

Health Canada report's found that the publicly released summary of safety and effectiveness data and information supporting Posilac's new animal drug application⁽¹¹⁾ used during the FDA decisionmaking process on rBGH did not include the ninety (90) day rat study results or a discussion of its findings. Attach. 2.

2. New Evidence Concerning IGF-1.

A. New Evidence of IGF-1 Surviving Digestion.

Insulin-like Growth Factor 1 (IGF-1) is a biochemical that mediates much of the cellular response to human growth hormone in cows and humans. In 1990, the FDA found that IGF-1 does not survive digestion based on oral rat feeding studies.⁽¹²⁾ A number of scientists have disputed this finding indicating that the FDA's own data suggests that IGF-1 survives digestion.⁽¹³⁾ Attach. 3, at 8. In addition, several oral rat feeding studies published since the FDA approval of Posilac® (rBGH) have confirmed that IGF-1 survives digestion, particularly when it is in the presence of the milk protein casein. The first study found that IGF-1 survived digestion in rat's stomachs and made its way into the intestine.⁽¹⁴⁾ Attach. 3, at 8. A more recent study found that considerable amounts of IGF-1 were absorbed into the systematic circulation and was physiologically active in rats.⁽¹⁵⁾ As a result, new evidence contradicts the FDA's previous findings that IGF-1 does not survive digestion.

B. New Evidence of IGF-1 Human Health Risks.

FDA has been presented ample data showing the levels of IGF-1 are elevated in milk from rBGH treated cows.⁽¹⁶⁾ Attach 1., at 2; Attach. 3 at 3-6. The Health Canada report also found that the potential adverse effect of elevated IGF-1 levels were not examined until 1995, significantly after the FDA approved Posilac®. Attach. 1, at 26. The Canadian

report continues that when IGF-1 was discussed, it based upon purely speculative reasoning and the rationale for not requiring chronic toxicity or teratology/reproductive studies was premised upon rBGH not being orally absorbed. Attach. 1, at 26. The FDA's failure to thoroughly analyze the human health impacts associated with elevated IGF-1 levels is grossly negligent. IGF-I is thought to be important growth factor in breast cancer,⁽¹⁷⁾ prostate cancer,⁽¹⁸⁾ and colon cancer.⁽¹⁹⁾ Such data mandate s the FDA to follow up the results of the ninety (90) day rat study.

3. New Evidence Concerning rBGH and BSE Exposure

Several lines of new evidence suggest that the use of rBGH could increase the risk of bovine spongiform encephalopathy (BSE) in dairy cows. There are two mechanism whereby rBGH could potentially lead to an increase in BSE. First, increased circulating IGF-1 levels might increase a cow's susceptibility to BSE should an animal be exposed to the infectious agent. Attach. 3, at 18-23. Second, rBGH treated cow's increased protein feed needs could magnify the odds of exposure to a BSE-infective agent. Attach. 3, at 18-23. This risk should be thoroughly reviewed by the FDA during any new evidentiary investigation concerning Monsanto's Posilac® NADA.

4. Current FDA Response.

In its 1990 human health determination the agency states, "If the initial toxicity study demonstrates that the protein (rBGH) is indeed orally active, additional testing may be required."⁽²⁰⁾ Such testing has not occurred. Since release of the Health Canada study, FDA, Center for Veterinary Medicine official, John Scheid stated, "We do not have data from that study."⁽²¹⁾ The FDA has further characterized its failure to review and follow up on the rat study findings as a reliance upon Monsanto's summary of the study as non-pivotal.⁽²²⁾

As characterized by the Health Canada reviewers, "The human health implications of the immunological findings in rats should have been thoroughly evaluated and dismissed only if adequately justified by evidence at the time." Attach. 1, at 26. The Health Canada study states, "Definitive studies demonstrating the lack of absorption of rBST or IGF-I upon oral administration were neither conducted or requested." Attach. 1, at 26. The report also found that "simply not enough is known about how IGF-I functions to properly evaluate the potential health impacts." Attach. 1, at 25. In sum, the Health Canada report reveals that to date the FDA has failed to fully evaluate the human health risks associated with oral exposure to rBGH.

III. Argument

The Federal Food, Drug and Cosmetic Act (FFDCA) is to be construed liberally to effectuate its overriding purpose to protect the public health. United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784 (1969). Under such a mandate, approval for sale of new animal drugs is premised upon applicant demonstrating that it is both safe and effective for its intended use. A.L. Pharma v. Shalala, 62 F. 3d 1484 (D.C. Cir. 1995). The burden on a new animal drug application (NADA) petitioner is not light and includes, but is not limited to, the proffering of (1) adequate tests by all methods reasonably applicable to show whether the drug is safe for use under the conditions suggested in the proposed labeling; and (2) evidence consisting of adequate and well-controlled investigations, including field investigation, on the basis of which it could be fairly and reasonably concluded by experts that the drug has the effect it purports to have. American Cyanamid Co. v. Young, 770 F. 2d 1213, 1218 (D.C. Cir. 1985). If these requirements are not met, the FDA's charge is to reject the new animal drug application. See Masti-Kure Products Co., Inc. v. Califano, 587 F.2d 1099, 1104 (D.C. Cir. 1978).

The new evidence released by Health Canada indicates that FDA failed to ensure that (1) Posilac® (rBGH) was adequately tested to show its safe use and (2) that the evidence supporting Monsanto's original NADA approval consisted of adequate and well-controlled investigations. Moreover, the evidence showing that possible human health risks associated with oral ingestion of rBGH were not adequately studied by the NADA applicant Monsanto and not thoroughly reviewed by the FDA during its administrative review. As a result, either Monsanto failed to meet the informational burden necessary to garner approval of its rBGH NADA and the FDA acted arbitrarily and capriciously in its evaluation of the data used to support its approval of Posilac®.

In identifying major shortcomings in the data used by the FDA for the approval of Posilac®, the Health Canada study triggers agency action to investigate and withdraw the NADA approval of rBGH. Under 21 U.S.C. § 360b(e)(1)(B) the Commissioner may withdraw an new animal drug application approval if new evidence not available to the Secretary until after such application was approved, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved. Court decisions suggest that this is not a discretionary duty.

If the FDA did not have the ninety (90) day rat testing information available when it approved Posilac®, then the Health Canada report is new evidence that suggests that oral consumption of rBGH may trigger human health risks.⁽²³⁾ As such, the Commissioner should suspend Posilac's NADA approval and immediately embark on an investigation of the human health risks associated with rBGH exposure. A failure to take such action

could be subject to judicial review. In Rhone-Poulenc, Inc v. FDA, the court indicated that the Commissioner must withdraw her approval when new evidence shows an animal drug to be unsafe. 636 F.2d 750, 752 (D.C. Cir. 1980) (upholding the FDA's order withdrawing new animal drug approval for the use of diethylstilbestrol (DES)). Failing to investigate this new scientific evidence concerning possible human health risks would be contrary to the overarching intent of the FFDCRA and a clear error in agency judgment.

In making a factual inquiry concerning whether an agency decision was "arbitrary and capricious," a reviewing court must consider whether the decision was based on a reasoned evaluation of the relevant factors and whether there has been a clear error of judgment. Marsh v. Oregon Natural Resources Council, 490 U.S. 360, 378 (1989). An agency must cogently explain why it has made a particular decision and enable a court to conclude that it was the product of reasoned decisionmaking. See Motor Vehicle Mfrs. Assn. v. Sate Farm Mut. Auto. Ins. Co., 463 U.S. 29 (1983). In this instance, the FDA has provided no explanation as to why it ignored evidence of the ninety (90) day rat study and rBGH's oral activity. Now that this evidence is clearly before the agency, failing to further investigate evidence of human health risk could only be concluded as unreasoned decisionmaking.

ENVIRONMENTAL IMPACT

The enforcement actions here requested will not cause the release of any substance into the environment. They are categorically excluded from the requirement of environmental documentation under 21 C.F.R. § 25.33(g).

CERTIFICATION

The undersigned certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data known to the petitioner which are unfavorable to the petition.

CONCLUSION

Wherefore the reasons contained herein, the petitioner request that the Commissioner:

(1). Immediately suspend the approval of the new animal drug application for Posilac® - recombinant bovine growth hormone (rBGH);

(2). Immediately publish a Notice of Opportunity for an Evidentiary Hearing concerning "new evidence" related to the new animal drug application approval of Posilac® (rBGH) in the Federal Register;

(3). Upon completion of the hearing, issue an order withdrawing the approval of the new animal drug application for Posilac® (rBGH); *and*

(4). Revoke all regulations associated with the approval of Posilac® (rBGH) including those found at 21 C.F.R. § 522.2112.

As established in 21 C.F.R. § 10.30(e)(2), petitioners request that the agency provide an answer to this citizen petition within 180 days.

Respectfully submitted,

Andrew Kimbrell

Executive Director

Joseph Mendelson, III

Legal Director

Center for Food Safety,

c/o International Center for

Technology Assessment

310 D Street, NE

Washington, DC 20002

Attorneys for Petitioners

Dated: 15 December 1998

ENDNOTES

1. The right to petition for redress of grievances is among the most precious of the liberties safeguarded by the Bill of Rights. United Mine Workers of America, Dist. 12 v. Illinois State Bar Association, 389 U.S. 217, 222, 88 S. Ct. 353, 356, 19 L. Ed. 2d 426 (1967). It shares the "preferred place" accorded in our system of government to the First Amendment freedoms, and has a sanctity and a sanction not permitting dubious intrusions. Thomas v. Collins, 323 U.S. 516, 530, 65 S. Ct. 315, 322, 89 L. Ed. 430 (1945). Any attempt to restrict those First Amendment liberties must be justified by clear public interest, threatened not

doubtful or remotely, but by clear and present danger." *Id.* The Supreme Court has recognized that the right to petition is logically implicit in, and fundamental to, the very idea of a republican form of government. United States v. Cruikshank, 92 U.S. (2 Otto) 542, 552, 23 L. Ed. 588 (1875)

2. 5 U.S.C. § 553(e) (1995).

3. 21 C.F.R. §§ 10.20,10.30 (1998).

4. Juskevich, J.C. and Guyer C.G., "Bovine Growth Hormone: Human Food Safety Evaluation," Science 249: 875-884 (August 24, 1990) at 877.

5. Id.

6. Id. at 875

7. Id. at 883.

8. Id. at 878

9. Chopra, S. , et al., "rBST (Nutrilac) "Gaps Analysis" Report," rBST Internal Review Team, Health Protection Branch, Health Canada (April 21, 1998).

10. Health Canada, Minutes of Meeting: Internal RBST Review Team, BVD AD HOC Advisory Committee (May 6, 1997).

11. See 58 Federal Register 59946, 59947 (November 12, 1993).

12. Juskevich, at 880.

13. See also, Epstein, SS. "Unlabeled Milk from Cows Treated with Biosynthetic Growth Hormones: A Case of Regulatory Abdication," Int. J. Health Serv. 1996: 26(1): 173-85.

14. See also, Xian, CJ, et al., "Degradation of IGF-1 in the Adult Rat Gastrointestinal Tract is Limited by A Specific Antiserum or Dietary Protein Casein," J. Endocrinology, 1995: 146: 215-225.

15. Kimura, T., et al., "Gastrointestinal Absorption of Recombinant Human Insulin-like Growth Factor-1 in Rats," J. Pharm. & Exper. Therap., 1997: 283: 611-618.

16. See also, Epstein, SS.

17. See e.g., Ng EH, et al., "Altered Serum Levels of Insulin-like Growth Factor Binding proteins in Breast Cancer Patients," Ann. Surg. Oncol. 1998 Mar; 5 (2): 194-201.

18. See e.g., Wolk, A, et al. "Insulin-like Growth Factor 1 and Cancer Risk," J. Natl. Cancer Inst. 1988 June 17; 90(12):911-5.

19. See e.g., Lamonerie, T., et al., "IGF-2 Autocrine Stimulation in Tumorigenic Clones of a Human Colon-Carcinoma Line," Int. J. Cancer 1995 May 16; 61(4): 587-92.

20. Juskevich, at 876.

21. Frederick Bever (AP), "Canadian Agency Questions Approval of Cow Drug by U.S.," Rutland Herald, October 6, 1998.

22. Id.

23. Material supporting this petition has also been transmitted to Secretary of Health and Human Services, Donna Shalala via correspondence from Senators James Jeffords and Patrick Leahy dated December 3, 1998. See Attach. 4.

