FOOD SAFETY VS. PROMOTION OF INDUSTRY: CAN THE USDA PROTECT AMERICANS FROM BOVINE SPONGIFORM ENCEPHALOPATHY?†

GREGORY L. BERLOWITZ*

When bovine spongiform encephalopathy (BSE), or mad cow disease, first struck the United States in December 2003, a debate raged over whether the tragedy that decimated Great Britain's beef industry had finally reached U.S. shores, or whether the infected cow was an anomaly which had somehow broken through a BSE "fire-wall." After major importers halted importation of U.S. beef, the United States Department of Agriculture (USDA) announced long-awaited new regulations, including increased testing for BSE. Shortly thereafter, two private producers petitioned the USDA for permission to test their own cattle for BSE, and were turned down on the authority of the 1913 Virus, Serum, and Toxin Act (VSTA).

† *Author's Note.* At the time this note was written, Japan had refused to open its markets to U.S. beef, although, as indicated within, Japan appeared to be succumbing to U.S. lobbying efforts. The American pressure paid off, and on December 11, 2005, Japan reopened its market to American beef products from cattle 20 months and younger. *See* Statement, Agric. Sec'y Mike Johanns Regarding the Opening of the Japanese Market to U.S. Beef, Dec. 11, 2005, http://www.usda.gov/ (follow "Newsroom" hyperlink; then follow "Latest Releases" hyperlink; then search by date) (last visited Jan. 20, 2006).

Hong Kong and Singapore followed suit shortly after. *See* Statement, Agric. Sec'y Mike Johanns Regarding Resumption of U.S. Beef Trade with Hong Kong, Dec. 29, 2005, http://www.usda.gov/ (follow "Newsroom" hyperlink; then follow "Latest Releases" hyperlink; then search by date) (last visited Jan. 20, 2006); News Release, Singapore Reopens Market to U.S. Beef, Jan. 19, 2006, http://www.usda.gov/ (follow "Newsroom" hyperlink; then follow "Latest Releases" hyperlink; then search by date) (last visited Jan. 20, 2006). Japan didn't last long. On January 20, 2006, it reimposed a complete ban on American cattle after receiving an American shipment containing beef with vertebral column. *See New U.S. Beef Import in Japan*, BBC NEWS ONLINE, January 20, 2006, http://news.bbc.co.uk/go/pr/fr//2/hi/business/4631580.stm. The USDA claimed the vertebral column wasn't specified risk material, but conceded it was a violation of the agreement between the United States and Japan. *See* Statement, Agric. Sec'y Mike Johanns Regarding U.S. Beef Exports to Japan, January 20, 2006, http://www.usda.gov/ (follow "Newsroom" hyperlink; then follow "Latest Releases" hyperlink; then search by date) (last visited Jan. 20, 2006).

To be sure, while the $1.4 billion Japanese market may eventually reopen to American beef, until the BSE problem is addressed more satisfactorily, similar intractable issues will remain.

* J.D. Candidate, University of Illinois College of Law; B.A., Hampshire College (1993). I want to thank the Institute for Agriculture and Trade Policy, especially Kristin Dawkins, Steve Suppan, and Mark Ritchie, and the Farmers Legal Action Group, especially Carl Flink, Jess Anna Speier and David Moeller, for their inestimable assistance and support at the birth of this project. Additionally, many thanks to Amy Dickerson, Ashley Burden and Bryan Endres for their helpful insight, critiques,and fine tuning of this note. Finally, my deepest appreciation goes to Laura for supporting me not only throughout the writing of this note, but through three years of law school in Champaign, Illinois. And to Miles APB—thank you for you.

The second case of BSE in the United States arrived among a mixture of criticism and praise. While some claimed the USDA's regulations were inadequate and unenforced, others pointed at the agency's BSE controls as minimizing BSE's impact on the American cattle herd. Either way, the second BSE case revealed inconsistencies in USDA policy and pointed to the need for a more comprehensive BSE prevention policy.

This note examines and questions the efficacy of the USDA's BSE testing policies. The author notes that the USDA inconsistently enforces BSE prevention regulations and argues that increased testing is necessary. The author also contends that the VSTA does not authorize the USDA to prevent cattle producers from testing their cattle for BSE.

To resolve the problem, the author recommends that the USDA create a comprehensive BSE testing and tracking policy. The author suggests that, among other things, the USDA widen the scope of testing to include younger cows and more random tests. Moreover, the USDA should license and regulate voluntary BSE testing. Finally, the author proposes that tracking, labeling, and mandatory recall policies and procedures be implemented by the USDA to more closely follow and contain the disease.

I. INTRODUCTION

Americans consume more beef than any other people in any other country in the world.[1] We slaughter and eat roughly thirty-five million cattle per year,[2] approximately one-eighth of a cow per person annually. We relish our hamburgers, steaks, tacos, chili, meatloaf, and stews. Bone marrow from cattle carcasses is turned into gelatin for marshmallows, candy, jelly, dairy, and diet products.[3] Dozens of common products—including soap, toothpaste, mouthwash, shaving cream, deodorant, cosmetics, pet food, pharmaceuticals, vitamins, antifreeze, asphalt, insecticides, and, of course, leather[4]—contain by-products of the beef industry.[5]

1. *See* Beef and Veal Summary Selected Countries, http://www.fas.usda.gov/dlp/circular/2004/04-10LP/bf_sum.pdf (last visited Mar. 17, 2005).

2. *See* Background Statistics: U.S. Beef and Cattle Industry, Economic Research Service, United States Department of Agriculture, http://www.ers.usda.gov/News/BSECoverage.htm (last visited Mar. 17, 2005).

3. Stephanie Simon, *Cows Come Home in Host of Products, One Animal Goes a Long Ways in Terms of Numbers of Uses*, L.A. TIMES, *reprinted in* SEATTLE TIMES, Jan. 6, 2004, at A1.

4. Leather spawns an entire other industry, worth approximately $1.8 billion annually in the United States alone. *See, e.g.*, Leather Statistics, Exporting Countries of Leather and Leather Products, http://www.indianleatherportal.com/leather-statistics/leather-exporting-countries.html (last visited Mar. 17, 2005).

5. *See* Ask the Meatman, Beef By-Products, http://www.askthemeatman.com/beef%20by%20products.htm (last visited Mar. 17, 2005).

Not only is our beef supply ample, but we proudly name it the safest in the world.[6]

Until December 23, 2003, bovine spongiform encephalopathy (BSE), popularly known as mad cow disease for its brain-destroying properties which cause its victims to act erratically, was a plight spreading primarily in Europe and Asia, most devastatingly in Britain.[7] The disease's distance from American cattle markets, however, did not mean the United States was unaware or unafraid of BSE. In response to a crisis which caused the death of more than 160 people, the incineration of millions of cattle, and billions of dollars in losses,[8] American officials ceased importation of beef from countries with BSE beginning in 1989 and banned the use of feed containing certain cattle parts,[9] thought to be a significant link in the causal chain of BSE,[10] in 1997.[11]

The motivations for preventing a BSE outbreak in the United States were manifold. Not only was BSE deadly to cattle, but its human counterpart, variant Creutzfeldt-Jakob Disease (vCJD) is fatal and untreatable in human beings.[12] In addition, intense debate arose concerning the possible impact of BSE on American health and the American beef industry, ranging from severe to destructive, from fear-mongering to outright denial.[13] American officials were all too aware of BSE's devastating

6. *See* BSEInfo.org, The Source for Bovine Spongiform Encephalopathy Information, http://www.bseinfo.org/ (last visited Sept. 19, 2005) (This web site is owned and operated by Cattlemen's Beef Board & National Cattlemen's Beef Association.); s*ee also* USAgNet, *AMI: U.S. Beef is Safe, Despite BSE Possibility*, WISCONSIN AG CONNECTION, Nov. 19, 2004, http://www.wisconsinagconnection.com/story-national.cfm?Id=1213&yr=2004 (last visited Mar. 17, 2005).

7. Op-Ed, *How Now Mad Cow? Are We Being Too Casual with Fatal Disease?*, PHILA. DAILY NEWS, Aug. 9, 2005, at 13.

8. *See* John Darnton, *The Logic of the "Mad Cow" Scare*, N.Y. TIMES, Mar. 31, 1996, § 4, at 1.

9. *See* Press Release, USDA Restricts Imports of Animals and Animal Products from Europe (Dec. 12, 1997), http://www.aphis.usda.gov/lpa/ news/1997/12/EUBSE.HTM (last visited Mar. 17, 2005). Although the USDA commonly refers to the feed restrictions as banning feeding "ruminants to ruminants," in fact the ban excludes cattle blood which is fed to cattle and which can transmit BSE. *See* Donald G. McNeil, Jr., *Testing Changes Ordered After U.S. Mad Cow Case*, N.Y. TIMES, June 25, 2005, at 47; Editorial, *Safer Beef*, N.Y. TIMES, Aug. 13, 2005, at A10 [hereinafter *Safer Beef*].

10. *See* APHIS News & Info., Bovine Spongiform Encephalopathy, http://www.aphis.usda.gov/lpa/pubs/fsheet_faq_notice/fs_ahbse.html (last visited Mar. 17, 2005).

11. The efficacy of this feed ban is the subject of fierce debate. *See USDA Admits to 1000 Violations of Mad Cow Rules*, REUTERS, August 15, 2005, http://www.organicconsumers.org/madcow/violations [hereinafter *1000 Violations*]; *see also* Posting of John Stauber, stauber@tds.net, to madcow@lists.iatp.org (June 29, 2005) (on file with author) ("The 1997 regulations which required feed mills to label cattle meat and bone 'Do Not Feed to Ruminants' specifically EXEMPTED CATTLE BLOOD AND CATTLE FAT, which continue to be fed to calves and cattle legally and in massive quantities. . . . In early 2004 the now-head of the Food and Drug Administration, Dr. Lester Crawford, testified before Congress on the need to ban the feeding of ruminant blood to ruminants in the U.S. Yet, the practice continues.")

12. *See* World Health Org. [WHO], Variant Creutzfeldt-Jakob disease, Nov. 2002, http://www.who.int/mediacentre/factsheets/fs180/en/index.html (last visited Mar. 17, 2005).

13. *See* SHELDON RAMPTON & JOHN STAUBER, MAD COW U.S.A. (2004); Jeffrey Kluger, *Could Mad—Cow Strike Here? A Year After the British Cattle Scare, Some Scientists Fear a Broader Outbreak of the Mysterious Disease*, TIME, Jan. 27, 1997, at 52. *But see Mad Cow Not a Problem in the U.S.*, NCBA News, National Cattlemen's Beef Association, http://www.beef.org/dsp/dsp_content.cfm?locationId=217&contentId=271&contentTypeId=2 (last visited Mar. 17, 2005).

effect on the British meat industry and were determined not to permit similar circumstances to unfold here.[14]

Unfortunately, the American luck did not last. On December 23, 2003, BSE arrived in the United States.[15] A cattle farm's discovery of a BSE-infected cow in Washington state made international news.[16] The global audience instantly reacted. The two largest American beef importers, Mexico and Japan,[17] halted all shipments of American beef, as did South Korea, Australia, Singapore, Hong Kong, Thailand, Taiwan, Malaysia, and Russia.[18]

The United States Department of Agriculture (USDA), mandated by Congress to protect the health and welfare of the people of the United States,[19] held multiple press conferences which were broadcast worldwide, in part to assure the world that the infected cow was of Canadian origin.[20] Media worldwide shined its spotlights on BSE, with reports dominating newspapers and airwaves through the Christmas and New Year season.[21] The American beef industry, whose exports were worth more than $70 billion annually,[22] assured the American public that the American beef supply was safe.[23]

As a result of the incident, the USDA issued a series of new regulations designed to increase protection against BSE.[24] In addition, the United States Food and Drug Administration (FDA) released two in-

14. Sandra Blakeslee, *Stringent Steps Taken by U.S. on Cow Illness*, N.Y. TIMES, Jan. 14, 2001, at 1.

15. *See* Sec'y Ann M. Veneman, News Conference on BSE (Dec. 23, 2003), *available at* http://www.usda.gov (follow "Newsroom" hyperlink; then follow "transcripts and speeches" hyperlink).

16. *See U.S. Confirms First "Mad Cow" Case*, BBC NEWS ONLINE, Dec. 25, 2003, http://news.bbc.co.uk/1/hi/world/americas/3348293.stm.

17. The Japanese beef market is worth more than $1.7 billion to American producers. *See* Statement, Agric. Sec'y Ann M. Veneman Regarding Resumption of Beef Trade with Japan, Oct. 23, 2004, http://www.usda.gov/ (follow "Newsroom" hyperlink; then follow "Latest Releases" hyperlink; then search by date) (last visited Mar. 17, 2005).

18. *See U.S. Mad Cow Scare Spreads to Asia, Mexico, Brazil*, U.S.A. TODAY, Dec. 24, 2003; *see also Countries Take Steps to Ban U.S. Beef*, WALL ST. J., Dec. 24, 2003.

19. *See* Animal Health Protection Act, 7 U.S.C.A. §§ 8301(1)(B), (5)(B)(iii) (West Supp. 2005).

20. *See* Statement, USDA BSE Update (Dec. 27, 2003), http://www.usda.gov/Newsroom/0445.03.html (last visited Sept. 19, 2005).

21. *See* David Rennie, *Nations Bar American Beef After First Mad Cow Case*, THE DAILY TELEGRAPH (London), Dec. 26, 2003, at 8; *Scarce Beef Up Stocks*, HERALD SUN (Melbourne), Dec. 25, 2003, at World 21; Alla Startseva, *Mad Cow in America Prompts Ban on Beef*, MOSCOW TIMES, Dec. 25, 2003, at 2834; Taig Uranka, *Japan's Eateries, Stores in Shock*, THE JAPANESE TIMES, Dec. 25, 2003.

22. *See* Foreign Agric. Services, U.S. Dep't of Agric., Global Cattle and Beef Statistics, Beef and Veal Summary Selected Countries (2004), http://www.fas.usda.gov/dlp/circular/2004/04-10LP/bf_sum.pdf (last visited Mar. 17, 2005).

23. *See* BSE Update from NCBA (Dec. 28, 2003), http://www.texascattleraisers.org/tscra2003/BSE_Info_Page/bse_update_from_ncba_12.28.03.htm (last visited Mar. 17, 2005); *see also* Sherri Day, *A Time for Finesse: Marketing Beef After a Mad Cow Discovery*, N. Y. TIMES, Jan. 1, 2004, at C1.

24. *See* Sec'y Ann M. Veneman, Announcing Additional Protection Measures to Guard Against BSE (Dec. 30, 2003), *available at* http://www.usda.gov/Newsroom/0450.03.html.

terim final rules to help prevent BSE.[25] Within days of the discovery, however, beef stock prices plummeted, followed by weakening sales.[26] In response, the beef industry attempted to influence public opinion by filming nondiseased cattle and sending the films to more than two dozen national, cable and local television stations.[27]

But as Britain had already learned, the BSE label was difficult, or impossible, to shake. On June 24, 2005, a second cow with BSE was discovered in the United States.[28] Unlike the cow in the first American BSE case, which tested immediately positive for BSE, and which the USDA was quick to announce was of Canadian origin, this cow was of American origin.[29] But even more disturbing was that this cow had been tested for BSE in November 2004, only seven months earlier. At that time, however, the test results were "inconclusive."[30] The sample had been retested only on the recommendation of the USDA's Office of Inspector General during its investigation of the USDA's handling of BSE.[31]

While the first case of BSE in the United States was quickly written off as a Canadian problem which had slipped over the U.S. border, the second is more difficult to regard as an anomaly, especially when the USDA's own surveillance system failed to detect it. Even though at the time of this writing there have been no more American cases, it is all but certain that more cases will arise.[32] Moreover, Japan—the largest international importer[33]—still has not resumed American beef imports, although it recently began to be persuaded by American negotiators.[34]

25. *See* News Release, U.S. Dep't of Health and Human Services, Expanded "Mad Cow" Safeguards Announced To Strengthen Existing Firewalls Against BSE Transmission (Jan. 26, 2004), http://www.hhs.gov/news/press/2004pres/20040126.html (last visited Mar. 17, 2005).

26. *See* Jennifer Bayot, *Mad Cow Disease in the United States: The Market; Many Stocks Linked to Beef Continue Fall*, N.Y. TIMES, Dec. 27, 2003, at A14.

27. *See* Day, *supra* note 23.

28. *See* News Release, USDA Announces BSE Test Results and New BSE Confirmatory Testing Policy (June 24, 2005), *available at* http://www.usda.gov (follow "Newsroom" hyperlink; then follow "Latest Releases" hyperlink; then search by date) [hereinafter New BSE Results].

29. Not only was the cow American born, but it was born before the 1997 FDA feed ban. *Id.*

30. *See* New BSE Results, *supra* note 28.

31. *See id.*; *see also* USDA Office of Inspector General Statement on Audit Work Related to the BSE Test Result Announced on June 10, 2005, http://www.usda.gov/oig/webdocs/BSEStatement050615.pdf (last visited Oct. 2, 2005).

32. *See* Jason R. Odeshoo, Note, *No Brainer? The USDA's Regulatory Response to the Discovery of 'Mad Cow' Disease in the United States*, 16 STAN. L. & POL'Y REV. 277, 278–79 (2005); *see also* Vedantam Shankar, *Assessing Risks of Mad Cow: Other Animals Likely Infected, Scientists Say*, WASH. POST, Jan. 11, 2004, at A09.

33. *See* Odeshoo, *supra* note 32 at 288.

34. Japan has said it won't consider lifting the ban until the United States tests all of its cattle for BSE. *Id.* The United States, however, has been pressuring Japan to resume the beef trade. *See Safer Beef*, *supra* note 9. On March 17, 2005, Japan informally agreed to partially lift its ban, limited to American cattle under 20 months of age, but the terms of this deal have not been worked out yet. *See, e.g.*, Embassy of the U.S., Japan, Questions and Answers on BSE (2005), http://tokyo.usembassy.gov/e/p/tp-20050304-71.html (last visited Mar. 17, 2005); U.S. Statement at WTO on Japan's Beef Import Ban (Mar. 9, 2005), http://tokyo.usembassy. gov/e/p/tp-20050309-77.html (last visited Mar. 17, 2005). But in late September 2005, Japan's Food Safety Commission postponed a decision on whether to resume imports of American beef. *See* Farm Minister Rebuffs U.S. Pressure to Resume Beef Imports,

More than just a second BSE case, however, clouds the USDA's apparent commitment to its food safety mandate. In May 2003, for example, the United States banned imports of all Canadian beef into the United States after an outbreak of BSE in Canada.[35] Four months later, though, the USDA violated its own ban and allowed more than thirty-three million pounds of Canadian beef to be imported into the United States over a six-month period;[36] this practice continued until a federal district court imposed an injunction on the USDA in May 2004.[37]

In addition, between December 2003, when the first mad cow was discovered, and June 2005, when the second mad cow was discovered, BSE prevention measures—such as the 1997 FDA feed ban, the ban against human food from advanced meat recovery machines, and reliable testing for BSE—were regularly violated.[38]

Finally, in February 2004, the food safety agency made a decision that appeared to be against food safety. The USDA prohibited an American beef producer, Creekstone Farms, from testing all of its cattle voluntarily for BSE.[39] The USDA claimed the 1913 Virus, Serum, and Toxin Act (VSTA) gave it authority to regulate the test for BSE, and claimed Creekstone's request was scientifically unjustified.[40] The National Cattlemen's Beef Association, the largest cattle industry group, formally opposed to voluntary testing on the grounds that it will lead to mandatory testing, approved the USDA's decision.[41]

The USDA's denial of Creekstone's request brought into question the agency's commitment to stopping the spread of BSE. First, the USDA's extremely broad interpretation of the ninety-two-year-old VSTA was suspect; the agency had never before cited the law for any

MAINICHI DAILY NEWS, Sept. 30, 2005, http://mdn.mainichi-msn.co.jp/business/news/20050930p2g00m0bu020000c.html (last visited Oct. 2, 2005).

35. *See* 9 C.F.R. § 94.18 (2005); *see also* Statement, Agric. Sec'y Ann M. Veneman, Statement Regarding Canada's Announcement of BSE Investigation (May 20, 2003), *available at* http://www.usda.gov/wps/portal/!ut/ (search "BSE Related Releases;" then follow "BSE Related Releases" hyperlink and "Announcement of BSE Investigation" hyperlink).

36. *See* Marc Kaufman, *USDA Allowed Canadian Beef In Despite Ban*, WASH. POST, May 20, 2004, at A01.

37. *See* R-CALF v. USDA, No. CV-04-BLG-RFC, at *1–2 (D. Mont. May 4, 2004) (order granting preliminary injunction), *available at* http://www.r-calfusa.com/BSE/Order%205-5-04.pdf (last visited Mar. 17, 2005).

38. *See Safer Beef*, *supra* note 9; *see also 1000 Violations*, *supra* note 11.

39. Telephone Interview with Bill Fielding, Chief Operating Officer, Creekstone Farms (June 3, 2004) [hereinafter Interview with Bill Fielding].

40. *Id.*; *see also Creekstone Farms to Challenge USDA's Decision to Decline Private BSE Testing* (Apr. 9, 2004), http://www.creekstonefarmspremiumbeef.com/BSEtesting. html (last visited Mar. 17, 2005); Press Release, Statement by Bill Hawks, Undersecretary for Marketing and Regulatory Programs Regarding a Request by Creekstone for Private BSE Testing, Release No. 0141.14 (Apr. 9, 2004), *available at* http://www.usda.gov/Newsroom/0141.04.html ("The test is now licensed for animal health surveillance purposes. The use of the test as proposed by Creekstone would have implied a consumer safety aspect that is not scientifically warranted.").

41. *See* National Cattlemen's Beef Association, *Questions Producers Are Asking about BSE Testing*, http://www.beef.org/newsquestionsproducers areaskingaboutbsetesting3406.aspx (last visited Mar. 17, 2005); *see also Safer Beef*, *supra* note 9.

purpose outside of the regulation of animal vaccines.[42] Second, in a time when consumers are armed with greater information and are demanding safer food than ever before, consumer demand for increased BSE testing, and a private producer's response to that, seems far from unreasonable. Above all, however, because of the vertical integration of the American beef market,[43] BSE can conceivably be controlled, if not eliminated, through strict controls and comprehensive testing.[44] While the USDA has implemented some of those controls, critics assert that the USDA's efforts fall short and have been influenced too strongly by industry interests.[45] The USDA, based on its Congressional mandate, must incorporate consumer and producer demands into its policies and protect the food supply from BSE.

This note will propose that instead of maintaining the status quo for BSE policy—minimizing food safety and promoting dominant industry concerns over smaller ones—the USDA should implement a more comprehensive BSE testing policy. The policy should incorporate a mix of mandatory and voluntary testing to ensure the largest possible number of cattle are tested, while working to open foreign markets for American beef on the basis of the reliability of that testing. Part II will explore the background of BSE, examine the issues complicating BSE testing, and report the stories of Creekstone and Gateway, two American producers prohibited by the USDA from testing their own cattle for BSE. Part III begins with an analysis of the VSTA, the statute used by the USDA to prevent private testing, and then illuminates American BSE testing policy within the context of food safety, international trade, and industry influence. Finally, Part IV will propose a more comprehensive BSE testing scheme that combines USDA authority with industry concerns and consumer food safety protection.

II. BACKGROUND

BSE had never been found in the United States until the USDA confirmed the Washington State case on December 23, 2003.[46] From the first press conference and through the first weeks, the USDA appeared alert and ready to police the problem.[47] The USDA recalled meat from

42. *See infra* note 189 and accompanying text.

43. *See* Note, *Challenging Concentration of Control in the American Meat Industry*, 117 HARV. L. REV. 2643, 2644 (2004).

44. *See infra* text accompanying notes 218–35.

45. *See generally*, RAMPTON & STAUBER, *supra* note 13, at 1–5; *see also* The Politics of Mad Cow Disease, CBS News, Dec. 29, 2003, http://www.cbsnews.com/Stories/2003/12/29/politics/main 590466.html (last visited Mar. 17, 2005).

46. *See* Transcript, *News Conference With Agriculture Secretary Ann M. Veneman on BSE*, Release No. 0433.03 (Dec. 23, 2003), http://www.usda.gov/Newsroom/0433.03.html (last visited Mar. 17, 2005).

47. *See* Anahad O'Connor, *New Measures Against Mad Cow Disease*, N.Y. TIMES, Dec. 31, 2003, at A15.

twenty cows processed with the infected cow in Washington, more than 10,000 pounds of beef.[48] It prohibited releasing cows tested for BSE until they tested negative.[49] Strict limits were placed on the uses of the skull, spinal cord and spinal nerve tissue (specified risk materials, or SRM) from cattle older than thirty months and small intestines from all cows.[50] Downers, cows too sick to walk, were banned from the human food supply, and air injections used to stun cattle before slaughter were prohibited because they scattered possibly infected bone and brain segments into the other meat.[51] Finally, the USDA committed to instituting a national animal tracking system.[52]

After BSE's second appearance in the United States, the USDA altered its testing policy by mandating the use of a pair of confirmatory BSE tests whenever the primary BSE test shows an "inconclusive" result.[53] The arrival of a second infected cow in the United States, however, suggested that greater controls against BSE—or greater enforcement of existing controls—were needed.

In order to more fully analyze the significance of BSE, the USDA's response to BSE, and the interests of the beef industry and consumer groups, this section will more carefully define BSE. It will describe the methods of testing for BSE, the USDA's testing policy, and problems with that policy. In addition, this section will introduce the deeper inconsistencies in the USDA's testing policy: the story of Creekstone and Gateway Farms, and the story of Canadian BSE and Canadian beef.

A. What Is BSE and How Is It Transmitted?

BSE, and its human form, vCJD, are in a disease family called TSEs, or transmissible spongiform encephalopathies, which occur naturally, although extremely rarely.[54] Scientists believe that BSE is caused by the presence of abnormal prions, proteins naturally occurring on the brain cells of cattle that convert into rapidly unstable protein structures.[55] Dr. Stanley Prusiner, who won the Nobel Prize for discovering the un-

48. *Id.*
49. *Id.*
50. *Id.*
51. *Id.*
52. *Id.*
53. *See* New BSE Results, *supra* note 28; McNeil, *supra* note 9; *see also infra* notes 89–104 and accompanying text.
54. *See* Centers for Disease Control, Prion Diseases, http://www.cdc.gov/ncidod/dvrd/prions (last visited Mar. 17, 2005).
55. *See* FDA, Commonly Asked Questions About BSE, http://vm.cfsan.fda.gov/~comm/bsefaq.html (last visited Mar. 17, 2005).

stable disease-causing proteins in 1997,[56] has been an outspoken proponent for a more comprehensive BSE testing policy.[57]

The BSE crisis in England, which led to the slaughter of 3.7 million cattle,[58] indicated that something more than the natural occurrence of BSE was spreading the disease. Several theories abounded.[59] Evidence of a species barrier-jump theory was bolstered when it was revealed that rendered sheep parts fed to British cattle as protein in the 1970s were infected with a sheep form of TSE, known as scrapies.[60] Some believed that feeding rendered cattle parts to cattle, an herbivorous species, led to the abnormal proteins, or prions, being formed.[61] Yet others believed that the disease spread due to changes in the technology used to create the cattle-based feed. The theory asserts that changes in the 1970s, both in regulation of the chemicals involved in rendering and new rendering methods, resulted in a lower rendering temperature which failed to kill the prions that had been killed in the previous process.[62] Yet even if BSE developed like many other diseases, as a combination of undeterminable chemical, physical, political, and even economic factors, what was clear after the British BSE crisis was that BSE was transmissible, and remarkably resilient.[63]

The effect of BSE on cattle is untreatable and well-documented.[64] The prions slowly attack the brain tissue, causing holes to form, similar to the patterns in a sponge.[65] As the brain loses function, the cows become disoriented and clumsy.[66] Eventually, the cattle lose all muscle control

56. *See* Press Release, Nobelprize.org, The 1997 Nobel Prize in Physiology or Medicine (Oct. 6, 1997), http://nobelprize.org/medicine/laureates/1997/press.html (last visited Feb. 28, 2006).

57. *See* Clint Peck, *The Cost of One Sick Cow*, BEEF, June 1, 2004, http://beef-mag.com/mag/beef_cost_one_sick/ ("Dr. Stanley Prusiner says the only way to assure beef is BSE-free is test all cattle at slaughter.") (last visited Feb. 28, 2006).

58. *See The Spread of Mad Cow Disease*, cnn.com, Dec. 24, 2003, http://edition.cnn.com/2003/HEALTH/12/23/madcow.chronology.reut/ (last visited Feb. 28, 2006).

59. *See* Animal and Plant Health Inspection Serv., USDA, *Bovine Spongiform Encephalopathy (BSE)*, Overview, *available at* http://www.aphis.usda.gov/lpa/issues/bse/bse-overview.html [hereinafter *Bovine Spongiform Encephalopathy*].

60. *See id.* ("The causative agent is suspected to be from either scrapie-affected sheep or cattle with a previously unidentified BSE.").

61. *See id*.

62. *See id*; *see also* RAMPTON & STAUBER, *supra* note 13, at 68–69.

63. *See Bovine Spongiform Encephalopathy*, *supra* note 59. BSE is unresponsive to medicine in the cattle, or high sterilization temperatures used to disinfect other foods. *Id.* In addition, BSE is currently believed only to live in the spinal tissues, brain tissues, and intestines of cattle; the discovery that BSE can live in more normally consumed parts such as muscles or livers would be disastrous, and there has been little evidence of this to date. *See* FDA, *Commonly Asked Questions About BSE in Products Regulated by the FDA*, http://vm.cfsan.fda.gov/~comm/bsefaq.html (last visited Aug. 19, 2005). The theory behind the ban on air injection, however, is an acknowledgement that brain tissue has the potential to infect other parts of the cattle, including muscle, the most common part of the cow to eat, through the killing process. *See* O'Connor, *supra* note 47, at A15. Like any other regulation, the proof is in the compliance, which remains to be seen.

64. *Bovine Spongiform Encephalopathy*, *supra* note 59.

65. *Id.*

66. *Id.*

and are unable to walk or eat.[67] No treatment is available; once BSE is contracted, all cattle die or are destroyed.[68]

The human form of BSE, vCJD,[69] is equally insidious, although humans have benefited from attempts at treatment.[70] Victims first become forgetful and depressed. Brain function decreases rapidly, resulting in loss of memory, and eventual loss of language, causing a schizophrenic-like psychosis.[71] Muscle control is lost; victims' limbs become uncontrollable and jerky, their voices random and erratic.[72] For example, a fourteen-year-old girl in England cried for two weeks straight, and then began screaming before finally dying.[73] Death after onset is normally quick; a healthy patient can succumb to vCJD and die in a matter of months.[74]

B. Testing for BSE

Three BSE tests currently exist, all having in common the impossibility of testing live animals.[75] The rapid test, used first in USDA surveillance, starts with a sample of bovine central nervous tissue dissected from the hind brain or upper cervical spinal column.[76] The sample is homogenized to liquefy the tissue and then centrifuged.[77] Enzymes digest the normal prions and leave untouched the abnormal prions, which are then tested with antibodies to detect BSE.[78] The rapid test is not perfect; many believe it gives false positive results.[79]

The second test is the "gold-standard" immunohistochemistry test (IHC), which the USDA uses to confirm the results of the rapid test.[80]

67. *Id.*

68. *Id.*

69. *See supra* note 54. Although the incubation period for traditional CJD could be as long as 20–30 years, and naturally attacks about only one per million people, the variant form seems to incubate more quickly, attack more ferociously, and have the potential for much more widespread damage.

70. *See CJD Drug Study to Start in Weeks*, BBC NEWS ONLINE, May 21, 2004, http://news.bbc.co.uk/1/hi/health/3735127.stm (last visited Feb. 28, 2006).

71. *See* Stefanie M. Gaffigan, Comment, *Developments in International Trade and the Environment*, 2003 COLO. J. INT'L. ENVTL. L. & POL'Y (Yearbook) 87, 87.

72. *See* David Schardt & Stephen Schmidt, *Mad About BSE*, NUTRITION ACTION HEALTH LETTER (U.S. Edition), 'Center for Science in the Public Interest', July/Aug. 1997, http://www.cspinet.org/nah/ja-bse.htm (last visited Feb. 28, 2006).

73. Rebecca Allison, *The Cries then Screams that Led a Mother to Discover her 14-Year-Old Daughter had CJD*, GUARDIAN UNLIMITED (UK), Oct. 26, 2000, http://www.guardian.co.uk/bse/article/0,2763,388251,00.html (last visited Feb. 28, 2006).

74. *See Bovine Spongiform Encephalopathy*, *supra* note 59.

75. *See id.*

76. *See* TSE Screening Process, http://www.abbottdiagnostics.com/Reagents_Tests/testdetailcfm?test=bse&path=1 (last visited Mar. 17, 2005).

77. *Id.*

78. *Id.*

79. *See* Donald G. McNeil & Sandra Blakeslee, *Second Test Indicates Animal Did Not Have Mad Cow Disease*, N.Y. TIMES, July 1, 2004, at A19.

80. *Id.* As a result of the BSE found in Washington in December 2003, the USDA expanded its testing of cattle for BSE, expecting to test more than 220,000 cattle in 2004, a greater than tenfold increase over 2003. Letter from Jean Halloran, Dir. Consumer Policy Inst., & Michael K. Hansen, Sen-

The IHC also uses a sample of brain tissue, which is treated with enzymes and examined under a microscope.[81] While the USDA believes this test to be more reliable than the rapid test, it is widely believed that "[t]he accuracy of the test depends on the expertise of the examiner."[82]

The third test, the Western blot test, was described by the USDA as "crucial" in identifying the positive Washington State cow in December 2003, but until June 24, 2005 was not part of the USDA testing protocol.[83] The testing standard of European Union countries and Japan,[84] both the IHC and the Western blot, will now be used to confirm the results of an "inconclusive" result on a rapid test.[85] Critics claim the IHC misses some BSE cases, while the Western blot is both more sensitive and less prone to misinterpretation than the IHC.[86]

In addition to the complexities of the BSE test, the testing process itself is far from straightforward.[87] As this note will show, the difference between testing cattle for BSE and the USDA's surveillance testing—testing cattle to determine the statistical incidence of BSE—can be analogized as the difference between solving a problem and creating a committee to discuss solving the problem. Further, the effectiveness of BSE testing can be manipulated by decisions about which cattle to test under what conditions, notification of testing, and a selective voluntariness to testing.[88]

C. USDA Testing Policy

In March 2004, the USDA announced the introduction of its surveillance program to determine the rate of BSE infection in the United

ior Research Assoc., to Michael Johanns, Sec'y, USDA (Feb 24, 1005), http://www.consumersunion.org/pub/campaignnotinmyfood/001931.html (last visited Mar. 17, 2005). Approximately 35.5 million cattle were slaughtered in 2003. Background Statistics on U.S. Beef and Cattle Industry, http://www.ers.usda.gov/news/BSE Coverage.htm (last visited Mar. 17, 2005). The USDA first uses the rapid test, and then the IHC to certify any positive results. Halloran & Hansen, *supra.* (There remains some controversy as to the accuracy of both the rapid tests and the IHC tests: the USDA publicly refers to positive rapid-test results as "inconclusive" while referring to the IHC tests as conclusive. *See* Statement, Dr. John Clifford, Deputy Adm. APHIS (July 2, 2004), http://www.usda.gov/Newsroom/0275.04.html (last visited Mar. 17, 2005)). As of March 17, 2005, three tests have come back positive (or "inconclusive") for BSE using the rapid test, all of which have been found to be negative by the subsequent IHC tests. *See* Factsheet, Animal and Plant Health Inspection Service, June 2005 BSE Test Step by Step, http://www.aphis.usda.gov/lpa/pubs/fsheet_faq_notice/faq_BSE_stepbystep.pdf (last visited Sept. 19, 2005).

81. McNeil & Blakeslee, *supra* note 79.

82. *Id.*

83. *See* New BSE Results, *supra* note 28; *see also* Halloran & Hansen, *supra* note 80.

84. Halloran & Hansen, *supra* note 80.

85. *See* New BSE Results, *supra* note 28; *see also infra* text accompanying note 97.

86. Halloran & Hansen, *supra* note 80.

87. *See* TSE Screening Process, *supra* note 76.

88. Ranchers are encouraged to report downer cattle to the USDA for testing. Stephanie Simon, *U.S., Some Ranchers Clash over Mad Cow Tests*, L.A. TIMES, May 24, 2004, at A11.

States.[89] Using a Harvard University statistical model,[90] the USDA stated that testing 268,500 high risk animals would result in being able to detect BSE in one out of ten million cattle with 99% accuracy.[91] The USDA claimed it could detect BSE even if there were only five BSE-positive animals in the United States.[92] High risk animals were defined as animals that were at least thirty months old and nonambulatory, demonstrating signs of a disorder of the central nervous system, emaciation or injury (signs of BSE), or dead. Approximately 446,000 animals in the United States fell into this category.[93]

Since June 1, 2004, when the surveillance testing began, a total of 478,050 cattle have been tested by the USDA.[94] As of this writing, three "inconclusive" results have been reported, one of which led to the discovery of the second American cow with BSE.[95] The USDA defines inconclusive tests as those in which a "negative result cannot be determined."[96] According to the USDA, the tests are designed to be highly sensitive, and false positives are normal under these circumstances. These "non-negative," or inconclusive, results are sent to another lab, where now the "gold-standard" IHC and the Western Blot will be performed.[97]

D. Problems with the USDA's Testing Policy

Consumer groups questioned why the USDA insisted that BSE testing was for surveillance purposes only, rather than for food safety, when

89. *See generally* Bovine Spongiform Encephalopathy (BSE) Surveillance Plan (2004), http://www.aphis.usda.gov/lpa/issues/bse/BSE_Surveil_Plan03-15-04.pdf (last visited Mar. 17, 2005) [hereinafter BSE Surveillance Plan].

90. *See generally*, *Preliminary Analysis of Interim Final Rules and an Interpretative Rule to Prevent the BSE Agent from Entering the U.S. Food Supply*, *available at* http://www.fsis.usda.gov/OPPDE/RDAD/FRPubs/03-025N/BSE_Analysis.pdf (citing Joshua T. Cohen & George M. Gray, *Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada 2003*, Harvard Center for Risk Analysis, Harvard School of Public Health); *see also* Joshua T. Cohen & George M. Gray, *Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada 2003*, Harvard Center for Risk Analysis, Harvard School of Public Health, *available at* http://www.aphis.usda.gov/lpa/issues/bse/ harvard_10-3/text_wrefs.pdf (last visited Mar. 17, 2005); Joshua T. Cohen et al., *Evaluation of the Potential for Bovine Spongiform Encephalopathy*, Harvard Center for Risk Analysis, Harvard School of Public Health, *available at* http://www.aphis.usda.gov/lpa/issues/bse/ risk_assessment/mainreporttext.pdf (last visited Mar. 17, 2005).

91. *See* USDA's BSE Testing Program, Frequently Asked Questions, http://www.aphis.usda.gov/lpa/issues/bse_testing/faq.html (last visited Mar. 17, 2005) [hereinafter USDA's Testing Program].

92. *Id.*

93. *See generally* BSE Surveillance Plan, *supra* note 89.

94. *See* USDA's BSE Testing, BSE Test Results, http://www.aphis.usda.gov/lpa/issues/bse_testing/test_results.html (last visited Oct. 2, 2005).

95. *See* New BSE Test Results, *supra* note 28.

96. By this definition, a positive result is inconclusive. This author's view is that the USDA uses the term "inconclusive" in order to avoid explaining a positive result. *See* USDA's Testing Program, *supra* note 91.

97. *Id*; *see also* New BSE Results, *supra* note 28.

American health and safety were at risk.[98] The USDA answered that the purpose of the testing was to determine the presence of BSE in the United States in order to formulate a specific plan should BSE be found.[99]

More specifically, however, consumer groups cited several reasons to be concerned with the USDA's testing policy. First, while 478,050 animals appears to be a great number of cattle, it is fewer than 2% of the animals slaughtered each year.[100] Second, while the USDA was testing animals only more than thirty months old, animals younger than that with BSE had been found in other countries.[101] Third, the USDA's policy of allowing producers to select the animals for testing, the voluntary nature of the testing, and the advance warning to producers whose cattle would be tested eliminated any random nature of testing which would ensure true representative sampling.[102] Finally, the surveillance program is a one-time occurrence.[103] No testing policy beyond this current program exists; in contrast, Japan and England test 100% of their slaughtered cattle.[104]

In addition, BSE infection itself is biological, not mathematical, and fits rather poorly into a statistical model.[105] No one knows why one cow is infected while another is not; while the industrial farming model is designed to regulate and normalize feeding contents and schedules, making it far more likely that all the cattle in a single place would eat the same food, be the same age, and have the same origin, the same is not true in processing plants, where meat from hundreds of cows, even from different states and countries, can be combined.[106] It is virtually impossible for any model to account for every possible variation and exception when dealing with living organisms. The USDA seems implicitly to understand this because it allows that BSE could exist despite no positive results in the surveillance testing; the surveillance is designed to expose the chance of BSE, not the actuality of it.[107]

Meanwhile, while the USDA, industry groups and consumer groups were busy debating the testing policy, at least two ranchers who were daily losing money to the Japanese ban on American beef were trying to create solutions of their own.

98. *See* Steve Mitchell, *Consumer Groups: New Mad Cow Plan Lacking*, UNITED PRESS INT'L, Mar. 16, 2004, *available at* http://www.upi.com/view.cfm?StoryID=20040316-062640-1692r.

99. *See* USDA's Testing Program, *supra* note 91.

100. *Cf.* Mitchell, *supra* note 98.

101. *See* Simon, *supra* note 88, at A1.

102. *See* Mitchell, *supra* note 98.

103. *See* BSE Surveillance Plan, *supra* note 89, at 1.

104. *See* Simon, *supra* note 88, at A11.

105. *See* Bovine Spongiform Encephalopathy, *supra* note 59.

106. *See* Wendy J. Umberger, *Will Consumers Pay a Premium for Country-of-Origin Labeled Meat?*, CHOICES, 4th Quarter, 2004, http://www.choicesmagazine.org/2004-4/cool/2004-4-04_print.htm (last visited Mar. 17, 2005).

107. *See Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States*, http://www.aphis.usda.gov/lpa/issues/bse/harvard_10-3/text_wrefs.pdf (last visited Mar. 17, 2005).

E. American Producers: Creekstone and Gateway

On February 19, 2004, in response to the Japanese ban on American beef, Creekstone Farms Premium Beef, LLC (Creekstone) sent an e-mail to the USDA[108] requesting permission to test all of its cattle for BSE, intending to persuade Japanese customers that its cattle were BSE-free with a USDA certification.[109] A significant percentage of the black angus cows that Creekstone raised and slaughtered were destined for the Japanese market, where they fetched a far higher price than was possible in the American market; a tongue that sold for $3.50 in the United States sold for $17.00 in Japan.[110] Creekstone estimated it was losing $200,000 daily from the Japanese ban, and planned to test all of its 300,000 cattle for BSE using a $500,000 testing site it had recently built to USDA specifications.[111] The request to the USDA was widely reported in the media; the first inkling that something untoward was afoot came in a meatingplace.com article by Daniel Yovich, who reported—before the USDA had responded to Creekstone's request—that the 1913 VSTA gave the USDA authority to prevent unauthorized diagnostic testing.[112]

On April 8, 2004, Creekstone's COO and CEO attended a meeting in Washington, D.C. with USDA Undersecretaries J.B. Penn and Bill Hawks, and USDA Chief of Staff Dale Moore.[113] What the Chief of Staff told the COO and the CEO of Creekstone surprised them.[114] Creekstone was being denied the authority to test based on three grounds: (1) BSE testing of animals younger than thirty months old was not scientifically justified or necessary;[115] (2) the BSE test kit was licensed for surveillance

108. Not just anybody can email the USDA requesting policy decisions. Even though Creekstone was an independent player in the beef market, it was not an insignificant one. *See* Daniel Yovich, *Creekstone lays plans to test 100 percent, bust through beef ban*, MEATINGPLACE.COM, http://www.vegsource.com/articles2/creekstone.htm (last visited Mar. 17, 2005). Bill Fielding, the COO of Creekstone, is a twenty-six-year veteran in the beef industry. *Id.* Before joining Creekstone, he had served as President of the Farmland Industries' refrigerated foods group, Chairman of the American Meat Institute, and President of ConAgra Foods' refrigerated meat group, significant positions with some of the largest American beef industry players. *Id.*

109. E-mail from Bill Fielding, COO of Creekstone, to Jim Butler, USDA Deputy Under Secretary for Farm and Foreign Agricultural Services (February 19, 2004, 04:51 CST) (on file with author).

110. *See* Donald G. McNeil, *Bored From Testing for Mad Cow, Niche Meatpacker Loses Clients*, N.Y. TIMES, April 18, 2004, at 14.

111. *See* Editorial, *A Strange Ban on Testing Beef*, N.Y. TIMES, April 18, 2004, at 12.

112. *See* Yovich, *supra* note 108.

113. *See* Interview with Bill Fielding, *supra* note 39. It is possible that Creekstone and the government officials knew one another; Dale Moore was the previous executive director for legislative affairs of the National Cattlemen's Beef Association. Regardless, Creekstone was an important enough market player that it was able to have its first meeting in Washington, D.C. with some of the most powerful and influential figures in the USDA. *See supra* note 107.

114. *See* Interview with Bill Fielding, *supra* note 39.

115. *See* Cohen et al., *supra* note 90, at 38.

purposes only; and (3) the VSTA gave the USDA authority to control the licensing and use of the BSE test kit.[116]

Creekstone followed up on the Washington meeting with a letter dated April 13, 2004, expressing hope that the USDA could find a political solution to lift the Japanese ban.[117] The letter made clear that Creekstone would consider legal action if the USDA continued to prevent it from testing.

Meanwhile, in Missouri, a much smaller operation, Gateway Beef Cooperative (Gateway), representing fifty-eight members that slaughter about 10,000 cattle a year (compared with Creekstone's 300,000), also sent a letter to the USDA, asking to voluntarily test its cattle for BSE.[118] Also a producer losing money due to the Japanese ban, Gateway reasoned that Japanese consumers would pay a premium for BSE-tested beef.[119] Unlike Creekstone, Gateway represented small farmers, many of whom did not employ the same technology as the larger processors and slaughterhouses, and many of whom raised their cattle on grass, instead of in feedlots.[120] Also unlike Creekstone, Gateway agreed in advance to submit to any of the USDA's demands regarding testing, including methods, locations, and cost.[121] Like Creekstone, however, Gateway saw its request not as a food-safety measure per se, but rather a marketing tool. If Gateway could somehow demonstrate to the Japanese market that its beef was safe, perhaps the ban would be lifted, at least selectively.[122]

Although the USDA never formally responded to Gateway, it was clear that the USDA's answer to Creekstone also applied to them. Gateway believes the USDA will not allow testing for a number of reasons: (1) the USDA is afraid that a false positive will significantly disrupt the economy (according to Gateway, 151 positive BSE tests in Japan resulted in only 12 confirmed BSE cases); (2) the USDA wants to reach an independent agreement with Japan; and (3) the USDA insists that cattle under thirty months old cannot develop BSE.[123]

On July 27, 2004, the Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of America (R-CALF), wrote a letter on behalf of Creekstone and Gateway to USDA Secretary Ann Veneman, urging the

116. *See* Interview with Bill Fielding, *supra* note 39; Statement by Bill Hawks, *supra* note 40; *see also Creekstone Farms to Challenge USDA's Decision to Decline Private BSE Testing*, http://www.creekstonefarmspremiumbeef.com/BSEtesting.html (last visited Mar. 17, 2005).

117. *See* Interview with Bill Fielding, *supra* note 39.

118. Telephone Interview with John Tarpoff, Manager, Gateway Beef Coop. (June 3, 2004) [hereinafter Interview with John Tarpoff].

119. *See* Press Release, Missouri Farmer's Union, Gateway Beef Requests Permission to Perform Voluntary BSE Testing (Apr. 30, 2004) http://missourifarmersunion.org/news/pr043004.htm (last visited Mar. 17, 2005).

120. *See* Interview with John Tarpoff, *supra* note 118.

121. *Id.*

122. *Id.*

123. *Id*.

USDA to allow private testing of cattle.[124] R-CALF argued that the USDA is working against American beef producers in opposing testing while failing to reopen American markets to the world, leaving American processors unable to meet market demands and standards.[125] In addition, R-CALF noted that the USDA already allows beef processors to advertise other perceived safety measures, such as meat being added-hormone-free, and that large American distributors, such as Costco, had joined the call for voluntary testing of beef. R-CALF further assured the USDA that Creekstone and Gateway would conform to all USDA protocols to test their cattle.[126] Finally, R-CALF demanded a timeline for resolution of BSE testing policy, suggesting a deadline of October 1, 2004.[127]

On March 2, 2005, in an opinion explored below, the first court to hear an argument in favor of voluntary BSE testing weighed in on the debate.[128] The court stated that the USDA's stance against private testing was "contrary to rational thinking because any private testing would actually assist in assuring proper testing for animal diseases and increase consumer confidence, both domestically and internationally, in U.S. cattle and beef."[129]

F. Canadian BSE and Canadian Cattle

It will be helpful here to outline briefly the issues of Canadian cattle and Canadian BSE because a significant percentage of USDA and consumer group energy has focused on this area. Many of the same issues—testing, the feed ban—have been borne out in the context of Canadian BSE and the American ban on Canadian cattle.

After an outbreak of BSE in Canada in May 2003, the United States banned imports of all Canadian beef into the United States.[130] But the USDA violated the ban almost as soon as it began. In May 2004, the USDA admitted it had allowed imports of processed beef into the United States in September 2003, despite the ongoing ban.[131] Between September 2003 and March 2004, when a federal judge imposed an in-

124. *See* Letter from Bill Fielding, Chief Operating Officer of Creekstone Farms, Russ Kramer, Gateway Beef Coop., and Bill Bullard, Chief Executive Officer of R-CALF USA to Ann Veneman, Secretary of the USDA, http://www.r-calfusa.com/BSE/WASHDOCS-757021-v1-Voluntary%20testing%20letter.pdf (last visited Mar. 17, 2005).

125. *Id*.

126. *Id*.

127. *Id*.

128. The true focus of this lawsuit, explored below, was to prevent Canadian beef from entering the United States; testing of cattle for BSE was a secondary issue. *See, e.g.*, Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. ("R-CALF") v. USDA, 359 F. Supp. 2d 1058 (D. Mont. 2005),*rev'd*,415 F.3d 1078 (9th Cir. 2005).

129. *See R-CALF*, 359 F. Supp. 2d at 1072 (granting preliminary injunction).

130. *See* Veneman, *supra* note 35.

131. *See* Kaufman, *supra* note 36.

junction on the USDA,[132] more than 33 million pounds of beef crossed the Canadian border in the trucks of American meatpackers, accompanied by permits signed by the USDA. Even after publicly affirming the Canadian ban, by declaring that the danger of Canadian ground beef was so great to American consumers that it could not be allowed into the United States, Ann Veneman allowed USDA officials to make exceptions upon finding "that certain products would not pose a health risk because of risk mitigations."[133]

Problems with Canadian beef had barely begun. The USDA announced in March 2004, that it planned to reverse its ban on Canadian products, reopen the Canadian border for most beef products, and recategorize Canada as a "minimal risk" country beginning on March 7, 2005; a final rule confirming reversal on the ban was issued on December 29, 2004,[134] despite extensive comments protesting the rule.[135] The discovery of two additional Canadian cows with BSE on January 2, 2005, and January 11, 2005, raised the Canadian BSE count to four (five if the Washington cow was counted) and breathed drama into American industry and consumer fears. Neither discovery caused the USDA to revise or reconsider Canada's proposed status as a minimal risk country.[136] R-CALF filed suit against the USDA on January 10, 2005.[137]

The federal district court in which R-CALF filed its suit dealt a significant blow to the USDA when it granted R-CALF's request to enjoin the USDA from opening the Canadian border on March 2, 2005. The Court found that the USDA's decision to open the border despite the new BSE cases would most likely be found arbitrary and capricious because (1) it failed adequately to assess the impact of its action on human health; (2) its assumption that the BSE incidence in Canada was very low was unsupported and demonstrably wrong; (3) its reliance on the Canadian feed ban was unjustified; (4) it arbitrarily assumed SRM removal eliminates all risks of BSE; and (5) it failed to respond adequately to comments suggesting mandatory BSE testing of Canadian Cattle.[138] In addition, the court found the USDA failed to satisfy procedures required by the National Environmental Policy Act and the Regulatory Flexibility Act.[139] R-CALF's lawsuit had been supported in *amicus curiae* briefs

132. *See* R-CALF v. USDA, No. CV-04-BLG-RFC (D. Mont. May 4, 2004), *available at* http://www.r-calfusa.com/BSE/Order%205-5-04.pdf (granting preliminary injunction).

133. *See* Kaufman, *supra* note 36.

134. *See* Bovine Spongiform Encephalopathy, Minimal Risk Regions and Importation of Commodities; Final Rule and Notice, 70 Fed. Reg. 460 (to be codified at 9 C.F.R. pts. 93, 94, 95, 96).

135. *See R-CALF*, 359 F. Supp. 2d at 1062 ("Plaintiff and over three thousand others submitted written comments on the proposal.").

136. *Id.* at 1063.

137. *See* Verified Complaint for Declaratory and Injunctive Relief, R-CALF v. USDA, (D. Mont. Jan. 9, 2005) (No. cv-05-6-BLG-RFC) *available at* http://www.r-calfusa.com/BSE/1-10-05,%20R-CALF%ZOUSA%20complaint%20against%20final%20Rule.pdf.

138. *R-CALF*, 359 F. Supp. 2d at 1065–69.

139. *Id*. at 1071, 1073.

filed by Connecticut, New Mexico, North Dakota, Montana, Nevada, South Dakota and West Virginia.[140]

A flurry of activity ensued in the days and weeks following the federal district court's grant of the temporary injunction. On March 3, 2005, the United States Senate voted 52-46 to overturn the USDA's January 29, 2004, final rule.[141] The House of Representatives introduced, but never voted on, a similar resolution.[142] Before the USDA even filed its appeal with the Ninth Circuit Court of Appeals on March 17, 2005,[143] the National Meat Association (NMA)—whose application to intervene in the federal district court case was denied[144]—filed an emergency motion for an expedited briefing and hearing,[145] which the Ninth Circuit Court of Appeals granted on March 11, 2005.[146] On April 21, 2005, a large number of trade associations, farm bureaus and individual cattle producers jointly moved to file an *amici curiae* brief in support of the USDA's appeal;[147]

140. Answering Brief of Ranchers Cattlemen Action Legal Fund United Stockgrowers of America at 5, Nat'l Meat Ass'n v. USDA, No. 05-35214 (9th Cir. July. 29, 2005), *available at* http://www.r-calfusa.com/BSE/bse_fmd.htm (follow "Answering Brief of R-CALF USA to NMA's Intervenor Application" hyperlink).

141. A joint resolution providing for congressional disapproval of the rule submitted by the Department of Agriculture under chapter 8 of title 5, United States Code, relating to risk zones for introduction of bovine spongiform encephalopathy. S.J. Res. 4, 109th Cong. (2005), *available at* http://thomas.loc.gov/cgi-bin/bdquery/z?d109:SJ00004:@@@L&summ2=m&.

142. Disapproving the rule submitted by the Department of Agriculture relating to the establishment of minimal-risk regions for the introduction of bovine spongiform encephalopathy into the United States, H.R.J. Res. 23, 109th Cong. (2005), *available at* http://thomas.loc.gov/cgi-bin/bdquery/z?d109:HJ00023:@@@X. Perhaps revealing the political nature of the USDA's position, President Bush vowed to veto the bill if it passed. *See* Press Release, Executive Office of the President, Office of Mgmt. & Budget, Statement of Administration Policy: S.J. Res. 4—Disapproving the Rule of the Department of Agriculture on Minimal Risk Zones Related to Bovine Spongiform Encephalopathy (Mar. 3, 2005) (on file with author).

143. *See* News Release, U.S. Government Requests Appeal In Minimal-Risk Rule Case (Mar. 17, 2005), http://www.usda.gov/ (follow "Newsroom" hyperlink; then follow "Latest Releases" hyperlink; then search by date) (last visited Mar. 17, 2005).

144. *See* R-CALF v. USDA, No. CV-04-51-BLG-RFC, at 4 (D. Mont. Dec. 13, 2004) (order denying intervention), *available at* http://www.r-calfusa.com/BSE/bse_fnd.htm (follow "caut Denres NMA's Intervention Request" hyperlink). The USDA also opposed the intervention by the NMA, on the grounds that the interests of the USDA and the NMA were identical. *See* Brief for Defendant-Appellees at 7, R-CALF v. USDA, No. 05-35214 (9th Cir. July 25, 2005), *available at* http://www.r-calfusa.com/BSE/bse_fnd.htm (follow "Answering Brief of USDA to NMA's Intervenor Application" hyperlink). In addition, the Ninth Circuit Court of Appeals affirmed the federal district court's denial of NMA's application for intervention on July 25, 2005. *See* R-CALF v. USDA, No. 05-35214, 2005 U.S. Lexis 15448, at *10, Memorandum (9th Cir. July 25, 2005) (on file with author).

145. *See* Emergency Motion Under Circuit Rule 27-3 at 7, R-CALF v. USDA (9th Cir. Mar. 11, 2005), *available at* http://www.r-calfusa.com/BSE/NMA's%20Emergency%20Motion%20for%20Appeal.pdf.

146. *See* Nat'l Meat Ass'n v. USDA, No. 05-35214 (9th Cir. Mar. 11, 2005), *available at* http://www.r-calfusa.com/BSE/NMA2%209thCir.%20briefing%20order.pdf.

147. Filing in support were the American Meat Institute, North American Meat Processors, Southwestern Meat Association, Eastern Meat Packers Association, American Association of Meat Processors, National Restaurant Association, and the United Food and Commercial Workers. *See* Motion for Leave to File Brief of *Amici Curiae* American Meat Institute et al., R-CALF v. USDA, No. 05-35264 (9th Cir. July 25, 2005), *available at* http://www.r-calfusa.com/BSE/9th%20Circuit%20Amicus%20Motion%20for%20Leave,%20AMI%20et%20al.pdf.

many more, including the National Cattlemen's Beef Association, also filed their own *amici curiae* briefs on the same day.[148]

Those filing in support of the USDA were primarily supporting commercial interests. On June 1, 2005, sixty-seven entities, primarily not-for-profit organizations representing more than 50 million U.S. consumers, citizens and agricultural producers, filed a brief of *amici curiae* in support of R-CALF.[149] While the *amici curiae* supporting the USDA represented powerful companies and workers who packed, processed, sold and purchased beef, the *amici curiae* supporting R-CALF represented those who produced and consumed beef, groups with vitally different interests.

On May 9, 2005, R-CALF filed a motion for summary judgment in the federal district court that had enjoined the USDA from opening the Canadian border, asking the court to hold unlawful and set aside the USDA's December 29, 2004, final rule.[150] The USDA followed with its own motion for summary judgment.[151] On July 14, 2005, a three-judge panel of the Ninth Circuit Court of Appeals stayed the federal district court's March 2, 2005, Preliminary Injunction Order, holding that the preliminary injunction was unwarranted and that R-CALF lacked stand-

148. Filing in support were the National Beef Cattlemen's Association, American Farm Bureau Federation, National Pork Producer's Council, twenty-nine State Cattlemen's Associations, eighteen State Farm Bureaus, and nine Individual Cattle Producers. Brief For Amici Curiae National Cattlemen's Beef Association et al. Supporting Appellants and Vacatur, R-CALF v. USDA, No. 05-35264 (9th Cir. July 25, 2005), *available at* http://www.r-calfusa.com/BSE/9th%20Circuit%20Amicus%20Brief,%20NCBA,%20AFBF.pdf.

149. Filing in support were national organizations such as the Consumer Federation of America, the National Farmers Union, Public Citizen, the Organization for Competitive Markets, Center for Food Safety, National Catholic Rural Life Conference, National Farmers Organization, the CJD Foundation, Women Involved in Farm Economics, and Institute for Agriculture and Trade Policy; regional and state organizations such as the California Farmers Union, Cattle Producers of Washington, Central Colorado Cattlemen's Association, Dakota Resource Council, Dakota Rural Action, Illinois Cattlemen's Association, Illinois Farmers Union, Independent Cattlemen of Nebraska, Iowa Farmers Union, Just Food, Kansas Cattlemen's Association, Kansas Farmer's Union, Merced-Mariposa Cattlemen's Association, Michigan Farmers Union, Minnesota Cattlemen's Association, Minnesota Farmers Union, Mississippi Livestock Markets, Missouri Farmers Union, Montana Cattlemen's Association, Montana Farmers Union, New England Small Farm Institute, Nebraska Farmers Union, Nevada Livestock Association, North Dakota Farmers Union, Northern Plains Resource Council, Oregon Livestock Producers Association, Pennsylvania Farmers Union, Rocky Mountain Farmers Union, South Dakota Farmers Union, South Dakota Livestock Marketing Association, South Dakota Stockgrowers Association, South Montana Angus Association, Texas Farmers Union, Utah Farmers Union, Western Organization of Resource Councils, and Wisconsin Farmers Union; and twenty local and private organizations. *See* Brief of Amici Curiae supporting Appelee R-CALF Seeking to Affirm Preliminary Injunction and Order Striking Down Administrative Ruling, R-CALF v. USDA, No. 05-35264 (9th Cir. Apr. 21, 2005), *available at* http://www.r-calfusa.com/BSE/614587.pdf.

150. *See* Memorandum of Points and Authorities in Support of Plaintiff's Motion for Summary Judgment at 39, R-CALF v. USDA, No. CV-05-06-BLG-RFC (D. Mont. May. 9, 2005), *available at* http://www.r-calfusa.com/BSE/R-CALF%20USA%20SJ%20Brief.pdf.

151. *See* Defendants' Reply in Support of Motion for Summary Judgment, R-CALF, Cause No. CV-05-06-BLG-RFC (D. Mont. July 13, 2005), *available at* http://www.r-calfusa.com/BSE/rcalf_sj_def_reply.pdf.

ing for a NEPA challenge.[152] In addition, the court found that the district court failed to abide by the correct deferential standard, and that none of the five grounds on which the district court based its finding supported its conclusion.[153]

R-CALF filed a Petition for Rehearing, with Suggestion for Rehearing En Banc, on September 7, 2005, calling the outcome of the case of "exceptional national importance" and arguing that the court's decision was inconsistent with other decisions in the Ninth Circuit, charging that the court overlooked or mistook important points of law and fact and reviewed facts not fully developed below.[154]

Whether the Ninth Circuit Court of Appeals will agree to a rehearing is anybody's guess, as is the result of R-CALF and the USDA's unanswered motions for summary judgment in the district court. Regardless of the outcomes, however, if R-CALF's *amici curiae* really represent fifty million constituents, shouldn't that voice be strong enough to influence the USDA? If not, does it mean that industry influence on the USDA has become unbreakable, or part of a larger anti-regulatory movement? Was the district court's awarding of a preliminary injunction an accidental victory? Has the Ninth Circuit ruling strengthened the USDA, preventing any chance of a reconsideration of its BSE prevention program? Can the dicta of the district court be used to pave the way for American producers to test their own cattle? Should it?

III. ANALYSIS

The saga of BSE is contemporary, yet shows no sign of subsiding. While the Canadian border may be open at the time this note is published, it seems that regardless of how BSE and the accompanying legal issues play out, BSE testing continues to be an inadequately addressed problem of health law, administrative law, and international law. This section will evaluate the likelihood of further judicial review in the context of BSE testing, and will analyze in detail the VSTA, the law which the USDA has used to prohibit Creekstone and Gateway's voluntary testing. Mandatory BSE testing, opposed by the largest industry groups, may or may not be in American agriculture's future. Voluntary testing, on the other hand, should be. As the federal district court noted above, for consumer confidence, market reliability, and testing consistency, opposing voluntary testing is "contrary to rational thinking."[155]

152. *See* R-CALF v. USDA, No. 05-35264, DC No. CV 05-006 RFC D. Mont. at 23, 50 (9th Cir. July 14, 2005) (on file with author).

153. *Id.* at 1096.

154. *See* Petition for Rehearing, with Suggestion for Rehearing En Banc, R-CALF v. USDA, No. 05-35264, (9th Cir. Oct. 13, 2005) (order denying petition for rehearing).

155. *See* R-CALF v. USDA, 359 F. Supp. 2d 1058, 1072 (D. Mont. 2005); *supra* text accompanying notes 128–29.

A. USDA Authority and Deference

Before beginning any analysis about the USDA's authority to regulate private testing of cattle, establishing the level of deference a court may show the agency during judicial review is crucial. Whether a court defers to USDA decisions depends on a number of factors.[156] A primary concern is whether the agency is acting under an unambiguous Congressional mandate. But also important is whether its decision was made in an Administrative Procedure Act (APA) formal rulemaking, or an informal notice-and-comment rulemaking.[157] The following paragraphs will show that because the USDA's decision to prohibit testing under the authority of the VSTA was not made under a formal rulemaking, nor any recognizable informal rulemaking under the APA, nor anything even as informal as an announcement or press release, the decision should not be afforded a very high level of deference. In fact, the relatively high "go-to" APA standard of arbitrary or capricious[158] on which courts usually rely in administrative law cases might not be appropriate in the present case at all. Here, a much lower standard may be warranted.

In 1944, the Supreme Court laid out an initial deference to agency decision standard, which would last for forty years, in *Skidmore v. Swift & Co.*[159] Justice Jackson, writing for the Court, held that the deference accorded to Administrators of agencies in reviewing agency decisions should include "the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade."[160] While not the most specific of standards, it nonetheless lasted until 1984, when *Chevron, U.S.A., Inc. v. Natural Resource Defense Council, Inc.*[161] was decided.

In *Chevron*, Justice Stevens set out a standard of judicial review for agency interpretations of statutes that has become the "central feature of contemporary administrative law argumentation";[162] if Congress has spoken directly, its intent must be followed.[163] If Congress is silent or ambiguous, the court should consider the agency's interpretation to be a valid statutory construction, unless it is "arbitrary, capricious or manifestly contrary to the statute."[164] In essence, the standard is agency reasonableness.[165] For twenty years, this almost unbeatable standard de-

156. *See* U.S. v. Mead Corp., 533 U.S. 218, 228 (2001) (citing Skidmore v. Swift & Co., 323 U.S. 134, 139–40 (1994).

157. Administrative Procedure Act, 5 U.S.C. §§ 554–557 (2001).

158. 5 U.S.C. § 706(2)(A) (2001).

159. *See* Skidmore, 323 U.S. at 139–40.

160. *Id*. at 140.

161. 467 U.S. 837, 842–45 (1984).

162. JERRY L. MASHAW ET AL., ADMINISTRATIVE LAW: THE AMERICAN PUBLIC LAW SYSTEM 802 (5th ed. 2003).

163. *See Chevron*, 467 U.S. at 842–43.

164. *Id.* at 844.

165. *See* United States v. Mead Corp., 533 U.S. 218, 229 (2001).

fined, and continues to define, the landscape of administrative law. Yet this standard is problematic because an agency could read almost any statute and find an interpretation to suit its goals.[166]

In the twenty years since *Chevron*, the Supreme Court has redefined its position on agency statutory interpretation. In perhaps the most significant case since then, *U.S. v. Mead Corp.*,[167] the Court noted "[t]he fair measure of deference to an agency administering its own statute has been understood to vary with circumstances, and courts have looked to the degree of the agency's care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency's position."[168] In other words, *Chevron*'s reasonableness cannot and should not be the sole test for the validity of an agency statutory interpretation. The Court also noted that *Chevron* did not eliminate *Skidmore*'s holding that "an agency's interpretation may merit some deference whatever its form, given the specialized experience and broader investigations and information available to the agency and given the value of uniformity in its administrative and judicial understandings of what a national law requires."[169] Finally, the Court acknowledged that even though an "overwhelming number of . . . cases applying *Chevron* deference" were reviewing informal rulemaking under the APA, an informal rulemaking procedure alone did not bar deference.[170]

In a final broad stroke, Justice Souter concluded that considering the variety of ways in which administrative rules were promulgated, it was "simply implausible that Congress intended . . . only two varieties of administrative action, demanding either . . . *Chevron* deference or none at all."[171] Justice Scalia, angrily dissenting, claimed the previous "presumption of authority in agencies to resolve ambiguity in the statutes they have been authorized to enforce has been changed to a presumption of no such authority, which must be overcome by affirmative legislative intent to the contrary."[172] He called *Mead* "one of the most significant opinions ever rendered by the Court dealing with the judicial review of administrative action. Its consequences will be enormous, and almost uniformly bad."[173]

Have the results been as bad as Scalia predicted? It is probably too early to tell. But in 2004, in *General Dynamics Land Systems, Inc. v. Cline*, the Court held "[e]ven for an agency able to claim all the authority possible under *Chevron*, deference to its statutory interpretation is called for only when the devices of judicial construction have been tried and

166. *See* MASHAW, *supra* note 162, at 801.
167. 533 U.S. 218 (2001).
168. *Id.* at 228 (citing Skidmore v. Swift, 323 U.S. 134, 139–40 (1944)).
169. *Id.* at 234 (citation omitted) (quoting *Skidmore*, 323 U.S. at 139).
170. *Id.* at 230–31.
171. *Id.* at 236.
172. *Id.* at 239 (Scalia, J., dissenting).
173. *Id.* at 261 (Scalia, J., dissenting).

found to yield no clear sense of congressional intent."[174] And in another vein, in 2000, Justice Thomas found in *Christensen v. Harris County* that "interpretations such as [opinion letters]—like interpretations contained in policy statements . . . which lack the force of law—do not warrant *Chevron*-style deference."[175]

In light of these decisions, various outcomes emerge when predicting what standard of review a court might assign to the USDA's application of VSTA to BSE testing. One, because the USDA's decision to prohibit testing was not carried out under any formal or informal rulemaking, it may not be entitled to *Chevron* deference. Two, because the USDA may not be entitled to *Chevron* deference, the USDA may be held to a standard higher than reasonableness to defend its interpretation. Three, if the *Chevron* standard does not apply, the appropriate standard may be a de novo standard under *Mead*, although accorded some weight under *Skidmore*. Keeping these possibilities in mind, the following section will analyze the VSTA, assessing the USDA's authority to regulate BSE testing by examining the legislative history, the text of the statute, other court interpretations, and at length, the plain language of the statute. The analysis will conclude that BSE testing is not within the USDA's authority under the VSTA.

B. The Virus, Serum, and Toxin Act; Legislative History

In *R-CALF v. USDA*, the counsel for the USDA confirmed that the BSE test is "licensed by USDA under the Virus-Serum-Toxin Act."[176] There is no question that the VSTA is the authority under which the USDA licensed the test; the issue is whether the VSTA gives the USDA authority to license the test and prevent private producers from testing their own cattle. While the hearings in the Montana federal district court were not the first time VSTA had been quoted as the source of the prohibition against Creekstone and Gateway, it was the first time it had been used that way in a court of law.[177]

The VSTA was originally enacted in 1913 as the USDA's response to anti-hog-cholera serum causing losses to American hog farmers.[178] Congress envisioned the VSTA as a prevention against

> dangerous and worthless viruses, serums and analogous products for use in the treatment of domestic animals, some of which products may be the means of introducing disease not now known in the

174. *See* Gen. Dynamics Land Sys., Inc. v. Cline, 540 U.S. 581, 583 (2004) (citing INS v. Cardoza-Fonseca, 480 U.S. 421, 446 (1987)).

175. *See* Christensen v. Harris County, 529 U.S. 576, 587 (2000).

176. Transcript of Hearing on Application for Preliminary Injunction at 72, R-CALF v. USDA, 359 F. Supp. 2d 1058 (D. Mont. March 2, 2005) (No. CV-05-06-BLG-RFC), *available at* http://www.r-calfusa.com/BSE/Hearing%20Transcript.pdf. [hereinafter Transcript of Hearing].

177. *See infra* notes 190–92 and accompanying text.

178. *See* Hall v. State, 158 N.W. 362, 363 (Neb. 1916).

> United States, [as well as] controlling the use . . . of similar dangerous and worthless products that may be manufactured within the United States.[179]

In a later 1913 Congressional hearing, the USDA claimed the VSTA was designed to "protect the farmer and stock raiser from improperly made and prepared serums, toxins and viruses."[180]

The VSTA was amended in 1985 to grant the USDA authority to regulate intrastate vaccines.[181] In legislative history, the VSTA is described as the "statutory authority for [the USDA's] regulation of animal vaccines and related products," ensuring "an ample supply of safe and effective animal vaccines and other biological products" to the American public.[182] The VSTA was again referenced in 2002, in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Here, the VSTA is described as the act under which the USDA regulates "dangerous agents."[183]

C. Text of the VSTA

> The VSTA provides, in pertinent part, that it is unlawful to
> prepare, sell, barter, or exchange . . . any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals [unless it was] prepared . . . in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding [a] . . . license issued by the Secretary of Agriculture.[184]

The VSTA further authorizes the Secretary of Agriculture to establish "rules and regulations as may be necessary to prevent the preparation, sale, barter, exchange, or shipment as aforesaid of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals" as well as the ability to "issue, suspend, and revoke licenses for the maintenance of establishments for [that] preparation."[185]

Importantly, the statute fails to define "virus, serum, toxin, or analogous product" or any other key terms, heightening the question of whether the USDA can regulate the BSE test under this statute.[186] Adding a layer of complexity, the statute further permits the Secretary to

179. *See* S. REP. NO. 62-1288, at 2 (1913).

180. *Hearing before the Committee on Agriculture on the Estimates of Appropriations for the Fiscal Year Ending June 30, 1914, H.R. 28283*, 62d Cong. 24 (1913) (statement of Dr. A.M. Farrington, Asst. Chief, Bureau of Animal Indus., Dept. of Agric.).

181. *See* Food Security Act of 1985, Pub. L. No. 99-198, § 1768, 99 Stat. 1654–56 (1985).

182. *See* S. REP. NO. 99-145, at 338 (1985).

183. *See* Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 201 at 51 (2002).

184. 21 U.S.C. § 151 (2000).

185. 21 U.S.C. § 154 (2000).

186. *See id.*

make and promulgate regulations through the Code of Federal Regulations (C.F.R.); the Animal and Plant Health Inspection Services (APHIS), an agency within the USDA, is responsible for the BSE regulations.[187] The corresponding C.F.R. section does not define viruses, serums, toxins or analogous products, but incorporates all of them in its definition of biological products. "[B]iological products . . . shall mean all viruses, serums, toxins . . . or analogous products at any stage of production, shipment, distribution, or sale, . . . intended for use in the treatment of animals and which act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response."[188] A long list of examples of biological products follows, including "diagnostic components, that are of natural or synthetic origin, or that are derived from synthesizing or altering various substances or components of substances such as . . . proteins, antigens, allergens, or antibodies."[189]

Is the BSE test a virus, serum, toxin, or analogous product? Is it intended for use in the treatment of animals and does it act primarily through the immune system? Since neither the text of the statute, the legislative history, and the APHIS regulations do not clearly answer these questions, the analysis will continue by examining the VSTA in the same way a court would: looking at previous court interpretations and examining the plain language.

D. Court Interpretation of the VSTA

In seven circuits since 1913, courts have evaluated the VSTA as a statutory tool to regulate vaccines.[190] The case which is widely

187. *Id.*; *see also* Animal and Plant Health Inspection Services Overview, http://www.usda.gov (follow "Agencies and Offices" hyperlink; then follow "Animal and Plant Health Inspection Service (APHIS)" hyperlink) (last visited Feb. 28, 2006).

188. 9 C.F.R. § 101.2 (2005).

189. 9 C.F.R. § 101.2 (2005).

190. *See*, *e.g.*, Silvey v. Mallinckrodt, Inc., 976 S.W.2d 497, 499 (8th Cir. 1998) ("In enacting VSTA Congress required that all animal vaccines produced in the United States and all establishments that manufacture such vaccines be licensed by the USDA."); United States v. Algon Chem. Inc., 879 F.2d 1154, 1163 n.5 (3d Cir. 1989) ("The VSTA is a separate act of Congress enacted in 1913 and amended in 1985, which governs the regulation of 'biologic' drugs, including serums, vaccines, toxins or antitoxins that are intended for use in the treatment of domestic animals. . . ."); Arnold v. Intervet, Inc., 305 F. Supp. 2d 548, 550 (D. Md. 2003) ("[The] use or administration of animal vaccines have been preempted by the regulations promulgated by the Department of Agriculture in its exercise of a plenary authority granted by Congress to regulate the field of animal vaccines."); Cooper v. United Vaccines, Inc., 117 F. Supp. 2d 864, 866 (E.D. Wis. 2000) ("The manufacture and sale of animal vaccines are extensively regulated by the federal government pursuant to the Virus, Serums, Toxins, Antitoxins and Analogous Products Act."); Gresham v. Boehringer Ingelheim Animal Health, Inc., Civ. 95-3376, 1996 WL 751126, at *2 (N.D. Ga. Aug. 7, 1996) ("It is undisputed that Congress intended through VSTA to create nationally uniform standards for the preparation and sale of animal vaccines."); Murphy v. SmithKline Beecham Animal Health Group, 898 F. Supp. 811, 817 (D. Kan. 1995) ("The language used by APHIS is quite broad: the agency pre-empts state requirements 'regarding the safety, efficacy, potency or purity' as well as the labeling of animal vaccines."); Found. on Economic Trends v. Lyng, 680 F. Supp. 10, 11 (D. D.C. 1988) ("The United States Department of Agriculture Animal &

considered "the leading circuit court decision on the preemptive effect of federal regulations governing animal vaccines"[191] noted that "APHIS . . . has promulgated an extensive regulatory scheme governing the design, manufacture, distribution, testing, and labeling of animal vaccines."[192]

E. Plain Language of the VSTA

To determine the plain meaning of the VSTA, the particular language of the statute, as well as its design and language as a whole, should be examined.[193] Then, to ascertain the correct interpretation, it must be decided "whether the language of the statute is clear or arguably ambiguous."[194] A number of questions, therefore, need to be answered in order to determine whether the USDA can regulate the BSE test under the VSTA: (1) Is a test for BSE a "worthless, contaminated, dangerous or harmful . . . virus, serum, toxin or analogous product" (and therefore a biological product) which (2) is "intended for use in the treatment of animals" and (3) "which act[s] primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response?"[195] Finally, (4) is the BSE test a diagnostic component?[196]

1. Worthless, Contaminated, Dangerous, or Harmful Virus, Serum, Toxin or Analogous Product (Biological Product)?

Before determining whether the BSE test is worthless, contaminated, dangerous or harmful, it should first be determined if the BSE test is a virus, serum, toxin or analogous product. As mentioned above, the VSTA provides no definitions for these key terms. A search through the Dictionary Act of the United States Code, which provides general rules of construction and definitions for various words in the United States Code, also does not provide definitions of these key terms.[197] Case law is similarly silent.[198] The fourth edition of the *American Heritage Diction-*

Plant Health Inspection Service . . . controls the production and marketing of veterinary medicines including vaccines through a licensing process under the Virus-Serum-Toxin Act."). The only other interpretation of the VSTA by courts was that the VSTA preempted any state laws. *See* Lynnbrook Farms v. Smithkline Beecham Corp., 79 F.3d 620, 629 (7th Cir. 1996).

191. *Cooper*, 117 F. Supp. 2d at 869.

192. *Lynnbrook Farms*, 79 F.3d at 624. No other interpretation or use of VSTA has appeared in any court except in the March 2005 oral argument quoted at the beginning of this section. *See* Transcript of Hearing, *supra* note 176, at 72.

193. *See* K Mart Corp. v. Cartier, Inc., 486 U.S. 281, 291 (1988).

194. *Id.* at 293 n.4 (Kennedy, J., plurality).

195. 9 C.F.R. § 101.2 (2005).

196. This is the most likely example of a biological product as envisioned by 9 C.F.R. § 101.2.

197. *See* 1 U.S.C. § 1 (2000).

198. Only one case has addressed the issue of definition under the VSTA, and not directly. In deciding whether a product was in compliance with the FDA or the VSTA, United States v. Pro-Ag,

ary of the English Language, however, provides definitions for all of the key terms in the VSTA. For example, virus is defined as "any of various simple submicroscopic parasites of plants, animals, and bacteria that often cause disease and that consist essentially of a core of RNA or DNA surrounded by a protein coat."[199] Serum is defined as "the clear yellowish fluid obtained upon separating whole blood into its solid and liquid components after it has been allowed to clot" or "blood serum from the tissues of immunized animals, containing antibodies and used to transfer immunity to another individual" or "watery fluid from animal tissue, such as that found in edema."[200] A toxin is defined as a "poisonous substance, especially a protein, that is produced by living cells or organisms and is capable of causing disease when introduced into the body tissues but is often also capable of inducing neutralizing antibodies or antitoxins."[201]

The BSE test is not a parasite, nor a fluid, nor a substance.[202] It perhaps is an examination, analysis, assessment, process or procedure, none of which are defined, regulated, or mentioned in the VSTA. APHIS does define analogous products in its regulations, however.

> (2) The term *analogous products* shall include:
>
> (i) Substances, at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and which are similar in function to biological products in that they act, or are intended to act, through the stimulation, supplementation, enhancement, or modulation of the immune system or immune response; or
>
> (ii) Substances, at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals through the detection or measurement of antigens, antibodies, nucleic acids, or immunity; or
>
> (iii) Substances, at any stage of production, shipment, distribution, or sale, which resemble or are represented as biological products intended for use in the treatment of animals through appearance, packaging, labeling, claims (either oral or written), representations, or through any other means.[203]

Inc., 968 F.2d 681, 683 (8th Cir. 1992), defined a term under 9 C.F.R. § 101.2. The court declined to rule on the merits of the claim and made no statement as to the appropriateness of that definition.

199. AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (4th ed. 2000).

200. *Id.*

201. *Id.*

202. *Id.* A substance is "that which has mass and occupies space; matter." *Id.* Many of the testing components may have mass and occupy space, but the test itself, being conceptual and procedural in nature, does not.

203. 9 C.F.R. § 101.2 (2005).

The BSE test does not replicate the actions, processes, results or properties of viruses, toxins or serums.[204] The regulations unambiguously are designed to cover all of the possible permutations and inventions of substances that act like viruses, serums, toxins or analogous products, i.e.. products that act upon animals and are harmful or dangerous to them.[205] It is simply contrary to rational thinking to state that a test that indicates disease in an animal is harmful or dangerous to the animal.

The title of Section 151 refers to the "preparation and sale of worthless or harmful products."[206] While titles are not dispositive of the meaning or intent of a statute, they often are examined in the context of a statute.[207] The clear plain meaning of this statute is to prevent worthless or harmful products in order to protect American livestock.[208] The BSE test, however, is not a worthless or harmful product because (1) it is used by the USDA as a valuable indicator of animal disease and (2) it is a postmortem test, and currently unable to be used otherwise.[209] The BSE test cannot be harmful or dangerous to domestic animals because the test is performed postmortem.

2. Intended for Use in the Treatment of Animals

The second requirement of the biological product definition is that the biological product must be intended for use in the treatment of animals. Treatment means the "prevention, diagnosis, management, or cure of diseases of animals."[210] As shown above, the test can identify the presence of BSE. While ultimately the use of the test may lead to prevention of the disease, the test itself does not accomplish prevention. Identification, however, is an aspect of diagnosis.[211] Based on identification and a very broad view of this part of the statute, the BSE test could be interpreted as a treatment, but without being a virus, serum, or toxin, it will not meet the remainder of the necessary components.

204. *See* USDA Food Safety and Inspection Service, Fact Sheets Production and Inspection, http://www.fsis.usda.gov/Fact_Sheets/Bovine_Spongiform_Encephalopathy_Mad_Cow_Disease/index.asp (last visited Aug. 23, 2005) (describing existing BSE "gold standard" tests as examinations of sponge-like changes in brain tissue and BSE fibrils).

205. *See* 21 U.S.C. § 154 (2000); 9 C.F.R. § 101.2 (2005).

206. 21 U.S.C. § 151 (2000).

207. *See* Bhd. of R.R. Trainmen v. Balt. & Ohio R.R. Co., 331 U.S. 519, 529 (1947) ("For interpretative purposes, [titles] are of use only when they shed light on some ambiguous word or phrase. They are but tools available for the resolution of a doubt. But they cannot undo or limit that which the text makes plain.")

208. *See* Hall v. State, 158 N.W. 362, 363 (Neb. 1916).

209. *See* Robert A. LaBudde, *Inside Microbiology: BSE in the USA Redux: How Mad Are We Getting?*, FOOD SAFETY MAGAZINE, Feb.–Mar. 2004, *available at* http://www.foodsafetymagazine.com/issues/0402/colmicro0402.htm.

210. 9 C.F.R. § 101.2 (2005).

211. Diagnosis is "[t]he act or process of identifying or determining the nature and cause of a disease or injury through evaluation of patient history, examination, and review of laboratory data." AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (4th ed. 2000).

3. Acting Primarily Through the Immune System

The third requirement of the biological product definition is that it must "act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response."[212] "The immune system consists . . . of a variety of specialized cells, enzymes, and other serum proteins which are spread throughout the blood and tissues of the body . . . concentrated within the spleen, thymus, lymph nodes, bone marrow, blood and parts of other organs and glands."[213]

The BSE test is conducted by using a sample of the dead cattle's brain.[214] Because removal of the brain sample is a postmortem operation, and immunity is the ability to resist disease, it is also contrary to rational thinking to categorize the BSE test as having a direct effect on the animal's immune system, which has ceased to function at the time of the test. Crucially, even BSE itself—not the test, but the disease—fails to trigger any immune response in cattle.[215] Therefore, because the test—and the disease—do not stimulate, supplement, enhance or modulate the immune system, the BSE test fails the third part of the definition for being a biological product.

In review, a plain language view of the VSTA indicates that the BSE test is not a worthless, contaminated, dangerous or harmful virus, serum, toxin or analogous product which operates primarily through the immune system. Even if it is intended for use in the treatment of animals, it fails the biological product definition. One more question is necessary before establishing that the BSE test should not be regulatable by the USDA under the VSTA.

4. Diagnostic Components

The last part of the plain meaning analysis is whether the BSE test could be a diagnostic component.[216] Fully, the question to be answered is whether the BSE test is a diagnostic component "of natural or synthetic

212. 9 C.F.R. § 101.2 (2005). The presence of the connector "and" after "the treatment of animals," in 9 C.F.R. § 101.2 makes it a requirement of this definition that the BSE test acts in this manner.

213. E. J. Richey, *The Immune System*, University of Florida, Inst. of Food and Agric. Sciences (Mar. 1997), http://edis.ifas.ufl.edu/BODY_VM027 (last visited Feb. 28, 2006).

214. *See* Bovine Spongiform Encephalopathy, *supra* note 59.

215. *See* Federal Measures to Mitigate BSE Risks: Considerations for Further Action, 69 Fed. Reg. 13442288, 13442289 (to be codified at 9 C.F.R. pts. 50-85, 9 C.F.R. pts. 309, 310, 311, 318, 319) (July 14, 2004).

216. 9 C.F.R. § 101.2 (2005). Examining this part of the analysis in this divisive manner can lead to absurd results. For example, by examining whether the BSE test is a diagnostic component after concluding that it is likely not a biological product, a possible result is that the BSE test can simultaneously not be a biological component (by its not being a virus, serum, toxin, or analogous product), but can be a diagnostic component, and therefore a biological product, without the characteristics of a biological product. Is this not the definition of statutory ambiguity?

origin, or . . . derived from synthesizing or altering various substances or components of substances such as microorganisms, genes or genetic sequences, carbohydrates, proteins, antigens, allergens, or antibodies."[217] No definition of "diagnostic components" exists in the APHIS regulations, nor does the phrase exist in the VSTA itself. In everyday language, the BSE test is a diagnostic test. But because the BSE test is a series of procedures and processes, it seems illogical to continue by analyzing whether the test is of natural or synthetic origin or whether it is derived from synthesizing or altering substances. The analysis may extend indefinitely, forcibly separating each of the test's individual parts, processes and elements, authorizing the USDA to regulate each part, process and element individually, a whirlwind of circular reasoning in which each component of a diagnosis is a diagnostic component, leading back to the beginning of the analysis. Using the VSTA to regulate the BSE test requires undeniable expansion of the meaning and purpose of the statute.

In sum, the USDA cannot regulate the BSE test through the VSTA because the BSE test is not worthless, contaminated, dangerous or harmful. The BSE test is not a virus, serum, toxin or analogous product, nor a biological product. Considering the BSE test as intended for use in the treatment of animals when it is designed for postmortem use is an overexpansion of the VSTA. It is likewise a stretch to manipulate the BSE test and force it into the definition of a diagnostic component (especially since the diagnostic component is necessarily a biological product) simply to allow VSTA inclusion. Finally, preventing testing for a disease is manifestly contrary to a statute whose purpose is to prevent disease. The USDA, by denying Creekstone and Gateway through application of the VSTA, sought not to regulate the procedures or substance in each individual element of the test, but the test itself. In its ninety-two years of existence, the VSTA has never before been used or interpreted to regulate testing of any kind. Manipulating the VSTA to include the BSE test in the age of BSE perverts the statute's purpose.

The USDA is responsible for the safety of American beef. When it uses the VSTA to prevent BSE testing, it is limiting its ability to impact food safety. The use of the VSTA implies a false assumption of authority that undermines the USDA's status as a regulator and protector of American health. Implementing a more comprehensive BSE policy will serve to strengthen the public's view of the USDA and food safety and more importantly, lead to actual protection for Americans from BSE.

217. 9 C.F.R. § 101.2 (2005).

IV. RESOLUTION

A comprehensive BSE testing strategy would ideally create a top-down approach, beginning with a philosophy of disease prevention and expanding outward to envelope all of the factors, issues, and circumstances to achieve the single goal of BSE prevention. The purpose of BSE testing would be multifold, and include surveillance and food safety concerns based on accepted scientific methods. All animals scientifically capable of testing positive for BSE would be tested. Decisions on whether to open borders would include a thoroughly reviewed plan to prohibit the entrance—or exit—of BSE. Ideally, private testing would be a non-issue as well, as USDA testing would be adequate.

In June 2004, a coalition of consumer safety and public interest organizations compiled a list of recommendations for a comprehensive BSE testing strategy incorporating many of these concerns.[218] If the USDA were to incorporate these rules into a comprehensive BSE testing strategy, not only would food safety in the United States be greatly increased, but a more consistent application of law and policy would be applied to the BSE problem, allowing producers and consumers accurately to assess the BSE costs within a balanced and predictable set of objectives. The following is a list of recommendations, adapted in part from the coalition noted above. Each of these recommendations would encourage foreign markets, especially Japan, to reopen their borders to American beef, satisfying the goals of the beef industry.

1. *Test all slaughtered cattle for BSE at 30 months.* It is inexcusable that more than 98% of the cattle slaughtered annually in the United States never get tested for BSE. Japan tests every single cow it slaughters—most EU countries test all slaughtered cattle over thirty months; Germany tests all slaughtered cattle at twenty-four months.[219] The cost to consumers? Six to ten cents per pound.[220] And the current policy of testing downers doesn't work either: 2142 (or 0.025%) of 8.5 million symptomless thirty-month-old cattle in Europe tested for BSE in 2001 were positive.[221]

218. The coalition of consumer safety and public interest organizations included the Center for Food Safety, Consumers Union, The Creutzfeldt-Jakob Disease Foundation, Friends of the Earth, Government Accountability Project, Institute for Agriculture and Trade Policy—Action, and Public Citizen. *See* Bush Administration Mad Cow Disease Prevention Report Card, June 22, 2004, *available at* http://www.agobservatory.org/library.cfm?refid=31808.

219. Thomas M. Burton & Martin Fackler, *Should U.S. Start to Screen Every Last Cow as in Japan? 'A Negligible Cost Increase'*, WALL ST. J., Jan. 2, 2004, at B1.

220. *Id.*

221. *Id.*

2. *Randomly administer BSE tests to slaughtered cattle starting at 20 months*.[222] Both England and Japan have discovered animals younger than thirty months with BSE.[223] This would align USDA policy with Japanese BSE-testing policy and hasten the reopening of the Japanese market.
3. *Test cattle randomly on unannounced visits to slaughterhouses, feedlots, and anywhere else cattle is raised*. The USDA calls their policy random, but in actuality, BSE tests are announced, and producers are permitted to select the animals to be tested.[224] While this may save time, it also allows an unacceptable level of discretion to the producers, who have a strong economic motive not to have BSE in their herd. Random testing would be far more representative of the incidence of BSE in the United States.
4. *Congress should require the USDA to license the BSE test*. The USDA should then license the test to private companies that choose to test their own cattle. The USDA should create standards for testing conditions and requirements, and promulgate an application process with objective criteria for private producers. A standard testing regime would enable private producers such as Creekstone and Gateway to market their beef as "tested for BSE."
5. *Ensure feed restrictions are enforced*. The FDA has the authority to enforce the feed ban which prevents rendered cattle from being fed to cattle. But a February 25, 2005, Government Accountability Office memo notes that the FDA is far behind on inspecting feed businesses subject to the feed ban, has no uniform plan to identify feed businesses, has no routine procedure for testing of cattle feed, does not require a notice about the ban to be placed on feed, and has repeatedly failed to notify the USDA when it discovered that cattle may have been fed banned feed.[225] The need to improve these deficiencies to lessen the possibility of BSE infection cannot be overstated.

222. *See* Letter from Jean Halloran, Dir., Food Policy Initiatives, and Michael K. Hansen, Senior Research Assoc., Consumers Union, to Mike Johanns, Sec'y of Agric., USDA (June 20, 2005) (on file with author), *available at* http://www.consumersunion.org/pub/foodmad_cow/002417.html.

223. *Safer Beef*, *supra* note 9.

224. *See* Letter from Jean Halloran, Dir. Food Policy Initiatives, and Michael K. Hansen, Senior Research Assoc., Consumers Union, to Mike Johanns, Sec'y of Agric., USDA (July 25, 2005) (on file with author).

225. *See generally* UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE, REPORT TO CONGRESSIONAL REQUESTERS, MAD COW DISEASE: FDA'S MANAGEMENT OF THE FEED BAN HAS IMPROVED, BUT OVERSIGHT WEAKNESSES CONTINUE TO LIMIT PROGRAM EFFECTIVENESS (Feb. 2005), http://www.gao.gov/new.items/d05101.pdf [hereinafter United States Government Accountability Office].

6. *Implement a national animal identification and tracking system*.[226] Every automobile sold in the United States has a unique identification number to prevent fraud and insure protection in the case of a recall. The USDA has acknowledged the need for a similar system for cattle in the past and held public meetings to evaluate costs and benefits; as outbreaks of *E. coli* have shown,[227] the ability to quickly recall infected beef will save lives. In addition, an identification and tracking system would not only help to remove tainted meat from store shelves and storage, but also present an opportunity to fix conditions at the source which fostered BSE initially.[228]
7. *Give the USDA authority for mandatory recall*.[229] Most Americans assume the USDA has the authority to recall infected meat. In fact, the USDA has never exercised this authority and regularly withholds information about the sources of infected meat on the basis that the information is proprietary.[230] But the national animal identification and tracking system will have no teeth if the USDA cannot exercise the authority to recall meat. The USDA must confirm with Congress its authority for mandatory recall.[231] This, too, is a food safety measure whose benefits vastly outweigh its costs.
8. *Implement Country of Origin Labeling (COOL)*. Although required under the 2002 Farm Bill, COOL remains unenforced and mired under unnecessary appropriations delays since its passage.[232] Why not give consumers the ability to know the national origin of their meat and the choice to buy American products?
9. *Increase surveillance for, and implement mandatory reporting of, Creutzfeldt-Jakob Disease*. The objective of BSE testing is to prevent infected beef from infecting humans, resulting in CJD, or vCJD, the incurable neurological disease already re-

226. *See generally*, Michael T. Roberts & Harrison M. Pittman, *Legal Issues in Developing a National Plan for Animal Identification*, NAT'L AGRIC. L. CENTER Feb. 2004, http://www.nationalaglawcenter.org/assets/articles/roberts_animalid.pdf (last visited Oct. 2, 2005).

227. *See* Sabin Russell, *Beef recall process draws criticism; USDA lacks power to inform public, mandate returns*, S.F. CHRON., Jan. 6, 2004, at A15, *available at* http://www.sfgate.com/cgi-bin/article.cgi?file=/c/a/2004/01/06/BAGJO443IA1.DTL&type=printable.

228. *See* Editorial, *Round 2 for Mad Cow Disease*, N.Y. TIMES, July 1, 2005, at A16.

229. *See generally*, Michael T. Roberts, *Anatomy of the Government's Role in the Recall of Unsafe Food Products*, NAT'L AGRIC. L. CENTER May 2004, http://www.nationalaglawcenter.org/assets/articles/roberts_recall.pdf (last visited Oct. 2, 2005).

230. Russell, *supra* note 227.

231. *See* Letter from Michael F. Jacobson & Caroline Smith DeWaal, Dir. Food Safety Program, Center for Science in the Public Interest, to Ann Veneman, Sec'y, USDA (Jan. 7, 2004) (on file with author), *available at* http://cspinet.org/new/pdf/uenemanbsesafeguards.pdf.

232. *See* Jane Kay, *The Fish You Buy to Carry a Label This Fall: You'll Know its Origin and Whether it's Wild or Farmed*, Feb. 4, 2004, at A1, *available at* http://www.sfgate.com/cgi-bin/article.cgi?f=16/a/2004/02/04/MNG744OER81.DTL.

sponsible for the death of more than 160 people in England.[233] Tracking the disease would aid BSE prevention from another angle; mandatory reporting of the disease would enable scientists to establish the routes of transmission and translate into better policy for the prevention of the disease.

Each of these recommendations come with costs attached, as do all regulations. But because beef is ultimately a consumer product, the costs of improving its safety can, and should, be shared between the USDA, producers and consumers. More significant are its benefits; the USDA's current BSE prevention policy is based on many sound principles, but has considerable weaknesses which must be resolved. The USDA's Office of Inspector General, in August 2004, released a report detailing many of these shortcomings.[234] The Government Accountability Office's February 2005 report on the FDA offers another set of sensible recommendations to improve the BSE policy.[235] An inclusive process in which these government recommendations, the consumer food safety concerns addressed in part in the above recommendations, and industry concerns were incorporated into a comprehensive BSE policy would translate into a successful open foreign market for American beef, and a safer beef product for all Americans.

V. CONCLUSION

BSE is a problem far from under control. A political economy that prevents the USDA from adequately considering legitimate food safety concerns must be curtailed; a comprehensive BSE prevention policy incorporating the recommendations of government agencies, consumer food safety concerns, and industry interests must be implemented. The consideration of rational, peer-reviewed science-based research is a strong foundation for the new comprehensive policy, as are public interest and industry concerns gathered during a public comment period. Only after these safeguards ensuring a fair balance between public and private concerns are in place can the USDA stand confidently behind a sound BSE policy which is wise, forward-thinking, and substantial.

233. *See supra* note 8.

234. *See* USDA AUDIT REPORT, ANIMAL AND PLANT HEALTH INSPECTION SERVICE AND FOOD SAFETY AND INSPECTION SERVICE BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) SURVEILLANCE PROGRAM-PHASE I (Aug. 18, 2004), *available at* http://www.usda.gov/oig/ webdocs/50601-9-final.pdf.

235. United States Government Accountability Office, *supra* note 225.