It's A New Type of Jungle Out There: An Overview of Bovine

Spongiform Encephalopathy, Its Current International and Domestic

Legal Climate, and the Challenges Presented to the Legal Community.



Prepared by: COZEN O'CONNOR John J. McDonough, Esquire MaryTeresa B. Soltis, Esquire December, 2006

These materials are intended to generally educate on current legal issues. They are not intended to provide legal advice. Accordingly these materials should not be relied upon without seeking specific legal advice on matters discussed herein.

In 1906, Upton Sinclair's novel, *The Jungle*, exposed the poor sanitation practices of the meatpacking industry and spurred revolutionary statutory protection for American meat consumers and industry workers. Today, exactly a century later, with Americans and others ingesting meat, which might be more properly labeled a biohazard, the ultimate conclusion of Sinclair's novel takes on a new meaning. In short, it's a new type of jungle out there. Although the jungle of 2006 may no longer be a world of slaughterhouses in which meat falls to the floor only to be placed back on the conveyor belt, it is one in which the food supply to that same source of meat has become contaminated giving rise to neurological disease and death to the ultimate human and animal consumers.

This new jungle takes the form of Bovine Spongiform Encephalopathy, (hereinafter, "BSE) commonly known as "Mad Cow Disease" and its human (although not yet verified) counterpart, variant Creutzfeldt-Jakob Disease. The United Sates became the twenty-sixth nation to report a case of BSE when a Holstein cow slaughtered at a plant in Washington State was diagnosed with the disease in December 2003.² While the industry faced severe consequences at the international level, reports indicate that domestic beef sales remain steady.³ For example, in 2003, beef consumption in the United States was reported at twenty-seven (27) billion pounds, down slightly from the 2002 pre-outbreak consumption of twenty-seven point

_

¹ Robyn Mallon, (Note) *The Deplorable Standard of Living Faced by Farmed Animals in America's Meat Industry and How to Improve Conditions by Eliminating the Corporate Farm*, 9 Mich. St. J. Med. & Law 389 (2005).

² 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'l. Rev. 277, 278 (2005).

³ See id. (noting that in March 2004, the Commerce Department reported that the U.S. trade deficit rose to a record \$43.1 billion due, in part, to a forty percent drop in meat shipments to nations that had banned American beef). But see Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. U.S. Dept. of Agric., Animal, & Plant Health Inspection Servs., (hereinafter, Ranchers Cattlemen), 415 F.3d 1078, 1105 (9th Cir. 2005) (noting that the American demand for beef in 2004 is estimated to have increased seven to eight percent over 2003 levels).

nine (27.9) billion pounds.⁴ In 2004, Americans consumed approximately twenty-seven point six (27.6) billion pounds of beef, and, in 2005, the estimated retail equivalent value of the United States' beef industry was seventy-eight billion dollars.⁵

This paper is presented in six parts. The first part features a discussion of the disease process of BSE and the symptoms, incubation period, tests for, and effects thereof. In the second part, the authors address variant Creutzfeldt-Jakob Disease, (hereinafter, "vCJD"), which is fatal to humans, and may be linked to the consumption of BSE contaminated products. The third part traces the evolution of BSE and, in some locations, vCJD, from their origins in the United Kingdom and across the world. The fourth part outlines the United States' Government's efforts to address the problems presented by BSE and the legal challenges thereto. The fifth part surveys BSE-related litigation in Canada and France. The paper, then, concludes with a discussion of a possible, albeit, undetected cluster of vCJD closer to home: in Cherry Hill, New Jersey, and observations of the challenges presented by BSE to the members of the legal community.

I. The Disease Process of BSE.

BSE, or Mad Cow Disease, is a chronic, degenerative, and fatal neurological disorder that affects the central nervous system of cattle.⁶ Current research confirms that BSE infectivity occurs in the brain, trigeminal ganglia, tonsils, spinal cord, and distal ileum of the small intestine,

_

⁴ Background Statistics: U.S. Beef and Cattle Industry, USDA Economic Research Service, Mar. 6, 2006, available at: http://www.ers.usda.gov/news/BSECoverage.htm (last visited Apr. 10, 2006).

⁵ *Id. See also Ranchers Cattlemen*, *supra* note 3, at 1105 (noting that the American demand for beef in 2004 is estimated to have increased seven to eight percent over 2003 levels).

⁶ USDA Fact Sheet: *Bovine Spongiform Encephalopathy – Mad Cow Disease*, (hereinafter, *USDA Fact Sheet*) available at: www.fsis.usda.gov/Fact_Sheets/Bovine_Spongiform_Encephalopathy_Mad_Cow_Disease/index.asp (last visited Apr. 10, 2006).

as well as the retina of the eyes of infected cattle.⁷ BSE gets its name from the spongy appearance of the brain tissue seen in infected cattle when said tissue is examined under a microscope.⁸

Based on the information known to date, BSE is not contagious and there is no evidence that the disease is transmitted through direct contact or animal-to-animal spread. Rather, animal consumption of BSE contaminated feed is the primary means of infection. BSE infected animals may display changes in temperament, such as, nervousness or aggression, abnormal posture, difficulty rising, decreased milk production, or loss of body weight despite continued appetite.

At present, there is no treatment for BSE.¹² The course of the disease varies from two weeks to fourteen months and usually results in death or humane destruction within four months in countries where the disease is present.¹³ The incubation period for BSE (the time from when an animal becomes infected until it first exhibits symptoms of the disease) is anywhere from

⁷ *Id*.

⁸ *Id.* (indicating that BSE belongs to a family of diseases known as the transmissible spongiform encephalopathies (hereinafter, "TSE"). TSE animal diseases found in the United States include scrapie in sheep and goats, chronic wasting disease in deer and elk, transmissible spongiform encephalopathy in mink, and feline spongiform encephalopathy in cats. There is, however, no evidence to date that BSE has emanated from TSEs in other animals). *See also Ranchers Cattlemen surpa* note 3, at 1085 (describing the effect of TSEs as creating myriad tiny hold in the brain and slowly deteriorating its victims' mental and physical abilities until death results).

⁹ USDA Fact Sheet, supra note 6.

¹⁰ *Id. But see Ranchers Cattlemen, supra* note 3, at 1086 (noting that in experiments on sheep, mice, and hamsters, BSE was transmitted through whole blood transfusion; at least one case of vCJD is believed to have been transmitted through human transfusion; and that other studies suggest that BSE may be transmitted through saliva and maternally).

¹¹ USDA Fact Sheet, surpa note 6.

 $^{^{12}}$ Id

¹³ *Id*.

thirty months to eight years, with a few rare exceptions for younger animals.¹⁴ An infected animal's condition rapidly deteriorates following an onset of symptoms, and such deterioration usually takes between two weeks and six months.¹⁵ Most cases of BSE in Great Britain occurred in dairy cows between three and six years of age.¹⁶

There is no current test to detect BSE in a live animal or muscle meat.¹⁷ Veterinary pathologists confirm the disease via a postmortem microscopic examination of brain tissue using laboratory techniques such as a histopathological examination to detect sponge-like changes in brain tissue.¹⁸ This test and immunohistochemistry, which examines BSE firrils are "gold standard" tests, which take more than a week to run.¹⁹ More rapid tests, which provide results within about two days, detect abnormal prion in dead animals' brain or spinal cord tissue, and are used to determine the presence of BSE and obtain an indication of its prevalence.²⁰ These tests, however, may be unable to detect the disease during the vast majority of the time a cow is infected.²¹

¹⁴ *Id. See also Ranchers Cattlemen, supra* note 3, at 1086 (noting that BSE has an incubation period that lasts an average of four to five years during which time the animal carries the disease, but demonstrates no outward symptoms).

¹⁵ USDA Fact Sheet, supra note 6.

¹⁶ *Id*.

¹⁷ *Id*.

¹⁸ *Id*.

¹⁹ *Id*.

²⁰ USDA Fact Sheet, supra note 6.

²¹ Ranchers Cattlemen, supra note 3, at 1086.

II. BSE Affects Humans in the Form of Creutzfeldt-Jakob Disease

Creutzfeldt-Jakob Disease, (hereinafter, "CJD") is a rare disease found in humans, which is similar to BSE. ²² Scientists report a possible link between consumption of BSE contaminated product and vCJD, a variant of CJD. ²³ According to current scientific research, neither cooking nor irradiation kills the BSE agent. ²⁴

The disease (vCJD) has an incubation period of several years, or decades, such that the symptoms thereof do not immediately present themselves.²⁵ If, for example, a person develops vCJD from consuming a BSE-contaminated product, (although the link between the two is not yet scientifically proven) he or she likely consumed the contaminated product a decade or more beforehand.²⁶ Symptoms of vCJD include memory lapse, loss of motor skills, depression, and mood swings.²⁷ Neurological abnormalities such as ataxia, dementia, and myoclonus present themselves late in the illness.²⁸ The median age at death of patients with vCJD is twenty-eight years.²⁹

²² Federal Agencies Take Special Precautions to Keep "Mad Cow Disease" Out of the U.S., U.S. Dep't. of Health and Human Servs., Aug. 23, 2001, <u>available at</u>, http://www.hhs.gov/news/press/2001pres/01fsbse.html (last visited Apr. 10, 2006).

²³ Id. See also, USDA Fact Sheet, supra note 6; Elizabeth Weise, Agriculture Dept. Confirms Third Case of Mad Cow; Animal Did Not Enter the Food Chain; Chief Vet Says U.S. Beef Remains Safe, USA TODAY, Mar. 14, 2006, 9A.

²⁴ USDA Fact Sheet, supra note 6.

²⁵ Robyn Mallon, *supra* note 1, at 393. *See also*, Jason, R. Odeshoo, *surpa* note 2, at 281; *Mad Cow Disease: Improvements in Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts, (hereinafter, GAO Report)* U.S. Gen. Accounting Office, Pub. No. GAO-02-183, at 4 (2002), available at: http://www.gao.gov/htext/d02183.html (last visited Apr. 10, 2006) (noting that CJD may have an incubation period of up to thirty years).

²⁶ USDA Fact Sheet, supra note 6.

²⁷ Robyn Mallon, *surpa* note 1, at 393; Jason, R. Odeshoo, *surpa* note2, at 281.

²⁸ USDA Fact Sheet, supra note 6. See also Jason, R. Odeshoo, supra note 2, at 281 (citing Philip Yam, Mad Cow's Human Toll, SCI.AM., May 2001, at 12) (noting that a person with CJD eventually falls into a coma and dies, almost always within a year of the onset of symptoms and usually within four months).

Examination of brain tissue obtained via biopsy or autopsy is the only method of confirming vCJD. ³⁰ No known cure exists for vCJD and the disease is fatal after at least four and usually within thirteen months of an onset of symptoms. ³¹ Scientists recently developed experimental drugs and, in cases outside the United States, vCJD sufferers have filed suit seeking access to these new medications. ³²

III. The Evolution and Origins of BSE and vCJD.

BSE among cattle was first described in the United Kingdom in November 1986, and epidemiological evidence established that the outbreak of BSE was related to many years of production and use of contaminated meat and bone meal.³³ While the exact source and nature of the contamination was unclear at first, it was later discovered that the cause was the recycling of

²⁹ USDA Fact Sheet, supra note 6.

³⁰ *Id. See also, Ranchers Cattlemen, supra* note 3, at 1086 (noting that no live animal test for BSE exists and cows must be slaughtered to be tested).

³¹ Robyn Mallon, *supra* note 1, at 393. *See also*, *USDA Fact Sheet*, *supra* note 6; United States Department of Health and Human Services, Fact Sheet No. 2001.08.23: *Federal Agencies Take Special Precautions to Keep "Mad Cow Disease" Out of the United States*, available at: http://www.hhs.gov/news/press/2001pres/01fsbse.html (last visited Apr. 10, 2006); Jason, R. Odeshoo, *supra* note 2, at 281.

³² Jason, R. Odeshoo, *supra* note 2, at 281 (citing Jeremy Laurance, *CJD Victim Improves with Revolutionary Drug Treatment*, INDEP. (U.K.), Sept. 27, 2003, at 5; Paul Gillbride, *Woman's Family Wins Court Fight for New CJD Drug*, DAILY EXPRESS (London), Jan. 24, 2004, at 7 (reporting husband's argument before Scottish Court of Session to procure experimental vCJD treatment for his wife); Jeremy Laurance, *Father's Legal Fight Wins Son Time*, *but Raises Ethical Issues*, INDEP. (U.K.), Sept. 27, 2003, at 5 (reporting British High Court's decision to allow CJD sufferer to receive injections of pentosanpolysulphate over objections of the Commission on the Safety of Medicines)).

³³ United States Department of Health and Human Services, Fact Sheet, supra note 31. See also Jason, R. Odeshoo, supra note 2, at 282 (noting that the BSE crisis originated in England in the mid-1980s when cows in the Sussex and Kent regions began showing signs of aggression and difficulty maintaining balance).

cattle infected with BSE.³⁴ There is also strong evidence and general agreement that feeding young calves rendered bovine meat and bone meal amplified the outbreak.³⁵

All told, there have been more than one hundred and eighty-seven thousand (187,000) confirmed cases of BSE worldwide, over ninety-five percent of which occurred in the United Kingdom. To date, at least one hundred and fifty (150) cases of vCJD have been identified worldwide with the vast majority of these cases occurring in England at the height of its BSE epidemic. Mad cow disease cases were reported in France, Japan, and Italy as recently as September and October of 2006. Although there is a reported case of vCJD in the United States, there is clear epidemiologic evidence that, in that case, the disease was acquired in the United Kingdom. Thus, to date, there is no evidence of a case of vCJD, which arose and/or was acquired inside the United States.

There have, however, been three documented incidents of BSE in the United States. 41

The first incident occurred in December 2003 in a Canadian born cow in Washington State. 42

³⁴ U.K. Min. of Agric., Fisheries & Food, The BSE Inquiry Vol. 1: Findings and Conclusions, at 20 (2000) available at: http://www.bseinquiry.gov.uk/pdf/ (last visited Apr. 9, 2006); Jason, R. Odeshoo, *supra* note 2, at 282-3.

³⁵ *United States Department of Health and Human Services, Fact Sheet, supra* note 31.

³⁶ Ranchers Cattlemen, supra note 3, at 1085.

³⁷ *Id.* at 1086.

³⁸ The Source for Bovine Spongiform Encephalopathy Information, available at http://www.bseinfo.org/Print.azpx?Name=index.aspx (last visited December 19, 2006).

³⁹ BSE in an Alabama Cow, CDC Release, Mar. 15, 2006, available at: www.cdc.gov/ncidod/dvrd/bse/news/alabama_cow_031506.htm (last visited Apr. 10, 2006). See also, Ranchers Cattlemen, supra note 3, at 1086, n.4 (noting that one case of vCJD in the United States occurred in a Florida woman born in England who was believed to have been exposed to vCJD before moving to the United States).

⁴⁰ See USDA Fact Sheet, supra note 6. See also, Ranchers Cattlemen, supra note 3, at 1086 (noting that no vCJD case has ever been linked to North American beef).

⁴¹ Elizabeth Weise, *supra* note 23. *See also* USDA Statement Release No. 0336.05, Aug. 30, 2005; FDA Statement on USDA Announcement of Positive BSE Test Result, Mar. 13, 2006.

The second occurred in June 2005 in a cow born and raised on a ranch in Texas. 43 March 2006 saw the third case of BSE involving an Alabama cow, whose origin and movement to Alabama remain undetermined. 44

IV. The United States Government's Efforts to Address BSE and the Accompanying Legal Challenges

A. Federal Regulatory Agencies Impose Restrictions, Promulgate Regulations, and Offer and Seek Guidance With Respect to BSE.

In 1988, soon after the BSE outbreak in England, the United States Department of Agriculture (hereinafter, "USDA") established a working group to review the scientific issues raised by the disease and recommend appropriate regulatory controls. In 1989, the USDA restricted imports on cattle from BSE infected countries and, in 1991, placed similar restrictions on cow meat, bone meal, and cow meat intended for human consumption. By 1997, the USDA prohibited the use of most mammialian protein in the manufacture of animal feed intended for cattle and other ruminant animals such as cows, sheep, and goats.

The USDA began a surveillance program in 1990 to monitor the nation's food supply for BSE. 48 This testing was expanded in 1993 to include "downer cows," (cattle too sick to walk or

⁴² *Id*.

⁴³ *Id.* The Texas cow was approximately twelve years old at the time of its death, meaning it was born prior to a 1997 feed ban instituted by the FDA to help minimize the risk that a cow might consume feed contaminated with the agent thought to cause BSE. The cow was sold through a livestock sale in November 2004 and transported to a packing plant where it was declared dead on arrival. The cow was then shipped to a pet food plant where it was sampled for BSE, was not used in any plant product, and was later destroyed. *See Investigation Results of Texas Cow that Tested Positive for Bovine Spongiform Encephalopathy*, USDA Release No. 0336.05, Aug. 20, 2005.

⁴⁴ *Id*.

⁴⁵ USDA Actions to Prevent Bovine Spongiform Encephalopathy, Animal & Plant Health Inspection Serv., USDA, (2004) available at: http://www.aphis.usda.gov/lpa/issues/bse/bsechron.html (last visited April 10, 2006).

⁴⁶ GAO Report, supra note 25, at 12.

⁴⁷ USDA Fact Sheet, supra note 6; HHS Fact Sheet, supra note 31.

⁴⁸ GAO Report, supra note 25.

stand) who eventually became the main focus of the USDA's surveillance.⁴⁹ Prior to 2001 only a few thousand cows were tested each year, but the number climbed to twenty thousand by 2002.⁵⁰

The Food and Drug Administration (hereinafter, "FDA") imposed regulations and took additional actions to prevent BSE from spreading to the United States. Beginning in 1992, the FDA restricted imports from BSE-infected nations on cattle by-products used in foods, drugs, dietary supplements, and cosmetics. The FDA expanded these restrictions in 2000 to cover countries at risk for BSE, imposed additional restrictions on cattle feed, and banned most mammalian protein. Current FDA regulations also require the implementation of process control systems to ensure that feed for ruminants does not contain the prohibited mammialian tissue. The FDA asked blood centers to exclude potential donors who had spent six months or more in the United Kingdom and/or other countries with verified BSE experiences and provided written guidance to manufacturers on the use of bovine materials coming from countries affected by BSE. All of these actions were designed to protect animals from BSE, minimize any risk of BSE or vCJD to humans, and prevent the spread of BSE through U.S. cattle feed.

⁴⁹ *Id.* (noting that downer cattle accounted for 4464 of the brains tested in 2001 as compared with the 199 brains of downer cattle tested in 1994).

⁵⁰ Jason, R. Odeshoo, *supra* note 2, at 291 (citing Guy Gugliotta & Christopher Lee, *Mad Cow Alerts Began Years Ago; Enforcement of Feed Ban Was Assailed as Inadequate in 2000*, WASH. POST, Dec. 27, 2003, at A6).

⁵¹ GAO Report, supra note 25, at 12.

⁵² *Id. See also Department of Health and Human Services Fact Sheet, supra* note 31; 21 C.F.R. § 589.2000 (West 2005) (discussing the feed ban that prohibits the feeding of ruminant protein to other ruminants).

⁵³ Department of Health and Human Services Fact Sheet, supra note 31.

⁵⁴ *Id*.

⁵⁵ Id.

A number of studies were also commissioned to assess the United States' vulnerability to BSE. For example, a study conducted by the European Commission's Scientific Steering Committee concluded that BSE was unlikely to exist in the United States.⁵⁶ Results of a study issued in 2001 by the Harvard Center for Risk Analysis, at the USDA's request, found the United States to be "highly resistant to any introduction of BSE or a similar disease," and that BSE was "extremely unlikely" to reach the United States.⁵⁷ In 2002, however, the General Accounting Office (hereinafter, "GAO") issued a report in response to a request from members of the U.S. Senate Committee on Agriculture, Nutrition, and Forestry finding USDA and FDA measures to prevent the spread of BSE to the United States to be "severely inadequate."⁵⁸

The GAO study identified several areas of concern, including the possibility that BSE entered the country via imported animals and materials and due to shortcomings in the FDA's feed ban. ⁵⁹ The FDA feed ban was more limited than those imposed by other countries in that the FDA allowed cattle feed to contain protein from horses and pigs. ⁶⁰ There were also noted problems with the FDA's enforcement efforts to ensure compliance with the feed ban. Although firms failing to comply with FDA regulations could be subject to criminal liability for adulteration and/or misbranding of food products, many firms went un-inspected and the FDA

_

⁵⁶ Jason, R. Odeshoo, *supra* note 2, at 291 (citing E.U. Scientific Steering Comm., Report on the Assessment of Geographical BSE-Risk of the United States of America, at 30 (2000), available at: http://eupora.eu.int/comm/food/fs/sc/ssc/out137_en.pdf (last visited April 10, 2006)).

⁵⁷ Joshua T. Cohen, et al., *Harv. Sch. of Pub. Health, Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States*, at I (2001) available at http://www.aphis.usda.gov/lap/issues/bse/bse-riskassmt.html (last visited April 10, 2006).

⁵⁸ GAO Report, supra note 25, at 1-2.

⁵⁹ *Id.*, at 3.

⁶⁰ GAO Report, supra note 25, at 36.

rarely took action against the noncompliant.⁶¹ The FDA's inspection database also contained incomplete records in the form of inconsistent, inaccurate, or missing information.⁶² In short, the GAO had become the Upton Sinclair of the twenty first century by exposing the inadequacies of the government's response to the new jungle created by BSE and vCJD.

As if on cue, the year after the GAO issued its report brought the announcement of the BSE infected cow in Washington State. The USDA determined that the cow was probably imported from Alberta, Canada in 2001 and born before the feed ban. ⁶³ The USDA then tried to locate the other cows that arrived with the infected cow as these animals may have eaten the same infected feed. ⁶⁴ The USDA concluded its investigation in February 2004 having found twenty-eight cows, tested over two hundred and fifty-five cattle connected in some way with the Washington cow, and determined that testing in all cases ultimately proved to be negative. ⁶⁵

B. The USDA Seeks to Relax Restrictions on Imports From Countries at Risk for BSE, which Gives Rise to Civil Litigation.

On November 4, 2003, then Secretary of Agriculture, Ann M. Veneman (hereinafter, "the Secretary") published notice of a proposed rule seeking to amend the regulations to allow importation of ruminants from countries that presented a minimal risk of introducing BSE into the United States via live ruminants and ruminant products. ⁶⁶ The new regulation proposed to

⁶³ Feed in Mad Cow Cases Traced to Two Mills, WASH. POST, Mar. 20, 2004, at A8.

⁶¹ *Id.*, at 22-3 (noting that the FDA sent warning letters to the non-compliant, bur rarely re-inspected at a later date).

⁶² *Id.*, at 24.

⁶⁴ Jason, R. Odeshoo, *supra* note 2, at 299.

⁶⁵ Shankar Vedantam, U.S. Ends Investigation of Mad Cow Disease; There's Little Risk Says Official, Though Eleven Cattle that Likely Ate Suspect Grain Can't Be Found, L.A. TIMES, Feb. 10, 2004, at A15.

⁶⁶ Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities, 68 Fed. Reg. 62,386 (Nov. 4, 2003).

designate only Canada as a minimal risk region. ⁶⁷ The comment period for this proposed rule was set to expire on January 5, 2004. ⁶⁸

In the interim, on December 20, 2003, the USDA announced new measures to protect against the spread of BSE including: 1) banning downer cattle from the food chain;⁶⁹ 2) ruling that cattle tested for BSE were not to be labeled "inspected and passed" until negative test results were obtained; 3) prohibiting air injection stunning of cattle prior to slaughter;⁷⁰ and 4) developing a national cattle identification system.⁷¹ The FDA also excluded older animals' brain, spinal cord, and eye materials from human food consumption and from rendered materials in animal feeds; eliminated poultry litter, cow blood, and processed plate waste as feed ingredients for cattle; and instituted labeling requirements for pet food and additional control measures to prevent cross contamination of feed and feed ingredients.⁷² Many of these measures were formally promulgated in regulations issued by agencies within the USDA such as the Food Safety and Inspection Service (hereinafter, "FSIS") and the Animal and Plant Health Inspection Service (hereinafter, "APHIS").⁷³

⁶⁷ *Id*.

⁶⁸ *Id*.

⁶⁹ 9 C.F.R. § 309.2 (West, 2005) (prohibiting the use of downer cattle as human food because the inability to stand exhibited by such cattle is a common BSE symptom).

⁷⁰ 9 C.F.R. § 310.13(a)(2)(iv)(C)(West, 2005) (prohibiting the use of "air-injection captive bolt stunning," a process through which a metal bolt and compressed air are driven into cattle crania because the practice poses a risk of contaminating edible meat with central nervous system tissue).

⁷¹ Food Safety & Inspection Serv., USDA Release No. 0449.03, BSE Update, (Jan. 8, 2004). *See also* http://www.aphis.usda.gov/lpa/issues/bse/bse.html (last visited April 10, 2006).

⁷² USDA Fact Sheet, supra note 6.

⁷³ See Ranchers Cattlemen, supra note 3, at 1087-8; Food Safety & Inspection Serv., Release No. 0449.03, USDA BSE Update (Jan. 8, 2004).

Scientists diagnosed the Washington State cow with BSE three days later.⁷⁴ An investigation revealed that the cow was born in Canada and imported to the United States in 2001.⁷⁵ Since the cow was born prior to Canada's 1997 feed ban, the USDA determined that contaminated feed was the likeliest cause of its BSE.⁷⁶ Yet, the USDA reopened the comment period for its proposed rule for an additional thirty days, until April 7, 2004.⁷⁷

a. The Ranchers Cattleman Action Legal Fund Brings Suit to Prevent the Secretary from Lifting the Ban on Imports of Canadian Beef.

On April 19, 2004, the USDA moved, without public notice, to expand the types of ruminant products eligible for importation from Canada. Such products included boneless, bone-in, ground meat, further processed bovine meat products, and bovine tongue, hearts, kidneys, trip, and lips. The Ranchers Cattleman Action Legal Fund (hereinafter, "RCALF") brought suit in the United States District Court for the District of Montana to prevent this action and the District Court granted a temporary restraining order on April 26, 2004, barring the Secretary from lifting the ban on imports of Canadian beef.

⁷⁴ Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities, 69 Fed. Reg. 10,633 (Mar. 8, 2004).

⁷⁵ *Id.* at 10, 634.

⁷⁶ *Id*.

⁷⁷ *Id.* at 10,633.

⁷⁸ Ranchers Cattlemen, supra note 3, at 1089 (internal citation omitted).

⁷⁹ *Id.*, at 1089, n.9 (internal citation omitted).

⁸⁰ RCALF describes itself as a non-profit cattle association that represents United States cattle producers, backgrounders, and independent feedlot owners on issues of international trade and marketing. *See Ranchers Cattlemen, supra* note 3, at 1090, n. 12 (internal citation omitted).

⁸¹ Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. U.S. Dept. of Agriculture, Animal, & Plant Health Inspection Serv., 2004 WL 1047837 (D. Mont. 2004).

The USDA published its Final Rule on January 4, 2005 and proceeded with its plan to reopen the border to Canadian ruminants and ruminant products. Among other provisions, the Rule allowed importation of Canadian cattle under thirty months of age provided that the cattle were immediately slaughtered, or fed and then slaughtered. Importation of beef products from Canadian cattle of all ages was also permitted.

Six days later, RCALF filed suit in the Montana District Court seeking to enjoin the Rule's implementation. RCALF alleged that the USDA's rulemaking violated, among others, the Administrative Procedure Act, (hereinafter, "APA"). Three weeks later, RCALF filed an application for a preliminary injunction, which the District Court issued on March 2, 2005. The court reasoned that the USDA ignored its statutory mandate to protect the health and welfare of the American people, established its goal of re-opening the border to the importation of live beef from Canada, and then attempted to "work backwards" to support and justify that goal. The court found the Final Rule to be arbitrary and capricious given the USDA's "preconceived intention, based on inappropriate considerations, to rush to reopen the borders regardless of uncertainties in the agency's knowledge."

The district court based its decision that the Final Rule was arbitrary and capricious under the APA on six USDA actions: 1) failing to adequately quantify the risk of Canadian cattle to

⁸² Final Rule, 70 Fed. Reg., at 460, 469.

⁸³ Final Rule, 70 Fed. Reg., at 460, 548.

⁸⁴ Final Rule, 70 Fed. Reg., at 461, 465.

⁸⁵ Ranchers Cattlemen, supra note 3, at 1090.

⁸⁶ Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. U.S. Dept. of Agriculture, Animal, & Plant Health Inspection Serv., 359 F. Supp. 2d 1058, 1074 (D. Mont. 2005).

⁸⁷ *Id.*, at 1066.

⁸⁸ *Id.*, at 1074.

humans and, instead, relying on a qualitative statement that said risk was "very low;" 2) erroneously calculating the prevalence of BSE in the Canadian herd; 3) unjustifiably relying on the Canadian feed ban when the science remained uncertain that consumption of contaminated feed was the only method of BSE transmission, the ban was not in place for an adequate amount of time, and was not fully effective; 4) unjustifiably removing specified risk materials; 5) arbitrarily failing to ban the importation of pregnant cows despite evidence that BSE may be transmitted maternally and through fetal bovine blood; and 6) failing to adequately respond to comments recommending mandatory BSE testing of Canadian cattle. ⁸⁹ The District Court concluded that the introduction of BSE into the United States would cause irreparable harm to the American public via an increased risk of vCJD to beef consumers and that the association with Canadian beef would stigmatize all U.S. meat causing a "serious, irreparable impact on ranchers in the U.S. and the U.S. economy. ⁹⁰

The USDA appealed the decision to the Ninth Circuit, which deemed the preliminary injunction unwarranted and reversed the District Court's decision. ⁹¹ The Circuit Court concluded that each of the USDA's determinations with which the District Court took issue had a sound basis in the administrative record and that it was error for the District Court to substitute its judgment for that of the USDA. ⁹² The Court viewed the federal government's BSE prevention measures previously discussed as part of a comprehensive system of "multiple," interlocking safeguards," and noted that consumer demand for and confidence in American beef

⁸⁹ Ranchers Cattlemen, supra note 3, at 1091-2.

⁹⁰ *Id.*, at 1092 (discussing 359 F. Supp. 2d at 1073-4).

⁹¹ *Id.*, at 1093, 1105.

⁹² *Id.*. at 1094-5.

remained strong following the 2003 Washington State case of BSE. ⁹³ Based on the low number of incidents of BSE in the Canadian herd, numerous safeguards against BSE in the United States, the lack of any Canadian cattle under thirty months old found with the disease, and the lack of any case of vCJD attributable to Canadian beef, the Court found any increased risk to human and animal health created by the Federal Rule to be negligible. ⁹⁴

b. An Individual Citizen Sues in an Attempt to Require the USDA to Ban to the Use of Downed Livestock as Food for Human Consumption.

Another reported lawsuit in the United States involving BSE dealt largely with the procedural issue of standing to bring suit. ⁹⁵ Plaintiff, Michael Baur, (hereinafter, "Baur") filed suit to require the Secretary and the USDA to ban the use of downed livestock as food for human consumption. ⁹⁶ "Downed" is an industry term used to describe animals that collapse for unknown reasons and are too ill to walk or stand prior to slaughter. ⁹⁷ USDA regulations allowed the use of downed livestock for human consumption if the livestock passed a mandatory postmortem inspection by a veterinary officer. ⁹⁸ Baur, however, alleged that this policy violated the Federal Meat Inspection Act ⁹⁹ and the Food, Drug, and Cosmetic Act, ¹⁰⁰ and that consumption of

⁹³ *Id.*, at 1105 (citing 70 Fed. Reg., at 522).

⁹⁴ Ranchers Cattlemen supra note 3, at 1104.

⁹⁵ See Baur v. Veneman, 352 F.3d 625, 627 (2d Cir. 2003).

⁹⁶*Id.*, at 628.

⁹⁷ *Id*.

⁹⁸ *Id*.

⁹⁹ The Federal Meat Inspection Act is codified at 21 U.S.C.§§ 601-605.

¹⁰⁰ The Federal Food, Drug, and Cosmetic Act is codified at 21 U.S.C. §§ 301-399.

downed animals created a risk of transmission of vCJD via ingestion of BSE-contaminated beef products. ¹⁰¹

The United States District Court for the Southern District of New York granted the Secretary's motion to dismiss for lack of standing and concluded that Baur's exposure to meat products from downed livestock did not create the cognizable injury-in-fact required to establish a right to bring a lawsuit. Specifically, the court reasoned that any alleged risk of disease was too hypothetical and speculative to support Baur's standing to sue given Baur's inability to allege that BSE was ever detected, or that BSE-contaminated food products were ever offered for sale in the United States. 103

Baur appealed to the Second Circuit, which vacated the District Court's opinion and remanded the case for further proceedings. ¹⁰⁴ The Circuit Court concluded that exposure to an enhanced risk of disease transmission could qualify as an injury-in-fact in consumer food and drug safety cases, and that Baur had alleged a sufficiently credible risk of harm to survive a motion to dismiss. ¹⁰⁵ The Court drew an analogy to environmental cases in which the potential harm is, by nature, "probabilistic," and yet, an unreasonable exposure to risk may cause cognizable injury. ¹⁰⁶ The court also found a tight connection between the type of injury Baur alleged and the statutory goals of ensuring the safety of the nation's food supply and minimizing

¹⁰¹ Baur v. Veneman, 352 F.3d at 628.

¹⁰² Id. (citing Farm Sanctuary, Inc. v. Veneman, 212 F. Supp. 2d 280, 282-84 (S.D.N.Y. 2002)).

 $^{^{103}}$ Id. But, note that both the District and Circuit Court cases were decided prior to the 2003 BSE case discovered in Washington State.

¹⁰⁴ *Id*.

¹⁰⁵ *Id*.

¹⁰⁶ *Id.*, at 634 (2d Cir. 2003).

the risk to public health from potentially dangerous food and drug products. ¹⁰⁷ Additionally, the Court found that Baur alleged a credible threat of harm, confirmed by government studies and statements, and which arose from an established governmental policy. ¹⁰⁸ The USDA and other governmental agencies acknowledged that downed cattle were especially susceptible to BSE infection, ¹⁰⁹ and the risk of transmission that Baur alleged arose directly from the USDA's regulatory policy of permitting the use of downed cattle for human consumption. ¹¹⁰ In vacating the judgment and remanding the case, the Circuit Court left open the question of Baur's standing to challenge government action with regard to downed livestock other than cattle. ¹¹¹ According to communications from Baur's counsel, the case settled soon after this remand.

C. The Few BSE Cases in the United States Give Rise to Criminal Fraud Investigations.

There is also a criminal aspect to the legal climate in the United States in response to mad cow disease in that the USDA's Office of Inspector General conducted a criminal fraud investigation arising out of the BSE incidents in Washington and Texas. The Washington incident stemmed from a February 2004 accusation by the House Committee on Government Reform that the USDA deliberately misled the American people in connection with its mad cow investigation. The committee specifically challenged the FDA's assertion that the infected cow discovered in Washington State was a downer cow when individuals directly involved with

¹⁰⁷ Baur v. Veneman, 352 F.3d at 634 (internal citations omitted).

¹⁰⁸ *Id.*, at 637.

¹⁰⁹ *Id.*, at 637-8 (internal citations omitted).

¹¹⁰ *Id.*, at 640.

¹¹¹ *Id.*, at 643.

¹¹² Marc Kaufman, USDA Accused of Misleading Public on Mad Cow; Whether Diseased Animal was a "Downer" Speaks to Surveillance System, Lawmakers Say, WASH. POST, Feb. 18, 2004, at A28.

that animal (the slaughterhouse owner, the individual transporting the cow to the plant, and the individual who slaughtered the cow) testified in sworn affidavits that the cow was ambulatory and showed no signs of weakness. ¹¹³ It has been argued that a finding of BSE in a non-downer cow would have suggested a greater need for testing than what the FDA required. ¹¹⁴

The Texas incident was uncovered in May 2004 when a federal veterinarian working at a Texas meatpacking plant condemned a cow exhibiting symptoms of BSE. ¹¹⁵ FSIS and APHIS officials' contradictory statements as to the necessity of testing the cow's brain led to the sending of the contaminated remains to a rendering plant where they were used in feed for other animals. ¹¹⁶ The Inspector General concluded her investigation in July 2004 and found no evidence that USDA personnel engaged in intentional misconduct. ¹¹⁷

V. BSE-Related Litigation in Canada and France

A. BSE-Related Litigation in Canada is Grounded in Traditional Tort Principles.

In April 2005, approximately one hundred thousand (100,000) Canadian farmers, ranchers, and others seeking to alleviate the financial pain stemming from the ongoing BSE crisis in Canada filed a class action lawsuit in the Ontario Court against the Canadian Federal Government, individually unnamed federal bureaucrats, Ridley, Inc., (a feed manufacturer) and

¹¹⁵ Scott Kilman, U.S. Confirms a Failure to Use Mad Cow Test, WALL St. J., May 4, 2004, at A6.

¹¹³ Jason, R. Odeshoo, *supra* note 2, at 300 (internal citations omitted).

¹¹⁴ Id

¹¹⁶ Jason, R. Odeshoo, *supra* note 2, at 301 (citing Joint Hearing to Review USDA's Expanded BSE Cattle Surveillance Program: Before the House Comm. on Agric. & the House Comm. on Gov't. Reform, 108th Cong., at 9 (2004) (statement of Phyllis K. Fong, USDA Inspector General)).

¹¹⁷ *Id.* (explaining that the Inspector General rationalized the dispute over the Washington cow's downer status by the fact that the witnesses involved were referring to different cows and that although there was a misjudgment made with respect to the Texas incident, there was no evidence of intentional misconduct).

Ridley's parent, Ridley Corporation, Limited, an Australian entity. The lawsuit, <u>Sauer v. Canada</u>, O.J. No. 26, arises out of a single case of BSE detected in Alberta, Canada in 2003 that led the United States, Mexico, and Japan to close their borders to the Canadian cattle industry and Canadian beef products. The lawsuit seeks the equivalent of five point seven billion U.S. dollars (\$5.7 billion) in actual damages for past, present, and future lost income, and for the diminution in value of plaintiffs' livestock, and eighty-seven million (\$87,000,000) U.S. dollars in punitive damages.

The representative Plaintiff, Bill Sauer, (hereinafter, "Sauer") a Niagara Falls, Ontario, farmer, alleges that the beef farmers' economic losses resulted from manufacturers' breaches of a duty of care and duty to warn purchasers of risks involved in using feed that included ruminant meat and bone meal. ¹²¹ Sauer alleged that Defendant, Ridley, continued using ruminants in its feed until the Canadian government banned such use in 1997 and despite the fact that Ridley's parent firm joined a voluntary Australian feed ban in 1996. ¹²² Sauer further alleged that the Canadian government was negligent in not imposing the feed ban earlier when it knew or should have known that a single case of BSE in Canada would result in the United States closing its borders to the Canadian cattle industry. ¹²³

Canadian Farmers Sue Over BSE, American Feed Industry Association, (2005), available at: http://www.afia.org/Feedgram Articles/2005/Volume 19 6/Class Actinb Suit.html (last visited Apr. 10, 2006); Thomas Claridge, Class Action Over Cattle Feed Survives Ontario Court Ruling, THE LAWYERS WEEKLY, Jan. 20, 2006, Nol. 25, No. 34.

¹¹⁹ Thomas Claridge, *Class Action Over Cattle Feed Survives Ontario Court Ruling*, THE LAWYERS WEEKLY, Jan. 20, 2006, Nol. 25, No. 34.

¹²⁰ Canadian Farmers Sue Over BSE, supra note 117.

¹²¹ Thomas Claridge, *supra* note 118.

¹²² Id.

¹²³ Id. (noting that the plaintiffs' Statement of Claim asserted that but for Ridley's breach of a duty to warn, the infected cow would not have contracted BSE and there would have been no intentional bans of importation of

On January 5, 2006, an Ontario Superior Court judge dismissed the claims against the Australian parent, Ridely, Corp., Ltd., but allowed the claims against the Canadian Federal Government and Ridley, Inc., to proceed. 124 The court noted that while governments do not owe duties of care with respect to legislative policy, a more complete evidentiary record was necessary to determine whether Sauer's claim was based on such a policy decision. 125 Absent that evidentiary record, Sauer's allegations provided "an arguable case that the alleged harm was sufficiently foreseeable and the relationship sufficiently proximate to ground a finding on a prima facie duty of care." Similar class action suits in Saskatchewan, Alberta, and Quebec were on hold pending this decision. 127 Assuming the class is certified and the case continues, all four actions may be consolidated into what would be the largest class action ever pursued in Canada. 128 Recent news reports indicate that a motion for class certification is pending and Sauer's counsel continues to actively solicit class members. 129

B. BSE-Related Litigation in France Focuses on Potential Criminal Liabilities.

In 2001, the families of French vCJD victims filed suit in France's Special Court of Justice alleging that between 1988 and 1996, the French Ministers of Agriculture should have

Canadian cattle and beef in May of 2003). *See also* Nobuko Juji & Bayan Rahman, *Japanese Minister Sued Over BSE*, FIN. TIMES, Oct. 2, 2002, at 8 (noting that in October 2002, Japanese cattle farmers filed two similar lawsuits alleging that the Japanese government was negligent in failing to prevent BSE).

¹²⁴ Thomas Claridge, *supra* note 118.

¹²⁵ Id.

¹²⁶ *Id.* (quoting Sauer v. Canada, O.J. No. 26).

¹²⁷ Canadian Farmers Sue Over BSE, supra note 117.

¹²⁸ *Id*.

¹²⁹ See Moore, Den, Quebec Farmer Seeking Class Action Over Mad Cow Crisis, available at: http://cnews.canoe.ca/CNEWS/Law/2006/10/16pf-2041050.html (last visited December 19, 2006); Register Your Mad Cow Disease Complaint, available at: http://financial.lawyersandsettlements.com/case/canadamadcow (last visited December 19, 2006).

banned high-risk products, such as brain and bone marrow, from the nation's food supply (this ban was instituted in 1996). This lawsuit triggered a French prosecutor's investigation into whether the Ministers might be found guilty of involuntary homicide. Similarly, once it was discovered that two French citizens who contracted vCJD had eaten at the Buffalo Grill, a French stakehouse chain, the French government launched an investigation seeking manslaughter charges against the Buffalo Grill based on a belief that the restaurant broke an embargo on British beef. All of these inquiries are ongoing.

VI. Additional Potential Lawsuits in the United Statesand Observations as to the Future Challenges Presented by BSE-Related Litigation.

A. A Possible Outbreak of vCJD in the United States. 134

In March 2004, the New York Times reported what may be a cluster of vCJD cases in New Jersey. ¹³⁵ This cluster involves seventeen possible victims, two of whom were twenty-nine years old, and all of whom worked at or frequented a racetrack in Cherry Hill, New Jersey. ¹³⁶ Senators, Frank Lautenberg and Jon Corzine, urged the Centers for Disease Control (hereinafter,

¹³⁴ *Id.*, at 304-5 (citing Elizabeth Williamson, *Amid Mad-Cow Fear, Worries in Md. Death; Lack of Autopsies Hampers Research*, WASH. POST, Jan. 11, 2004, at C3). (discussing another potential case of vCJD in Maryland).

¹³⁰ See Pierre-Antione Souchard, Five Families File Suit Against Four Former Agricultural Ministers, ASSOCIATE PRESS NEWSWIRES, Jan. 22, 2003.

¹³¹ See Verena Von Derschau, Prosecutor Asks for Court to Decide Whether Agriculture Ministers Can Be Prosecuted for Their Handling of Mad Cow Crisis, ASSOCIATE PRESS NEWSWIRES, Oct. 28, 2003.

¹³² Jason, R. Odeshoo, *supra* note 2, at 287 (citing Caroline Davies, *Prince Goes to France to Champion Le Rosbif; Charles Gets Teeth into Beef Drive*, DAILY TELEGRAPH, Feb. 7, 2003, at P8).

¹³³ *Id*.

¹³⁵ D.T. Max, *The Case of the Cherry Hill Cluster*, N.Y. TIMES MAG., Mar. 28, 2004, at 50.

¹³⁶ Jason, R. Odeshoo, *supra* note 2, at 304 (citing *Mad Cow Inquiry Sought in New Jersey*, WASH. POST, Apr. 7, 2004, at A29).

"CDC") to investigate whether these deaths were BSE-related. Although the CDC concluded that fourteen of the deaths were not related to vCJD, three remain under investigation. 138

B. The Future Challenges Presented by BSE-Related Litigation.

Although the cases previously discussed focus largely on economic harm resulting from government action or inaction, it may not be long before traditional tort, and specifically, product liability principles enter the BSE Jungle. Underlying the preceding discussion are several implications for the legal community and, more specifically, the toxic tort litigator faced with a case involving BSE. For example, any case involving BSE may implicate issues of federal preemption given the FDA and its various agencies' extensive regulatory scheme. The unusually long incubation period for BSE and vCJD will challenge current standards with respect to the triggering of statutes of limitations and may lead courts to adopt a discovery rule and/or rules analogous to those applied in the asbestos context in which the statute is triggered by the later onset of symptoms. This long incubation period may also require the development of statutes of repose to protect manufacturers and distributors of allegedly contaminated products from having to defend remote claims. Complex choice of law issues will invariably present themselves and may even require proof of foreign law depending on the origin of the infected animal and/or contaminated feed. Continual developments in the scientific methods of testing for BSE will present fertile ground for challenging the admissibility of expert testimony with respect to the cause and origin of BSE or vCJD. Finally, any BSE related case will invariably present problems with respect to the essential element of causation given that there is still no scientifically confirmed link between the fatal vCJD and BSE contaminated products. In sum, it

-

¹³⁷ *Id.* (internal citations omitted).

¹³⁸ Creutzfeldt-Jakob Disease Not Related to a Common Venue – New Jersey, Centers for Disease Control, U.S. Dep't. for Health and Human Servs., 1995-2004, available at: http://www/cdc.gov/mmwr/preview/mmwrhtml/mm53e507a1.htm (last visited April 10, 2006).

is still a Jungle out there whose radius of legal issues is as wide as the scientific and practical challenges which BSE presents to the domestic and international public and economies.