MAD COWS AND ANGRY PLAINTIFFS: WHY COMPLIANCE WITH GOVERNMENTAL REGULATIONS WILL NOT PROTECT BUSINESS FROM LAWSUITS BY INDIVIDUALS THAT CONTRACT MAD COW DISEASE[1]

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I. THE ROLE OF GOVERNMENTAL AGENCIES

The United States probably has one of the safest food supplies in the world. A total of twelve different federal government agencies share responsibil-

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1. Bovine Spongiform Encephalopathy, or BSE. Creutzfeldt-Jacob Disease is similar to BSE and is found in humans. A variant form of CJD (vCJD) is believed to be caused by eating contaminated beef products.

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ity for this enormous feat, although this approach is subject to criticism.[4] In particular, the Food and Drug Administration ("FDA") and the less well-known Food Safety and Inspection Service ("FSIS") of the Department of Agriculture play crucial roles in assuring Americans that their food is safe to eat. The FSIS "is the public health agency in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged."[5]

The FDA, created in 1906 as a result of the Food and Drug Act, has a much broader charge. The FDA is

> [R]esponsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.[6]

The FDA's Center for Food Safety and Applied Nutrition ("CFSAN") explains that

> This regulation takes place from the products' point of U.S. entry or processing to their point of sale, with approximately 50,000 food establishments (includes more than 30,000 U.S. food manufacturers and processors and over 20,000 food warehouses) and 3,500 cosmetic firms. These figures do not include the roughly 600,000 restaurants and institutional food service establishments and the 235,000 supermarkets, grocery stores, and other food outlets regulated by state and local authorities that receive guidance, model codes, and other technical assistance from FDA. FDA enhances its programs by supporting state and local authorities with training and guidance to ensure uniform coverage of food establishments and retailers.[7]

To enforce the law, the FDA utilizes more than 1,000 inspectors.[8] Those inspectors must cover almost 95,000 businesses that are regulated by the FDA.[9] The inspectors must assure that the products are made correctly and properly

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4. Transcript of Robert A. Robinson's Testimony before the Senate Committee on Agriculture, Nutrition, and Forestry, *Food Safety: Fundamental Changes Needed to Improve the Nation's Food Safety System* at 1 (Oct. 8, 1999) [hereinafter Robinson Testimony].

5. USDA, About FSIS, http://www. fsis.usda.gov/about_FSIS/index.asp (last visited Sept. 28, 2006).

6. FDA, Mission Statement, http://www.fda.gov/opacom/morechoices/mission.html (last visited Sept. 28, 2006).

7. FDA, CFSAN: Overview, http://www.cfsan.fda.gov/~lrd/cfsan4.html.

8. FDA: An Overview (1999), http://www.cfsan.fda.gov/fdaoview.html.

9. *Id.*

labeled.[10] They collect around eighty thousand samples from both domestic and imported products for further testing.[11]

Globalization of the nation's food supply arguably presents the greatest challenge to maintaining food safety. Billions of dollars worth of seafood, fresh produce and other foods are imported into the United States and this figure continues to increase.[12] While the volume of food imports has grown dramatically, inspection has not kept pace with the increased volume.[13] The General Accounting Office ("GAO") has also noted that "the existing federal system to ensure a safe food supply is fragmented, characterized by a maze of often inconsistent legal and regulatory requirements carried out by 12 different federal agencies."[14]

II. THE ROLE OF CONGRESS

The FDA must also contend with food safety regulation problems created by Congress. The Delaney Clause, a 1958 amendment to the Food, Drug and Cosmetic Act of 1938, is rigidly inflexible and unyielding.[15] While its purpose is laudatory - it forbids the addition to food of any substance known to produce cancer in any species, in any dosage, and under any circumstances - its application is problematic.[16] Virtually all foods are likely to contain traces of carcinogens, usually pesticide residue. The FDA, faced with the strict requirements of the Delaney Clause, has tried to avoid banning substances that exist in minute amounts, and are unlikely to cause harm. The courts have rejected this approach by the FDA, pointing to the inflexible language of the Delaney Clause.[17] The courts have noted, quite correctly, that any change in the law is the province of the legislature.[18]

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10. *Id.*

11. *Id.*

12. "Sixty-two percent of all fish, fish products, and shellfish," and thirty-four percent of all fresh fruit and ten percent of vegetables consumed in this country come from abroad. Jeffrey P. Cohn, *The International Flow of Food: FDA Takes on Growing Responsibilities for Imported Food Safety*, FDA CONSUMER MAGAZINE, Jan. – Feb. 2001, http://www.fda.gov/fdac/features/2001/101_food.html.

13. The GAO's Food Safety notes that in 1999 less than one percent of all seafood imported into the U.S. was tested. U.S. GEN. ACCOUNTING OFFICE, FOOD SAFETY: FEDERAL OVERSIGHT OF SEAFOOD DOES NOT SUFFICIENTLY PROTECT CONSUMERS (2001).

14. Robinson Testimony, *supra* note 2.

15. *See* CFSAN, *The Story of the Laws Behind the Labels, Part II: 1938 - - The Federal Food, Drug and Cosmetic Act*, FDA CONSUMER (1981), *available at* http://www.cfsan.fda.gov/~lrd/histor1a.html; *see also* 21 U.S.C.A. § 348 (2006).

16. *See* CFSAN, *supra* note 13.

17. *See* Les v. Reilly, 968 F.2d 985, 989 (9th Cir. 1992).

18. *See id.* at 990.

The situation is further complicated by the Federal Insecticide, Rodenticide, and Fungicide Act ("FIFRA") of 1972.[19] FIFRA, unlike the Delaney Clause, allows concentrations of pesticides in most raw fruits and vegetables, since a Delaney-like approach would ban the use of a large number of valuable pesticides. This led to a paradox: pesticide levels that are acceptable to the EPA in fresh fruits and vegetables are unacceptable to the FDA when occurring in processed foods made from the same crops.

This problem led to the passage of the Food Quality Protection Act of 1996,[20] allowing both raw and processed foods to be sold so long as the pesticide residue is at a point where there is "a reasonable certainty that no harm will result from aggregate exposure . . . ."[21] Unfortunately, restrictions on the use of pesticides and food additives in foreign countries are not as strong and the great majority of the food that is imported is not tested.

Even with all of the foregoing challenges, the efforts of the FDA have not gone unrewarded. A safe food supply is constantly being made safer. However, the efforts to make the food supply safer must constantly adjust to the threat of new and different concerns, including, but not limited to BSE, terrorism, new pesticides, and other chemical contaminants.

III. RESPONDING TO A THREAT

Occasionally, a food safety issue is identified. The Center for Disease Control's ("CDC") FoodNet is the government's primary method for recalls of contaminated food.[22] Once a pathogen that is harmful to humans is identified, the FDA quickly provides information and recalls the affected food. As an example, in December 2003, an animal suffering from BSE was identified.[23] The USDA and FDA activated the BSE Emergency Response Plan and immediately recalled the meat.[24] Any meat that had entered the food supply from that source was tracked and removed from the market.[25] In addition, a temporary ban was placed

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19. 7 U.S.C. § 136 et seq (1996).

20. Food Quality Protection Act, Pub. L. No. 104–170, 110 Stat. 1489 (codified as amended in scattered section of 7 & 21 U.S.C.A.).

21. 21 U.S.C.A. § 346a-(b)(2)(A)(ii) (1998).

22. FoodNet, http://www.cdc.gov/foodnet (last visited Sept. 28, 2006).

23. CDC, Preliminary Investigation Suggests BSE-Infected Cow in Washington State was Likely Imported From Canada (2005), http://www.cdc.gov/ncidod/dvrd/bse/bse_washington_2003.htm.

24. CFSAN, Commonly Asked Questions About BSE in Products Regulated by FDA's CFSAN (2005), http://www.cfsan.fda.gov/~comm/bsefaq.html [hereinafter Commonly Asked Questions].

25. *Id.*

on the importation of live ruminants (cattle, sheep and goats) from countries known to have BSE.[26]

IV. THE ROLE OF BUSINESS

The threats that pose a challenge to the FDA also pose a challenge for all the companies that, one way or another, are involved in the distribution of affected products. Implicated parties include growers, processors, and retailers. As will be seen, in some situations the challenge goes well beyond the normal food distribution chain; even businesses that are in strict compliance with government requirements face the possibility of a lawsuit. For businesses that are not in compliance with those requirements, whether by accident, or not, the threat is far greater, including the risk of punitive damages. Moreover, companies that are not in compliance increase the risk of litigation for any company that buys products from them. The issue for any company that buys products from a non-complying company is whether the purchaser "knew or should have known" about the supplier's failure to comply.[27] While the focus of this paper is primarily on civil litigation, it is important to realize that criminal prosecution for violations of the Pure Food and Drug Act are not uncommon.[28]

The specific focus of this article is the human variant of Mad Cow Disease, (Bovine Spongiform Encephalopathy, or "BSE") a rare neurological disease that usually affects people over the age of fifty-five.[29] BSE is a Transmissible Spongiform Encephalopathy ("TSE"), a family of diseases that includes scrapie in sheep and goats, BSE in cattle, chronic wasting disease ("CWD") in deer and elk as well as Creutzfeldt-Jacob disease ("CJD") in humans.[30] (Hereinafter, BSE will be used to refer to both the human and cattle strains).

The CDC notes that the rate of CJD in the United States has remained relatively stable since 1986,[31] the year that BSE was first identified.[32] CJD has

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26. *Id.*

27. *See* United States v. Park, 421 U.S. 658, 672 (1975) (noting that the Act doesn't turn on awareness of wrongdoing).

28. *See, e.g., id*. at 658. *See also* United States. v. Dotterweich 320 U.S. 277, 282 (1943) (holding that the Act should be interpreted broadly so as to hold all officers, agents and other employees responsible for acts, omissions or any failure to act).

29. BSEInfo.org, FAQ, http://www.bseinfo.org/PageHandler.aspx?XML= faq.aspx# typeofbeef (last visited Sept. 28, 2006); S. Wiersma, et. al., *Probable Variant Crevtzfeld Jakob Disease in a US Resident – Florida,* 2002, JAMA, Vol. 288, No. 23 at 2965 (2002).

30. Commonly Asked Questions, *supra* note 23.

31. BSEInfo.org, CJD, http://www.bseinfo.org/resoCJD.aspx (last visited Sept. 28, 2006) [hereinafter CJD].

32. Commonly Asked Questions, *supra* note 23.

been diagnosed in vegetarians as well as people in countries where BSE has never been reported.[33]

BSE, and its variants, present a number of challenges to ensuring food safety. At the present time, government regulations do not require that all animals be tested for BSE.[34] An even greater challenge for the beef industry (as well as sheep and goat producers, and any other industry that relies on products from such animals) exists because, at the present time, there is no antemortem test for BSE; tests are performed after death. [35] While cattle with BSE may exhibit behavioral changes, the incubation period for BSE ranges from two to eight years.[36] Furthermore, there is no treatment and the disease is fatal.[37]

While it was once believed that the risk of BSE entering the United States was minimal, the events of December 2003 - the first diagnosis of BSE in the United States - forced the government to place even more stringent controls to protect foods, cosmetics, and animal feed.[38] Surprisingly, in a decision that some argue will only make a bad situation worse, the USDA has not only *not* instituted rules that require testing of all animals that are susceptible to BSE, but has also denied a request by at least one beef producer to privately test animals.[39] The FDA validates the USDA's decision by correctly, but perhaps shortsightedly, noting that the United States does not face the same issues as those faced by many countries in Western Europe where BSE is widespread.[40]

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33. *Id.*

34. USDA, BSE Update (Jan. 2, 2004), http://www.usda.gov/news/releases/2004/01/0457.htm ("USDA has tested 20,000 animals annually for each of the last two years . . . .").

35. BSEInfo.org, BSE, http://www.bseinfo.org/resobse.aspx (last visited Sept. 28, 2006) [hereinafter BSE Info].

36. *See id.*

37. *Id.*

38. *The Madness of Herds*, WALL ST. J., Jul. 18, 2005, at A12; BSEInfo.org, Timeline, http://www.bseinfo.org/resoTimeline.aspx (noting that these controls were announced in January 2004).

39. Japan banned the importation of American beef. In a bid to again be able to sell in Japan, Creekstone Farms Premium Beef LLC asked the USDA to allow it to conduct private testing for BSE at its Arkansas City, Kansas processing plant. Creekstone's request was denied on the ground that it would imply that there is a safety issue with American beef. And, although Japan's ban of U.S. beef has been lifted, it may have no effect on the consumption of American beef in Japan. Japanese consumers may refuse to purchase American beef, establishing an equally effective ban. The Japanese government may be counting on this. Donald G. McNeil Jr., *Barred From Testing for Mad Cow, Niche Meat Packer Loses Clients*, N.Y. TIMES, Apr. 18, 2004, *available at* http://query.nytimes.com/gst/fullpage.html?sec=health&res=9C0CE4DD103BF93BA25757C0A9629C8B63.

40. *See generally* Federal Measure to Mitigate BSE Risks: Considerations for Further Action, 69 Fed. Reg. 134 (proposed July 14, 2004) (to be codified at 21 CFR pt. 589) (statement from FDA explaining that APHIS extended restrictions on importing certain European products

However, the government, and specifically the FDA, must keep in mind a significant difference between the United States and Europe. In Europe, with extensive socialism, individuals injured by a product receive care from the government.[41] Conversely, in the United States, when individuals are injured by a product, the potential result is a flood of litigation, including a significant number of fraudulent claims.[42] A limited response by the government, as witnessed here by the USDA's decision, may only serve to increase the threat of litigation for the affected industries.

What few realize is that the risk presented by BSE is not limited simply to the beef industry. Sheep and goats are also susceptible to BSE.[43] As a result, importation of sheep that may have been exposed to potentially BSE-contaminated protein concentrates in Europe are banned in the United States.[44] And, since 1992, the FDA has advised dietary supplement manufacturers and distributors that they should avoid dietary supplement ingredients that come

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because of "concerns about wide spread risk factors and inadequate surveillance for BSE in many European countries . . . .").

41. For example, in 1948 Great Britain passed the National Health Service Act that provides free physician and hospital services for all citizens. In addition, European legal policies discourage litigation. Plaintiffs are generally limited to actual loss or damages suffered. The award of punitive damages is rare and it is judges, not juries, that decide awards. Finally, the absence of a contingent fee arrangement as well as the "loser pays" requirement are significant deterrents to litigation. The "loser pays" or "British Rule" requires that the loser pay the legal expenses, including the attorneys' fees of the prevailing party and is prevalent in Europe. It is arguably the greatest deterrent to litigation. *See* FRESHFIELDS BRUCKHAUS DERRINGER LLP, PRODUCT RISK AND LIABILITY: LITIGATION IN EUROPE (2006), http://www.freshfields.com/publications/pdfs/2006/14298.pdf (discussing the litigation system in Europe and changes currently being made with respect to tort litigation).

42. For example

> [C]ancer cases don't constitute all of the asbestos claims. On the contrary, *at least 80 percent of asbestos claimants have no asbestos-related illness, according to both Austern and the Manhattan Institute.* Filings by these so-called unimpaired claimants multiplied in the late 1990s following the emergence of a "litigation screening industry" composed of attorneys and for-profit screening companies. These entities hire medical personnel to administer X-rays on potential plaintiffs and then file claims en masse, alleging that the X-rays show "physical changes consistent with asbestosis," explains Eliot S. Jubelirer, a trial lawyer at Morgenstein & Jubelirer in San Francisco.

Deborah Rosenthal, *Marathon Run: A Surge in Asbestos Cases Floods the Courts*, CAL. LAWYER, Oct. 2004 at 13 (emphasis added).

43. *See* BSE Info *supra* note 33 (explaining that the agent causing BSE is believed to have originated from scrapie affected sheep).

44. *Id.*

"from cattle born, raised, or slaughtered" in any country known to have BSE or that has inadequate methods to detect and control it.[45]

In addition, although the World Health Organization ("WHO") considers tallow to be a low risk for transmission of BSE, it has encouraged cosmetic manufacturers to acquire tallow from sources that do not include cattle with BSE.[46] Finally, gelatin made from bovine-related material is found not only in dietary supplements, but cosmetics and other foods.[47] Although most food-grade gelatin in the United States is of porcine origin, in 1997 the FDA recommended that bones and hides from cattle with any neurologic disease not be used to manufacture gelatin.[48] The FDA is currently revising the 1997 recommendations.[49]

These diseases also present a significant challenge to a safe supply of blood. As with AIDS, the risk of spreading the disease is presented by someone who contracts BSE and donates blood before evidence of infection becomes apparent.[50] Unsurprisingly, the risk of BSE transmission (as with AIDS) is not lim-

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45. *See* FDA Backgrounder, BSE: Background, Current Concerns, and U.S. Responses (2001), http://www.cfsan.fda.gov/~lrd/bgbse.html.

46. Commonly Asked Questions, *supra* note 23.

47. *Id.*

48. U.S. DEPT. OF HEALTH AND HUMAN SERVICES, FDA, GUIDANCE FOR INDUSTRY: THE SOURCING AND PROCESSING OF GELATIN TO REDUCE THE POTENTIAL RISK POSED BY BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) IN FDA – REGULATED PRODUCTS FOR HUMAN USE (1997), *available at* http://www.fda.gov/opacom/morechoices/industry/guidance/gelguide.htm.

49. FDA, 1997 Food Code: Preface at #9 (1997), http://www.cfsan.fda.gov/~dms/fc-pref.html

50. The Red Cross has restrictions on blood donations by individuals that have visited countries where BSE has been found. There is no evidence that vCJD can be transmitted from donors to patients through transfusion. However, nobody knows for certain that this cannot happen, and animal studies indicate that it is theoretically possible. There is no test for vCJD in humans that could be used to screen blood donors and to protect the blood supply.

This means that blood programs must take special precautions to keep vCJD out of the blood supply by avoiding collections from those who have been where this disease is found. At this time, the American Red Cross donor eligibility rules related to vCJD are as follows:
You are not eligible to donate if, since 1980, you :

- Spent (lived or visited) a total time of 3 months or more in any of these countries: England, Scotland, Wales, Northern Ireland, Isle of Man, Falkland Islands, Gibraltar, Channel Islands, or

- Spent a total time of 5 years or more in any combination of these countries: Albania, Andorra, Austria, Azores, Belarus, Belgium, Boznia/Herzegovina, Bulgaria, Channel Islands, Croatia, Czech Republic, Denmark, England, Estonia, Falkland Islands, Faroe Island, Finland, France, Germany, Gibraltar, Greece, Greenland, Hungary, Iceland, Ireland (Republic of), Isle of Man, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia, Ma-

ited to blood transfusions, but includes virtually all "plasma derivative products."[51]

It is against this background that we review the legal threat that is posed to individuals and companies at virtually every stage of the food supply, as well as even beyond. The seriousness of the issue is made worse because of the potential that individuals exposed to BSE may not show symptoms for years or even decades.

V. THE THREAT TO BUSINESS FROM LAWSUITS

A long-standing barrier to litigation has existed in the form of statutes of limitation. While the delay between exposure and the onset of symptoms might ordinarily give rise to a statute of limitations defense for any defendant, the courts are unlikely to accept such a defense.[52] Statutes of limitations, usually on the order of one to three years, exist because documents are lost and memories fade. Their purpose is to eliminate stale claims. In addition, future plaintiffs, because of the passage of time, may have difficulty identifying the specific defendant, or defendants, that are responsible for their injury. While this has presented an obstacle to plaintiffs in the past, courts have found a variety of novel ways around this.

Because courts, when faced with similar issues in the past, have come up with a variety of unique solutions, in the case of an individual that contracts BSE, it is unlikely that a statute of limitations will provide a defense to the defendants.

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deira Islands, Malta, Moldova, Monaco, Netherlands (Holland), Northern Ireland, Norway, Oman, Poland, Portugal, Romania, San Marino, Scotland, Slovak Republic (Slovakia), Slovenia, Spain, Svalbard, Sweden, Switzerland, Turkey, Ukraine, Vatican City, Wales, Yugoslavia (includes Kosovo, Montenegro and Serbia)

- Received insulin derived from cattle (bovine) from any of the countries listed above
- Received a blood transfusion in any of these countries: England, Scotland, Wales, Northern Ireland, Isle of Man, Falkland Islands, Gibraltar, Channel Islands.

See American Red Cross, In-Depth Discussion of Variant Creutzfeld – Jacob Disease and Blood Donation, http://redcross.org/services/biomed/blood/supply/cjdv.html (last visited Sept. 28, 2006); *see also* American Red Cross, Blood Donation Eligibility Guidelines, http://www.redcross.org/services/biomed/0,1082,0_557_,00.html#ble (last visited Sept. 28, 2006).

51. American Red Cross, In the News, http://www.redcross.org/news/archives/2000/3-6a-00.html (last visited Sept. 28, 2006) (noting that "plasma derivatives are made from large pools of donated plasma").

52. *See generally* CAL. CIV. PROC. CODE §§ 335 – 349 (West 2003) (outlining the statute of limitation for actions other than recovery of real property in California).

It is also unlikely that a plaintiff's inability to identify the specific source of the product from which the plaintiff contracted BSE will present a significant barrier. [53]

For those reasons, the threat of lawsuits against companies, even those companies that are in strict compliance with all governmental regulations, is potentially enormous. Such companies may also create liability on the part of downstream companies that purchase the wide variety of products that come from infected animals, even if those products are processed into a non-food product. For those companies that are not in compliance with governmental requirements, the risk of punitive damages makes a major risk even worse, and the same is true for companies that purchase products from such a supplier. [54]

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53. *See* Smith v. Cutter Biological, Inc., 911 F.2d 374, 376n.1 (9th Cir. 1990) (discussing legal theories states have developed in order to deal with multiple tortfeasors.) As the court noted in *Smith,*

> There are essentially three types of approaches that have been developed by other states. In the classic approach of *Summers v. Tice*, 33 Cal. 2d 80, 199 P.2d 1 (1948), the California Supreme Court held that if several defendants act negligently and it is not possible to determine which defendant caused plaintiff's injury, the burden shifts to defendants to prove that they did not cause the injury. Under the second approach, the enterprise liability theory, if the plaintiff can prove that an entire industry was negligent the burden shifts to the members of that industry to prove that they did not supply the specific product that caused the injury. *Hall v. E.I. Du Pont*, 345 F. Supp. 353 (E.D.N.Y. 1972). Finally, the California Supreme Court in *Sindell v. Abbott Lab.*, 26 Cal. 3d 588, 163 Cal. Rptr. 132, 607 P.2d 924 (Cal. 1980), *cert. denied*, *E.R. Squibb & Sons, Inc. v. Sindell*, 449 U.S. 912, 101 S. Ct. 285, 66 L. Ed. 2d 140 (1980), held that when it was impossible for a plaintiff alleging injury from a drug taken while her mother was pregnant to prove which of the numerous manufacturers produced the drug her mother consumed, each manufacturer would be responsible for a percentage of the recovery matching its share of the market for the drug.

54. Punitive damages are intended to punish and are not covered by insurance. *See, e.g.*, BMW v. Gore, 517 U.S. 559 (1996). The trial court awarded a plaintiff $4,000 in damages and $4 million in punitive damages because the defendant failed to advise the plaintiff that the vehicle purchased by the plaintiff had been repainted because of acid rain damage. *Id.* at 560. The defendant appealed to the Alabama Supreme Court which found that the jury had improperly calculated the punitive damages and reduced that award to $2 million. *Id.* After granting cert, the U.S. Supreme Court noted that "[p]unitive damages may properly be imposed to further a State's legitimate interests in punishing unlawful conduct and deterring its repetition." *Id*. at 568 (citations omitted). "Perhaps the most important indicium of the reasonableness of a punitive damages award is the degree of reprehensibility of the defendant's conduct." *Id* at 575. The Court overturned the award but declined to specify a precise formula for calculating punitive damages. On remand from the U.S. Supreme Court, the Alabama Supreme Court agreed and noted, "[a]fter carefully reconsidering this case, analyzing the Hammond-Green Oil factors in the light of the United States Supreme Court's opinion in BMW, and incorporating the guideposts articulated therein, we agree that the $ 2 million award of punitive damages against BMW was grossly excessive." BMW v. Gore, 701 So. 2d 507, 515 (Ala. 1997) "The trial court's order denying BMW's motion for a new trial is affirmed

A. *DES*

Consider, for example, the drug diethylstilbestrol ("DES"). This pharmaceutical product, approved by the FDA, was taken by expectant mothers in the hope that it would reduce the incidence of miscarriage.[55] Decades later it was alleged that the drug caused cancer in the daughters of those expectant mothers.[56] Because of the passage of time, deaths of witnesses, the destruction of records, and dimming of memories, the daughters were unable to prove which manufacturer (out of approximately three hundred) supplied the allegedly defective product to the expectant mothers.[57]

The solution for some courts was to apply the principle of market-share liability.[58] This concept holds that all firms that were involved in the manufac-

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on the condition that the plaintiff file with this Court within 21 days a remittitur of damages to the sum of $50,000; otherwise, the judgment will be reversed and this cause remanded for a new trial." *Id.* at 515.

55. In *Sindell v.Abbott Labs,*67 P.2d 924, 927-928, the court noted the magnitude of the problem:

> This case is but one of a number filed throughout the country seeking to hold drug manufacturers liable for injuries allegedly resulting from DES prescribed to the plaintiffs' mothers since 1947. According to a note in the Fordham Law Review, estimates of the number of women who took the drug during pregnancy range from 1 1/2 million to 3 million. Hundreds, perhaps thousands, of the daughters of these women suffer from adenocarcinoma, and the incidence of vaginal adenosis among them is 30 to 90 percent. . . . Most of the cases are still pending. With two exceptions, those that have been decided resulted in judgments in favor of the drug company defendants because of the failure of the plaintiffs to identify the manufacturer of the DES prescribed to their mothers. The same result was reached in a recent California case (citations omitted). The present action is another attempt to overcome this obstacle to recovery.

In finding for the plaintiffs, the California Supreme Court noted its departure from traditional tort law, reasoning that "as between an innocent plaintiff and negligent defendants, the latter should bear the cost of the injury." *Id.* at 936. The Court also noted that imposing liability on manufacturers also provided an incentive to produce safer products with clear warnings of potential harmful effects. *Id*.

56. *Id.* at 925.

57. *Id.* at 929 – 930 (discussing how the passage of time makes it difficult for plaintiff to identify which manufacturer made the pills taken by her mother).

58. Acceptance of market share liability has been limited. The highest state courts in six states, Hawaii, New York, Wisconsin, Washington, Florida, and California, adopted market share liability in a variety of forms. *See, e.g., Sindell*, where the California Supreme Court held that it was reasonable to measure the likelihood that any of the defendants supplied the product which allegedly injured plaintiff by the percentage which the DES sold by each of them for the purpose of preventing miscarriage bears to the entire production of the drugs sold by all for that purpose. *Id*. at 937. The court also held that plaintiff was obligated to join in the action the manufacturers of a substantial share of the DES, and that the burden of proof would then shift to defendants to demon-

ture and distribution of a product during the relevant time frame for the plaintiff's injury were liable for the injuries in proportion to the company's share of the market.[59] The market-share approach is not limited to cases involving pharmaceutical drugs such as DES, and has been applied in a variety of other situations.[60]

Although some courts specifically rejected the market-share approach in DES litigation, the results reached under different theories of liability were virtually the same as though market-share liability had, in fact, been utilized. Consider, for instance, the Supreme Court of Wisconsin's reasoning in *Collins*:

> Each defendant contributed to the risk of injury to the public . . . Thus each defendant shares, in some measure a degree of culpability in producing or marketing what the FDA, many scientists, and medical researchers ultimately concluded was a drug with possibly harmful side effects. Moreover, as between the injured plaintiff and the possibly responsible drug company, the drug company is in a better position to absorb the cost of the injury. *The drug company can either insure itself against liability, absorb the damage award, or pass the cost along to the consuming public as a cost of doing business. We conclude that it is better to have drug companies or consumers share the cost of the injury than to place the burden solely on the innocent plaintiff.*[61]

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strate that they could not have made the substance which injured plaintiff. *Id.* Additionally, the court held that once plaintiff has met her burden of joining the required defendants, they in turn may cross-complain against other DES manufacturers not joined in the action, which they can allege might have supplied the injury-causing product. *Id.; see also Martin v. Abbott Laboratories,* 689 P.2d 368, 381-389 (Wash. 1984), where the court not only approved market-share liability but went further and held a successor corporation liable for the plaintiff's injuries, noting that three of the manufacturers could be held liable under a theory of market-share alternate liability and that the successor corporation could be held liable under the product-line exception to successor nonliability in product liability actions. *Id*. *See also Smith,* 823 P.2d 717; Hymowitz v. Eli Lilly & Co. 539 N.E.2d 1069 (N.Y. 1989), *cert. denied*, 493 U.S. 944 (1989); Collins v. Eli Lilly Co., 342 N.W. 2d 37 (Wis. 1984), *cert. denied*, 469 U.S. 826 (1984); Conley v. Boyle Drug Co., 570 So. 2d 275 (Fla. 1990).

59. *Sindell,* 607 P.2d at 938.

60. *See, e.g.*, *Smith*, 823 P.2d 717, where the plaintiff, a hemophiliac, sued after acquiring HIV from a clotting factor (referred to as Factor VIII) synthesized by defendant. The Hawaii Supreme Court acknowledged the difficulties with market-share liability and noted,

> Acknowledging that [applying the basic market-share theory of multi tortfeasors]could open a Pandora's box of questions, we believe that we have defined at least a starting point as to appropriately responding to the certified questions. However, as we are deciding issues in a virtual factual vacuum, we recognize that our opinion is limited to the facts presented to us, and we reserve the right to modify or amend our answers to these questions. *Id.* at 729.

61. *Collins*, 342 N.W. 2d at 49-50 (internal citations omitted and emphasis added).

Thus, even though the court in *Collins* rejected the market-share approach that was used in *Sindell* and held that the plaintiff need sue only one manufacturer of the allegedly defective product, the result is virtually the same as in *Sindell*. The court in *Collins* noted that if the plaintiff could prove the defendant manufactured a drug of the kind taken by the plaintiff's mother at the relevant time, that defendant could be held liable for all damages.[62] However, the court in *Collins* also noted that the defendant could join other defendants in the lawsuit and the jury could apportion liability among all of the defendants.[63] Lastly, the court observed that this approach could be applied in cases that were factually similar to *Collins*.[64]

> Arguably, the most significant case involving DES (and, by logical extension to Mad Cow Disease) is *Hymowitz v. Eli Lilly & Co*.[65] In *Hymowitz,* the court ruled that even if a defendant can prove that it did not manufacture the particular product that allegedly caused injury to the plaintiff, it can still be held liable based on its share of the national market.[66] The court noted that it chose to apportion liability so as to correspond to the over-all culpability of each defendant, measured by the amount of risk of injury each defendant created to the public-at-large. Use of a national market is a fair method, we believe, of apportioning defendants' liabilities according to their total culpability in marketing DES for use during pregnancy. Under the circumstances, this is an equitable way to provide plaintiffs with the relief they deserve, while also rationally distributing the responsibility for plaintiffs' injuries among defendants.
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> *. . . [B]ecause liability here is based on the over-all risk produced, and not causation in a single case, there should be no exculpation of a defendant who, although a member of the market producing DES for pregnancy use, appears not to have caused a particular plaintiff's injury.* It is merely a windfall for a producer to escape liability solely because it manufactured a more identifiable pill, or sold only to certain drugstores. These fortuities in no way diminish the culpability of a defendant for marketing the product, which is the basis of liability here. [67]

The *Hymowitz* decision, holding that even if a company can prove it did not manufacture the allegedly-defective product can still be held liable based on its share of the national market, should give all potential BSE defendants serious cause for concern.

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62. *Id*. at 50.
63. *Id*. at 51.
64. *Id.* at 53.
65. *Hymowitz*, 539 N.E. 2d 1069 (N.Y. 1989).
66. *Id*. at 1078.
67. Id. at 1078 (emphasis added).

B. *Asbestos*

However, DES is hardly the only example of litigation against an entire market. Consider also the challenge to national markets presented by lawsuits as far back as World War II that alleged exposure to asbestos caused asbestosis and mesothelioma. *Borel v. Fibreboard Paper Products Corp* is one of the earliest cases on this particular issue and may have opened the way for other plaintiffs to sue.[68] In *Borel*, the plaintiff had been exposed to asbestos in different industrial jobs between 1936 and 1969.[69] A jury found in favor of the plaintiff and the defendants appealed.[70] The appellate court, in upholding the verdict, noted that "[t]he evidence . . . indicated . . . that during Borel's working career no manufacturer ever warned contractors or insulation workers, including Borel, of the dangers associated with inhaling asbestos dust . . . ."[71]

> [I]nsulation materials containing asbestos may be viewed as "unavoidably unsafe products." . . . As a practical matter, the decision to market such a product requires a balancing of the product's utility against its known or foreseeable danger . . . [E]ven when such balancing leads to the conclusion that marketing is justified, the seller still has a responsibility to inform the user or consumer of the risk of harm. The failure to give adequate warnings in these circumstances renders the product unreasonably dangerous.. . . .
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> Furthermore, in cases such as the instant case, the manufacturer is held to the knowledge and skill of an expert. This is relevant in determining (1) whether the manufacturer knew or should have known the danger, and (2) whether the manufacturer was negligent in failing to communicate this superior knowledge to the user or consumer of its product . . . .The manufacturer's status as expert means that at a minimum he must keep abreast of scientific knowledge, discoveries, and advances and is presumed to know what is imparted thereby. But even more importantly, a manufacturer has a duty to test and inspect his product. The extent of research and experiment must be commensurate with the dangers involved. . . . *[E]ach manufacturer must bear the burden of showing that its own conduct was proportionate to the scope of its duty.*[72]

The court's language in *Borel* regarding warnings should be of particular interest to beef providers facing liability for products contaminated with BSE. Providing a warning of possible harm is not sufficient if the warning is inade-

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68. *Borel*, 493 F.2d 1076 (5th Cir. 1973); *cert. denied* 419 U.S. 869 (1974).
69. *Id*. at 1081.
70. *Id*.
71. *Id.* at 1086.
72. *Id*. at 1088-1090 (emphasis added).

quate in scope or information.[73] Consider also *Beshada v. Johns-Manville Products Corporation,*[74] which represented six consolidated cases for personal injury and wrongful death brought against manufacturers and distributors of asbestos products.[75] In essence, defendants argued a "state-of-the-art" defense, claiming that because the dangers posed by asbestos were unknown – and *unknowable* at the time of the plaintiff's exposure to the product - they were excused from providing a warning.[76] The Supreme Court of New Jersey gave the defendant's argument short shrift and, in language particularly applicable to BSE, noted,

> Defendants have argued that it is unreasonable to impose a duty on them to warn of the unknowable. Failure to warn of a risk which one could not have known existed is not unreasonable conduct. But this argument is based on negligence principles. We are not saying what defendants should have done. That is negligence. *We are saying that defendants' products were not reasonably safe because they did not have a warning. Without a warning, users of the product were unaware of its hazards and could not protect themselves from injury. We impose strict liability because it is unfair for the distributors of a defective product not to compensate its vic-*

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73. For example, in *Borel,* Johns-Manville and two other defendants requested a rehearing en banc, noting that a warning had been put in place in the mid-1960s. The court addressed the issue as follows:

> Three of the movants, Johns-Manville Corporation, Fibreboard Corporation, and Ruberoid Company contend that the Court erred in basing its opinion on "the overriding factor" of "the alleged failure of the defendants to at any time warn Borel of the dangers involved in working with asbestos insulation while employed by various independent contractors". They state that the record shows that Johns-Manville placed a warning label on packages of its products in 1964, and that Fibreboard and Ruberoid placed warning labels on their products in 1966. (Borel filed suit in 1969.) The three warnings were substantially the same. Johns-Manville's read as follows: 'This product contains asbestos fiber. 'Inhalation of asbestos in excessive quantities over long periods of time may be harmful. 'If dust is createdwhen this product is handled, avoid breathing the dust. 'If adequate ventilation control is not possible wear respirators approved by the U.S. Bureau of Mines for pneumoconiosis producing dusts.' It should be noted that none of these so-called "cautions" intimated the gravity of the risk: the danger of a fatal illness caused by asbestosis and mesothelioma or other cancers. The mild suggestion that inhalation of asbestos in excessive quantities over a long period of time "*may* be harmful" conveys no idea of the extent of the danger. The admonition that a worker should "avoid breathing the dust" is black humor: There was no way for insulation workers to avoid breathing asbestos dust. As for wearing respirators if adequate ventilation control is not possible, Borel and other insulators never worked in any place where there was adequate ventilation, and respirators were ineffective: "you can't breathe with the respirator." *Id.* at 1103-1104 (footnote omitted & emphasis in original).

74. *Beshada*, 447 A.2d 539, 548 (N.J. 1982) (discussing how the manufacturer is in a better position to make an assessment as to risk and to act upon that assessment).

75. *Id.* at 542.

76. *See id*. at 542-543.

> *tims. As between those innocent victims and the distributors, it is the distributors -- and the public which consumes their products -- which should bear the unforeseen costs of the product.*[77]

C. *Surgical Products*

Even a situation where a product may or may not be defective may provide the basis for a lawsuit. In *Khan v. Shiley, Inc.,* the defendant manufactured heart valves.[78] Sometime after a Shiley heart valve was implanted in plaintiff, plaintiff was notified that there was a risk that the valve would fracture.[79] Although the failure rate of 11 out of 1000 was quite low, approximately 88,000 of the valves had been implanted and 243 had failed.[80] The plaintiff had been notified that the valve implanted in her heart fell into the range of manufactured valves that could experience a failure.[81] The court noted, "[f]or purposes of establishing fraud, it matters not that the valve implanted in Khan's heart is still functioning, arguably as intended. Unlike the other theories, in which the safety and efficacy of the product is assailed, the fraud claim impugns defendants' *conduct*."[82]

> Plaintiffs assert defendants misrepresented the characteristics and safety of the valve while concealing other material, adverse information. Specifically, they contend defendants misrepresented the valve's propensity to fail, and omitted material facts showing the product had a history of strut failure even before one was implanted into Khan's heart. And they did so with knowledge of the substantial risk of death and without providing adequate warnings which fairly reflected the known risks. Furthermore, defendants allegedly made these misrepresentations with the intention plaintiffs would rely on them in selecting the Shiley valve. Plaintiffs relied on and were induced by these representations in making their selection. They would not otherwise have selected the Shiley valve; indeed, at least six other mechanical heart valves were available at the time of Khan's surgery. . . . .
>
> [Our conclusion] merely confirms that a manufacturer of a product may be liable for fraud when it conceals material product information from potential users. This is true whether the product is a mechanical heart valve or frozen yogurt." [83]

So, although the plaintiff in *Shiley* could not recover under theories of product liability, including warranty (after all, the product had not failed), she validly pursued a cause of action for fraud.

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77. *Id*. at 549 (emphasis added).
78. *Khan*, 266 Cal. Rptr. 106 (1990).
79. *Id.* at 107.
80. *Id.* at 107n.1, 109n.8.
81. *Id*. at 107.
82. *Id.* at 112.
83. *Id.* (footnotes omitted and emphasis added).

D. *Agent Orange*

Consider also Agent Orange. Sprayed on the jungles of Vietnam for years, some individuals claim to have developed health problems as a result of their exposure to the chemical.[84] This led to a class-action lawsuit by numerous individuals against the companies that manufactured Agent Orange.[85] Of particular interest to industry should be the concern that Agent Orange was manufactured to government specifications.[86] Yet, when it came time for a lawsuit, not only was the government sued, so were the manufacturers. Even though a judge specifically found that there was virtually a total absence of convincing scientific evidence to support the plaintiffs' claims,[87] the various manufacturers contributed $180 million to settle the matter.[88]

As in the DES case, multiple manufacturers were involved. In some cases different Agent Orange products manufactured by the various defendants were mixed; thus the plaintiffs were unable to identify the particular manufacturer of the product to which they were exposed.[89] This made no difference to the court, however, in approving the settlement reached.

It should be noted, however, that the defendants in the Agent Orange litigation had a defense that is unlikely to be available in a case alleging exposure to

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84. *In Re* Agent Orange Prod. Liab. Litig., 818 F.2d 145, 148 (2d Cir. 1987).
85. *Id*.
86. *Id.* at 153.
87. On appeal, the court noted that while

> The size of the settlement seems extraordinary. . . . [G]iven the serious nature of many of the various ailments and birth defects plaintiffs attributed to Agent Orange, the understandable sympathy a jury would have for the particular plaintiffs, and the large number of claimants, 240,000, the settlement was essentially a payment of nuisance value. Although the chances of the chemical companies' ultimately having to pay any damages may have been slim, *they were exposed potentially to billions of dollars in damages if liability was established and millions in attorneys' fees merely to continue the litigation.* *Id.* at 151 (emphasis added).

88. *Id.* at 171.
89. The Court notes that

> The plaintiffs' claims are further complicated by the fact that an individual's exposure to Agent Orange cannot be traced to a particular defendant because the military mixed the Agent Orange produced by various companies in identical, unlabeled barrels. No one can determine, therefore, whether a particular instance of spraying involved a particular defendant's product. In addition, the Agent Orange produced by some defendants had a considerably higher dioxin content than that produced by others. Because the alleged ailments may be related to the amount of dioxin to which an individual was exposed, it is conceivable that if Agent Orange did cause injury, only the products of certain companies could have done so. *Id.* at 149-150.

BSE: the government contractor defense. As the court in the Agent Orange case noted,

> It would be anomalous for a company to be held liable by a state or federal court for selling a product ordered by the federal government, particularly when the company could not control the use of that product. Moreover, military activities involve high stakes, and common concepts of risk averseness are of no relevance. To expose private companies generally to lawsuits for injuries arising out of the deliberately risky activities of the military would greatly impair the procurement process and perhaps national security itself.[90]

VI. CONCLUSION

The foregoing list is hardly exclusive of the mass torts that have plagued the American legal system but do provide critical details regarding the way that courts are likely to approach a problem such as BSE.[91]

The first significant question is whether a court will allow a statute of limitations defense to completely bar any and all claims by consumers that contract BSE. Given the cases presented, it is unlikely. The next question, since it is unlikely that a consumer that acquires BSE will be able to identify the specific defendant, or defendants, that supplied the allegedly defective product, is whether a court will apply a market-share, or similar approach, to cases involving BSE. Although speculative, the answer is likely to be in the affirmative.

The next significant question is whether the affected industries are facing a massive threat of litigation similar to the hundreds of thousands of asbestos cases, or a more limited threat such as with DES. At the present time, given the limited number of BSE cases worldwide and the government's response, the best guess is that the threat of litigation is limited. However, this should provide small comfort to affected industries for several reasons.

First, as noted with asbestos, and the same is probably true for any other similar situation, there are going to be fraudulent claims. Second, as noted with *Khan v. Shiley,* actual physical injury may not always be a necessary requirement for a lawsuit. Next, as noted with the Agent Orange litigation, defendants with deep pockets must deal with sympathy from the courts and juries. This problem exists even for companies that are in strict compliance with governmental requirements. Even more serious is the problem presented by the small number of companies that are not in compliance with governmental regulations; noncompliance may give rise to an award of punitive damages. Such an award may extend

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90. *Id*. at 150.

91. Lawsuits against tobacco manufacturers by long-term smokers, for instance. *See, e.g*., *Cipollone v. Liggett Group, Inc*., 505 U.S. 504 (1992).

well beyond the original violator to any downstream recipients of products. If a downstream recipient "knew or should have known" of violations by the supplier, a serious potential for an award of punitive damages also exists for that recipient. In addition, the individuals that "knew or should have known" about such violations face personal liability as well as criminal prosecution.

Last, potential defendants should keep in mind the court's language in what is arguably one of the first applications of strict liability for a defective consumer product, a case in the area of food and drink, *Mazetti v. Armour*.[92] In the *Mazetti* case, the court held, "[i]n the absence of an express warranty of quality, a manufacturer of food products under modern conditions impliedly warrants his goods when dispensed in original packages, and that such warranty is available to all who may be damaged by reason of their use in the legitimate channels of trade."[93]

These issues present a significant threat to the American beef industry (and other industries as well) by way of Mad Cow Disease. These issues will continue to present a significant threat well into the foreseeable future and it is the conclusion of this article that all of the government's requirements that are in place may not be enough to protect the affected industries from litigation by consumers that contract the human variant of BSE.

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92. *Mazetti*, 135 P. 633 (Wash. 1913).
93. *Id.* at 636.