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Edited by

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Bradley Arant Boult Cummings LLP

Bradley Arant Boult Cummings LLP (BABC) is one of the largest and longest established law firms in the southeastern United States. The firm has more than 370 attorneys serving individuals, emerging businesses, and established regional, national and international clients from our offices in Alabama, North Carolina, Mississippi, Tennessee and Washington, DC.

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Chapter 20
Regulation of Product Liability and Sanctions: United States

Tripp Haston & Andrew Johnson

Bradley Arant Boult Cummings LLP

1. INTRODUCTION

In the United States, the federal government regulates products primarily through two regulatory statutes – the Consumer Product Safety Act (CPSA) and the Food, Drug and Cosmetic Act of 1938 and its subsequent amendments (FDCA).[1] These regulations are generally enforced by the Consumer Product Safety Commission (CPSC) and the Food and Drug Administration (FDA), respectively. As their names indicate, the Consumer Product Safety Act regulates consumer products, while the FDA regulates products that generally are ingested or used as medications.

It should also be noted that the 50 individual states within the United States have their own laws and judicial systems, and may have their own regulations relating to products. These laws typically take the form of tort laws that may impose strict liability for defective designs and require warnings on products regarding their dangers. These laws may also take the form of statutory regulations regarding pricing or "deceptive trade practices." Generally speaking, some federal laws and regulations pre-empt state laws in the fields regulated by the Consumer Products Safety Act and the Food and Drug Act, but there are exceptions to this rule. The laws of these individual states are not addressed in this chapter.

1. A notable exception to this would be the regulation of automobiles which are regulated under the National Transportation and Motor Vehicle Safety Act, 49 U.S.C. § 301 (2006). Automotive regulation is outside the scope of this chapter.

2. GENERAL REGULATORY PROVISIONS

2.1. Consumer Product Safety Act

2.2. Potential Liabilities for Production or Supply of Unsafe Products

Any person who is injured as a result of any knowing violation of the CPSA may bring suit in a federal district court. The offender may be found liable for damages, the costs of suit, including attorneys' fees, provided the amount in controversy exceeds USD 10,000.00, exclusive of costs[2] and interest.[3] This private remedy can be asserted in addition to any other remedies provided by federal and state common law.[4] If suit is filed under the CPSA, the remedies available to the injured party are limited to those provided in the CPSA as set out above.[5] Moreover, if proper notice is given pursuant to the CPSA, a person may bring an action in federal district court to enforce any promulgated standard or to obtain any appropriate injunctive relief.[6]

Courts have reasoned that private rights of actions are limited to knowing and wilful violations of a promulgated standard or other rule of the CPSC.[7] Generally, courts agree that the Act does not provide a private right of action to enforce the statutory reporting requirements of the Act.[8] Most private rights of action involving the Act raise the issue of whether an entity has violated a hazard reporting regulation.[9] The CPSC has determined that it has no authority to participate in or offer counsel in any actions for damages by injured persons,[10] and that it will not intervene in such actions.[11]

2. The American rule provides that each party is responsible for paying its own litigation costs unless specific authority granted by statute or contract allows the assessment of those fees against the other party. Under the American rule every party—even the party prevailing—must pay its own costs. The CPSA has incorporated the American rule into the statute. See e.g., 15 U.S.C. § 2072; *Wahba v. H & N Prescription Center, Inc.*, 539 F. Supp. 352 (E.D.N.Y. 1982).
3. 15 U.S.C. § 2072 (1981); see also "Products Liability", in *American Jurisprudence*, 2nd edn 63B (St. Paul, MN: West, 2008), § 2008.
4. "Products Liability", *supra* n. 3, at § 2008.
5. 15 U.S.C. § 2072(c).
6. 15 U.S.C. § 2073.
7. "Products Liability", *supra* n. 3, at § 2008.
8. *Newlin v. Invensys Climate Controls*, Civ. No. 05-5746(RBK), 2006 WL 2385079, *3 (D.N.J. Aug. 16, 2006).
9. "Products Liability", *supra* n. 1, at § 2010.
10. CPSC Advisory Op. No. 17 (Aug. 6, 1973).
11. CPSC Advisory Op. No. 44 (Nov. 13, 1973).

2.3. What Establishes That a Product is Unsafe?

The CPSC has the authority to promulgate consumer products safety standards[12] for over 15,000 different consumer products – from toys, to toasters, to bean bag chairs[13] – and its directives are intended to override inadequate and conflicting state and local regulations over consumer products.[14]

These safety standards may be voluntary[15] or mandatory. Initially, the primary purpose for the CPSC was to establish mandatory product safety standards; however, today the CPSC generally promulgates 8 to 14 mandatory safety standards per year and 40 to 50 voluntary safety standards.[16]

The CPSC promulgates mandatory safety standards through the notice and publication process.[17] In order to promulgate a mandatory safety standard, the CPSC must first publish an advanced notice of proposed rulemaking in the Federal Registry.[18] Next, the CPSC must publish the proposed new safety standard in the Federal Registry, along with the CPSC's preliminary regulatory analysis and findings.[19] Within 60 days of the publication of the new safety standard, the CPSC must submit an expression of the risk of injury associated with the new standard, and allow public comment from interested persons.[20] Prior to promulgating the new rule, the CPSC must publish its final findings taking into account all research, testing, and public comments regarding the new safety standard.[21] The new safety standard is subject to judicial review[22] under an "arbitrary and capricious"[23] or "illegal"[24] standard.

12. 15 U.S.C. § 2056.
13. Steve Berry & Jeff Brazil, "Federal Safety Law Targets 15,000 Items, but Not Guns", *Los Angeles Times*, Feb. 1, 1998, A-1.
14. *U.S. v. Anaconda Co.*, 445 F. Supp. 486 (D.D.C. 1977).
15. 15 U.S.C. § 2056(b)(1).
16. Geraint G. Howells, "The Relationship Between Product Liability and Product Safety – Understanding a Necessary Element in European Product Liability Through a Comparison with the U.S. Position", *Washburn Law Journal* 39 (Spr. 2000): 309.
17. See 15 U.S.C. § 2058.
18. *Ibid*. (The publication must include the identity of the product, a summary of the regulatory alternatives, information on the existing standards, and an invitation to interested persons to comment on the new standard).
19. 15 U.S.C. § 2058(c).
20. 15 U.S.C. § 2058(d)-(e).
21. 15 U.S.C. § 2058(f).
22. No later than 60 days after a new safety standard is promulgated, any person adversely affected by the rule may file a petition in the United State Court of Appeals for the District of Columbia or the Circuit in which the affected person has a principal place of business. 15 U.S.C. § 2060.
23. *Zotos Intern. Inc. v. Kennedy*, 460 F. Supp. 268 (D.D.C. 1978).
24. *Borden, Inc. v. Comm'r of Pub. Health*, 448 N.E.2d 367 (1983).

2.4. Penalties for Production/Supply of Unsafe Products

Persons found in violation of the CPSA may be subject to both civil and criminal penalties.[25] Recent amendments to this statute set forth that civil penalties may not exceed USD 100,000.00 per violation.[26] The maximum aggregate penalty for such violations cannot exceed USD 15,000,000.00.[27]

Violations of the Act may also result in criminal penalties of up to five years incarceration, a fine, or both for individuals who knowingly and wilfully violate the Act.[28] Persons subject to criminal penalties may also be subject to civil penalties[29] and forfeiture of assets.[30]

The CPSC may also enjoin any entity from violating the CPSA by filing an action in the federal district court wherein a continuous violation is taking place.[31] State Attorneys General may also seek injunctive relief in federal court to enforce specific provisions of the CPSA.[32]

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25. 15 U.S.C. § 2069-2070. Violations of the Act include the manufacture, sale, distribution or import of products which are not in conformity with the Act; the manufacture, sale, distribution or import of a banned product; an entity's failure to permit the inspection of an establishment; an entity's failure to provide information pursuant to the Act; an entity's failure to comply with a directive passed pursuant to the Act; an entity's failure to provide certification; an entity's failure to comply with the Act regarding the stockpiling of products; an entity's failure to comply with the Act regarding the performance and maintenance of technical data; an entity's failure to comply with Act regarding the labeling and testing of cellulose insulation; and an entity's failure to file a statement with the CPSC. *See* 15 U.S.C. § 2068(1)-(11).
26. 15 U.S.C. § 2069(1) (as amended by Pub. L. No. 110-314, § 217(A), 122 Stat. 3016, which was signed into law on Aug. 14, 2008). The civil penalties may be adjusted for the rate of inflation and cost-of-living adjustments. 15 U.S.C. § 2069(2)–(3). In determining the amount of a civil penalty, the CPSC considers "the nature, circumstances, extent, and gravity of the violation, including the nature of the product defect, the severity of the risk of injury, the occurrence or absence of injury, the number of defective products distributed, the appropriateness of such penalty in relation to the size of the business of the person charged, including how to mitigate undue adverse economic impacts on small businesses, and such other facts as appropriate." 15 U.S.C. § 2069(3)(D)(ii)(b). Prior to the amendment in August 2008, the respective penalty limits were USD 5,000 and USD 1,250,000.
27. 15 U.S.C. § 2069 (as amended by Pub. L. No. 110-314, 122 Stat. 3016, which was signed into law on Aug. 14, 2008).
28. 15 U.S.C. § 2070(a) (as amended by Pub. L. No. 110-314, 122 Stat. 3016, which was signed into law on Aug. 14, 2008).
29. 15 U.S.C. § 2070(b)-(c).
30. 15 U.S.C. § 2070(c)(1) (as amended by Pub. L. No. 110-314, 122 Stat. 3016, which was signed into law on Aug. 14, 2008).
31. 15 U.S.C. § 2071.
32. 15 U.S.C. § 2073 (as amended by Pub. L. No. 110-314, 122 Stat. 3016, which was signed into law on Aug. 14, 2008).

2.5. Who Prosecutes a Violation?

The Office of Consumer Litigation is responsible for civil and criminal affirmative litigation.[33] Affirmatively, OCL may assist the CPSC in its enforcement work by invoking a variety of statutory remedies for violations. OCL may also support the CPSC's enforcement work by seeking court intervention when necessary to overcome resistance to administrative proceedings.[34]

2.6. What Defenses are Available?

At the request of a party, the CPSC may reduce a levied fine.[35] In determining whether to reduce the amount of a fine, the CPSC considers the size of the business of the person charged, the nature of the product defect, the severity of the risk of injury, the occurrence or absence of injury, and the number of defective products distributed.[36]

If named in civil litigation asserting a claim under the CPSA, a defendant may avail itself of the CPSA's pre-emption clause.[37] In pertinent part, the clause states:

> Whenever a ... standard ... applies to a risk of injury ... no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a safety standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labelling of such product which are designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical to the requirements of the Federal standard.[38]

The pre-emption clause defense has arisen infrequently in products liability cases.[39] That said, relying on the pre-emption clause, courts have determined that to enforce state and federal common laws which impose greater liability on manufacturers than that provided for by the CPSA would conflict with federal law, and, would therefore be impermissible.[40]

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33. Office of Consumer Litigation Website, <www.justice.gov/civil/ocl/monograph/cpsc.htm> (last visited Jan. 22, 2010).
34. *Ibid.*
35. 15 U.S.C. § 2069(c).
36. *Ibid.*
37. 15 U.S.C. §§ 2074–2075.
38. 15. U.S.C.A. 2075(a).
39. David G. Owen, "Professional Symposium, Federal Pre-emption of Products Liability Claims", *South Carolina Law Review* 55 (Winter 2003): 438 & nn. 175–79.
40. See e.g., *Bic Pen Corp. v. Carter*, 251 S.W.3d 500, 507 (Tex. 2008) (noting that "a common-law tort claim could impose duties that conflict with the federal regulatory scheme and

3. FOOD, DRUG AND COSMETIC ACT

3.1. INTRODUCTION

The FDA is a federal agency within the United States Department of Health and Human Services[41] that is, responsible for the safety of most types of food, dietary supplements, medicines, vaccines, biological medical products, blood products, medical devices, radiation-emitting devices, veterinary products, and cosmetics.[42] The FDA is also responsible for ensuring that these products are represented to the public accurately and informatively.[43] The FDA has five regions[44] and nine centers or offices: the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, the Center for Drug Evaluation and Research, the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, National Center for Toxicological Research, the Office of Chief Counsel, the Office of the Commissioner, and the Office of Regulatory Affairs.[45] Its codified mission is to promote the public health through regulation, research, and product approvals.[46] As a general matter, the FDA "issues several types of product approvals, in three general categories: specific product approvals for one drug or medical device; product batch approvals, including batches of antibiotics, color additives, and certain biological approvals; and product category approvals, including new medication and food additives which can be manufactured without batch approval so long as they comply with FDA specifications stated in a formal approval notice."[47]

The modern era of the FDA began with President Theodore Roosevelt signing into law the Food and Drug Act, also known as the "Wiley Act," in 1906.[48] The Food and Drug Act prohibited the interstate transport of adulterated food and adulterated drugs, as well as the misbranding of food and

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therefore would "stand as an obstacle to the accomplishment and execution of the full purpose and objections of Congress"); *compare Colon ex rel. Molina v. BIC USA, Inc.*, 136 F. Supp.2d 196, 209 (S.D.N.Y. 2000) (finding that the CPSC's goal of reducing injuries to the public was best served by supplementing the federal standards on a case-by-case basis, according to stricter requirement set forth by state law).

41. The FDCA's delegation of authority is to the Secretary of the Department of Health and Human Services. 21 U.S.C. § 321(d).
42. <www.fda.gov/comments/regs.html>.
43. *Ibid.*
44. See 21 C.F.R. § 5.100. The five regions are based in San Francisco, Dallas, Chicago, Atlanta, and New York.
45. <www.fda.gov/opacom/7org.html>, reviewed on Feb. 1, 2009.
46. 21 U.S.C. § 393(b).
47. James T. O'Reilly, *Food and Drug Administration*, 3rd edn (St. Paul, MN: Thomson West, 2007), § 26:11.
48. "A History of the FDA." <www.fda.gov/oc/history/historyoffda/section1.html>.

drugs.[49] The penalty for violations was the seizure of the adulterated goods.[50] Adulterated food referred to the added fillers which reduced ''quality or strength,'' coloring which concealed ''damage or inferiority,'' additives ''injurious to health,'' or the use of ''filthy, decomposed, or putrid'' substances.[51] Adulterated drugs were those for which the ''standard of strength, quality, or purity'' of the relevant ingredient was not described clearly on the label or listed in the *United States Pharmacopoeia* or the *National Formulary*.[52]

In 1938, in the wake of a therapeutic crisis involving a Tennessee drug company's marketing of a new drug, Elixir Sulfanide,[53] Congress passed the Federal Food, Drug and Cosmetic Act[54] (FDCA), a set of laws that gives authority to the FDA to oversee the safety of food, medication,[55] and cosmetics. Elixir Sulfanide was marketed as a ''wonder drug'' for paediatric patients, but the product's formula utilizes a toxic chemical similar to antifreeze as its solvent, and was believed to cause over 100 deaths, including the deaths of many children.[56] The FDCA significantly increased the federal government's authority to regulate medicines by mandating a pre-market review of the safety of any new drug and banning false therapeutic claims for medicines.[57] Additionally, the FDCA authorized federal inspections of manufacturing facilities, expanded the government's enforcement powers, set new standards for foods, and gave regulatory authority to the federal government over cosmetics and therapeutic devices.[58] The FDCA, although extensively amended since 1938, remains the FDA's basic foundation of authority.

The FDA has great discretion in determining which products are subject to its jurisdiction.[59] The FDCA, as well as other statutes enforced by the FDA, provide the FDA with the authority to regulate interstate and foreign commerce in the food, drug, and cosmetic industries.[60,61] Typically, courts do not

49. Federal Food and Drugs Act of 1906 (The ''Wiley Act''), 34 STAT. 768 (1906), 21 U.S.C. §§ 1–15 (1934) (repealed in 1938 by 21 U.S.C. § 329(a)).
50. *Ibid.*
51. *Ibid.*
52. *Ibid.*
53. <www.fda.gov/oc/history/historyoffda/section2.html>.
54. 21 U.S.C. § 301.
55. For purposes of this chapter, the terms ''medicine'' and ''medication'' are used interchangeably for pharmaceutical drugs.
56. <www.fda.gov/oc/history/historyoffda/section2.html>.
57. 21 U.S.C. § 301.
58. *Ibid.*
59. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973).
60. Other statutes include the Filled Milk Act, 21 U.S.C. § 61; the Federal Import Milk Act, 21 U.S.C. § 141; the Tea Importation Act, 21 U.S.C. § 41; the Federal Caustic Poison Act, 15 U.S.C. §§ 410–411; the Fair Packaging and Labelling Act, 15 U.S.C. § 1451; parts of the Public Health Service Act, 42 U.S.C. §§ 241–361.
61. Congress delegated the powers under the FDCA to the Department of Health & Human Services (HHS). 21 U.S.C. §§ 321(d), 341.

question the FDA's representation that an item has been in interstate commerce.[62] Only one component or ingredient of a product needs to have been in interstate commerce, not the entire product, for the FDA to have jurisdiction.[63] Additionally, imports are a part of interstate commerce over which the FDA has jurisdiction, even if they never reach United States commerce, so long as the products were intended for the United States.[64]

Currently, the FDA is responsible for the safety and regulation of most foods, dietary supplements, medications, blood products, radiation-emitting devices (such as microwave ovens, cell phones, x-ray equipment, lasers, ultrasound devices, and MRI machines[65]), veterinary products (medication and devices used for animals, both pets and animals that produce food[66]), and cosmetics.[67,68] Additionally, the FDA regulates medical products: medicines; biologics, which include vaccines, biotechnology products, and gene therapy; and medical devices.[69] The FDA must approve any animal medications before they can be marketed, but the FDA does not have to approve veterinary medical devices before they are marketed, though these devices still must be safe, effective, and properly marked.[70] Similarly, although the FDA monitors cosmetic products, it does not approve them before marketing nor require any sort of safety testing.[71] The FDA also regulates the labelling information on foods, over-the-counter medicines, dietary supplements, and medicines and medical devices used by healthcare professionals.[72]

The FDA regulates the nation's food supply, must approve new food additives before they can be used, and controls the safety of dietary supplements, infant formulas, and medical foods.[73] Under the FDCA, food includes: "(1) articles used for food or drink for man or other animals; (2) chewing gum; and (3) articles used for components of any such article."[74] The FDA does not, however, regulate meat or poultry, which are, instead, regulated by

62. *U.S. v. 14 Cases More or Less, "Naremco Medi-Matic Free Choice Poultry Formula"*, 374 F. Supp. 922 (W.D. Mo. 1974).
63. *Ibid.*
64. *U.S. v. Eight Unlabeled Cases, More or Less, of an Article of Food*, 909 F. Supp. 129 (E.D. N.Y. 1995).
65. <www.fda.gov/oc/opacom/fda101/sld006.html>.
66. <www.fda.gov/oc/opacom/fda101/sld007.html>.
67. <www.fda.gov/oc/opacom/fda101/sld002.html>. In fact, the FDA regulates so many products that products that FDA regulates account for roughly 25% of every consumer dollar spent in the United States, totaling about USD 1 trillion a year in products regulated.
68. Additionally, the FDA's budget request for 2008 was roughly USD 2.1 billion, USD 105.8 million more than the previous year's request. <www.fda.gov/oc/oms/ofm/budget/2008/summary.html>.
69. <www.fda.gov/oc/opacom/fda101/sld005.html>.
70. <www.fda.gov/oc/opacom/fda101/sld007.html>.
71. <www.fda.gov/oc/opacom/fda101/sld008.html>.
72. <www.fda.gov/oc/opacom/fda101/sld009.html>.
73. <www.fda.gov/oc/opacom/fda101/sld004.html>.
74. 21 U.S.C. § 321.

the United States Department of Agriculture.[75] It also does not regulate advertising, alcohol, consumer products, drugs of abuse, insurance, pesticides, restaurants, grocery stores, or water, except the labelling and safety of bottled water.[76]

When the FDA evaluates new products, it does so through a balancing of factors to determine "whether a new product's benefits will outweigh its risks."[77]

3.2. What Establishes That a Product is Unsafe?

The FDCA,[78] the basic foundation of the FDA's authority, prohibits, among other things: putting into commerce any adulterated or misbranded food, drug, device, or cosmetic;[79] adulterating or misbranding any food, drug, device, or cosmetic that is, already in interstate commerce;[80] and manufacturing any adulterated or misbranded food, drug, device or cosmetic.[81]

Under the FDCA, a food is adulterated if, among other things, it: (1) contains any poisonous, unsanitary, or harmful substance that could make it dangerous to health; (2) was prepared, packaged, held, or transported under unsanitary conditions that could have contaminated it; (3) has decreased in value without notification to consumers; (4) contains any unsafe color additives; (5) is a confectionary containing alcohol or non-nutritive substance; or (6) is an oleomargarine containing filthy, putrid, or decomposed substances.[82]

A food is misbranded under the FDCA if, among other things, it: (1) has a misleading label, brand, tag, or notice with respect to its kind, grade, quality, or composition; (2) is an imitation of another food and the word "imitation" is not prominently written on the label; (3) is in a misleading container or package; (4) has false or misleading statements about the sanitary conditions where it was manufactured on the label; (5) does not have all required information on the package; or (6) contains artificial coloring, artificial flavoring, or a chemical preservative, but the label does not indicate this ingredient.[83]

Under the FDCA, a cosmetic is adulterated if, among other things, it: (1) contains a poisonous or harmful substance that could make it dangerous to users for its intended use;[84] (2) contains any filthy, putrid, or decomposed substance; (3) is prepared, packed, or held under unsanitary conditions;

75. <www.fda.gov/oc/opacom/fda101/sld004.html>.
76. <www.fda.gov/comments/noregs.html>.
77. <www.fda.gov/oc/opacom/fda101/sld003.html>.
78. 21 U.S.C. § 301.
79. 21 U.S.C. § 331(a).
80. 21 U.S.C. § 331(b).
81. 21 U.S.C. § 331(g).
82. 21 U.S.C. § 342.
83. 21 U.S.C. § 343.
84. This does apply to coal-tar hair dye.

(4) is in a container that has any poisonous or harmful substance that may make it injurious to health; or (5) if not a hair dye, it contains or is an unsafe color additive.[85]

A cosmetic is deemed misbranded under the FDCA if, among other things, it: (1) has a false or misleading label; (2) is in a package that does not contain the name and place of business of the manufacturer, packager, or distributor and an accurate description of its quantity; (3) does not have all required information prominently displayed on its label; (4) is in a misleading container; (5) in the case of a color additive, does not have the requisite packaging and labelling;[86] or (6) is in a package that violates the Poison Prevention Packaging Act[87] of 1970.[88]

A medicine or medical device may be adulterated for purposes of the FDCA if the FDA concludes after investigation, among other things, it: (1) has any filthy, putrid, or decomposed substance; (2) has been prepared, packaged, or held in unsanitary conditions; (3) is a medicine and its manufacturing, processing, packaging, or holding does not conform to current good manufacturing practices that ensure it is safe and of its purported strength, quality, and purity; (4) is in a container that has any poisonous or harmful substance that may make it injurious to health; (5) contains, for coloring purposes only, a color additive that is, unsafe; (6) is an unsafe new animal medicine; (7) is not of the strength or purity that it purports to be; (8) is a medicine that has been mixed with or replaced by another substance that reduces its strength or quality; (9) is a device that does not perform as it is purported to perform; (10) is a device that must obtain approval and has either not obtained approval or has had its approval denied, suspended, or withdrawn; (11) is a banned device; (12) is a device and its manufacture, packaging, storage, or installation does not conform to applicable requirements; or (13) is a device approved for investigational use, but has been improperly used.[89]

A medicine or device may be misbranded under the FDCA if, among other things, the FDA concludes after investigation that it: (1) has a false or misleading label; (2) is in a package that does not contain the name and place of business of the manufacturer, packager, or distributor and an accurate description of its quantity; (3) does not have all required information prominently displayed on its label; (4) does not have adequate directions for use on its label; (5) does not have adequate warnings on its label; (6) purports to be a medicine which is recognized in an official compendium, but is not packaged and labelled as prescribed in the compendium; (7) is a medication liable to

85. 21 U.S.C. § 361.
86. This also does not apply to hair dye.
87. 15 U.S.C. § 1471–1477.
88. 21 U.S.C. § 362.
89. 21 U.S.C. § 351.

deterioration, but not packaged and labelled as required; (8) is a medicine and its container or labelling is misleading; (9) is a medicine and is an imitation of another drug; (10) is dangerous to health if used as prescribed, suggested, or recommended on its label; (11) is a prescription medication and its manufacturer, packer, or distributor does not, in all advertisements and descriptive printed materials, provide a statement of the established name of the medication in print at least half as large as the trade name, the formula of the medication, and information on the medication's side effects, contraindications, and effectiveness; (12) was manufactured, prepared, propagated, compounded or processed in an unregistered establishment; (13) is a medicine and its label is in violation of the Poison Prevention Packaging Act of 1970;[90] (14) is a restricted device and uses false or misleading advertisements; (15) is a device and does not have in all advertisements or descriptive printed matters a true statement of the device's established name in print at least half as large as the trade name, a brief statement of the intended use, and all relevant warnings, precautions, potential side effects, and contraindications; (16) is a device and does not have the manufacturer's name, abbreviation, or symbol prominently displayed on it; (17) is a reprocessed device and all labelling on the device does not prominently explain that it is reprocessed; (18) is a new animal medicine and its labelling does not comply with all applicable regulations; or (19) is a non-prescription medication and its label does not have a domestic address or phone number for a responsible person to receive a report of serious adverse events.[91]

The FDA ensures compliance with the FDCA through periodic inspections of manufacturing facilities and products, analyses of samples of products, and legal proceedings.[92] The FDA has the authority to inspect the facilities it regulates. The FDA chooses to inspect facilities for a number of different reasons – *e.g.,* the Compliance Policy Guideline system, complaint letters, previous inspections that showed the need for follow-up inspections, and statutory provisions which require periodic inspections.[93] When the FDA observes conditions that might result in violations, it gives a written report to the manufacturer.[94] Although the FDA has several judicial remedies to ensure compliance, it tries to promote compliance without litigation.[95]

90. 15 U.S.C. § 1471–1477.
91. 21 U.S.C. § 352.
92. <www.cfsan.fda.gov/~dms/qa-ind3.html>.
93. For instance, as discussed in the food case study, spinach producing facilities are to be inspected annually.
94. <www.cfsan.fda.gov/~dms/qa-ind3.html>.
95. *Ibid.*

3.3. Penalties for Production/Supply of Unsafe Products?

The FDA's enforcement process can begin when an inspection reveals a defective product, defective condition, or other violation. The FDA is selective in bringing enforcement actions.[96] A large number of the cases that the FDA brings as seizures end by default and destruction of the seized goods, or by a consent decree under which the violator agrees to bring its goods into compliance with FDA guidelines.[97] Before the FDA begins an enforcement action, it often sends the violator a warning letter, which is a written notice to an entity that the FDA believes that entity is in violation of laws or regulations enforced by the FDA and which warns that "failure to take prompt corrective action may result in enforcement action."[98] Although the FDA does not need to send a warning letter as a prerequisite to bringing an enforcement action, the FDA often utilizes them to strengthen an enforcement case that it ultimately brings.[99,100]

The FDA has a number of different channels for regulating violations of the FDCA, including voluntary destruction or recall of the goods, seizure of the goods, imposition of civil penalties, imprisonment, and judicial injunctions.[101] The FDA's written policy for when a problem arises with one of the products it regulates is to first work "with the manufacturer to correct the problem voluntarily."[102] The FDA has no obligation to report minor violations of the FDCA if a warning or written notice will sufficiently protect the public's interest.[103]

As discussed above, the FDA can send a warning letter to an entity it believes is violating the laws it regulates, which is a written notice that the "failure to take prompt corrective action may result in enforcement action."[104] Although not required, the FDA often allows those sent warning letters to place a reply on the FDA's website.[105] The public has access to warning letters sent by the FDA on the FDA's website.

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96. Sam D. Fine, "The Philosophy of Enforcement", *Food Drug Cosmetic Law Journal* 31 (1976): 324.
97. In fact, over 99% of these cases end with one of those two results. Peter B. Hutt, "The Philosophy of Regulation under the Federal Food, Drug and Cosmetic Act", *Food Drug Cosmetic Law Journal* 28 (1973): 186.
98. 56 Fed. Reg. 27026 (June 12, 1991); *FDA Regulatory Procedures Manual* (rev. May 23, 1991), Chs. 8–10.
99. 56 Fed. Reg. 27026 (June 12, 1991).
100. See, e.g., *Biotics Research Corp. v. Heckler*, 710 F.2d 1375 (9th Cir. 1983).
101. <www.cfsan.fda.gov/~dms/qa-ind3.html>.
102. <www.fda.gov/oc/opacom/fda101/sld021.html>.
103. 21 U.S.C. § 336.
104. 56 Fed. Reg. 27026 (June 12, 1991); *FDA Regulatory Procedures Manual* (rev. May 23, 1991), Chs. 8–10.
105. FDA Notice, 68 Fed. Reg. 37162 (June 23, 2003).

Another informal alternative for those entities found to be in violation of FDA rules and regulations is a voluntary recall. A recall is "the removal or correction of a marketed product by a responsible firm, usually the manufacturer, which product is considered by the FDA to be subject to recall as an alternative to court actions such as seizure."[106] Recalls "have become a major means of consumer protection under the law."[107] Further, recalls are generally considered by the FDA the fastest and most effective way to protect consumers.[108]

A recall of a product, in most instances, is voluntary because the FDA does not have express statutory recall authority in most areas, but the FDA has the statutory authority to force recalls in the case of certain medical devices and radiological products for repair or replacement.[109] Although the FDA does not have statutory authority to demand a recall in most cases, the FDA can request an entity issue a recall, and entities often issue a voluntary recall as a result. Because the FDA has the discretion to bring penalties such as criminal proceedings, injunctions, and monetary penalties, entities will often agree to recall affected products to potentially avoid the FDA's pursuit of other penalties. A voluntary recall, however, will not always keep the FDA from pursuing other penalties for violations of the FDCA, such as a criminal or injunctive action or by seizure.[110]

Manufacturers or companies responsible for products have alternatives to a recall when faced with a product which potentially violates the FDCA. First, an entity can attempt to convince the FDA that there is no need for a recall because there is no (or merely a small) violation of the FDCA, making a market withdrawal more appropriate.[111] A market withdrawal is a removal of a product where there no is recall, no public listing is made, and the FDA does not check or review the progress of the removal.[112] Second, the entity can attempt to convince the FDA that a "stock recovery" is more appropriate. A stock recovery occurs when there is little movement in the goods because the FDA learns of a product defect before any part of that product has been released into commerce.[113] Finally, so long as the product in question is not a medical device or radiological product, the entity can withdraw the product from commerce without informing the FDA.[114]

106. O'Reilly, *supra* n. 47, at § 21:2 (citing 21 C.F.R. § 7.3(g)).
107. <www.cfsan.fda.gov/~dms/qa-ind3.html>.
108. *Ibid*.
109. 21 U.S.C. § 360.
110. 43 Fed. Reg. 26205 (June 16, 1978); 21 U.S.C. § 336; <www.cfsan.fda.gov/~dms/qa-ind3.html>.
111. 1 C.F.R. § 7.3(j).
112. *Ibid.;* 21 C.F.R. § 7.50.
113. 1 C.F.R. § 7.3(k).
114. 1 U.S.C. § 360(h).

If the FDA requests a recall of a product or food, but the entity responsible for the product or food declines the request, the FDA can issue a public warning about the safety of product or food.[115] Additionally, if the FDA requests a voluntary recall that the entity responsible for the product or food for which the FDA is requesting a recall refuses, the FDA can inform the public of the entity's refusal.[116]

Although the FDA typically attempts to first informally work with manufacturers and entities responsible for products that violate the laws it enforces, the FDA also has a number of formal regulatory options. These formal regulation tools can be used independently or simultaneously.[117] To act, the FDA must have jurisdiction over any product that it attempts to seize, enjoin, or otherwise formally regulate.

The FDA can seek judicial seizures of the products it regulates, including food, medicines, cosmetics, and medical devices.[118] The purpose of the seizure, which is simply a court action against goods that removes them from commerce,[119] is to give "speedy protection" to the public from goods that could cause harm.[120] Even if only part of a shipment of goods is contaminated or adulterated, the FDA can seize the entire shipment.[121] After goods are seized, they cannot be altered, used, or moved in any way without permission by the court.[122]

Another formal regulation tool is the use of injunctions, which the FDA considers to have the "highest priority" of its legal alternatives.[123] Under the FDCA, the FDA can request injunctive relief from a court when the injunctive relief is specific and properly tailored towards correcting a violation of the FDCA[124] and the FDA can show irreparable injury and a likelihood of prevailing on the merits in the case.[125] Additionally, the FDA cannot request an injunction for disclosure of trade secrets, counterfeiting of drugs identities, or giving a false promise of compliance.[126]

The FDA can also debar an entity that it concludes has submitted false research data, bribed reviewers of data, or other offenses that potentially

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115. FDA Issues Public Warning Against Ma Huang Product', *Food Labeling News* (Mar. 2, 1995), 15.
116. *DA Talk Paper T02-44, Nationwide Alert on Injectable Drugs Prepared by Urgent Care Pharmacy* (Nov. 15, 2002).
117. See, e.g., *U.S. v. Bowen*, 172 F.3d 682 (9th Cir. 1999).
118. 21 U.S.C. § 334.
119. <www.cfsan.fda.gov/~dms/qa-ind3.html>.
120. *Ewing v. Mytinger & Casselberry*, 339 U.S. 594 (1950).
121. *U.S. v. 935 Cases, More or Less, Each Containing 6 No. 10 Cans of Tomato Puree*, 65 F.Supp. 503 (N.D. Ohio 1976).
122. <www.cfsan.fda.gov/~dms/qa-ind3.html>.
123. *FDA Regulatory Procedures Manual* 8–6–10 (1982).
124. *S. v. Spectro Foods Corp.*, 544 F.2d 1175 (3d Cir. 1976).
125. "Reilly, *supra* n. 47, at § 7:18.
126. 1 U.S.C. § 332(a).

damage the credibility of the approval process from future product approvals in the generic drugs program.[127] The FDA can debar both individuals and companies.[128] In the case of an individual, that person cannot be involved with any entity or person submitting a drug to the FDA for approval for a proportionate amount of time.[129] Additionally, the FDA lists on its website those entities and persons disbarred.[130]

Another formal regulation tool available for the FDA's use is disqualification, which is a final order that bars an entity or facility from conducting FDA-regulated research.[131]

If an FDA inspection calls for formal regulation, the FDA can temporarily halt a product until it makes a decision at an enforcement hearing; this penalty is called detention.[132] The amount of time that the FDA can detain an item varies: it can detain a medical device until the time of the hearing[133] and can detain "an article of food that presents a threat of serious adverse health consequences or death to humans or animals" for 20 days.[134]

The FDA can also withdraw licenses or permits from entities that require such licenses. When suspending licenses for food manufacturers, suspension is effective immediately and an entity only gets a hearing when it requests reinstatement under a new license or permit.[135] In the case of medical devices and medicines with pre-market approval, the FDA must give an entity a hearing before withdrawing a license or permit.[136]

The FDA can impose civil monetary penalties for violations of its regulations.[137]

Additionally, although rarely done, the FDA also has the authority to bring criminal actions.[138]

The FDA makes official policies in three different ways: (1) rulemaking; (2) adjudication; and (3) informal means such as guidelines or advice letters.[139] A rule, which has the greatest precedental impact, is an "agency statement of general or particular applicability and future effect designed to implement, interpret or prescribe law or policy."[140] The FDA's rules

127. 1 U.S.C. § 335(a).
128. *Ibid.*
129. 21 U.S.C. § 331.
130. <www.fda.gov/ora/compliance_ref/debar/default.htm>.
131. 21 C.F.R. § 58.202.
132. 21 C.F.R. § 800.55.
133. 21 U.S.C. § 334(g).
134. 21 U.S.C. § 334(h).
135. 21 U.S.C. § 344(a).
136. 21 U.S.C. § 360.
137. 21 U.S.C. § 333.
138. *Ibid.*
139. *Ibid.* at § 4:1.
140. 5 U.S.C. § 551(4).

can either be interpretive rules or substantive rules.[141] The FDA generally circulates draft rules internally, but only discloses the drafts in certain circumstances in order to check accuracy of technical statements.[142] Subsequently, the FDA lists proposed rules in the semi-annual Federal Regulatory Agenda.[143] After the FDA issues the proposed rule, the public, the courts, and congress have a chance to review it. After these comments, the FDA drafts responses and makes any necessary modifications to or withdraws the proposed rules before they are finally published in the *Federal Register*.[144]

Adjudication is an "agency process for the formulation of an order."[145] An order, which is the result from adjudication, is "a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency matter other than rule making."[146] Orders set precedent based on particular facts.

Finally, advice letters and other informal policymaking devices are not binding precedent.[147]

3.4. FDA Administrative Proceedings

The FDA holds hearings for both enforcement and rulemaking purposes. The majority of hearings are enforcement adjudicative hearings of charges brought against products, persons, or companies by the FDA.[148] Although in an enforcement hearing, the FDA gives notice to the individual or company being charged, allows rebuttal, and allows challenge, the FDA does not have to consider those who will be impacted by the rule in rulemaking hearings.[149] However, the FDCA requires the rulemaking process to contain a notice-and-comment stage which allows for objections.[150] The FDA is required to have formal rulemaking hearings only when making rules in limited areas: special dietary food regulations;[151] food manufacturing special permit regulations;[152] pesticide tolerance regulations;[153] drug assay test regulations;[154] and rules on packaging of medication subject to deterioration.[155]

141. O'Reilly, *supra* n. 47, at § 4:1.
142. 21 C.F.R. § 10.80.
143. O'Reilly, *supra* n. 47, at § 2:5.
144. *Ibid.*
145. Administrative Procedure Act § 551.
146. 5 U.S.C. § 551(6).
147. O'Reilly, *supra* n. 47, at § 4:1.
148. O'Reilly, *supra* n. 47, at § 5:2.
149. *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645 (1973).
150. 21 U.S.C. § 371(e).
151. 21 U.S.C. § 343(j).
152. 21 U.S.C.§ 344(a).
153. 21 U.S.C.§ 346.
154. 21 U.S.C.§ 351(b).
155. 21 U.S.C.§ 352(h).

FDA enforcement hearings are either adjudicative regulatory hearings[156] or hearings before criminal actions.[157] With criminal actions, the FDA provides notice before pursuing the action. Before any criminal proceeding for FDCA violations begins, the person against whom the proceedings are being considered has "an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding."[158] A regulatory hearing begins with the FDA giving notice of an opportunity for a hearing.[159] After receiving notice of an opportunity for a hearing, a party impacted by the proposed rule can file a request for a hearing, though the FDA is not required to grant that request.[160] The notice for the opportunity for a hearing includes a brief summary of the information that the FDA will present.[161] The FDA is required to explain its "reasons for proposing or taking, or refraining from taking, the action that is, the subject of the hearing" and to "provide sufficient information to support its action under the applicable law."[162] These hearings are informal and the rules of evidence do not apply, meaning that all evidence offered is considered.[163] Any decision made at these regulatory hearings is subject to judicial review,[164] but the courts give great deference to FDA decisions.[165]

The FDA does not hold hearings on enforcement matters that it deems entirely discretionary. If the FDA plans to withdraw a product without a hearing, though, it must present a prima facie case to justify the withdrawal without a hearing.[166]

Generally, FDA decisions interpreting statutes are given deference in court.[167] Additionally, the FDA has "discretionary function" coverage under the Federal Torts Claims Act[168] (FTCA), meaning that it is immune from most suits against it by injured parties.[169] Plaintiffs cannot sue the FDA for damages based on the FDA's approval of medical devices.[170] The exception to the general rule against FDA liability occurs when the "FDA binds itself by law or by rule to a particular duty," such as if an FDA staff does follow required procedures.[171]

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156. 21 C.F.R. pt. 16.
157. 21 U.S.C. § 335.
158. *Ibid.*
159. 21 C.F.R. § 16.24.
160. *Ibid.*
161. *Ibid.*
162. "FDA Preamble", 41 Fed. Reg. 48260 (Nov. 2, 1976).
163. 21 C.F.R. § 16.60.
164. 5 U.S.C. § 706.
165. *Riegel v. Medtronic*, 128 S. Ct. 999 (U.S. 2008).
166. *Hess & Clark, Division of Rhodia, Inc. v. FDA*, 495 F.2d 975 (D.C. Cir. 1974).
167. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 125 (2000).
168. 28 U.S.C. § 2680(a).
169. *Berkovitz by Berkovitz v. U.S.*, 486 U.S. 531 (1988).
170. *King v. U.S. Federal Drug Admin.*, 35 Fed. Appx. 511 (9th Cir. 2002).
171. O'Reilly, *supra* n. 47, at § 26:46 (citing *Fisher Bros. Sales, Inc. v. U.S.*, 17 F.3d 647 (3d Cir. 1994)).

3.5. Potential Liabilities for Production or Supply of Unsafe Products

Because the FDCA does not create a private right of action,[172] as a practical matter, the FDA has only a background role in the arena of private causes of action for products liability.[173] For the most part, the FDA's role is limited to plaintiffs attempting to establish negligence per se as a result of an FDA violation or warning letter.

With some products, such as medication that is, potentially dangerous to children, the FDA only allows marketing if there is a warning on the official label of the product.[174] The FDA's regulations on such warning information are detailed and cover both pre-market investigation and post-market surveillance. Currently there is a split in the case law regarding the pre-emptive effect of such warnings on traditional tort liability claims.[175]

In 2008, the U.S. Supreme Court held that certain FDA decisions and regulations could pre-empt certain claims for certain medical devices.[176]

In 2009, the U.S. Supreme Court held that FDA decisions and regulations did not pre-empt all claims in the field of pharmaceuticals, but indicated that certain claims might be pre-empted.[177]

FDA documents, such as warning letters and documents on recalls, are generally available and often admissible in products liability lawsuits, but the FDA typically does not allow employees to testify in lawsuits to which the agency is not a party.[178]

Other FDA documents may also be admitted into evidence in products liability cases. For instance, in a pharmaceutical products liability case, litigants can typically obtain clinical trial results.[179] Not all FDA documents can be used as evidence, however. With many pharmaceutical and device products, a manufacturer is required to file self-reported adverse reaction reports; these reports may not be admissible as evidence against a manufacturer in a products liability case, as they are generally not considered scientifically reliable.[180]

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172. Just as violation of the FDCA does not create a private cause of action, compliance with the FDCA is not a complete defense. A manufacturer is not immune from liability merely because of FDA approval. See, e.g., Richard Merrill, "Compensation for Prescription Drug Injuries", *Virginia Law Review* 59 (1973): 14.
173. *Harris v. McDonald's Corp.*, 901 F.Supp. 1552 (M.D. Fla. 1995).
174. 21 U.S.C. § 352.
175. See e.g., *Levine v. Wyeth*, 944 A.2d 179 (Vt. Oct. 27, 2006) and *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008).
176. *Riegel v. Medtronic*, 128 S. Ct. 999 (2008).
177. *Wyeth v. Levine*, 129 S. Ct. 1187 (2009).
178. 21 C.F.R. § 20.1; *Cleary, Gottlieb, Steen & Hamilton v. Dep't of Health & Human Servs.*, 844 F. Supp. 770 (D.D.C. 1993).
179. *In re Rezulin Products Liability Litigation*, 178 F.Supp. 2d 412 (S.D. N.Y. 2001). Of course, patients' information must be redacted.
180. 21 U.S.C. § 379v; *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378 (4th Cir. 1995).

Although FDA approval is not a complete bar to a products liability case, in some states, FDA approval is a defense to a products liability claim that a product is dangerous.[181] In the states that accept this as a defense, expert testimony that claims that a warning could be different does not defeat a presumption that the FDA-approved warnings are sufficient.[182]

4. CASE STUDIES

4.1. Case Study Involving Consumer Product: Toy Recall Due to Lead Poisoning Hazard

The CPSC banned lead paint on toys and children's furniture in 1978, but it was not authorized under law to regulate lead in a product unless the product may cause "substantial personal injury."[183] During the summer of 2007, Mattel Incorporated's internal testing discovered that the lead levels in paints used on its toys were as much as 200 times the accepted safety ceiling – 110,000 parts per million (ppm) versus 600 ppm.[184] In response to this discovery, Mattel and the CPSC announced a voluntary recall on approximately 253,000 units of "Sarge" die cast toy cars.[185] This recall accompanied recalls by RC2 Corporation, Marvel Toys, and Dolgencorp. In September 2007 alone, 13.2 million toys were recalled.[186]

After the recall, the CPSC launched its own investigation into whether Mattel had initially investigated reports of dangerous toys without informing the CPSC first.[187] Mattel CEO Robert acknowledged that Mattel's practice of performing an internal investigation before reporting to the CPSC in a Wall Street Journal article stating, "The company discloses problems on its own timetable because it believes both the law and the commission's enforcement practices are unreasonable. Mattel said it should be able to evaluate hazards internally before alerting any outsiders, regardless of what the law says."[188] The CPSC disagreed.[189] The article cited several instances in which Mattel failed to disclose information to the CPSC regarding defective toys

181. See, e.g., *Hufft v. Horowitz*, 4 Cal. App. 4th 8 (4th Dist. 1992).
182. *Kernke v. The Menninger Clinic, Inc.*, 173 F.Supp. 2d 1117 (D. Kan. 2001).
183. "Agency: Lead Recall Due to Reduced Clout", <www.cbsnews.com/stories/2007/09/19/national/main3279261.shtml.>, Sept. 19, 2007.
184. *Ibid.*
185. "Press Release, Consumer Product Safety Commission, Mattel Recalls "Sarge" Die Cast Toy Cars Due To Violation of Lead Safety Standard" (Aug. 17, 2007) (on file with author)).
186. "Agency: Lead Recall Due to Reduced Clout", *supra* n. 183.
187. "Safety Agency, Mattel Clash Over Disclosures", <http://online.wsj.com/article/SB118886996338816516.html?mod=hpp_us_whats_news>, last visited Dec. 23, 2008.
188. *Ibid.*
189. *See ibid.*

immediately.[190] In one case, the CPSC learned independently that toys manufactured by Mattel were causing fires and fined Mattel USD 1.1 million for failing to notify the CPSC of the defect.[191] Subsequent to the recall and CPSC investigation, Mattel entered a USD 12 million nationwide settlement to resolve all claims related to the toys involved in the recall.[192]

In response to the numerous recalls related to lead paint and children's toys, members of the CPSC went before Congress and requested an increase in the CPSC's budget and an expansion of its scope and powers.[193] They showed that the CPSC's staff had been reduced from 800 in 1973 to less than half of that amount in 2007.[194] Of that number, fewer than 90 staff members were field investigators who visited ports of entry to inspect the more than 15,000 product types under the CPSC's jurisdiction.[195] Only one staff member was a full-time toy tester.[196]

On August 14, 2008, President Bush signed the Consumer Product Safety Improvement Act of 2008, significantly expanding the authority of the CPSC and imposing new consumer product safety requirements for several consumer products, including children's products.[197] Under the Act, "children's products" are broadly defined to include "consumer product[s] designed or intended primarily for children 12 years of age or younger."[198] The bill bans children's products containing certain amounts of lead, by designating such products as "Banned Hazardous Substances" under the Federal Hazardous Substances Act (FHSA).[199] The Act establishes a phase-in period that prohibits the sale of children's products if any part of the product contains lead at certain levels.[200]

The Act also contains mandatory third party testing of toys;[201] a more stringent lead paint ban;[202] manufacturer labelling of children's products with tracking information to facilitate recalls;[203] retailers to identify, upon CPSC request, the manufacturers of the products they sell;[204] manufacturer identification;[205] and conformity certification for all consumer products.[206]

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190. *Ibid.*
191. *Ibid.*
192. "Mattel Settles With Thirty-Nine States Over Tainted Toys", <www.msnbc.msn.com/id/28241169/>, last visited Dec. 19, 2008.
193. *Ibid.*
194. *Ibid.*
195. *Ibid.*
196. *Ibid.*
197. Pub. L. No. 110–314, § 217(A), 122 Stat. 3016 (2008).
198. *Ibid.,* at § 108.
199. *Ibid.,* at § 101.
200. *Ibid.*
201. *Ibid.,* at § 102.
202. *Ibid.,* at § 101.
203. *Ibid.,* at § 103.
204. *Ibid.*
205. *Ibid.*
206. *Ibid.,* at § 101.

4.2. Case Study Involving Food Product: 2006 E. coli Outbreak

In September of 2006, an outbreak of a food borne illness occurred in the U.S., which officials ultimately found to be linked to spinach. By the time the outbreak ended, 205 people in 26 states and Canada reported being sick, 104 people had been hospitalized, 31 had developed hemolytic-uremic syndrome (HUS), and three had died as a result of the food borne illness.[207] The FDA investigated the cause of the illness and, after linking it to subject spinach, followed its policy of working with producers to correct any problem voluntarily.[208]

The Center for Disease Prevention and Control (CDC) first learned of an outbreak of a food borne illness in Wisconsin on September 11, 2006.[209] Two days later, Wisconsin public health officials determined the outbreak was linked to bagged spinach.[210] The next day, September 14, after the CDC confirmed that spinach was the source of the outbreak, the FDA made a public announcement, telling consumers not to eat bagged fresh spinach because of an outbreak of illness due to contamination with the deadly bacterium *Eschericia coli* O157:H7 (E. coli).[211] The FDA, on September 15, announced that consumers should not eat any fresh spinach, which amounted to the most sweeping announcement ever made about a food by the FDA.[212] As a result of this warning, grocery stores and restaurants across the U.S. stopped selling and serving bagged spinach, and no fresh spinach was sold in the U.S. for five days.[213] Throughout the outbreak, the FDA posted daily announcements on its website indicating the number of individuals impacted by the E. coli infection.

Within a day of the FDA's first public announcement regarding the potential contamination of spinach, producers of spinach voluntarily recalled products that contained spinach.[214] Even as companies were issuing voluntary recalls, the FDA continued to investigate whether other companies that had not yet issued recalls were involved in the outbreak.[215]

By September 21, 2006, the FDA traced the spinach implicated in the outbreak to spinach grown in certain areas of California.[216] Thus, on September 22, 2006, the FDA announced that its initial advisory against

207. <www.fda.gov/bbs/topics/NEWS/2007/NEW01593.html>.
208. <www.fda.gov/oc/opacom/fda101/sld021.html>.
209. <www.ers.usda.gov/AmberWaves/June07/Features/Spinach.htm>.
210. *Ibid.*
211. <www.fda.gov/bbs/topics/NEWS/2006/NEW01450.html>.
212. <www.ers.usda.gov/AmberWaves/June07/Features/Spinach.htm>.
213. *Ibid.*
214. <www.fda.gov/bbs/topics/NEWS/2006/NEW01451.html>.
215. *Ibid.*
216. <www.fda.gov/bbs/topics/NEWS/2006/NEW01460.html>.

eating any fresh bagged spinach was no longer in effect.[217] After several more days of investigation, the FDA narrowed its focus on the cause of the outbreak to one farm in California.[218] Although it never determined exactly how the spinach became contaminated,[219] the FDA did conclude that the problem was field-level contamination.[220] Eventually, on September 29, 15 days after its original warning, the FDA announced that spinach was as safe as it was before the outbreak.[221] The FDA explained that the producer responsible for the contaminated spinach, as well as four other companies that had received products from that producer, had already issued voluntary recalls for all implicated products.[222] Additionally, the FDA announced that it was working with the spinach industry to develop a plan to minimize the risk of another E. coli outbreak.[223] Although the plan was voluntary, the FDA did not exclude "the possibility of regulatory requirements in the future."[224]

Over the course of the outbreak, in order to protect the public health, the FDA held press conferences, issued press releases, and posted updates on its websites almost daily.[225] Additionally, even after the FDA determined the cause of the outbreak, it continued to conduct on-site investigations of spinach producers from September 14, 2006 to October 12, 2006.[226] Although the FDA conducted investigations and worked with producers to implement safety precautions, ultimately, all actions taken by producers at the urging of the FDA were voluntary.

In the wake of the E. coli outbreak, the U.S. Congress Oversight and Government Reform Committee issued a report on March 12, 2008, criticizing the FDA.[227] The report found that, although the FDA found serious sanitary problems in nearly half of its inspections of spinach facilities, the FDA did not report a single one to its internal enforcement authorities, nor did it send any warning letters or seek any injunctions.[228] In fact, according to the report, in 38 cases, there were repeat violations, but the FDA never did anything more than request voluntary compliance; 14 of the repeat requests for voluntary compliance were for the exact same violations. Only one facility

217. *Robert E. Bracket, Ph.D.'s Statement Before the U.S. Senate Committee on Health, Education, Labor and Pensions*, <www.fda.gov/ola/2006/foodsafety1115.html>, Nov. 5, 2006.
218. <www.ers.usda.gov/AmberWaves/June07/Features/Spinach.htm>.
219. <www.fda.gov/bbs/topics/NEWS/2007/NEW01593.html>.
220. <www.ers.usda.gov/AmberWaves/June07/Features/Spinach.htm>.
221. <www.fda.gov/bbs/topics/NEWS/2006/NEW01474.html>.
222. <www.fda.gov/bbs/topics/NEWS/2006/NEW01474.html>.
223. *Ibid.*
224. *Ibid.*
225. Bracket, *supra* n. 217.
226. <www.fda.gov/oia/Mepi/Handouts/Spinach-Outline.pdf>.
227. House Committee on Oversight and Government Reform, *Report: FDA and Fresh Spinach Safety* (March 2008).
228. *Ibid*.

was referred to state authorities.[229] Additionally, the report found that, although the FDA should have inspected each facility annually, it only inspected each one every 2.4 years.[230]

As of November 1, 2008, all action taken in response to the E. coli outbreak by spinach producers has been voluntary.

4.3. Case Study Involving Drug Product

In 1993, FDA approved Propulsid (Cisapride), a medication manufactured and marketed by Janssen Pharmaceutica, a division of Johnson & Johnson Co., for the treatment of night time heartburn, related to gastroesophageal reflux disease (GERD).[231]

During these first years of use of Propulsid, data was collected by FDA and the manufacturer through the adverse event report process.

In June of 1998, the manufacturer and FDA strengthened the warnings in Propulsid's labelling due to increased concerns over the side effects involving alleged heart rhythm abnormalities:[232]

> On March 23, 2000 Janssen announced its decision to end general distribution of Propulsid in the United States as of July 14, 2000. The stated reason for the removal of the drug was that, despite clear label warnings regarding Propulsid's adverse effects when combined with contraindicated medicines and risk factors, the drug was being inappropriately prescribed by physicians. It is estimated that prior to its removal some thirty million U.S. residents had taken Propulsid. Following its removal, thousands of claimants began filing suits against Johnson & Johnson and Janssen Pharmaceutica in federal and state courts across the country.[233]

Due to the number of tort cases filed against the manufacturers, ''on August 7, 2000, the Judicial Panel on Multidistrict Litigation (JPMDL) conferred multidistrict litigation status on the Propulsid suits filed in the federal courts, and pursuant to Title 28, United States Code, Section 1407, transferred all federal Propulsid suits'' and consolidated these cases before United States District Court Judge Fallon in the Eastern District of Louisiana (''the MDL Court''), ''to coordinate discovery and to consolidate pretrial matters.''[234]

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229. *Ibid.*
230. *Ibid.*
231. *In re Propulsid Products Liability Litigation,* 208 F.R.D. 133, 135 (E.D. La. 2002).
232. <www.cnn.com/HEALTH/9806/30/heartburn.drug/>.
233. *In re Propulsid Products Liability Litigation,* 208 F.R.D. at 135–36. *See also* <www.fda.gov/bbs/topics/ANSWERS/ANS01007.html>.
234. *Ibid.,* at 136.

The MDL Court ''appointed committees of counsel to represent the parties, and the litigation commenced. This multidistrict litigation, designated MDL-1355 and captioned *In re Propulsid Products Liability Litigation,* involves hundreds, perhaps thousands of individual claimants including over thirty class actions from some fifteen states, all alleging various tort and products liability claims against the manufacturers of Propulsid.''[235]

Litigation proceeded in the MDL Court until the claimants and the manufacturer reached an agreement for a settlement program, which was announced on February 4, 2004,[236] and approved by the MDL Court on December 19, 2005.[237]

This settlement program required that 85% of the nearly 300 wrongful death claims, and 75% of the 4,000 personal injury claims agree to the terms of the settlement. ''In addition, 12,000 individuals who have not filed lawsuits, but whose claims are the subject of 'tolling agreements' suspending the running of the statutes of limitations against those claims,'' also had to accept the terms of the settlement to make it effective.[238]

To fund the settlement, Janssen agreed to pay ''as compensation a minimum of USD 69.5 million and a maximum of USD 90 million, depending upon the number of plaintiffs who enrol in the program. Janssen will also establish an administrative fund not to exceed USD 15 million, and will pay legal fees to the PSC not to exceed USD 22.5 million.''[239]

235. *Ibid.*
236. <http://propulsid.laed.uscourts.gov/settlement.htm>.
237. <http://propulsid.laed.uscourts.gov/Orders/consent%20order.pdf>.
238. <http://propulsid.laed.uscourts.gov/settlement.htm>.
239. *Ibid.*