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## The Expansion of FDA's Enforcement Powers from 1906-2003

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# CATHERINE KARUGA PROFESSOR HUTT

## COMBINATION PAPER: FOOD AND DRUG LAW & 3<sup>RD</sup> YEAR PAPER

### THE EXPANSION OF FDA'S ENFORCEMENT POWERS FROM 1906-2003

#### BRIEF HISTORY OF THE FDA

The Food and Drug Administration of the Health and Human Services Department is the largest American regulatory agency. Its regulatory authority covers most food products (other than meat and poultry), human and animal drugs, therapeutic agents of biological origin, medical devices, radiation-emitting products for consumers, medical, and occupational use, cosmetics and animal feed. The FDA regulates over \$1 trillion of products a year (25% of all money spent in the USA). "The basis for the FDA and the expansion of its powers follow a shift in American economic focus from the pro-industrial growth that dominated the 19th century to the pro-consumer health standards that is a cornerstone of 20th century American economic development."<sup>1</sup>

The Pure Food and Drug Act of 1906 (1906 Act) was enacted to prevent the manufacture, sale or transportation of adulterated or misbranded foods, drugs, medicines and liquors. It vested enforcement power in the Bureau of Chemistry, of the U.S. Department of Agriculture. In July 1927, the non-regulatory research functions of the bureau were transferred to a different segment of the department and the Bureau of Chemistry was renamed as the Food, Drug and Insecticide Administration.<sup>2</sup> That name was eventually reduced to the Food and Drug Administration (FDA) in July 1930.<sup>3</sup> The FDA was transferred from the U.S. Department of Agriculture to the Federal Security Agency in June 1940.<sup>4</sup> In 1953, the Federal Security

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<sup>1</sup>Zaltman, Haim, "Legal Purpose, Risk Stimulators, and Foreign Investment: A Comparative Legal Analysis of the American and Russian Experiences." (2001), <http://www.iet.ru/guest/zaltman/dis.htm>

<sup>2</sup>Swann, John P., Ph.D., *History of the FDA*, FDA History Office (adapted from George Kurian, ed., *A Historical Guide to the U.S. Government* (New York: Oxford University Press, 1998)), <http://www.fda.gov/oc/history/historyoffda/fulltext.html>.

<sup>3</sup>*Id.*

<sup>4</sup>*Id.*

Agency was turned into the Department of Health, Education and Welfare (HEW).<sup>5</sup> The education aspect of HEW was extricated in May 1980, to form the Department of Health and Human Services, which is where the FDA is currently located.<sup>6</sup> In 1938, Congress passed the Food Drug and Cosmetic Act (FDCA) which partially repealed the 1906 Act. This paper focuses on the expansion of the enforcement powers granted to the FDA beginning with the 1906 Act, through the FDCA and the subsequent amendments to the FDCA. It also discusses the treatment of FDA's enforcement functions in courts.

Congress tends to pass acts expanding the FDA's regulatory authority following "outrageous industry practices, public health tragedies, or significant scientific advances."<sup>7</sup> Prior to the passage of the 1906 Act, the practices of the food industry produced food that was unsafe and tainted.<sup>8</sup> Upton Sinclair's description of the hideous condition of the meat-packing industry in *The Jungle* began a turmoil over tainted meat,<sup>9</sup> which was a very important factor in moving Congress to pass a meat inspection law and the 1906 Act.<sup>10</sup>

### **ENFORCEMENT POWERS OF THE 1906 FOOD AND DRUG ACT**

Very few enforcement powers were provided in the 1906 Act to enforce the act. The Act provided the authority to bring legal proceedings against violators of the Act's provisions.<sup>11</sup> These could be brought by any district attorney to whom the Secretary of Agriculture reported any violations of the act.<sup>12</sup> Violations of the provisions against the manufacture, sale and transportation of adulterated food and drugs constituted misdemeanors.<sup>13</sup> The Act included the authority to promulgate uniform rules and regulations to enforce its

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<sup>5</sup>See Wallace F. Janssen, *The U.S. Food and Drug Law: How It Came; How It Works*, 35 FOOD DRUG COSM. L. J. 132, 134 (1980).

<sup>6</sup>Swann, *supra* note 2.

<sup>7</sup>Ann Mileur Boeckman, *Comment: An Exercise in Administrative Creativity: The FDA's Assertion of Jurisdiction Over Tobacco*, 45 Cath. U. L. Rev. 991, n.1 (Spring, 1996).

<sup>8</sup>*Id.* at n.1, (quoting C.C.Regier, *The Struggle for Federal Food and Drugs Legislation*, 1 Law & Contemp. Probs. 3, 7-8 (1933) (describing sausages and hamburger steak that contained boracic acid in amounts approaching five to ten times that of a typical medical dosage)).

<sup>9</sup>James Harvey Young, *The Pig That Fell Into The Privy: Upton Sinclair's The Jungle and The Meat Inspection Amendments of 1906*, in *Bulletin of the History of medicine* 59, 467-80 (1985).

<sup>10</sup>Swann, *supra* note 2.

<sup>11</sup>Pure Food and Drug Act of 1906 Act, Pub. L. No. 59-384, § 5, 34 Stat. 768 (1906) (repealed 1938).

<sup>12</sup>*Id.*

<sup>13</sup>*Id.* at § 1 and 2.

provisions. It vested this rulemaking authority in the Secretary of the Treasury, the Secretary of Agriculture and the Secretary of Commerce and Labor.<sup>14</sup> The Act authorized the Bureau of Chemistry to examine specimens of foods and drugs.<sup>15</sup> Any violations found would be reported by the Secretary of Agriculture for prosecution. The act authorized seizure of any article of food, drug or liquor in interstate commerce, or being warehoused after interstate transportation, that was found to be adulterated or misbranded.<sup>16</sup> Finally, the Act authorized the Secretary of the Treasury to refuse admission into the U.S. any foods or drugs being imported into the U.S., upon a finding by the Secretary of Agriculture that they were adulterated or misbranded.<sup>17</sup> Further, charges for storage and labor on goods that were refused admission were to be paid by the owner of those goods. A default of such payment was to constitute a lien against any future importation made by such owner.<sup>18</sup>

#### **SHORTCOMINGS OF THE 1906 FOOD AND DRUG ACT**

The 1906 Act was ridden with deficiencies in the enforcement powers that it provided for its enforcement.<sup>19</sup> The original 1906 Act proscribed “false or misleading statements on the labels of foods and drugs.”<sup>20</sup> In the first test case to reach the Supreme Court, *Johnson v. U.S.*,<sup>21</sup> the Court ruled that the prohibition against false and misleading statements only related to the identity of the product and not to its curative properties.<sup>22</sup> This ruling encouraged manufacturers who had begun to bring their labels into compliance with the 1906 Act to revert to making false therapeutic claims on their product labels.<sup>23</sup> In 1912, Congress enacted the Sherley Amendment to the 1906 Act outlawing false therapeutic claims for patent medicines, but

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<sup>14</sup>*Id.* at § 3.

<sup>15</sup>*Id.* at § 4.

<sup>16</sup>*Id.* at § 10.

<sup>17</sup>*Id.* at § 11.

<sup>18</sup>*Id.*

<sup>19</sup>See Ruth deForest Lamb, *American Chamber of Horrors: The Truth About Food and Drugs* (New York: Farrar and Rinehart 1936) for an analysis of the substantive shortcomings of the 1906 Act. Ruth De Forest Lamb was FDA’s chief educational officer, who organized consumer support for the FDCA.

<sup>20</sup>Pub. L. No. 59-384, § 8, 34 Stat. 768 (1906)

<sup>21</sup>221 U.S. 488, 506-507 (1911).

<sup>22</sup>Lamb, *supra* note 19, at 12.

<sup>23</sup>See *id.*

requiring the government to prove that the promoter intended to defraud his victim.<sup>24</sup> The problem with this intent to defraud requirement was that so long as violators demonstrated that they subjectively believed their false curative claims, they could not be proceeded against.<sup>25</sup> This presented a big obstacle to the FDA's efforts at prosecuting violators, as it meant that the FDA had no real control of the package-medicine industry. Furthermore, since violators of this provision were assessed very light penalties, they seemed to view the penalties as "license fees for carrying on an illegitimate business."<sup>26</sup>

Another problem with the 1906 Act was that, while it required the listing of certain addictive substances on drug labels, it did not require enough additional information to make those statements meaningful to the average person.<sup>27</sup> Thus, drugs taken according to directions could be harmful but out of FDA's reach. An example of this is a case that the FDA investigated that involved a woman who had taken a headache medicine made of a coal-tar derivative. She had ingested a powder containing six grains of acetanilid, followed soon afterwards by a similar dose. The average dose of acetanilid prescribed by physicians is three grains. Her death was instantaneous.<sup>28</sup> The FDA could not proceed against the manufacturers of this product, because it was labeled truthfully and the quantity of acetanilid was indicated on the label in accordance with the law. The FDA's sole recourse was to warn the public about such "remedies" and encourage them to read the labels.<sup>29</sup>

Even for products that made false therapeutic claims that the FDA would have no difficulty proving that they were made with fraudulent intent, the manufacturers found a loophole by which they could escape FDA enforcement action. Manufacturers would simply make the curative claims in advertising, rather than making them on the package.<sup>30</sup> This left the FDA with no recourse at all against such products and their

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<sup>24</sup>Janssen, *supra* note 5 at 135. *See also* The Sherley Amendment, ch. 352, 37 Stat. 416 (1912)

<sup>25</sup>Janssen at 135

<sup>26</sup>Lamb, *supra* note 19, at ix.

<sup>27</sup>*Id.* at 81.

<sup>28</sup>*Id.* at 81-82.

<sup>29</sup>*Id.* at 81-82

<sup>30</sup>*See id.* at 109-114, for a discussion on how the manufacturer of Crazy Water Crystals circumvented the FDA's enforcement

manufacturers.

The 1906 Act authorized the Secretary of the Treasury, the Secretary of Agriculture and the Secretary of Commerce and Labor to make uniform rules and regulations for the enforcement of the Act.<sup>31</sup> However, the Act did not authorize the Secretary to establish legal standards for the regulated products, or tolerance standards for poisonous residues in produce, choosing to let courts and juries handle that undertaking.<sup>32</sup> The courts however were not interested in taking up this responsibility.<sup>33</sup> They however did not accord FDA regulations legal effect. A frustrated David F. Houston, Secretary of Agriculture, remarked in his first Annual Report,

“The establishment of legal standards for judging foods would render the food and drugs act more effective, less expensive in its administration, and supply needed legal criteria. Under the present conditions it is necessary in the individual prosecution to establish by evidence a standard for each individual article. This procedure is very expensive, and sometimes its cost is out of proportion to its value. Moreover, it may result in lack of uniformity in different jurisdictions. With legal standards established, the control of foods would be more uniform and measurably less expensive. The lack of such standards is today one of the greatest difficulties in the administration of the food and drugs act.”<sup>34</sup>

In 1914 Secretary Houston revived the Food Standards Committee to provide advisory criteria for what constituted economic adulteration forbidden by the 1906 Act.<sup>35</sup> These did not have the force and effect of law and thus the government still had to introduce several witnesses to testify as to the standards expected by consumers and recognized by the reputable majority of the trade.<sup>36</sup> In 1923, Congress enacted a legislation that established a legal standard for butter, for purposes of the enforcement of the 1906 Act.<sup>37</sup> Congress is

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efforts through advertising.

<sup>31</sup>Pub. L. No. 59-384, § 3, 34 Stat. 768 (1906)

<sup>32</sup>See Lamb, *supra* note 19, at 146-147, for a discussion on the food lobby’s successful efforts at preventing the 1906 Act from granting the Secretary of Agriculture authority to establish legal standards.

<sup>33</sup>See *id.* at 149, quoting the court’s opinion on determination of the appropriate standard for milk fat in ice-cream, in a case against an Arizona ice-cream manufacturer, “It should not be left, it seems to me, for the decision of the court, but should be determined by Congress or by authorization of the Secretary so that the trade may know...”

<sup>35</sup>*Id.* at 154

<sup>36</sup>*Id.* at 154-155.

<sup>37</sup>42 Stat. 1500 (1923) - butter was described as “the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for.”

however not the appropriate body for setting legal standards generally for two reasons. First, it is such a tremendous undertaking that no Congress could manage it.<sup>38</sup> Second, technological advances would require changes in the standards from time to time and these could only be effected through Congressional action, a slow process, which would render the standards inflexible.<sup>39</sup> The lack of authority to promulgate legal standards was indeed one of the greatest shortcomings of the 1906 Act.

Imitations of certain standard products sold under the name of the standard product were considered misbranded and thus proscribed by the 1906 Act.<sup>40</sup> However there was a loophole through which imitation products escaped regulation under the 1906 Act: imitations were exempted from prohibition if they are sold under their own distinctive names, as long as they did not contain any added poisonous or deleterious ingredients.<sup>41</sup> Some of these exempted products even though not poisonous, amounted to economic adulteration.<sup>42</sup> The 1906 Act had no provision requiring the declaration of these products' ingredients (unless they included addictive substances), in proportion, so that the consumer would have sufficient information on the label to make a well-informed choice.<sup>43</sup>

The 1906 Act authorized the FDA to regulate food that was adulterated because it was filthy, decomposed or had in it any portion of an animal unfit for food.<sup>44</sup> Enforcement officials were aware that unsanitary conditions at the manufacturing plants meant that the finished product had to be contaminated.<sup>45</sup> They however had no authority to inspect these manufacturing plants. Since their jurisdiction began only when the finished product entered interstate commerce they were limited to examining samples taken from actual

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<sup>38</sup> See Lamb, *supra* note 19 at 147.

<sup>39</sup> *Id.*

<sup>40</sup> Pub. L. No. 59-384, § 8, 34 Stat. 768 (1906).

<sup>41</sup> *Id.*

<sup>42</sup> See Lamb, *supra* note 19 at 160-161, for a discussion on the economic adulteration worked by the addition of colored soya-bean flour to plain macaroni to change its color so it can look like the more expensive semolina macaroni, to extract more money for it.

<sup>43</sup> *Id.* at 164.

<sup>44</sup> Pub. L. No. 59-384, § 7, 34 Stat. 768 (1906).

<sup>45</sup> See Lamb, *supra* note 19, at 252.

interstate shipments.<sup>46</sup> The methods available at the time were not sophisticated enough to detect invisible filth.<sup>47</sup> A method of micro-analyzing butter was innovated and an examination of butter that looked perfectly clean to the naked eye revealed filth suggesting contamination from way back in the farm: hay, chicken feathers, maggots, beetles, rodent hairs, fly legs, cockroaches, metallic filings, etc.<sup>48</sup> Butter that was found to be adulterated in this way was sometimes released for renovating at the discretion of the courts.<sup>49</sup> There was a special law regulating the manufacture and sale of renovated butter and oleomargarine.<sup>50</sup> The manufacturers of renovated butter or oleomargarine were required to be licensed and to use prescribed labels and containers. The Bureau of Dairy Industry was responsible for the sanitary inspection of these factories. The FDA did not have general inspection authority and it was thus difficult to administer the filth provisions of the 1906 Act. In 1934, the Shrimp Amendment to the 1906 Act was passed, authorizing supervisory inspection of the seafood industry for all packers desiring the service.<sup>51</sup> This inspection was not mandated, but was provided when the shrimp packers applied for it, at the discretion of the Secretary of Agriculture.<sup>52</sup> A therapeutic disaster in 1937 provided the force that led to the passage of a bill that had been in congress for five years.<sup>53</sup> In 1937, a new sulfa wonder drug called Elixir Sulfanilamide was marketed by a Tennessee drug company, the S. E. Massengill Company.<sup>54</sup> “The solvent in this untested product was a highly toxic chemical analogue of antifreeze that killed over 100 people, many of whom were children.”<sup>55</sup> This event caused the FDA’s division of pharmacology to conduct research that developed a “statistically based method for

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<sup>46</sup>*Id.* at 252.

<sup>47</sup>*Id.*

<sup>48</sup>*Id.* at 253.

<sup>49</sup>*Id.* at 255.

<sup>50</sup>*Id.* at 254. 21 U.S.C. § 347 (2003) of the FDCA regulates intrastate sales of colored oleomargarine or colored margarine.

<sup>51</sup>*See id.* at 277, for a brief discussion of the events leading to the passing of the Shrimp Amendment. *See also* The Shrimp Amendment, 48 Stat. 1204 (1934) (codified as, Pub. L. No. 59-384, § 10A, 34 Stat. 768 (1906)).

<sup>52</sup>*See* The Shrimp Amendment, 48 Stat. 1204 (1934) (codified as, Pub. L. No. 59-384, § 10A, 34 Stat. 768 (1906)).

<sup>53</sup>Swann, *supra* note 2.

<sup>54</sup>James Harvey Young, *Sulfanilamide and Diethylene Glycol*, in CHEMISTRY AND MODERN SOCIETY: HISTORICAL ESSAYS IN HONOR OF AARON J. IHDE, JOHN PARASCANDOLA AND JAMES C. WHORTON, EDS., 105-25, 105 (Washington, D.C.: American Chemical Society, 1983).

<sup>55</sup>Swann, *supra* note 2.



determining the comparative toxicity of compounds.”<sup>56</sup> It was also in the wake of this event that congress passed the Food Drug and Cosmetic Act (FDCA), which was signed on June 25, 1938.<sup>57</sup> Once again, this is a demonstration of Congress’ passing of a law safeguarding public health only after a therapeutic disaster.<sup>58</sup>

### **ENFORCEMENT POWERS OF THE 1938 FOOD DRUG AND COSMETIC ACT**

The FDCA provides the FDA with significant enforcement powers and tools for the enforcement of the act.<sup>59</sup>

The Act for the first time in §302 (a) gave U.S. district courts jurisdiction to issue injunctions and restraining orders for the violations of its provisions.<sup>60</sup> The Act provides the authority to bring legal proceedings to prosecute violations of the provisions listed in §301.<sup>61</sup> Such violations constitute misdemeanors.<sup>62</sup> The fines provided for in the FDCA are much more significant than those that had been provided in the 1906 Act.<sup>63</sup> Section 303 (b) further provides that violations committed with an intent to defraud or mislead, are punishable by imprisonment for not more than three years, or a fine of not more than \$10,000, or both. Whereas fraud was not a prerequisite for assessing penalties on violators, where fraud could be proved, higher penalties would be applied.

The FDCA in §304 (a) provides for the seizure of any food, drug, device or cosmetic in interstate commerce that is adulterated or misbranded. Seized goods are proceeded against on libel of information and condemned in any district court of the U.S. within the jurisdiction where the article was found. In addition, upon entry

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<sup>56</sup>Young, *Sulfanilamide and Diethylene Glycol*, supra note 54 at 105.

<sup>57</sup>Swann, *supra* note 2.

<sup>58</sup>Swann, *supra* note 2.

<sup>59</sup>Federal food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301-399 (2003)).

<sup>60</sup>See Pub. L. No. 75-717, § 301, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. § 331(2003)), for a listing of the FDCA’s prohibited acts.

<sup>61</sup>Pub. L. No. 75-717, § 303, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. § 333 (2003)).

<sup>62</sup>*Id.*

<sup>63</sup>*Id.* at § 303(a), provided that violators would be subject to imprisonment for not more than one year, or a fine of not more than \$1,000, or both. Subsequent violations would subject violators to imprisonment for not more than three years, or a fine of not more than \$10,000, or both. While, Pub. L. No. 59-384, § 1, 34 Stat. 768(1906), provided for a fine of not more than \$500 or one year imprisonment or both for the manufacture of adulterated food and drugs, while section 2 provided a fine of not more than \$200 for the first offense and a fine of not more than \$300 or one year imprisonment or both, for subsequent violations of interstate commerce of adulterated goods.

of a decree of condemnation against the seized goods, §304 (e) provides that court costs and fees, and storage and other expenses, are to be awarded against the claimant of the goods. In the case of minor violations, the FDA can use its discretion to issue a written notice or warning, rather than reporting violations for prosecution.<sup>64</sup> Most importantly, §401 gave the FDA the authority to promulgate regulations fixing and establishing legal standards for food. This includes establishing “reasonable definitions and standards of identity, reasonable standards of quality and reasonable standards of fill of containers.” Section 404 (a) gives the FDA emergency permit control authority. This applies if the FDA finds that any class of food in interstate commerce has been contaminated with micro-organisms during its manufacture, processing, or packing and that such contamination cannot be adequately determined after the articles have entered interstate commerce. In this situation, the FDA is required to promulgate regulations providing for the issuance of permits to the manufacturers, processors, or packers of that class of food in the affected locality. The permit would set forth conditions governing the manufacture, processing, or packing of that class of food, for a temporary period of time, as may be necessary to protect the public health. During this time, only permit-holders can manufacture, process or pack this class of food for introduction into interstate commerce. The FDA is authorized under §404 (b), to suspend immediately upon notice any permit if it is found that any of the conditions of the permit have been violated. The permit can only be reinstated after a hearing and an inspection of the establishment, to assure that adequate measures have been taken to comply with and maintain the conditions of the permit. During this period, permit-holders are required under §404 (c) to provide FDA officers access to any factory for the purpose of ascertaining whether or not the conditions of the permit are being complied with. Denial of access for such an inspection is a ground for suspension of the permit, until such access is freely given by the operator.

In situations where a poisonous or deleterious substance is required in the production of a food, or cannot

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<sup>64</sup>Pub. L. No. 75-717, § 306, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. § 336 (2003)).

be avoided by good manufacturing practice, §406 (a) gives the FDA authority to promulgate regulations limiting the quantity of such poison on or in the food to the extent necessary for the protection of the public. A food with any amount of the poison below the tolerance established by the FDA is to be deemed safe, but any quantity of the poison exceeding such tolerance is to be deemed unsafe.<sup>65</sup> The FDA was also given the authority to list harmless coal-tar colors suitable for use in food, drugs and cosmetics and also for the certification of batches of such colors.<sup>66</sup> Section 706 provides that the admitting to listing and certification of coal-tar colors, shall be performed only upon payment of fees that shall be specified in regulations promulgated by the FDA.

A very important improvement in the FDCA was the elimination of the requirement to prove fraud in the prosecution of manufacturers that made false claims for drugs.<sup>67</sup> It now became easier for the FDA to go after manufacturers that made false therapeutic claims for drugs. For the purposes of prosecution under misbranding, not only did the drug labels have to list the ingredients, under §502 (f), they now had to include adequate directions for use and warnings against use under certain conditions or by children where it would be dangerous. Even more significant was the provision requiring FDA approval of new drugs for safety before they are introduced into interstate commerce.<sup>68</sup> Pre-market approval protected consumers more by preventing violations, rather than merely prosecuting violations after the injuries had occurred.<sup>69</sup> Under §505 (e), the FDA was also given the authority to suspend applications for new drugs already approved when clinical experience and tests by new methods showed the drug to be unsafe, or when the application was later found to contain any untrue statement of a material fact. This is a very important enforcement power, because it allows the FDA to revisit approved applications for new drugs after new technological advances

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<sup>65</sup>*Id.* at § 406(a) (codified as amended 21 U.S.C. § 346 (2003)).

<sup>66</sup>For this provision with respect to food, *see id.* at § 406(b), 52 Stat. 1040 (1938) (repealed 1960), for drugs, *see id.* at § 504 (repealed 1960), and for cosmetics, *see id.* at § 604 (repealed 1960).

<sup>67</sup>*Id.* at 502(a) (codified as amended 21 U.S.C. § 352(a) (2003)), simply provided that a drug or device shall be deemed to be misbranded if its labeling is false or misleading in any particular.

<sup>68</sup>*See id.* at §505 (codified as amended 21 U.S.C. § 355 (2003)).

<sup>69</sup>Wallace F. Janssen, *The Story Of The Laws Behind The labels: Part II, 1938 - The FDCA*, <http://vm.cfsan.fda.gov/~lrd/history1a.html>.

show the approved drugs to be unsafe.

Other general powers are given to the FDA for the purposes of enforcement of the FDCA. Section 702 (c) gives the FDA authority to inspect the records of any department or independent establishment in the executive branch of the Government. Also, under §703, carriers engaged in interstate commerce are required to permit FDA officers to have access to and to copy all records showing the movement in interstate commerce of any food, drugs and cosmetics. Failure to permit such access is unlawful.<sup>70</sup> This enables the FDA to be aware when these articles are in interstate commerce and to examine them for compliance.

More importantly, FDA officers are authorized under §704, upon request and consent, to inspect factories, warehouses and establishments in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce, or held after such introduction. They are also authorized to inspect any vehicle being used to transport or hold such articles in interstate commerce. The FDA is authorized under §705 (b) to disseminate information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the FDA, imminent danger to health or gross deception of the consumer. Publicity is a very important and effective enforcement tool.<sup>71</sup> The FDA is also authorized under §801 (a), to examine samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the U.S. If such samples are found to be adulterated, misbranded, or forbidden or restricted in sale in the country in which it was produced or from which it was exported, then the FDA is authorized to refuse such article admission. Furthermore, §801 (c) provides that all charges for storage and labor on any article which has been refused admission, shall be paid by the owner or consignee.

The FDCA and the FDA's regulations do not authorize the FDA to order a recall.<sup>72</sup> The FDA however has

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<sup>70</sup>Pub. L. No. 75-717, § 703, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 373 (2003)).

<sup>71</sup>See, Richard S. Morey, *FDA Publicity Against Consumer Products – Time for Statutory Revitalization?* 30 BUSINESS LAWYER 165 (November 1974) (discussing FDA's use of publicity and concluding that the FDA exceeds its statutory bound in exercising its publicity powers).

<sup>72</sup>John M. Packman, *Civil and Criminal Liability Associated With Food Recalls* 53 FOOD DRUG L. J. 437 (1998).

regulations that set forth its recall policy should a manufacturer decide to recall a product.<sup>73</sup> “These recall regulations are guidelines only and do not have the force of law.”<sup>74</sup> If a company refuses to voluntarily recall a violative product, there are no penalties provided by the FDCA or the FDA regulations.<sup>75</sup> However, that company’s liability would arise from the product’s violations.<sup>76</sup> The company’s liability from possible class actions and punitive damages can be increased significantly by a refusal to recall a violative product.<sup>77</sup>

Many of the problems of the 1906 Act were solved by the FDCA. The FDA could not only bring legal proceedings with higher penalties, it could seek injunctions, seize violative goods, establish legal standards for food, establish tolerance levels for poisons in food, exercise emergency permit control authority, pre-approve new drugs, suspend pre-approved drugs, inspect factories, refuse admission to violative imported goods, list approved coal-tar colors and certify each batch of such colors for use in food, drugs and cosmetics. Even with this significant expansion of the FDA’s enforcement powers there was still room for improvement.

## **FURTHER EXPANSION OF FDA ENFORCEMENT POWERS BY THE AMENDMENTS TO THE FDC**

Congress later passed amendments to the FDCA further expanding FDA’s enforcement powers. Congress provided for the certification of batches of drugs composed wholly or partly of insulin,<sup>78</sup> penicillin,<sup>79</sup> strep-

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<sup>73</sup> See 21 C.F.R. §§ 7.40 - 7.59 (1997)

<sup>74</sup> Packman, *supra* note 72, at 439 n.1.

<sup>75</sup> *Id.* at 439

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> Act of December 22, 1941, Pub. L. No. 77-366, ch. 613, 55 Stat. 851 (1941) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (repealed 1997).

<sup>79</sup> Act of July 6, 1945, Pub. L. No. 79-139, ch. 281, 59 Stat. 463 (1945) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (repealed 1997).

tomycin,<sup>80</sup> chlortetracycline,<sup>81</sup> chloramphenicol<sup>82</sup> and bacitracin.<sup>83</sup> The FDCA prohibited poisonous substances in food but required no showing that food ingredients were safe. The FDA could therefore put an end to the use of poisons it knew of, but did not have adequate resources to carry out research needed to assure that all food chemicals were safe.<sup>84</sup> The problem of chemicals in food produced three amendments: the Pesticide Amendment (1954), the Food Additives Amendment (1958), and the Color Additive Amendments (1960).<sup>85</sup>

The Pesticide Amendment of 1954 gave the FDA the authority to promulgate regulations establishing tolerances for pesticide chemicals in or on raw agricultural commodities.<sup>86</sup> This law provided that persons that had registered, or had submitted an application for the registration of an economic poison under the Federal Insecticide, Fungicide and Rodenticide Act, could petition the FDA to promulgate regulations establishing a tolerance for a pesticide chemical that was a constituent of such economic poison.<sup>87</sup> The FDA was further authorized to charge fees to persons petitioning for the promulgation of regulations setting tolerances for different pesticide chemicals.<sup>88</sup>

The Food Additives Amendment of 1958 requires FDA approval of food additives for safety.<sup>89</sup> This law provides that any person intending to use a food additive has to file a petition with the FDA, proposing the

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<sup>80</sup>Act of March 10, 1947, Pub. L. No. 80-16, ch. 16, 61 Stat. 11 (1947) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (repealed 1997).

<sup>81</sup>Act of August 5, 1953, Pub. L. No. 83-201, ch. 334, 67 Stat. 389 (1953) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (repealed 1997).

<sup>82</sup>Ac of July 13, 1949, Pub. L. No. 81-164, ch. 305, 63 Stat. 409 (1949) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (repealed 1997).

<sup>83</sup>*Id.*

<sup>84</sup>Janssen, *supra* note 69.

<sup>85</sup>*Id.*

<sup>86</sup>The Pesticide Amendment of 1954, Pub. L. No. 83-518, ch. 559, 68 Stat. 511 (1958) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified as amended 21 U.S.C. § 346a (2003)).

<sup>87</sup>*Id.* at § 3, adding § 408(d) (codified as amended 21 U.S.C. § 346a (2003)).

<sup>88</sup>*Id.* at § 3, adding § 408 (o). (codified as amended 21 U.S.C. § 346a (2003)) *See also* the Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (1996) (amending 21 U.S.C. § 346a (2003)), for the procedure and conditions for establishing, modifying, and revoking tolerances and exemptions for pesticide chemical residues.

<sup>89</sup>The Food Additives Amendment of 1958, Pub. L. 85-929, 72 Stat. 1784, (1958) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified as amended at 21 U.S.C. § 348 (2003)).

issuance of a regulation prescribing the conditions under which such additive may be safely used.<sup>90</sup> This amendment gives the FDA the authority to fix tolerances where a tolerance limitation is required to assure that the proposed use of an additive will be safe.<sup>91</sup> The amendment however denies the FDA authority to issue tolerance regulations where the food additive is found to induce cancer when ingested by man or animal.<sup>92</sup>

The Color Additive Amendments of 1960 require FDA approval of color additives for safety.<sup>93</sup> The FDA is authorized to list through regulation, color additives for use in food, drugs and cosmetics separately, if such additives are safe for such use.<sup>94</sup> The FDA is further authorized to provide for the certification of batches of color additives so listed, for compliance with the requirement for such additives established by regulation.<sup>95</sup> This amendment, like the Food Additives Amendment, has an anticancer clause, which denies the FDA authority to list for any use, a color additive which is found to induce cancer when ingested by man or animal.<sup>96</sup> “With these laws on the books, it could be said for the first time that no substance can legally be introduced into the U.S. food supply unless there’s been a prior determination that it is safe.”<sup>97</sup> The problem of inadequate resources for research to assure that all food chemicals were safe was solved by requiring the manufacturers to do the research.<sup>98</sup>

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<sup>90</sup>Id. at § 4, adding § 409 (b)(1) (codified at 21 U.S.C. § 348(b)(1) (2003)).

<sup>91</sup>See Pub. L. No. 75-717, § 409(c)(4), 52 Stat 1040 (1938) (codified as amended 21 U.S.C. § 348(c)(1)(A) (2003)).

<sup>92</sup>See Pub. L. No. 75-717, § 409(c)(3)(A), 52 Stat 1040 (1938) (codified at 21 U.S.C. § 348(c)(3)(A) (2003)), which provides “that no additive shall be deemed to be safe if it found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal.”

<sup>93</sup>The Color Additive Amendments of 1960, Pub. L. No. 86-618, 74 Stat. 397 (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified as amended at 21 U.S.C. § 379e (2003)).

<sup>94</sup>Id. at § 103(b), amending § 706 (b)(1) (codified at 21 U.S.C. § 379e(b)(1) (2003)).

<sup>95</sup>Id. at § 103(b), amending § 706 (c) (codified at 21 U.S.C. § 379e(c) (2003)).

<sup>96</sup>See id. at § 103(b), amending § 706 (b)(5)(B) (codified at 21 U.S.C. § 379e(b)(5)(B) (2003)), which provides “that a color additive shall be deemed unsafe...if the additive is found by the FDA to induce cancer when ingested by man or animal, or if it is found by the FDA, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal.”

<sup>97</sup>Janssen, *supra* note 69.

<sup>98</sup>Id.

There was another therapeutic disaster in Europe between 1961 and 1962. Thousands of infants were born deformed to mothers who had taken thalidomide, a new sedative.<sup>99</sup> Although thalidomide had never been approved in the U.S., these incidents drove Congress to enhance legislation that was pending in Congress and to pass the Drug Amendments of 1962.<sup>100</sup> The 1962 Drug Amendments further strengthened the FDCA by increasing control over prescription drugs, new drugs, and investigational drugs.<sup>101</sup> The law required all new drugs to be approved by the FDA before being introduced into interstate commerce.<sup>102</sup> It requires effectiveness as well as safety before a drug could be approved for marketing.<sup>103</sup> It transferred the regulation of prescription drug advertising from the Federal Trade Commission (FTC) to the FDA and requires drug advertisements to contain a brief summary relating to side effects, contraindications and effectiveness.<sup>104</sup> The Act required drug manufacturers to conform to good manufacturing practices for the drug industry,<sup>105</sup> and required drug companies to establish and maintain records of data relating to clinical experience with respect to their drugs and report such data to the FDA.<sup>106</sup> It also granted the FDA greater powers to access company records.<sup>107</sup> It required certification of all antibiotics by the FDA before they could be marketed.<sup>108</sup> The Act authorized the FDA to carry out inspections of factories, warehouses and consulting laboratories where prescription drugs are manufactured, processed, packed or held. The inspection authorized extended to all things in the establishments being inspected, as well as records, files papers processes, controls and facilities.<sup>109</sup>

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<sup>99</sup>Janssen, *supra* note 5, at 137.

<sup>100</sup>Wallace F. Janssen, *The Story Of The Laws Behind The labels, Part III, 1962 Drug Amendments*, <http://vm.cfsan.fda.gov/~lrd/histor1b.html>.

<sup>101</sup>Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified principally at 21 U.S.C. §§ 351, 352, 355, 374 (2003)).

<sup>102</sup>*Id.* at § 104(a) (codified at 21 U.S.C. § 355(a) (2003)).

<sup>103</sup>*Id.* at § 102(a) & (b) (codified at 21 U.S.C. §§ 321(p), 355(b) (2003)).

<sup>104</sup>*Id.* at § 131(a) (codified at 21 U.S.C. § 352(n) (2003)).

<sup>105</sup>*Id.* at § 101 (codified at 21 U.S.C. § 351(a) (2003)).

<sup>106</sup>*Id.* at § 103(a) (codified at 21 U.S.C. § 355(k)(1) (2003)).

<sup>107</sup>*Id.* (codified at 21 U.S.C. § 355(k)(2) (2003)).

<sup>108</sup>*Id.* at § 105 (repealed 1997).

<sup>109</sup>*See id.* at § 201(a) (codified at 21 U.S.C. § 374(a) (2003)), this inspection does not however extend to “financial data, sales data (other than shipment data), pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data (other than data relating to new drugs subject to



Since 1962, “thousands of prescription drugs have been taken off the U.S. market because they lacked evidence of safety and or effectiveness, or they have had their labels changed to reflect the known medical facts.”<sup>110</sup> The requirement of monitoring new drugs for efficacy as well as safety has been criticized for delaying the introduction of new drugs into the market. Economist Sam Peltzman of the University of Chicago conducted a study that concluded that the 1962 amendments had significantly reduced the introduction of effective new drugs from an average of 41.5 annually from 1951-1962, to just 16.1 annually from 1963-1970.<sup>111</sup> Peltzman blames increased clinical testing requirements and more stringent efficacy standards of the 1962 Drug amendments for this “decline in drug innovation.”<sup>112</sup> Other studies have found that the average cost of developing a new drug from discovery to approval has risen from \$138 million in the 1970s, to \$802 million in the 1990s.<sup>113</sup> The FDA was under pressure particularly from AIDS activists, to allow higher levels of risk for new drugs that were intended to treat individuals who were terminally ill, in order to facilitate faster approval of those drugs.<sup>114</sup>

In response to the criticism of “drug lag,” the FDA introduced “fast-track” approval of the AIDS drug AZT, which was cleared for use within two years after it was discovered to be effective against the HIV virus.”<sup>115</sup> AZT was approved despite its deadliness and the serious side effects observed during clinical trials.<sup>116</sup> Since the Prescription Drug User Fee Act was passed in 1992, the average combined clinical and approval times for new drugs has dropped by 25% (from 9.2 years to 6.9 years).<sup>117</sup> Recently, the FDA “launched an initiative

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reporting and inspection).

<sup>110</sup>Janssen, *supra* note 100.

<sup>111</sup>See Sam Peltzman, *An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments*, JOURNAL OF POLITICAL ECONOMY, 1049-91, 1053 (Sept - Oct. 1973).

<sup>112</sup>*Id.* at 1089.

<sup>113</sup>See the Tufts Center for the Study of Drug Development 2002 Outlook Report, 2, <http://csdd.tufts.edu/InfoServices/OutlookPDFs/Outlook2002.pdf>. (assessing major drug development issues for the year 2002).

<sup>114</sup>See Daniel Henninger, *Drug Lag*, in THE CONCISE ENCYCLOPEDIA OF ECONOMICS, The Library of Economics and Liberty, <http://www.econlib.org/library/Enc/DrugLag.html>, for the various tactics used by AIDS activists to finally get the FDA to introduce the “fast track” approach of approving AIDS drugs.

<sup>115</sup>*Id.*

<sup>116</sup>*Id.*

<sup>117</sup>See the Tufts Center for the Study of Drug Development 2003 Outlook Report, 1, <http://csdd.tufts.edu/InfoServices/OutlookPDFs/Outlook2003.pdf>. (assessing major drug development issues for

to further improve the development and availability of innovative medical products.”<sup>118</sup> The initiative is geared towards “making innovative medical technologies available sooner and reducing the costs of developing safe and effective medical products, while maintaining FDA’s traditional high standards of consumer protection.”<sup>119</sup>

Around 1960, there was publicity involving the abuse of depressant and stimulant drugs in the U.S. An official report stated that 852,000 pounds of barbiturates had been produced in 1960. This meant that there were thirty-three one-grain capsules for each person in the U.S.<sup>120</sup> In 1961, there were claims that tranquilizers were competing with barbiturates as suicide drugs.<sup>121</sup> It was revealed and publicized, that the pilot of a plane that had crashed had been taking tranquilizers, and that benzedrine was probably involved in causing a multiple-car accident on the New Jersey Turnpike.<sup>122</sup> The sentiment was that there was widespread abuse of barbiturates and other sedatives, stimulants, and tranquilizers. In January 1965, President Johnson urged Congress to expedite legislation to bring the production and distribution of barbiturates, amphetamines, and other psychotic drugs under more effective control.<sup>123</sup> A bill addressing this issue had already been introduced in the legislature and resulted in the Drug Abuse Control Amendments of 1965. These amendments were passed to “establish special controls for depressant, stimulant and counterfeit drugs.”<sup>124</sup> They authorized the FDA to promulgate regulations designating any drug that it found to have a potential for abuse because of its depressant, stimulant or hallucinogenic effect, as a “depressant or stimulant drug.”<sup>125</sup>

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the year 2003).

<sup>118</sup> See the Press release, *FDA Launches Initiative to Improve the Development and Availability of Innovative Medical Products*, (January 31, 2003), <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00867.html>.

<sup>119</sup> *Id.* See also, *Improving Innovation in Medical Technology: Beyond 2002* (January 31, 2003), <http://www.fda.gov/bbs/topics/news/2003/beyond2002/report.html>, for a report containing an outline of FDA’s proposed actions.

<sup>120</sup> Rufus King, *The Drug Hang Up, America’s Fifty-Year Folly*, ch. 26, Drug Abuse Control, 1965. SCHAFFER LIBRARY OF DRUG POLICY. <http://www.druglibrary.org/special/king/dhu/dhu26.htm>.

<sup>121</sup> *Id.*

<sup>122</sup> *Id.*

<sup>123</sup> *Id.*

<sup>124</sup> Drug Abuse Control Amendments of 1965, Pub. L. No. 89-74, 79 Stat. 226-235 (1965) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified principally at 21 U.S.C. §§ 331(i), 351-360 (2003)).

<sup>125</sup> *Id.* at § 3(a).

Such drugs can only be manufactured or processed by specified persons,<sup>126</sup> who have to register,<sup>127</sup> keep records,<sup>128</sup> and are subject to FDA inspection.<sup>129</sup> An FDA Bureau of Drug Abuse Control was formed in 1965. This bureau conducted undercover drug investigations and enabled the prosecution and “conviction of hundreds of racketeers and pushers.”<sup>130</sup> In 1968, this bureau was transferred to the Federal Bureau of Narcotics in the Department of Justice.<sup>131</sup> Congress also found that there had been significant traffic in counterfeit drugs that posed a considerable risk to the public health.<sup>132</sup> Congress recognized that while such drugs were considered misbranded under the FDCA, it was difficult to determine “the place for interstate origin of such drugs and, if that place is discovered, the fact that the implements for counterfeiting are not subject to seizure” meant that there was a need for more effective controls of these drugs regardless of their interstate or intrastate origins.<sup>133</sup> This law makes it a crime to make, sell, possess or conceal any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, on any drug or container or labeling thereof, so as to cause such drug to be a counterfeit drug.<sup>134</sup> This therefore means that counterfeit drugs can be seized for misbranding and possession of instruments used to counterfeit can be proceeded against as a prohibited act.

Prior to 1968, there was a very inefficient and cumbersome system for the regulation of animal drugs. Animal drugs were governed by one of or a combination of the new drug law, the antibiotic law and the food additive law.<sup>135</sup> This involved “three separate statutory provisions; three separate administrative procedures and; three separate parts of the [FDA]”<sup>136</sup> The Animal Drug Amendments of 1968 combined these three regula-

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<sup>126</sup> *Id.* at § 3(b), adding § 511(a) (repealed 1970).

<sup>127</sup> *Id.* at § 4 (b), adding § 510(b) (repealed 1970).

<sup>128</sup> *Id.* at § 3(b), adding § 511(d)(1) (repealed 1970).

<sup>129</sup> *Id.* at § 3(b), adding § 511(d)(2)(A) (repealed 1970).

<sup>130</sup> Janssen, *supra* note 100.

<sup>131</sup> *Id.*

<sup>132</sup> Pub. L. No. 89-74, § 9(a), 79 Stat. 226-235 (1965).

<sup>133</sup> *Id.*

<sup>134</sup> *Id.* at § 9(c)(2).

<sup>135</sup> Eugene I. Lambert, *The Reformation of Animal Drug Law: The Impact of 1996*, FOOD AND DRUG LAW JOURNAL, vol. 52, 277 (1997), [http://www.fdl.org/pubs/Journal%20online/52\\_3/3art.pdf](http://www.fdl.org/pubs/Journal%20online/52_3/3art.pdf).

<sup>136</sup> *Id.*

tory systems into a unified process for the approval of animal drugs.<sup>137</sup> The FDA established the Bureau of Veterinary Medicine, today, the Center for Veterinary Medicine, to carry out animal drug approval. This center however only received “full authority over both human and animal aspects of animal drug approvals” in 1983.<sup>138</sup> The Animal Drug Amendments of 1968 were passed to assure the safety and effectiveness of new animal drugs.<sup>139</sup> The amendments mandate FDA approval of new animal drugs and animal feed containing a new animal drug, before they can be introduced into interstate commerce.<sup>140</sup> They also authorize the FDA to suspend approved applications if the drug presents an “imminent hazard”<sup>141</sup> or withdraw approved applications if the applicant fails to maintain required records<sup>142</sup> or make required reports to the FDA.<sup>143</sup> The FDA is also authorized to certify “batches of new animal drugs composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin or any derivative thereof.”<sup>144</sup> In order to facilitate more effective regulation of drugs, the FDA created two voluntary programs in an effort to compile a “comprehensive drug inventory for drug listings.”<sup>145</sup> Following the failure to accomplish this task through the voluntary programs, the FDA passed regulations pursuant to the Drug Listing Act of 1972, to make drug listing mandatory.<sup>146</sup> The Act authorizes the FDA to require all registered drug manufacturers to submit a list of all the drugs they manufacture and market.<sup>147</sup> In addition, it requires them to report twice a year in June and December, a list of all drugs introduced by the registrant since the last list filed,

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<sup>137</sup>*Id.*

<sup>138</sup>*Id.* at 277 n.11.

<sup>139</sup>The Animal Drug Amendments of 1968, Pub. L. No. 90-399, 82 Stat. 342 (1968) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified principally at 21 U.S.C. §§ 351-360 (2003)).

<sup>140</sup>*Id.* at § 101(b), adding § 512(a) (codified at 21 U.S.C. § 360b(a) (2003)).

<sup>141</sup>*Id.* at § 101(b), adding § 512(e)(1)(E) (codified at 21 U.S.C. § 360b(e)(1)(E) (2003)).

<sup>142</sup>*See id.* at § 101(b), adding § 512(l) (codified at 21 U.S.C. § 360b(l) (2003)), for record-keeping requirements for new animal drugs and Section 512(m)(5) for record-keeping requirements for animal feed containing a new animal drug.

<sup>143</sup>*See id.* at § 101(b), adding § 512 (e)(2)(A) (codified at 21 U.S.C. § 360b(e)(2)(A) (2003)), for more reasons why the FDA may withdraw approved applications, see Section 512 (e).

<sup>144</sup>*Id.* at § 101 (b), adding § 512 (n)(1) (repealed 1988).

<sup>145</sup>*See Drug Registration and Listing System*, <http://www.fda.gov/cder/handbook/druglist.htm>.

<sup>146</sup>The Drug Listing Act of 1972, Pub. L. No. 92-387, 86 Stat. 560-562 (1972) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified at 21 U.S.C. § 360(j) (2003)).

<sup>147</sup>*Id.* at § 3, adding § 510(j)(1) (codified at 21 U.S.C. § 360(j)(1)).

give a notice of discontinuance of a drug and of resumption of a previously discontinued drug.<sup>148</sup>

Title V of the Health Research and Health Services Amendments of 1976 authorizes the FDA, through a U.S. attorney, to bring suit against the manufacturer of a food that is misbranded due to its advertising, if the FTC declines to bring such action.<sup>149</sup> In addition to the FDA's enforcement power with respect to false and misleading advertising of drugs,<sup>150</sup> it can now proceed against false and misleading advertising of food. Technological advances had increased the number and complexity of medical devices. These advances improved medical care significantly.<sup>151</sup> However, there were also many complications involving medical devices: "mechanical failure, faulty design, poor manufacturing quality, adverse effects of materials implanted in the body, improper maintenance/specifications, user error, compromised sterility/shelf life and electromagnetic interference among devices."<sup>152</sup> The Cooper Commission reported in 1970 that medical devices had caused, or were involved in more than 700 deaths and 10,000 injuries.<sup>153</sup> Congress, then passed the Medical Device Amendments of 1976 further increasing FDA's enforcement authority with respect to medical devices, and to ensure the safety and effectiveness of medical devices intended for human use.<sup>154</sup> The law authorizes the FDA to classify medical devices into three categories:<sup>155</sup> class I devices subject only to general controls;<sup>156</sup> class II devices subject to performance standards and;<sup>157</sup> class III devices subject to premarket approval.<sup>158</sup>

The FDA is authorized to prescribe regulations setting forth the basis for determining and authorizing the

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<sup>148</sup>Id. at § 3, adding § 510(j)(2) (codified at 21 U.S.C. § 360(j)(2)).

<sup>149</sup>Act of April 22, 1976, Pub. L. No. 94-278, Title V, § 707, 90 Stat 412 (1976) (codified at 21 U.S.C § 378 (2003)).

<sup>150</sup>See *supra* note 101.

<sup>151</sup>Statement by Michael Friedman, M.D., Lead Deputy Commissioner of the FDA, before the U.S. House of Representatives Subcommittee on Health and the Environment Committee on Commerce (April 30, 1997), <http://www.fda.gov/ola/1997/devices.htm>.

<sup>152</sup>*Id.*

<sup>153</sup>*Id.*

<sup>154</sup>The Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539-583 (1976) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified principally at 21 U.S.C. §§ 360c - 360k (2003)).

<sup>155</sup>*Id.* at § 2, adding § 513 (b)(1) (codified as amended 21 U.S.C § 360c(b)(1) (2003)). See the rest of § 513(b) for the process the FDA has to follow in classifying and reclassifying medical devices.

<sup>156</sup>See *id.* at § 2, adding § 513 (a)(1)(A) (codified as amended 21 U.S.C § 360c(a)(1)(A) (2003)), for the conditions necessary for a drug to be classified under class I

<sup>157</sup>See *id.* at § 2, adding § 513(a)(1)(B) (codified as amended 21 U.S.C § 360c(a)(1)(B) (2003)), for the conditions necessary to for a drug to be classified under class II.

<sup>158</sup>See *id.* at § 2, adding § 513(a)(1)(C) (codified as amended 21 U.S.C § 360c(a)(1)(B) (2003)), for the conditions necessary to for a drug to be classified under class III.

effectiveness of a medical device.<sup>159</sup> It is authorized to promulgate regulations establishing performance standards for class II devices,<sup>160</sup> and can also amend or revoke them.<sup>161</sup> The amendments also authorize the FDA to prescribe regulations requiring premarket approval of class III devices,<sup>162</sup> and to withdraw approval of applications already given where certain conditions are present.<sup>163</sup>

In keeping with the FDA's mission to safeguard the public health, the Medical Device Amendments of 1976 also authorize the FDA to promulgate regulations banning a device if it "presents substantial deception or an unreasonable and substantial risk of illness or injury."<sup>164</sup> In addition, the FDA is authorized to prescribe regulations conditioning the sale, distribution and use of a medical device upon authorization of a licensed practitioner if it determines that "there cannot otherwise be reasonable assurance of its safety and effectiveness."<sup>165</sup> The amendments also require manufacturers of medical devices to register<sup>166</sup> with the FDA, to establish and maintain records and make reports that the FDA may require of them through regulations.<sup>167</sup> They authorize the FDA to inspect facilities where medical devices are manufactured,<sup>168</sup> and give it access to records that it requires them to keep.<sup>169</sup> The FDA is also authorized to promulgate regulations setting forth good manufacturing practice for the medical device industry, to assure the safety, effectiveness and compliance of the devices with the FDCA as amended.<sup>170</sup> To ensure the effectiveness of FDA's regulation of medical devices, the amendments provide that FDA regulations preempt any state regulation of medical

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<sup>159</sup>*Id.* at § 2, adding § 513(a)(2) (codified as amended 21 U.S.C. § 360c(a)(2) (2003)).

<sup>160</sup>*Id.* at § 2, adding § 514(a)(1) (codified as amended 21 U.S.C. § 360d(a)(1) (2003)). *See also* § 514 for the rules setting forth the procedure for setting performance standards.

<sup>161</sup>*Id.* at § 2, adding § 514(g)(4)(A) (codified as amended 21 U.S.C. § 360d(b)(4)(A) (2003)).

<sup>162</sup>*Id.* at § 2, adding § 515(b)(1)(B) (codified as amended 21 U.S.C. § 360e(b)(1)(B) (2003)). *See also* the Section 515 for the premarket approval requirements.

<sup>163</sup>*See id.* at § 2, adding § 515(e)(1) (codified as amended 21 U.S.C. § 360e(e)(1) (2003)), for the conditions that if present, allow the FDA to withdraw approval of an application.

<sup>164</sup>*Id.* at § 2, adding § 516(a) (codified at 21 U.S.C. § 360f(a) (2003)).

<sup>165</sup>*See id.* at § 2, adding § 520(e) (codified as amended 21 U.S.C. § 360j(e) (2003)), such devices are referred to as "restricted devices."

<sup>166</sup>*Id.* at § 4(a), Section 510 (codified as amended 21 U.S.C. § 360 (2003)).

<sup>167</sup>*Id.* at § 2, adding § 519(a) (codified as amended 21 U.S.C. § 360i(a) (2003)).

<sup>168</sup>*Id.* at § 6(a), § 704 (a) (codified as amended 21 U.S.C. § 374(a) (2003)).

<sup>169</sup>*Id.* at § 6(e) (codified as amended 21 U.S.C. § 374(e) (2003)).

<sup>170</sup>*Id.* at § 2, § 520(f)(1)(A) (codified at 21 U.S.C. § 360j(f)(1)(A) (2003)).

devices.<sup>171</sup> The Act gives the FDA the authority to make exemptions from this provision if a state requirement is more stringent than an FDA requirement and is required by compelling local conditions.<sup>172</sup>

The Safe Medical Devices Act of 1990 was passed further improve the regulation of medical devices.<sup>173</sup> This Act requires “device user facilities” to report to the FDA if they reasonably believe that a device caused or contributed to the death, serious illness or injury of a patient of the facility.<sup>174</sup> The Act further requires registered manufacturers of medical devices that are permanently implantable, or life sustaining (and any others that the FDA may designate), to adopt a method of “device tracking” to trace these devices to the user level, and to conduct “postmarket surveillance” to monitor products that have been introduced into commerce.<sup>175</sup> This Act changed class II devices from being subject to performance standards, to being subject to “special controls,” which include performance standards.<sup>176</sup> Most importantly this Act gives the FDA the authority to issue orders requiring immediate cessation of distribution and use of a device that it finds would “cause serious adverse health consequences or death.” Further, if after an informal hearing the FDA finds that adequate grounds exist to support the order, it can amend the order to require a recall of the device.<sup>177</sup> The Act also authorized the FDA to exempt “devices designed to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the U.S.,” from the effectiveness requirements of the FDCA as amended.<sup>178</sup>

There was another crisis in 1978 when one of the big infant formula manufacturers stopped adding salt to

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<sup>171</sup>*Id.* at § 2, § 521(a) (codified at 21 U.S.C. § 360k(a) (2003)).

<sup>172</sup>*Id.* at § 2, § 521(b) (codified at 21 U.S.C. § 360k(b) (2003)).

<sup>173</sup>The Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511-4529 (1990) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified principally at 21 U.S.C. §§ 360c – 360l (2003)).

<sup>174</sup>*Id.* at § 2(a), adding § 519(b)(1) (codified as amended 21 U.S.C. § 360i(b)(1) (2003)).

<sup>175</sup>*See id.* at § 3(b)(1), adding § 519(e) (codified as amended 21 U.S.C. § 360i(e) (2003)), for “device tracking” requirements, and *id.* at § 10, adding § 522, (codified as amended 21 U.S.C § 360l (2003)), for “postmarket surveillance requirements.

<sup>176</sup>*Id.* at § 5(a)(2) (codified as amended 21 U.S.C § 360c(a)(1)(B) (2003)), special controls also include “postmarket surveillance, patient registries, development and dissemination of guidelines...and other appropriate actions” deemed necessary by the FDA, to assure safety and effectiveness.

<sup>177</sup>*Id.* at § 8 (codified as amended 21 U.S.C § 360h(e) (2003)).

<sup>178</sup>*See id.* at § 14, adding § 520(m)(2) (codified as amended 21 U.S.C § 360j(m)(2) (2003)), for the conditions necessary to obtain such a “humanitarian device exemption.”

two of its soy products.<sup>179</sup> These reformulated infant formula products ended up having insufficient amounts of chloride, which is an important nutrient for the growth and development of infants. “By mid-1979, a substantial number of infants had been diagnosed with hypochloremic metabolic alkalosis, a syndrome associated with chloride deficiency.”<sup>180</sup> A connection was found between this condition and the protracted use of the reformulated soy formula.<sup>181</sup> Congress then passed the Infant Formula Act of 1980 to assure the safety and nutrition of infant formulas.<sup>182</sup> The Act lists the nutrients and amounts of which must be contained in an infant formula.<sup>183</sup> It authorizes the FDA to revise the list of nutrients and the required level for the nutrients listed in the Act.<sup>184</sup> It also authorizes the FDA to establish quality control procedures, which include the periodic testing of infant formulas for compliance with the Act.<sup>185</sup> Manufacturers of infant formula are also required to keep records of distribution of the infant formula, to facilitate recalls of the formula when necessary.<sup>186</sup> In the 1986 amendments to this Act, the FDA is authorized to promulgate regulations setting forth good manufacturing practices and quality control procedures.<sup>187</sup>

In 1982, there was a tragic incident that involved the sudden deaths of seven people in Chicago that had ingested tylenol capsules that had been laced with cyanide. The capsules had been placed in six different stores by an unknown person.<sup>188</sup> This act was dubbed “product tampering.”<sup>189</sup> The FDA responded to this tragedy by issuing regulations prescribing tamper-resistant packaging requirements for all over-the-

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<sup>179</sup> *Food Advisory committee Meeting on Infant Formula*, [http://www.fda.gov/OHRMS/DOCKETS/ac/02/briefing/3852b1\\_01.pdf](http://www.fda.gov/OHRMS/DOCKETS/ac/02/briefing/3852b1_01.pdf).

<sup>180</sup> *Id.*

<sup>181</sup> *Id.*

<sup>182</sup> The Infant Formula Act of 1980, Pub. L. No. 96-359, 94 Stat. 1190-1193 (1980) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified principally at 21 U.S.C. § 350a (2003)).

<sup>183</sup> *See id.* at § 2, adding § 412(g) (codified as amended 21 U.S.C. § 350a(i) (2003)).

<sup>184</sup> *Id.* at § 2, adding § 412(a)(2) (codified as amended 21 U.S.C. § 350a(i)(2) (2003)).

<sup>185</sup> *Id.*

<sup>186</sup> *Id.* at § 2, adding § 412(e) (codified as amended 21 U.S.C. § 350a(g) (2003)).

<sup>187</sup> Act of October 27, 1986, Pub. L. No. 99-570, § 4014(a)(7), adding § 412(b)((2)(B) 100 Stat 3207-116 (1986) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified at 21 U.S.C. § 350a(b)(2)(B) (2003)), these quality control procedures include: testing each nutrient premix to assure compliance with the certifications of such premix by a premix supplier; testing each batch of infant formula for each required nutrient by manufacturers before distribution and ; regularly scheduled testing for each required nutrient by manufacturers during the shelf life of the infant formula.

<sup>188</sup> *The Tylenol Murders*, <http://www.personal.psu.edu/users/w/x/wxk116/tylenol/>.

<sup>189</sup> *Id.*



counter (OTC) drug products and certain cosmetic products.<sup>190</sup> These regulations require that such product packages provide visual evidence of package tampering and a statement informing the consumer about the tamper-resistant feature.<sup>191</sup> The regulations provide that OTC drug products not packaged in a tamper resistant package that are offered for retail sale will be considered adulterated under the FDCA.<sup>192</sup> Congress also passed the Federal Anti Tampering Act of 1983.<sup>193</sup> While this Act is not an amendment to the FDCA, it authorizes the FDA and the Department of Agriculture to investigate violations of its provisions.<sup>194</sup> The Act principally makes tampering with consumer product a crime and provides for various fines and prison terms for: attempting to tamper and actual tampering;<sup>195</sup> knowingly communicating false information that a consumer product has been tampered;<sup>196</sup> threatening to tamper in circumstances in which a threat may reasonably be expected to be believed, and;<sup>197</sup> conspiring to tamper plus any conduct in furtherance of such tampering.<sup>198</sup> While product tamperings have decreased, there has still been a few incidents of product tampering throughout the country.<sup>199</sup>

Before the 1980s, there were very few drugs for rare diseases, “orphan drugs.” There had not been adequate development of drugs for such rare diseases because the cost of developing the drugs is extremely high in relation to the sales of the drugs.<sup>200</sup> Jack, Klugman, an actor in a hit TV medical drama, “Quincy,” is recognized as part of the driving force that increased public awareness of the orphan drug problem. Klugman used his show to publicize this problem, at one time airing an “episode...mirroring the real-life holdup of the

<sup>190</sup> *Packaging Regulations*, <http://www.polybottle.com/Pages/Filling/PackagingRegulations.html#TAMPER-RESISTANT%20PACKAGING%20REGULATION>.

<sup>191</sup> See 21 CFR 211.132(a).

<sup>192</sup> See 21 CFR 211.132(a).

<sup>193</sup> The Federal Anti Tampering Act of 1983, Pub. L. No. 98-127, 97 Stat. 831 (1983) (codified at 18 U.S.C. § 1365 (2003)).

<sup>194</sup> *Id.* at § 2, adding § 1365(f) (codified at 18 U.S.C. § 1365(g) (2003)).

<sup>195</sup> *Id.* at § 2, adding § 1365(a) (codified at 18 U.S.C. § 1365(a) (2003)).

<sup>196</sup> *Id.* at § 2, adding § 1365 (c) (codified at 18 U.S.C. § 1365(c) (2003)).

<sup>197</sup> *Id.* at § 2, adding § 1365 (d) (codified at 18 U.S.C. § 1365(d) (2003)).

<sup>198</sup> *Id.* at § 2, adding § 1365 (e) (codified at 18 U.S.C. § 1365(e) (2003)).

<sup>199</sup> *The Tylenol Murders supra* note 188, later product tamperings that resulted in deaths included, “Lipton Cup-A-Soup in 1986, Exedrin in 1986, Tylenol again in 1986, Sudafed in 1991, and Goody’s Headache Powder in 1992.”

<sup>200</sup> John Henkel, *How TV Launched The Orphan Drug Law*, [http://www.fda.gov/fdac/features/1999/399\\_orph.html](http://www.fda.gov/fdac/features/1999/399_orph.html). (John Henkel is a staff writer for FDA Consumer).

[orphan drug] bill taking place on Capitol Hill.”<sup>201</sup> This created widespread support that resulted in the passage of the Orphan Drug Act of 1983.<sup>202</sup> This Act was passed to encourage the development of orphan drugs.<sup>203</sup> The act amends several laws, including the internal revenue code, in order to create incentives for the development of orphan drugs. The Act authorizes the FDA to provide recommendations upon request, for the non-clinical and clinical investigations that have to be conducted with an orphan drug before it is approved for the disease it is meant to treat.<sup>204</sup> The FDA is authorized to designate a drug, upon the request of the drug manufacturer, as a drug for a rare disease.<sup>205</sup> The FDA is authorized by this act to “make grants to and enter into contracts with public and private entities and individuals to assist in defraying the costs of qualified clinical testing expenses incurred in connection with the development of drugs for rare diseases and conditions.”<sup>206</sup> The FDA is authorized to create technical and scientific review groups that facilitate its enforcement of the FDCA as amended.<sup>207</sup>

Prior to 1986, the FDA had construed the FDCA to allow the export of approved drugs, but not unapproved new drugs.<sup>208</sup> This construction disadvantaged the U.S. pharmaceutical industry in the international markets.<sup>209</sup> Congress then passed the Drug Export Amendments Act of 1986, which expands the FDA’s

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<sup>201</sup> *Id.*

<sup>202</sup> *Id.*

<sup>203</sup> The Orphan Drug Act of 1983, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified principally at 21 U.S.C. §§ 360aa – 360ee (2003)).

<sup>204</sup> *Id.* at § 2(a), adding § 525(a) (codified at 21 U.S.C § 360aa(a) (2003)).

<sup>205</sup> *Id.* at § 2(a), adding § 526(a)(1) (codified at 21 U.S.C § 360bb(a)(1) (2003)). *Id.* at § 527(b) (codified at 21 U.S.C § 360cc(b) (2003)), provides that the FDA shall not approve a drug application for an orphan drug for seven years after it has already approved an orphan drug treating the same medical condition the new orphan drug proposes to treat, unless the first applicant consents, or cannot produce enough of the drug to meet the needs of those with the rare disease.

<sup>206</sup> *Id.* at § 5(a) (codified as amended 21 U.S.C. 360ee(a) (2003)).

<sup>207</sup> The Food and Drug Administration Revitalization Act, Pub. L. 101-635, Title III, 104 Stat. 4584 (1990) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified at 21 U.S.C. § 394 (2003)).

<sup>208</sup> *FDA Guidance for Industry on: Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996, FDA, U.S. Department of Health and Human Services*, (February 1998), <http://www.fda.gov/opacom/fedregister/frexporthtml>.

<sup>209</sup> *Id.*

enforcement power with respect to drugs being exported.<sup>210</sup> Such drugs must meet certain criteria in order to be exported,<sup>211</sup> and can only be exported to certain countries.<sup>212</sup> Accordingly, the FDA is mandated to review and approve applications for the export of unapproved drugs, to assure that they comply with this Act.<sup>213</sup> There were however a few problems with these amendments. The process of approval of drugs for export was criticized for being too lengthy.<sup>214</sup> The amendments were criticized for requiring drugs to be approved for export, especially when the importing countries had their own health authorities, or had already approved the drug product.<sup>215</sup> The export of unapproved drugs was confined to 21 countries, and although the FDA could add more countries to the list, it lacked an “administrative mechanism” to accomplish this.<sup>216</sup> In addition, the law’s requirement that the unapproved drug being exported must have the same active ingredient as a drug for which approval is being “actively pursued,” in the U.S. created some problems. It was not clear “the degree to which the active ingredient had to be the same or how actively the manufacturer had to be seeking approval.”<sup>217</sup> Congress later passed the FDA Export Reform and Enhancement Act of 1996 to address these issues. This Act created an administrative mechanism for adding countries onto the list.<sup>218</sup> The act replaced the export approval process with a simple notification to the FDA.<sup>219</sup> The Act frees from regulation the export of drugs for investigational use, or for further processing in anticipation of market authorization in any of the listed importing countries.<sup>220</sup> The Act also provides for the export of unapproved drugs when the exporter provides the FDA with credible scientific evidence of the

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<sup>210</sup>The Drug Export Amendments Act of 1986, Pub. L. No. 99-660, 100 Stat. 3743 (1986) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified principally at 21 U.S.C. § 382 (2003))

<sup>211</sup>*See id.* at § 102, adding § 802(b)(1), (repealed 1996), for requirements that must be met before a drug can be approved by the FDA for exportation.

<sup>212</sup>*See id.* at § 102, adding § 802(b)(4)(B) (codified as amended 21 U.S.C. § 382(b)(1)(B) (2003)), for the criteria used to select which countries get to be on the list of those that can receive drug exports from the U.S., see Section 802 (b)(4)(B).

<sup>213</sup>*Id.* at § 102, adding § 802(b)(3) (codified as amended 21 U.S.C. § 382(b)(3) (2003)).

<sup>214</sup>*FDA Guidance for Industry on, supra* note 208.

<sup>215</sup>*Id.*

<sup>216</sup>*Id.*

<sup>217</sup>*Id.*

<sup>218</sup>The FDA Export Reform and Enhancement Act of 1996, Pub. L. 104-134, § 2102(a), adding § 802 (b)(1)(C) 110 Stat.. 1321-313 (1996) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified principally at 21 U.S.C. §§ 381, 382 (2003)).

<sup>219</sup>*Id.* at § 2012(a), adding § 802(g) (codified at 21 U.S.C § 382(g) (2003)).

<sup>220</sup>*Id.* at § 2012(a), adding § 802(c) & (d) (codified at 21 U.S.C § 382(c) & (d) (2003)).

drug’s safety and effectiveness, and the importing country requests the approval of the export of that drug to it.<sup>221</sup> The exporters of drugs that treat tropical diseases still need to get FDA approval to export those drugs. They are also required to report any information they receive indicating adverse reactions to such drugs.<sup>222</sup> The FDA was also empowered to prohibit the export of drugs intended to treat tropical diseases if it determines that such export presents an “imminent hazard.”<sup>223</sup>

Congress made some findings that resulted in its passage of the Prescription Drug Marketing Act of 1987.<sup>224</sup> Congress found that there were inadequate safeguards “to prevent the introduction and eventual retail sale of substandard, ineffective, or even counterfeit drugs.”<sup>225</sup> It also found that there was a wholesale submarket, called the “diversion market,” that interfered with FDA regulation of prescription drugs and made it difficult to ascertain the true sources of those drugs.<sup>226</sup> Congress found that there was a massive reimportation of drugs into the U.S. as “American goods returned,” that presented a health risk from possible adulteration during foreign handling and shipping.<sup>227</sup> It also found that the drug reimports had an established market that provided a “cover for the importation of foreign counterfeit drugs.”<sup>228</sup> It was found that the “system of providing drug samples to physicians through manufacturers’ representatives had been abused for decades and had resulted in the sale to consumers of misbranded, expired, and adulterated pharmaceuticals.”<sup>229</sup> These findings prompted Congress to pass the Prescription Drug Marketing Act of 1987 to

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<sup>221</sup> *Id.* at § 2012(a), adding § 802(b)(3) (codified at 21 U.S.C. § 382(b)(3) (2003)).

<sup>222</sup> *Id.* at § 2012(a), adding § 802(e)(2) (codified at 21 U.S.C. § 382(e)(2) (2003)).

<sup>223</sup> *Id.* at § 2012(a), adding § 802(e)(3)(B) (codified at 21 U.S.C. § 382(e)(3)(B) (2003)).

<sup>224</sup> The Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, 102 Stat. 96-99 (1988) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified principally at 21 U.S.C. §§ 353, 381 (2003))

<sup>225</sup> *Id.* at § 2(2) (appears as a note to 21 U.S.C. § 353 (2003)).

<sup>226</sup> *Id.* at § 2(3) (appears as a note to 21 U.S.C. § 353 (2003)).

<sup>227</sup> *Id.* at § 2(4) (appears as a note to 21 U.S.C. § 353 (2003)).

<sup>228</sup> *Id.* at § 2(5) (appears as a note to 21 U.S.C. § 353 (2003)).

<sup>229</sup> *Id.* at § 2(6) (appears as a note to 21 U.S.C. § 353 (2003)).

“assure the integrity of the distribution system for prescription drugs.”<sup>230</sup> This Act restricts the importation of prescription drugs that had previously been exported from the U.S.,<sup>231</sup> and also restricts the sale and distribution of prescription drug samples.<sup>232</sup> The FDA is mandated to license wholesale distributors of prescription drugs in interstate commerce and to prescribe regulations establishing the terms and conditions for such licensing.<sup>233</sup> The Act also provides for severe penalties for its violation.<sup>234</sup>

According to Ed Scarbrough, Ph.D., director of the Office of Food Labeling in the FDA’s Center for Food Safety and Applied Nutrition, the food industry’s attitude before 1980, was “Nutrition won’t sell food. It’s price, taste and convenience.” However, in the 1980s Scarbrough noted that nutrition became a big factor in product sales prompting the industry to start making nutrition claims on food.<sup>235</sup> Two reports, “the 1988 Surgeon General’s Report on Nutrition and Health, and the 1989 National Research Council’s Diet and Health: Implications for Reducing Chronic Disease Risk, concluded that evidence substantiates an association between diet and risk of chronic disease and recommended some dietary changes.” The National Research Council’s report actually recommended amounts of what it considered healthy intakes for certain nutrients.<sup>236</sup> However, food labels did not have adequate information to assist consumers to make informed healthy choices.<sup>237</sup> The Nutrition Labeling and Education Act of 1990 was passed to prescribe nutrition labeling for foods.<sup>238</sup> The Act prescribes the nutrition information that must be on the label of a food.<sup>239</sup>

The Nutrition Labeling and Education Act of 1990 gives the FDA the authority to require through regula-

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<sup>230</sup>*Id.* at § 2(2) (appears as a note to 21 U.S.C. § 353 (2003)).

<sup>231</sup>*Id.* at § 3 (codified at 21 U.S.C. § 381(d)(1) (2003)).

<sup>232</sup>*See id.* at § 4 (codified at 21 U.S.C. § 353(c) (2003)), for sales restrictions, and *id.* at § 5 (codified at 21 U.S.C. § 353(d) (2003)), for distribution restrictions.

<sup>233</sup>*Id.* at § 6, adding § 503(e)(2)(B) (codified at 21 U.S.C. § 353(e)(2)(B) (2003)).

<sup>234</sup>*See id.* at § 7 (codified at 21 U.S.C. § 333(b)(1) (2003)), for the penalties provided for violation of various sections of the Act.

<sup>235</sup>Paula Kurtzweil, *Good Reading for Good Eating*, <http://www.fda.gov/fdac/special/foodlabel/goodread.html>. (Paula Kurtzweil is a member of FDA’s public affairs staff).

<sup>236</sup>*Id.*

<sup>237</sup>*Id.*

<sup>238</sup>The Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified principally at 21 U.S.C. § 343 (2003)).

<sup>239</sup>*Id.* at § 2(a) adding § 403 (q)(1) (codified at 21 U.S.C. § 343(q)(1) (2003)).

tions, that any of the required nutrition information be highlighted on the label, if it is deemed necessary to help consumers make informed dietary decisions.<sup>240</sup> The FDA is also authorized to add or remove a nutrient from the list of required nutrition information.<sup>241</sup> The FDA is authorized to issue nutrition information guidelines to retailers of raw agricultural commodities and seafood. It is also up to the FDA to designate the 20 varieties (or more if necessary) of vegetables, of fruit and of raw fish most frequently consumed, that have to observe the nutrition information guidelines.<sup>242</sup> Further, pursuant to a determination made every two years, if the FDA finds that retailers have not substantially complied with the guidelines, it is authorized to make such nutrition information requirements mandatory on every retailer selling raw agricultural commodities or raw fish.<sup>243</sup> The FDA is authorized to regulate claims of relationships between a nutrient whose information is required on the label, and a disease or health-related condition.<sup>244</sup> The Act authorizes the FDA to promulgate regulations defining terms used to describe the level of a nutrient in a food, and require that such terms should not be used in a way that is misleading or inconsistent with their definitions.<sup>245</sup> The FDA's nutrition information regulations preempt state laws requiring such information,<sup>246</sup> unless they are exempted from such preemption.<sup>247</sup> John Vanderveen, Ph.D., director of FDA's Office of Plant and Dairy Foods and Beverages, observed that this Act made the "United States the first country in the world to have mandatory nutrition labeling and to allow health claims on food labels."<sup>248</sup>

In 1989, the FDA discovered that a few generic drug manufacturers had engaged in unlawful conduct:

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<sup>240</sup>*Id.* at § 2(a) adding § 403(q)(1)(A) (codified at 21 U.S.C. § 343(q)(1)(A) (2003)).

<sup>241</sup>*Id.* at § 2(a) adding § 403(q)(2)(A) (codified at 21 U.S.C. § 343(q)(2)(A) (2003)).

<sup>242</sup>*Id.* at § 2(a) adding § 403(q)(4)(B) (codified at 21 U.S.C. § 343(q)(4)(B) (2003)), and § 403(q)(4)(D)(ii) (codified at 21 U.S.C. § 343(q)(4)(D)(ii) (2003)).

<sup>243</sup>*Id.* at § 2(a) adding § 403(q)(4)(D)(i) (codified at 21 U.S.C. § 343(q)(4)(D)(i) (2003)).

<sup>244</sup>*Id.* at § 3(a) adding § 403(r)(3) (codified at 21 U.S.C. § 343(r)(3) (2003)), in order to make such claims, the FDA requires that they be "based on the totality of publicly available scientific evidence..., that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence."

<sup>245</sup>*Id.* at § 3(b)(1)(A) (appears as a note to 21U.S.C. § 343 (2003)), terms used to describe nutrient level in a food include "free, low, light or lite, reduced, less and high"

<sup>246</sup>*Id.* at § 6(a) (codified at 21 U.S.C. § 343-1(a) (2003)).

<sup>247</sup>*See id.* at 6(b) (codified at 21 U.S.C. § 343-1(b) (2003)), for the procedure and conditions necessary to receive exemption from preemption.

<sup>248</sup>Kurtzweil, *supra* note 233.

“falsifying data on drug formulations and illegally giving money to FDA chemists reviewing their drug applications—to gain preferential treatment.”<sup>249</sup> This was done to avoid FDA’s regulations.<sup>250</sup> In response to this “confidence-shaking discovery,” Congress passed the Generic Drug Enforcement Act of 1992 to ensure the integrity of abbreviated drug applications.<sup>251</sup> This Act mandates the FDA to debar entities and individuals that have been convicted of certain felonies, from participating in the submission of any abbreviated drug application, or from assisting persons that have an approved or pending drug application.<sup>252</sup> The FDA is authorized to suspend the distribution of a drug if it finds that the applicant has engaged in the proscribed conduct.<sup>253</sup> The FDA also has the authority to withdraw approval of an abbreviated drug application if such approval was obtained fraudulently, or the applicant cannot conform with the application’s requirements.<sup>254</sup> In addition to these measures, “the FDA also tightened its regulatory processes, for better verification of data used to support approval decisions.”<sup>255</sup>

The idea of charging applicants fees for reviewing their drug applications first came up in 1971 and then again in 1982, both times being repudiated or failing to garner adequate support.<sup>256</sup> In 1992, FDA Commissioner David A. Kessler, M.D., testified before Congress during budget proceedings for the 1993 fiscal year. He impressed upon Congress the significance of user fees to the functioning of the FDA, and urged Congress to give the issue due consideration.<sup>257</sup> The FDA and the pharmaceutical industry cooperated to “create performance goals and determine what fees would be needed to reach those goals.”<sup>258</sup> Previous

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<sup>249</sup>Tamar Nordenberg, *Inside FDA: Barring People from the Drug Industry*, [http://www.fda.gov/fdac/features/1997/297\\_debar.html](http://www.fda.gov/fdac/features/1997/297_debar.html). (Tamar Nordenberg is a staff writer for FDA Consumer).

<sup>250</sup>*Id.*

<sup>251</sup>*Id.* See also The Generic Drug Enforcement Act of 1992, Pub. L. No. 102-282, 106 Stat. 149 (1992) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified principally at 21 U.S.C. §§ 335a, 335c (2003)).

<sup>252</sup>See, Pub. L. No. 102-282, *supra* note 251, at § 2, adding § 306, (codified at 21 U.S.C. § 335a (2003)), for the various felony convictions that can result in debarment, the debarment period, and the procedure for termination of debarment.

<sup>253</sup>*Id.* at § 2, adding § 306(g) (codified at 21 U.S.C. § 335a(g) (2003)). See also § 306 (h) (codified at 21 U.S.C. § 335a(h) (2003)), for the procedure for termination of a suspension.

<sup>254</sup>*Id.* at § 4, adding § 308(a) (codified at 21 U.S.C. § 335c(a) (2003)).

<sup>255</sup>Nordenberg, *supra* note 249.

<sup>256</sup>John Henkel, *User Fees to Fund Faster Reviews*, FDA CONSUMER SPECIAL REPORT (January 1995). <http://www.fda.gov/fdac/special/newdrug/userfees.html>.

<sup>257</sup>*Id.*

<sup>258</sup>*Id.*

discussions of user fees included many products regulated by the FDA, but the final proposal only comprised of prescription drugs and certain biologics.<sup>259</sup> Congress then passed the Prescription Drug User Fee Act of 1992 to “make additional funds available for the purpose of augmenting the resources of the FDA that are devoted to the process for review of human drug applications.”<sup>260</sup> This Act authorizes the FDA to assess and collect fees from human drug applicants.<sup>261</sup> The Act also authorizes the FDA to assess and collect fees that must be paid annually by prescription drug establishments and also for every prescription drug product.<sup>262</sup> It also sets forth a payment schedule and fee schedule for drug application fees, prescription drug establishments fees and prescription drug product fees.<sup>263</sup> Such fees are mandatory and any application is considered incomplete if they are not paid.<sup>264</sup> The Act provides that such fees are to be used only for the review of human drug applications.<sup>265</sup> The FDA is also mandated to increase the total fee revenues to reflect an increase in the Consumer Price Index, and to adjust the fees to meet the revenue increase.<sup>266</sup> The FDA is authorized to waive or reduce fees if it finds it necessary to protect the public health or if it would cause an innovation barrier.<sup>267</sup>

Even though the FDCA did not allow uses for animal drugs other than the uses they had been approved for (“extra-label” uses), the FDA “exercised regulatory discretion regarding extra-label use of animal drugs provided certain criteria were met.”<sup>268</sup> The FDA issued a Compliance Policy Guide that set forth these

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<sup>259</sup> *Id.*

<sup>260</sup> The Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491 (1992) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified principally at 21 U.S.C. §§ 379f, 379g, 379h (2003)). *See also id.* at § 102 (appearing in a note to 21 U.S.C. § 379g (2003)), for Congress’ findings that set forth the purposes of this act.

<sup>261</sup> *Id.* at § 103 adding § 736(a) (codified as amended 21 U.S.C. § 379h(a) (2003)).

<sup>262</sup> *See id.* at § 103 adding § Section 736(a)(2) (codified as amended 21 U.S.C. § 379h(a)(2) (2003)), for more information regarding the prescription drug establishment fee and *id.* at § 736(a)(3) (codified as amended 21 U.S.C. § 379h(a)(3) (2003)), for more information regarding the prescription drug product fee.

<sup>263</sup> *See id.* at § 103 adding § 736(a)(1)(B) (repealed 1997), for the payment schedule and § 736(b)(1) (repealed 1997) (replaced by 21 U.S.C. § 379h(b) (2003)), for the fee schedule.

<sup>264</sup> *Id.* at § 103 adding § 736(e) (codified as amended 21 U.S.C. § 379h(e) (2003)).

<sup>265</sup> *Id.* at § 103 adding § 736(g) (codified as amended 21 U.S.C. § 379h(g) (2003)).

<sup>266</sup> *Id.* at § 103 adding § 736(c) (codified as amended 21 U.S.C. § 379h(c) (2003)).

<sup>267</sup> *Id.* at § 103 adding § 736 (d) (codified as amended 21 U.S.C. § 379h(d) (2003)).

<sup>268</sup> *Draft CPG on Use of Medicated Feeds for Minor Species Available*, CVM UPDATE, FDA CENTER FOR VETERINARY MEDICINE (August 26, 1999), <http://www.fda.gov/cvm/index/updates/minorelu.html>.



criteria, which then largely became part of the Animal Medicinal Drug Use Clarification Act of 1994.<sup>269</sup> This Act was passed to “clarify the application of the Act with respect to alternate uses of new animal drugs.”<sup>270</sup> This Act authorizes the FDA to make regulations establishing conditions for uses of an animal drug other than the use it was approved for.<sup>271</sup> The FDA can also establish safe levels for an animal drug residue for such authorized different use, if there’s a public health risk involved.<sup>272</sup> If no analytical method has been developed to detect residues above the safe level, then the FDA has the authority to prohibit such use.<sup>273</sup>

Prior to 1994, the FDA subjected dietary supplements to the same regulatory requirements as foods.<sup>274</sup> The FDA therefore “ensured that they were safe and wholesome, and that their labeling was truthful and not misleading.”<sup>275</sup> However, Congress passed the Dietary Supplements Health and Education Act of 1994 to “establish standards with respect to dietary supplements.”<sup>276</sup> The act empowers the FDA to report dietary supplement violations to a U.S. attorney for the institution of civil proceedings. In such proceedings, the U.S. has the burden of proof to show that a dietary supplement is adulterated, misbranded or that its label is false or misleading.<sup>277</sup> The Act requires dietary supplement manufacturers to notify the FDA about any claim of a relationship between a nutrient and a disease or health condition.<sup>278</sup> The FDA is given the authority to issue an order “prescribing the conditions under which a new dietary ingredient under its intended conditions of use will reasonably be expected to be safe.”<sup>279</sup> Therefore, other than when a new dietary

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<sup>269</sup> *Id.*

<sup>270</sup> The Animal Medicinal Drug Use Clarification Act of 1994, Pub. L. 103-396, 108 Stat. 4153 (1994) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified principally at 21 U.S.C. § 360b (2003)).

<sup>271</sup> *Id.* at § 2(a), adding § 512(a)(4)(A) (codified at 21 U.S.C. § 360b(a)(4)(A) (2003)).

<sup>272</sup> *Id.* at § 2(a), adding § 512(a)(4)(B) (codified at 21 U.S.C. § 360b(a)(4)(B) (2003)).

<sup>273</sup> *Id.* at § 2(a), adding § 512(a)(4)(D) (codified at 21 U.S.C. § 360b(a)(4)(D) (2003)).

<sup>274</sup> *Dietary Supplement Health and Education Act of 1994*, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, U. S. FOOD AND DRUG ADMINISTRATION (December 1, 1995), <http://www.cfsan.fda.gov/~dms/dietsupp.html>.

<sup>275</sup> *Id.*

<sup>276</sup> The Dietary Supplements Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified principally at 21 U.S.C. §§ 342(f) & (g), 343-2, 343(r) & (s), 350b (2003)).

<sup>277</sup> *Id.* at § 4 (codified at 21 U.S.C. § 342(f)(1) (2003)).

<sup>278</sup> *See id.* at § 6 (codified at 21 U.S.C. § 343(r)(6) (2003)), for requirements that must be met before such claims may be made.

<sup>279</sup> *Id.* at § 8, adding § 413(b) (codified at 21 U.S.C. § 350b(b) (2003)).

ingredient is involved, dietary supplements do not need premarket approval.<sup>280</sup> The FDA is also authorized to promulgate regulations prescribing good manufacturing practices for the dietary supplements industry.<sup>281</sup> Due to a collaboration between the FDA, a coalition of animal industry groups, and manufacturers of animal drugs, Congress passed the Animal Drug Availability Act of 1996 to increase the number of animal drugs on the market.<sup>282</sup> It sets the conditions under which the FDA can decline to approve applications for animal drugs with multiple active ingredients or an animal drug suggested for use in combination with another animal drug (“combination drugs”).<sup>283</sup> The FDA is authorized to pass regulations specifying the information to be included in a “veterinary feed directive,” supervising the use of a “veterinary feed directive drug.”<sup>284</sup> Distributors of animal feed containing a veterinary feed directive drug are required to notify the FDA of their name and place of business before initiating distribution. They are also required to keep records that are subject to inspection by the FDA.<sup>285</sup> The Act authorizes the FDA to pass regulations establishing tolerances for new animal drug residues in animals being imported into the U.S.<sup>286</sup> The Act also requires manufacturers of animal feeds containing new animal drugs to obtain a license from the FDA authorizing such manufacture.<sup>287</sup> A single license for each manufacturer eliminates the previous requirement that each manufacturer obtain multiple “Medicated Feed Applications” for each feed mill.<sup>288</sup> This Act “reflects the spirit of the White House program to reinvent the government (REGO) by reducing regulatory burdens on

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<sup>280</sup> *Overview of Dietary Supplements*, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, U.S. FOOD AND DRUG ADMINISTRATION (January 3, 2001), <http://www.cfsan.fda.gov/~dms/ds-oview.html>.

<sup>281</sup> Public Law 103-417, *supra* note 276, at § 9 (codified at 21 U.S.C. § 342(g) (2003)),

<sup>282</sup> Jarilyn Dupont, *Animal Drug Availability Act (ADAA) of 1996: Legislative History of ADAA and Import Tolerances* (January 22, 2002), [http://www.fda.gov/ohrms/dockets/ac/02/slides/3816s1\\_01.DUPONT.ppt](http://www.fda.gov/ohrms/dockets/ac/02/slides/3816s1_01.DUPONT.ppt). (Jarilyn Dupont is the Senior Legislative Counsel at the FDA).

<sup>283</sup> The Animal Drug Availability Act of 1996, Pub. L. No. 104-250, 110 Stat. 3151 (1996) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified principally at 21 U.S.C. §§ 360b, 354 (2003)). *See id.* at § 2(c) adding § 512(d)(4)(A) (codified at 21 U.S.C. § 360b(d)(4)(A) (2003)).

<sup>284</sup> *Id.* at § 5(b), adding § 504(a)(1) (codified at 21 U.S.C. § 354(A)(1)(2003)) (providing that “a drug intended for use in or on animal feed which is limited by an approved application . . . to use under the professional supervision of a licensed veterinarian is a veterinary feed directive drug.”)

<sup>285</sup> *Id.* at § 5, adding § 504(a)(3)(b) (codified at 21 U.S.C. § 354(a)(3)(B) (2003)).

<sup>286</sup> *Id.* at § 4, adding § 512(a)(6) (codified at 21 U.S.C. § 360b(a)(6) (2003)).

<sup>287</sup> *Id.* at § 6(b), amending § 512(m)(1) (codified at 21 U.S.C. § 360b(m)(1) (2003)).

<sup>288</sup> *Feed Mill Licensing Now a Reality*, CVM UPDATE, FDA CENTER FOR VETERINARY MEDICINE (November 5, 1996), <http://www.fda.gov/cvm/index/updates/update11596.html>.

the animal health industry without undermining the safety of animal drug products.<sup>289</sup>

Congress passed the Food and Drug Administration Modernization Act (FDAMA) of 1997 to improve FDA's regulation of food, drugs, devices and cosmetics.<sup>290</sup> Through this Act, "Congress affirmed FDA's role as a protector and promoter of the public health of American citizens, endorsed many actions that FDA had already taken to streamline its operations, and added substantial new obligations."<sup>291</sup> This Act renewed the Prescription Drug User Fee Act of 1992 for an additional five years.<sup>292</sup> It also exempted from the payment of user fees, orphan drugs and supplemental drug applications that propose a new use in the pediatric population.<sup>293</sup> The FDA is authorized to request applicants with pending applications for new drugs, to conduct pediatric studies to determine if the new drug can be used in the pediatric population. The FDA can also make such requests to holders of approved drug applications "for which additional pediatric information may produce health benefits in the pediatric population."<sup>294</sup> The Best Pharmaceuticals for Children Act of 2002 passed later by Congress, provides more details with respect to the conduct of pediatric studies and pediatric drug approvals.<sup>295</sup> The FDA is authorized by FDAMA to designate a new drug as a "fast track product" if it is intended to treat a serious or life-threatening condition whose medical needs are unmet, in order for it to receive expedited review.<sup>296</sup> The sponsor for such a fast track product has to conduct post-approval studies and submit copies of all promotional material of the product before and after approval.<sup>297</sup>

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<sup>289</sup> *President Signs Animal Drug Availability Act*, CVM UPDATE, FDA CENTER FOR VETERINARY MEDICINE (October 18, 1996), <http://www.fda.gov/cvm/index/updates/adaa.html>.

<sup>290</sup> The Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (making amendments to most sections of the FDCA)

<sup>291</sup> *A Message to FDA Stakeholders, FDA Modernization Act of 1997*, FDAMA COMMUNICATIONS, <http://www.fda.gov/oc/fdama/comm/message.htm>.

<sup>292</sup> Public Law 105-115, *supra* note 290, at § 101(3) (appears as a note to 21 U.S.C. § 379g (2003)).

<sup>293</sup> *Id.* at § 103(a)(2)(C) (codified at 21 U.S.C. § 379h(a)(1)(E) (2003)).

<sup>294</sup> *Id.* at § 111, adding § 505A(a) & (c) (codified at 21 U.S.C. § 355a(b) & (c) (2003)). *See also id.* at § 505A(d) (codified at 21 U.S.C. § 355a(d) (2003)), for more information on the conduct of pediatric studies.

<sup>295</sup> The Best Pharmaceuticals for Children Act of 2002, Pub. L. No. 107-109, 115 Stat 1408 (2002) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified principally at 21 U.S.C. §§ 355a, 379h, 393a and at 42 U.S.C. § 284m (2003)). *See id.* at § 6 (codified at 21 U.S.C. § 393a), providing for the establishment of an Office of Pediatric Therapeutics within the FDA to handle all FDA activities that involve pediatric issues.

<sup>296</sup> Public Law 105-115, *supra* note 290, at § 112, adding § 506(a) (codified at 21 U.S.C. § 356(a) (2003)).

<sup>297</sup> *Id.* at § 112, adding § 506(b)(2) (codified at 21 U.S.C. § 356(b)(2) (2003)).

FDAMA requires the FDA to approve a supplemental drug application for a major manufacturing change from the process previously approved, before the drug made with the change can be distributed.<sup>298</sup> The FDA is authorized to issue guidelines on when a drug applicant can submit an abbreviated study report instead of a full report.<sup>299</sup> The FDA is also authorized to establish and use scientific advisory panels to provide the FDA with “expert scientific advice and recommendations . . . regarding a clinical investigation of a drug or the approval for marketing of a drug.”<sup>300</sup> FDAMA eliminates the requirement to get FDA certification of drugs containing insulin or antibiotics.<sup>301</sup> The FDA is authorized to promulgate regulations setting forth the conditions and manner in which drugs can be compounded by a licensed pharmacist or licensed physician.<sup>302</sup> Such regulations would also include a list of drug substances that have not been approved by the FDA, or which do not have a monograph, that may be used in compounding.<sup>303</sup> Licensed pharmacists and licensed physicians can advertise the compounding service, but cannot advertise the compounding of any particular drug, class of drug, or type of drug.<sup>304</sup> FDAMA requires a manufacturer that is the only manufacturer of a drug that is life-supporting, life-sustaining, or is used in the prevention of a debilitating disease or condition, to notify the FDA of the discontinuance of such manufacture.<sup>305</sup> The FDA is authorized to give review priority to medical devices that are to be used in the treatment or diagnosis of a life-threatening or debilitating diseases.<sup>306</sup>

FDAMA authorizes the FDA to recognize and withdraw recognition of performance standards for medical devices that have been established by a nationally or internationally recognized standard development orga-

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<sup>298</sup> See *id.* at § 116, adding § 506A(c) (codified at 21 U.S.C. § 356a(c) (2003)), for the changes that would be considered major and that would thus required FDA approval.

<sup>299</sup> *Id.* at § 118 (appears at a note to 21 U.S.C. § 355 (2003)).

<sup>300</sup> *Id.* at § 120 (codified at 21 U.S.C. § 355(n) (2003)).

<sup>301</sup> *Id.* at § 125 (repeals previous sections that required the certification of drugs containing insulin or antibiotics).

<sup>302</sup> *Id.* at § 127, adding § 503A(b)(1)(A) (codified at 21 U.S.C. § 353a(b)(1)(A) (2003)).

<sup>303</sup> *Id.* at § 127, adding § 503A(d)(2) (codified at 21 U.S.C. § 353a(d)(2) (2003)).

<sup>304</sup> *Id.* at § 127, adding § 503A(c) (codified at 21 U.S.C. § 353a(c) (2003)).

<sup>305</sup> *Id.* at § 131, adding § 506C(a) (codified at 21 U.S.C. § 356c(a) (2003)).

<sup>306</sup> See *id.* at § 202 (codified at 21 U.S.C. § 360e(d)(5) (2003)), these devices have to represent breakthrough technologies, have no approved alternatives, or have significant advantages over existing approved alternatives.

nization.<sup>307</sup> The FDA is also authorized to accredit persons to review reports and make recommendations to the FDA regarding the initial classification of medical devices.<sup>308</sup> The FDA is authorized to pass regulations setting forth the conditions under which a food additive that is a food contact may be safely used.<sup>309</sup> A “food contact substance” is “any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have a technical effect in such food.”<sup>310</sup> FDAMA requires manufacturers of food contact substances to provide only a simple notification to the FDA identifying the substance, its intended use and a determination that such use is safe, before introduction into interstate commerce. If the FDA determines that a food contact substance has not been shown to be safe, it can object to the notification, “which shall constitute final agency action subject to judicial review.”<sup>311</sup> FDAMA requires the manufacturer of a drug or device to have submitted a supplemental application for a new use before circulating information regarding the safety and effectiveness of such new use to certain individuals and entities.<sup>312</sup> The FDA has to review a copy of the information before it is circulated and can require further objective information regarding the safety or effectiveness of such new use.<sup>313</sup> The FDA is also authorized to order a cessation of circulation of the information if it determines that the information fails to conform to the requirements established by FDAMA.<sup>314</sup>

FDAMA empowers the FDA to authorize the use of unapproved investigational drugs or devices for the treatment of a serious disease or condition in emergency situations, or pursuant to an “expanded access protocol.”<sup>315</sup> FDAMA mandates the FDA to establish and publish regulations setting forth standards

<sup>307</sup> *Id.* at § 204 (codified at 21 U.S.C. § 360d(c) (2003)).

<sup>308</sup> *See id.* at § 210, adding § 523(a)(3) (codified at 21 U.S.C. § 360m(a)(3) (2003)), for activities the accredited persons may not perform, and Section 523(b) for the procedure, qualifications and withdrawal of accreditation.

<sup>309</sup> *Id.* at § 309(a), adding § 409(a)(3) (codified at 21 U.S.C. § 348(a)(3) (2003)).

<sup>310</sup> *Id.* at § 309(b)(2), adding § 409(h)(6) (codified at 21 U.S.C. § 348(h)(6) (2003)).

<sup>311</sup> *Id.* at § 309(b)(2), adding § 409(h)(2) (codified at 21 U.S.C. § 348(h)(2) (2003)).

<sup>312</sup> *Id.* at § 401(a), adding § 551(a) and § 554(a) (codified at 21 U.S.C. § 360aaa(a) and § 360aaa-3(a) respectively (2003)).

<sup>313</sup> *Id.* at § 401(a), adding § 551(c) (codified at 21 U.S.C. § 360aaa(c) (2003)).

<sup>314</sup> *Id.* at § 401(a), adding § 555(b)(1) (codified at 21 U.S.C. § 360aaa-4(b)(1) (2003)).

<sup>315</sup> *Id.* at § 402, adding § 561(a) and (c) (codified at 21 U.S.C. § 360bbb(a) (2003)).

for the timely review of supplemental applications submitted for approved articles under the FDCA.<sup>316</sup> The FDA is also mandated to pass regulations establishing a procedure for the resolution of any scientific controversies between the FDA and an applicant requesting any FDA action.<sup>317</sup> The FDA is also authorized to develop guidelines, after public participation, “setting forth initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues.”<sup>318</sup> The FDA is mandated to establish an information system to monitor the status and progress of each application submitted to it requesting its action.<sup>319</sup> The FDA is authorized to promulgate regulations restricting the sale of mercury intended to be used as a drug or dietary supplement if it determines that such use poses a threat to human health.<sup>320</sup> The FDA is authorized to contract for expert review to obtain recommendations with respect to applications submitted to the FDA.<sup>321</sup> FDAMA also requires foreign establishments “engaged in the manufacture, preparation, propagation, compounding or processing of a drug or device that is imported into the U.S.,” to register with the FDA.<sup>322</sup>

Congress passed the Medicine Equity and Drug Safety Act of 2000 in order to make accessible to Americans prescription drugs available in other countries at significantly lower prices than in the U.S.<sup>323</sup> This Act authorizes the FDA to promulgate regulations allowing pharmacists and wholesalers to import prescription drugs into the U.S.<sup>324</sup> Such imported prescription drugs have to meet the safety and effectiveness requirements

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<sup>316</sup>*Id.* at § 403(a) (appears as a note to 21 U.S.C. § 371 (2003)).

<sup>317</sup>*Id.* at § 404, adding § 562 (codified at 21 U.S.C. § 360bbb-1 (2003)).

<sup>318</sup>*Id.* at § 405, adding § 701(h)(1)(C) (codified at 21 U.S.C. § 371(h)(1)(C) (2003)).

<sup>319</sup>*Id.* at § 407(a), adding § 741 (codified at 21 U.S.C. § 379k (2003)).

<sup>320</sup>*Id.* at § 413(c)(2) (appearing as note to 21 U.S.C. § 393 (2003)).

<sup>321</sup>*Id.* at § 415, adding § 907(a)(1) (codified at 21 U.S.C. § 397(a)(1) (2003)).

<sup>322</sup>*Id.* at § 417, amending § 510(i) (codified at 21 U.S.C. § 360(i) (2003)).

<sup>323</sup>The Medicine Equity and Drug Safety Act of 2000, Pub. L. 106-387, 114 Stat 1549A-35 (2000) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified at 21 U.S.C. § 384 (2003)).

<sup>324</sup>*Id.* at § 745(c), adding § 804(a) (codified at 21 U.S.C. § 384(a) (2003)).

of the FDCA.<sup>325</sup> The importers are required to keep records on such importation and to provide the FDA certain information.<sup>326</sup> The importers are also required to test the imported shipment for authentication and degradation and to assure that the product's labeling conforms to FDCA requirements.<sup>327</sup> This act also provides that the prescription drugs can only be imported from countries that are listed or designated by the FDA.<sup>328</sup> The FDA is authorized to suspend the importation of a specific prescription drug if it determines that such importation is in violation of a requirement of this Act, or that the imported product is counterfeit.<sup>329</sup> The Act however can only become effective if the Secretary of the HHS determines that it will "pose no additional risk to the public's health and safety and [will] result in a significant reduction in the cost of covered products to the American consumer."<sup>330</sup> HHS secretary Tommy G. Thompson found that these conditions could not be assured and declined to implement this Act upon determining that it would "sacrifice public safety by opening up the closed distribution system in the United States."<sup>331</sup>

Congress passed the Prescription Drug Import Fairness Act of 2000 to clarify the FDA's obligations with respect to importation of approved drugs by patients and their families.<sup>332</sup> If the FDA decides that a certain drug import that an individual is seeking violates the FDCA, this Act requires the FDA to provide the individual with a detailed notice of the reasons for the decision.<sup>333</sup>

Following the terrorist attacks of September 11, 2001, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. This Act was passed to "improve the ability of the U.S. to

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<sup>325</sup>*Id.* at § 745(c), adding § 804(b)(1) (codified at 21 U.S.C. § 384(b)(1) (2003)).

<sup>326</sup>*Id.* at § 745(c), adding § 804(c) (codified at 21 U.S.C. § 384(c) (2003)). *See id.* at § 804(d) (codified at 21 U.S.C. § 384(d) (2003)), for the information that importers need to provide the FDA.

<sup>327</sup>*Id.* at § 745(c), adding § 804(e) (codified at 21 U.S.C. § 384(e) (2003)).

<sup>328</sup>*Id.* at § 745(c), adding § 804(f) (codified at 21 U.S.C. § 384(f) (2003)).

<sup>329</sup>*Id.* at § 745(c), adding § 804(g) (codified at 21 U.S.C. § 384(g) (2003)).

<sup>330</sup>*Id.* at § 745(c), adding § 804(l) (codified at 21 U.S.C. § 384(l) (2003)).

<sup>331</sup>Michelle Meadows, *Imported Drugs Raise Safety Concerns*, FDA CONSUMER MAGAZINE (September-October 2002), [http://www.fda.gov/fdac/features/2002/502\\_import.html](http://www.fda.gov/fdac/features/2002/502_import.html).

<sup>332</sup>The Prescription Drug Import Fairness Act of 2000, Pub. L. No. 106-387, 114 Stat 1549A-40 (2000) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified at 21 U.S.C. § 381(g) (2003)).

<sup>333</sup>*Id.* at § 746(b)(3) (appears in note to 21 U.S.C. § 381 (2003)). *See id.* at § 746(c) (codified at 21 U.S.C. § 381(g) (2003)), for the requirements that such a notice must meet.

prevent, prepare for, and to respond to bioterrorism.<sup>334</sup> Title III of this Act specifically deals with protecting the safety and security of the food and drug supply. In order to protect against bioterrorist threats to the food supply, the FDA is mandated to give high priority to increasing the number of inspections of food being imported, at the ports of entry into the U.S.<sup>335</sup> The FDA is also mandated to develop an information management system that deals with imported foods, to enable the FDA to allocate sufficient funds for the purposes of detecting purposeful adulteration of the food.<sup>336</sup> The FDA is also charged with developing “rapid detection” tests and sampling methodologies for the detection of intentional adulteration of food and to conduct an assessment of the threat of intentional adulteration of food.<sup>337</sup> This Act also adds onto the list of persons subject to debarment, those that have been “convicted of a felony for conduct relating to the importation into the U.S. of any food.”<sup>338</sup> The Act also requires domestic and foreign facilities that manufacture, process, pack or hold food for consumption in the U.S., to register with the FDA.<sup>339</sup> Food importers are also required to notify the FDA of any imported food shipments to facilitate inspection of such food at the port of entry.<sup>340</sup> The Act empowers the FDA to require that food that has been barred from entry, bear the sign “UNITED STATES: REFUSED ENTRY,” until it is brought into compliance with the FDCA.<sup>341</sup> The Act also prohibits “port shopping.”<sup>342</sup> This Act requires annual registration with the FDA of foreign manufacturers of drugs and devices that are imported into the U.S.<sup>343</sup> The Act requires persons importing components of drugs and devices to be incorporated in a product intended for export, to submit to the FDA certain detailed information, to keep records, and make reports that the FDA may require.<sup>344</sup>

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<sup>334</sup>The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, Title III, 116 Stat. 662 (2002) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified principally at 21 U.S.C. §§ 381, 334(h), 335a(b), 350d, 350c, 374, 360, 342(h) (2003)).

<sup>335</sup>*Id.* at § 302(a), adding § 801(h)(1) (codified at 21 U.S.C. § 381(h)(1) (2003)).

<sup>336</sup>*Id.* at § 302(b) adding § 801(h)(2) (codified at 21 U.S.C. § 381(h)(2) (2003)).

<sup>337</sup>*Id.* at § 302(d) adding § 801(i) (codified at 21 U.S.C. § 381(i) (2003)), and *id.* at § 801(e).

<sup>338</sup>*Id.* at § 304(a)(2)(C), adding § 306(b)(3) (codified at 21 U.S.C. § 335a(b)(3) (2003)).

<sup>339</sup>*Id.* at § 305, adding § 415(a) (codified at 21 U.S.C. § 350d(a) (2003)).

<sup>340</sup>*Id.* at § 307(a), adding § 801(m)(1) (codified at 21 U.S.C. § 381(m)(1) (2003)).

<sup>341</sup>*Id.* at § 308(a), adding § 801(n) (codified at 21 U.S.C. § 381(n) (2003)).

<sup>342</sup>*Id.* at § 309, adding § 402(h) (codified at 21 U.S.C. § 342(h) (2003)).

<sup>343</sup>*Id.* at § 321(a), amending § 510(i)(1) (codified at 21 U.S.C. § 360(i)(1) (2003)).

<sup>344</sup>*Id.* at § 322(a), amending § 801(d)(3) (codified at 21 U.S.C. § 381(d)(3) (2003)).



Congress recognized that the resources the FDA allocated to reviewing medical device applications had been decreasing in recent years, and consequently, review was taking longer periods of time.<sup>345</sup> Congress then passed the Medical Device User Fee and Modernization Act of 2002 to make “additional funds available for the purpose of augmenting the resources of the FDA that are devoted to the process for the review of devices and the assurance of device safety and effectiveness so that statutorily mandated deadlines may be met.”<sup>346</sup> The FDA was authorized to assess user fees against premarket applications, premarket reports, supplement applications and premarket notifications.<sup>347</sup> The Act sets forth the fee revenue to be collected each year from 2003 to 2007, which then determines the amount of fees to be paid by persons making medical device-related submissions to the FDA.<sup>348</sup> Applications submitted without the required fees are considered incomplete.<sup>349</sup> The FDA is authorized to adjust these revenues for inflation, workload and shortfalls from previous years.<sup>350</sup> The Act mandates that the fees assessed are to be used only for the review of medical device applications.<sup>351</sup> A condition of assessing user fees, is that the FDA is expected to meet all its “performance goals.”<sup>352</sup> The Act also makes additional appropriations to the FDA for the purpose of conducting postmarket surveillance of medical devices.<sup>353</sup> This Act authorizes the FDA to accredit persons to inspect facilities that manufacture, prepare, propagate, compound or process class II or class III devices.<sup>354</sup> The Act also gives the FDA the authority to debar an accredited person that is convicted of a felony for conduct relating to an inspection.<sup>355</sup>

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<sup>345</sup>*The Medical Device User Fee and Modernization Act of 2002: FAQs* (November 7, 2002), <http://www.fda.gov/cber/mdufma/mdufma02faq.htm>.

<sup>346</sup>The Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107-250, § 101(2), 116 Stat. 1588 (2002) (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified principally at 21 U.S.C. §§ 379i, 379j, 374(g), 360m(d), 335a(m) 353(g)(4), 352(f), 352(u) (2003)).

<sup>347</sup>*Id.* at § 102(a), adding § 738(a)(1)(A) (codified at 21 U.S.C. § 379j(a)(1)(A) (2003)). *See also id.* at § 738(a)(1)(B) (codified at 21 U.S.C. § 379j(a)(1)(B) (2003)), for the exceptions to the user fee requirements of this Act.

<sup>348</sup>*Id.* at § 102(a), adding § 738(b) (codified at 21 U.S.C. § 379j(b) (2003)).

<sup>349</sup>*Id.* at § 102(a), adding § 738(f) (codified at 21 U.S.C. § 379j(f) (2003)).

<sup>350</sup>*Id.* at § 102(a), adding § 738(c) (codified at 21 U.S.C. § 379j(c) (2003)).

<sup>351</sup>*Id.* at § 102(a), adding § 738(h)(1) (codified at 21 U.S.C. § 379j(h)(1) (2003)).

<sup>352</sup>*Id.* at § 102(a), adding § 738(g) (codified at 21 U.S.C. § 379j(g) (2003)).

<sup>353</sup>*Id.* at § 104(a).

<sup>354</sup>*See id.* at § 201, adding § 704(g)(3) (codified at 21 U.S.C. § 374(g)(3) (2003)), for the requirements accredited persons need to meet, the procedure of accreditation and withdrawal of accreditation.

<sup>355</sup>*See id.* at § 203, adding § 306(m) (codified at 21 U.S.C. § 335a(m) (2003)), for information on the debarment period and termination of debarment.

The FDA's enforcement powers have been expanded dramatically by Congress over time, through the passage of the FDCA and its amendments.

### **THE COURTS' TREATMENT OF FDA ENFORCEMENT OBLIGATIONS**

In a 1986 case, the Supreme Court concluded that the FDCA does not create or imply a private right of action for individuals injured as a result of violations of the Act.<sup>356</sup> The FDA is therefore the sole authority that can enforce the provisions of the FDCA and ensure compliance with the FDCA. Injured individuals can still sue a violator for negligence in state courts. A court could interpret a violation of the FDCA as an indication of a manufacturer's negligence in such a suit. The Fourth Circuit held in a diversity suit by a plaintiff against the manufacturer of a misbranded medical device, whose misbranding was the proximate cause of the plaintiff's injury, that the violation of the FDCA is negligence per se in Virginia.<sup>357</sup> The court noted that while the FDCA does not provide a private right of action for injured consumers, it "imposes an absolute duty on manufacturers not to misbrand their products and a breach of this duty may give rise to civil liability."<sup>358</sup>

### **Courts' Treatment of FDA's Inspection and Seizure Powers**

The Supreme Court in *United States v. Cardiff*<sup>359</sup> found that on its face, the FDCA only prohibited the refusal to permit entry and inspection if permission had previously been granted. The Court pointed out that Section 704 of the FDCA conditioned entry and inspection on "making request and obtaining permission," and that on its face, the FDCA apparently gave factory managers the right to withhold permission

<sup>356</sup>Merrell Dow Pharmaceuticals, Inc. v. Thompson, 478 U.S. 804, 815 (1986).

<sup>357</sup>Orthopedic Equipment Co. v. Eutsler, 276 F.2d 455, 461 (4<sup>th</sup> cir. 1960)

<sup>358</sup>*Id.* at 460.

<sup>359</sup>344 U.S. 174, 176-177 (1952) - in this case, the Supreme court affirmed the reversal of the respondent who had been convicted of violating Section 301(f) of the FDCA (codified as 21 U.S.C. § 331(f)), which prohibits the refusal to permit entry and inspection pursuant to authorized by Section 704 (codified as 21 U.S.C. § 374).

to enter and inspect.<sup>360</sup> This construction of the FDCA would obviously have crippled the FDA's efforts at inspecting facilities and protecting the public health. Congress thus amended Section 704 of the FDCA eliminating the provision requiring the FDA to obtain permission before entering at reasonable times to inspect facilities in which food, drugs, devices, or cosmetics are manufactured, processed, packed or held for introduction into interstate commerce, or held after such introduction.<sup>361</sup> The Amended section 704 only requires the FDA to give a written notice to the owner or operator of a facility before entering to inspect, but does not require the FDA to obtain consent.<sup>362</sup> This section "simply and unequivocally authorizes FDA to enter and inspect certain specified premises at reasonable times."<sup>363</sup>

Although Administrative searches are subject to the safeguards of the Fourth Amendment, and thus require a warrant issued upon a showing of probable cause,<sup>364</sup> there is an exception eliminating the warrant requirement in administrative searches of "closely regulated" industries.<sup>365</sup> This exception is referred to as the *Colonnade-Biswell* exception.<sup>366</sup> Courts have held that warrantless searches under Section 374 of the FDCA are valid as they fall within the *Colonnade-Biswell* exception.<sup>367</sup> Courts have also consistently held that FDA officials conducting inspections pursuant to Section 374 do not need to give *Miranda* warnings, as such inspections are non-custodial.<sup>368</sup> The Ninth Circuit has held that the FDA is not required to give advance

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<sup>360</sup>*Id.*

<sup>361</sup>See Act of Aug. 7, 1953, Pub. L. No. 83-217, amending § 704(a), 67 Stat. 476 (amending Pub. L. No. 75-717, 52 Stat 1040 (1938)) (codified at 21 U.S.C. §§ 374 (a)(1) (2003)).

<sup>362</sup>See *id.*

<sup>363</sup>*Daley v. Weinberger*, 400 F. Supp. 1288, 1291, n.3 (E.D.N.Y. 1976), *aff'd*, 536 F.2d 519 (2nd Cir. 1976), *cert. denied*, 430 U.S. 930 (1977).

<sup>364</sup>See *v. Seattle*, 387 U.S. 541, 546 (1967), requires that an administrative search of commercial property be supported by a search warrant. It however provides that the standard of probable cause required to obtain a warrant for an administrative search is lower than that required for the issuance of a warrant in criminal cases.

<sup>365</sup>*New York v. Burger*, 482 U.S. 691, 719 n.2 (1987) cites as examples of "closely regulated" industries, the liquor industry, firearm and ammunition sales, the coal mine industry and then finds the vehicle dismantlers industry to be closely regulated as well.

<sup>366</sup>*U.S. v. Argent Chem. Lab.*, 93 F.3d 572, 575-576 (9th Cir. 1996)

<sup>367</sup>*U.S. v. New England Grocers Supply Co.*, 488 F. Supp. 230, 238 (D. Mass. 1980) The court pointed out that there was a long history of pervasive federal regulation of the food and drug industry and thus that warrantless inspections pursuant to § 374 are fully consistent with the Fourth Amendment. See also *Argent Chem. Lab.*, 93 F.3d at 575-576 (concluding that the drug industry, including the animal drug segment, was closely regulated by the government, and thus subject of warrantless search and seizure by the FDA). See also, *U.S. v. Fogari*, 1988 U.S. Dist. LEXIS 10166 (D. N.J. 1988) (concluding t the pharmaceutical industry is a closely regulated field and thus subject to warrantless inspection by the FDA).

<sup>368</sup>*New England Grocers Supply Co.*, 442 F. Supp. at, 48 (D. Mass. 1977), *citing*, *U.S. v. Thriftmart, Inc.*, 429 F.2d 1006

notice of an inspection, as “the necessity and constitutionality of a surprise search was expressly upheld” by the Supreme Court.<sup>369</sup> Further, the FDA is not required to give a separate notice of inspection for each day of a multiple day inspection,<sup>370</sup> nor even specify in the notice the reason underlying the inspection or what it expects to find.<sup>371</sup> The FDA is also not required to inform the party being inspected whether it intends to proceed criminally or civilly against such party.<sup>372</sup> In order to facilitate FDA’s inspection obligation, Section 373 provides a method by which the FDA can obtain interstate shipment information from carriers. The fourth circuit gave a broad interpretation to Section 373, finding that it does not exclude permissive investigation of interstate shipment records from manufacturing facilities.<sup>373</sup> The court also affirmed the FDA’s authority to take samples during inspections by noting that “Section 372(b) of the Act clearly contemplates the taking of samples.”<sup>374</sup>

The Supreme court concluded that Section 304(a), which “authorizes multiple libels for condemnation of misbranded articles upon the FDA’s finding of probable cause that a misbranded article is dangerous to health, or that its labeling is fraudulent, or would be in material respect misleading to the injury and damage of a purchaser or consumer,” does not violate due process.<sup>375</sup> The Court found that the owner of the seized articles has an opportunity to have a fully hearing in court when the FDA files the libel and that this hearing satisfies the requirements of due process.<sup>376</sup>

### **Courts’ Treatment of FDA’s Power to Seek Injunctions**

The First Circuit has held that there is no right to a jury trial in an action for an injunction under 21 U.S.C. §

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(9th Cir. 1970) *cert. denied*, 400 U.S. 926 (1970) *reh. denied*, 400 U.S. 1002 (1971).

<sup>369</sup> *Thriftmart, Inc.*, 429 F.2d at 1010, *citing*, *See v. Seattle*, 387 U.S. at 545 n.6 (1967).

<sup>370</sup> *See* U.S. v. Durbin, 373 F. Supp 1136, 1137 (E.D. Okla. 1974).

<sup>371</sup> *See Weinberger* 400 F. Supp at 1291 n.3.

<sup>372</sup> *Thriftmart, Inc.*, 429 F.2d at 1010, *citing*, U.S. v. Kordel, 397 U.S. 1 (1970).

<sup>373</sup> U.S. v. 75 Cases, etc., 146 F.2d 124, 127 (4th Cir. 1944), *cert. denied*, 325 U.S. 856 (1945).

<sup>374</sup> *Id.* at 128.

<sup>375</sup> *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, 598 (1950), *reh. denied*, 340 U.S. 857 (1950).

<sup>376</sup> *Id.* at 598.

332(a), as the action is purely equitable in nature.<sup>377</sup> The Ninth Circuit stated that the standards for granting a preliminary injunction are different where the injunction is being sought pursuant to a statute, such as the FDCA, rather than pursuant to claims of two private litigants.<sup>378</sup> That court declared that the FDA was not required to show irreparable injury in seeking a statutory injunction, and that such irreparable injury should be presumed.<sup>379</sup> After noting that the required degree of a showing of probable success on the merits decreases as the likelihood of irreparable harm increases, the Ninth Circuit announced that the FDA would only need to show some chance of probable success on the merits, since the irreparable injury requirement is presumed for statutory injunctions.<sup>380</sup> The court also announced that in balancing the hardships that would result from the issuance of a preliminary injunction the court has to balance the hardships that face the party to be enjoined, against the public's interest in consuming unadulterated food.<sup>381</sup> It then cited *Smith v. California*,<sup>382</sup> which stated that "the usual rationale behind food and drug legislation is that 'the public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors.'<sup>383</sup> In discussing the required showing of the likelihood of recurring violations, the court noted that the cessation of violations does not itself foreclose issuance of an injunction.<sup>384</sup> It also cautioned courts to "beware of attempts to forestall injunctions through remedial efforts and promises of reform that seem

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<sup>377</sup>See *U.S. v. Articles of Drug Consisting of Following: 5,906 Boxes, etc.*, 745 F.2d 105, 112 (1st Cir. 1984), *cert. denied*, 470 U.S. 1004 (1985). See also *U.S. v. Ellis Research Laboratories, Inc.*, 300 F.2d 550, 554 (7th Cir. 1962) *cert. denied*, 370 U.S. 918 (1962) (stating that the Seventh Amendment which preserves the right of trial by jury to "suits at common law," does not apply to an action for injunctive relief, which has historically been equitable in nature, with the factual issues raised triable by the court). See also *U.S. v. Louisiana*, 339 U.S. 699, 706 (1950) (noting that the Seventh Amendment only applies to actions at law and not equity actions for injunctions).

<sup>378</sup>In *U.S. v. Odessa Union Warehouse Co-op*, 833 F.2d 172, 174-175 (9th Cir. 1987), the court announced the factors traditionally considered in determining whether to grant a preliminary injunction in a suit between two private litigants in the 9th circuit: (1) the likelihood of plaintiff's success on the merits; (2) the possibility of plaintiff's suffering irreparable injury if relief is not granted; (3) the extent to which the balance of hardships favors the respective parties; and (4) in certain cases, whether the public interest will be advanced by the provision of preliminary relief.

<sup>379</sup>See *id.* at 175, *citing*, *Navel Orange Admin. Comm. v. Exeter Orange Co.*, 722 F.2d 449, 453 (9th Cir. 1983), and, *SEC v. Mgmt. Dynamics, Inc.*, 515 F.2d 801, 808 (2d Cir. 1975).

<sup>380</sup>See *Odessa Union*, 833 F.2d at 176.

<sup>381</sup>*Id.*

<sup>382</sup>361 U.S. 147, 152 (1959)

<sup>383</sup>See, *Odessa Union*, 833 F.2d at 176.

<sup>384</sup>See *id.*, *citing*, *City of Mesquite v. Aladdin's Castle, Inc.*, 455 U.S. 283, 289 (1982).

timed to anticipate legal action, especially when there is the likelihood of recurrence.”<sup>385</sup> District courts have also held that the FDA does not need to show that the food in question was injurious to health in order to get an injunction against the shipment of such food.<sup>386</sup>

The Sixth Circuit held that a district court sitting in equity pursuant to 21 U.S.C. § 332(a),<sup>387</sup> had the authority to order restitution in addition to issuing an injunction.<sup>388</sup> This court noted that the Supreme Court in *Porter v. Warner Holding Co.*<sup>389</sup> established that, unless otherwise provided by statute, all the inherent equitable powers of the District Court are available for the proper and complete exercise of that jurisdiction... and that restitution is within the recognized power and within the highest tradition of a court of equity.<sup>390</sup> The Court then went on to hold that nothing in the FDCA precludes a district court from ordering restitution and that restitution is therefore a remedy available to a district court in appropriate cases under 21 U.S.C. § 332(a).<sup>391</sup>

## **Courts’ Treatment of FDA’s Criminal and Civil Proceedings and the Pre-Prosecution Hearing Requirement**

Courts have observed that if the FDCA is literally enforced, all processed food would be excluded from interstate commerce.<sup>392</sup> They have accordingly recognized that the FDA has the discretion to develop “administrative working tolerances” to aid in deciding which violations to proceed against, and which to consider *de minimis*.<sup>393</sup> The Fifth Circuit has held that a court can apply a stricter standard than the FDA

<sup>385</sup>See, *Odessa Union*, 833 F.2d at 176, citing, U.S. v. Oregon State Medical Society, 343 U.S. 326, 333 (1952).

<sup>386</sup>See, U.S. v. Lazere, 56 F. Supp. 730, 732 (D.C. Iowa 1944). See also, U.S. v. Medwick Lab. Inc., 416 F. Supp. 832, 833 (N.D. Ill. E. Div. 1976) (noting that proof of irreparable injury or proof that the drugs are unsafe is unnecessary for injunctive relief under the FDCA).

<sup>387</sup>This section grants the district court jurisdiction to enjoin violations of the FDCA.

<sup>388</sup>See, U.S. v. Universal Mgmt. Servs., 191 F.3d 750, 762 (6th Cir. 1999).

<sup>389</sup>328 U.S. 395, 398 and 402 (1946).

<sup>390</sup>*Universal Mgmt. Servs.*, 191 F.3d at 761.

<sup>391</sup>*Id.* at 762.

<sup>392</sup>In U.S. v. 484 Bags, More or Less, 423 F.2d 839, 841 (5<sup>th</sup> Circuit 1970), the court notes that Section 343(a)(3) considers any food adulterated if it consists in whole or in part of any filthy, putrid or decomposed substances, and then observes that “a scientist with a microscope could find filthy, putrid, and decomposed substances in almost any canned food we eat.

<sup>393</sup>*Id.* at 841, citing, U.S. v. 133 Cans of Tomato Paste, 22 F. Supp. 515, 516 (E.D. Pa. 1938) (accepting an FDA tolerance

in finding a food adulterated, even though it is within the FDA's tolerances. It however noted that due to the FDCA's purpose of protecting the public health, a court cannot apply a standard below the FDA's tolerances.<sup>394</sup>

Section 306 of the FDCA authorizes the FDA to issue warnings for minor violations rather than report them for prosecution, or for the institution of libel or injunction proceedings.<sup>395</sup> A district court has interpreted the FDCA as vesting this discretion on the FDA and as not requiring the FDA to "establish rules and regulations for procedures to determine whether a warning instead of a prosecution or injunction serves to vindicate the public interest."<sup>396</sup>

The Second Circuit has held that the FDA's decision to institute criminal proceedings against a violator does not preclude it from carrying out further inspections of the violator's facility under Section 374.<sup>397</sup> This court noted that protecting the health and safety of the public is the FDA's primary function, and that the FDA should thus not be prohibited from performing this function even temporarily while a prosecution is underway.<sup>398</sup> The court further noted that the Supreme Court in *U.S. v. Kordel*<sup>399</sup> stated that "it would stultify enforcement of federal law to require a governmental agency such as the FDA invariably to choose either to forgo recommendation of a criminal prosecution once it seeks civil relief, or to defer civil proceedings pending the ultimate outcome of a criminal trial."<sup>400</sup>

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as a standard for determining whether a food is adulterated within the meaning of the FDCA).

<sup>394</sup> *184 Bags, More or Less*, 423 F.2d at 842.

<sup>395</sup> This section is codified in 21 U.S.C. § 336.

<sup>396</sup> *U.S. v. Hunter Pharmacy, Inc.*, 213 F. Supp. 323, 324 (S.D.N.Y. 1963).

<sup>397</sup> *U.S. v. Gel Spice Co.*, 773 F.2d 427, 432 (2d Cir. 1985) *cert. denied*, 474 U.S. 1060 (1986).

<sup>398</sup> *Id.* at 432.

<sup>399</sup> 397 U.S. 1, 11 (1970).

<sup>400</sup> *Gel Spice Co.*, 773 F.2d at 432.

A district court has upheld the constitutionality of the Drug Abuse Control Amendments Act of 1965,<sup>401</sup> which does not require the government to show that the sale of a drug covered by the Act (depressant or stimulant drugs) was involved in interstate commerce.<sup>402</sup> This court found that Congress made findings supported by evidence that the intrastate sales of LSD have a significant effect on interstate commerce.<sup>403</sup> It then concluded that the Drug Abuse Control Amendments Act of 1965 was a constitutional exercise of Congress' power under the commerce clause, both on its face and as applied to purely intrastate manufacture and sale of LSD.<sup>404</sup> FDA could thus report for prosecution purely intrastate violations of the FDCA as provided by this Act.

Section 305 of the FDCA, codified at 21 U.S.C. § 335, provides that “before any violation of this chapter is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.” Defendants have attempted to invoke this section in seeking to enjoin criminal proceedings that have been instituted against them before they have presented their views before the FDA. The Supreme Court has twice held that the denial of such a hearing is not a bar to criminal prosecution. In *U.S. v. Morgan*,<sup>405</sup> the Supreme Court in interpreting a similar provision in the 1906 Act, stated that “there is nothing in the nature of the offense under the pure food law, or in the language of the statute, which indicates that Congress intended to grant violators of this act a conditional immunity from prosecution, or to confer upon them a privilege not given every other person charged with a crime.” The Court confirmed this holding in *U.S. v. Dotterweich*,<sup>406</sup> this time interpreting the FDCA.

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<sup>401</sup> See, Public Law 89-74, *supra* note 124.

<sup>402</sup> *U.S. v. Erlin*, 283 F. Supp. 396, 397 (N.D. Cal. 1968).

<sup>403</sup> *Id.* at 398.

<sup>404</sup> *Id.* at 399.



It has further been held that the hearing provided for in Section 335 is not a “full dress trial with all the formal attributes thereof, but only a fair opportunity [for suspects] to present their views.”<sup>407</sup> The Seventh Circuit also noted that the Section 335 hearing is not one that leads to a final administrative order, subject to statutory judicial review.<sup>408</sup>

#### Courts’ Treatment of FDA’s Debarment Power

21 U.S.C. 335a(a) requires the FDA to debar anyone convicted of a felony with respect to federal regulation of drug products, from providing services in any capacity to a person that has an approved or pending drug product application. Courts have had the occasion to rule on whether debarment under this section violates the Double Jeopardy<sup>409</sup> and Ex Post Facto<sup>410</sup> Clauses of the U.S. Constitution. The D.C. Circuit announced that the answer to this question depended on whether debarment is wholly remedial or in part a punitive measure.<sup>411</sup> It then concluded after analysis that it agreed with the Seventh Circuit<sup>412</sup> that debarment under § 335a(a) is solely remedial. Since debarment was found to be remedial, imposing debarment after assessing civil penalties, which are punitive, against a violator does not violate the double jeopardy clause of the Constitution.<sup>413</sup> Likewise the court concluded that a remedial measure such as debarment cannot violate the ex post facto clause of the Constitution.<sup>414</sup>

In a debarment notice published in the Federal Register, the FDA pointed out that debarment does not amount to “an unconstitutional taking of the right to earn a living in the U.S.”<sup>415</sup> It noted that Circuit

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<sup>407</sup>*Hunter Pharmacy, Inc.*, 213 F. Supp. at 323-324 (S.D.N.Y. 1963). This court also notes that this hearing is not a prerequisite to criminal prosecution.

<sup>408</sup>*Durovic v. Richardson*, 479 F.2d 242, 244 (7th Cir. 1973) *cert. denied*, 414 U.S. 944 (1973) *reh. denied*, 414 U.S. 1099 (1973)

<sup>409</sup>This is found in the Fifth Amendment of the U.S. Constitution.

<sup>410</sup>This is found in Article 1, § 9 of the U.S. Constitution.

<sup>411</sup>*DiCola v. FDA*, 77 F.3d 504, 506 (D.C. Cir. 1996).

<sup>412</sup>*Bae v. Shalala*, 44 F.3d 489, 497 (7th Cir. 1995).

<sup>413</sup>*DiCola*, 77 F.3d at 508.

<sup>414</sup>*Id.* at 508. This conclusion came after the court cited *DeVeau v. Braisted*, 363 U.S. 144, 160 (1960) for its statement that “the mark of an ex post facto law is the imposition of what can fairly be designated punishment for past acts” *Id.* at 506.

<sup>415</sup>*John D. Copanos; Denial of Hearing; Final Debarment Order*, 61 FR 9711, DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS), FDA, Docket No. 94N-0033, Federal Register Vol. 61, No. 48.

Courts have held that “the expectation of employment is not recognized as a protected property interest under the Fifth Amendment,”<sup>416</sup> and that the Supreme Court has held that the “loss of potential profit is not a sufficient basis for a ‘takings’ claim.”<sup>417</sup>

### **Courts’ Treatment of FDA’s Publicity Powers**

The D.C. district court decided that Section 375(b), which authorizes the FDA to disseminate information regarding food, drugs, devices, or cosmetics when it determines that any such article presents an imminent danger to health or gross deception of the consumer, was “obviously constitutional.”<sup>418</sup> The court stated that even without that statutory authority, the FDA could still disseminate such information to the public.<sup>419</sup> The court also noted that in such a situation, a person can sue the FDA for damages if they can establish that the information being disseminated is libelous.<sup>420</sup> A district court has held that it has the power to enjoin the FDA from issuing news releases and other public statements about a manufacturer’s product where such publicity would prejudice a trial against such product.<sup>421</sup>

### **Courts’ Treatment of FDA’s Regulation of Exports and Imports**

The Ninth Circuit has held that the FDCA authorizes the FDA to refuse to admit food being imported upon

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<sup>416</sup>The FDA cited to *Hoopa Valley Tribe v. Christie*, 812 F.2d 1092, 1102 (9th Cir. 1986), and *Chang v. U.S.*, 859 F.2d 893, 896-97 (Fed. Cir. 1988).

<sup>417</sup>*Citing*, *Andrus v. Allard*, 444 U.S. 51, 66 (1979).

<sup>418</sup>*See Hoxsey Cancer Clinic v. Folsom*, 155 F. Supp. 376, 378 (D. D.C. 1957).

<sup>419</sup>*See id.* at 378.

<sup>420</sup>*See id.* at 378. It might not be possible to sue the FDA for damages without its consent, as it is an agency of the federal government and thus covered by sovereign immunity.

<sup>421</sup>*U.S. v. Diapulse Mfg. Corp.*, 262 F. Supp. 728, 730 (D. Conn. 1967) – in this case however the court refused to issue an injunction because the manufacturer had failed to show irreparable injury or any threat thereof.

“the mere appearance of adulteration,” a finding of actual adulteration being unnecessary.<sup>422</sup> Furthermore, the court found that such a finding is not subject to judicial review.<sup>423</sup> The Second Circuit has held that a court has no discretion to release articles that have been condemned due to adulteration, for export to another country.<sup>424</sup> It stated that while articles intended for export are exempt from some of the provisions of the FDCA, a court cannot accord condemned articles that were not originally intended for export, a “delayed exemption for export.”<sup>425</sup> It further noted that the FDCA provides that a court can only release condemned articles to the owner for destruction or for being brought into compliance with the FDCA.<sup>426</sup>

### Courts’ Treatment of the Intersection Between FTC False Advertising Proceedings and Libel Actions for M

The fourth Circuit has stated that a proceeding before Federal Trade Commission (FTC) under 15 U.S.C. § 45, 52 and 53 (to enjoin the use of unfair or deceptive acts or practices and the dissemination of false advertisements to induce the purchase of goods in interstate commerce), does not conflict with libel actions under 21 U.S.C. § 334 (which invoke the power of courts to seize and condemn falsely branded goods which have been unlawfully shipped in interstate commerce in past).<sup>427</sup> This means that these suits can proceed simultaneously. The court further noted that a favorable decision to the manufacturer of the goods that the government is seeking to condemn in a libel suit, has preclusive effect on the promulgation of a cease and desist order by the FTC in a proceeding based on the same charge of misrepresentation of the character of

<sup>422</sup>Sugarman v. Forbragd, 267 F. Supp. 817, 824 (N.D. Cal. 1967), *aff’d*, 405 F.2d 1189 (9<sup>th</sup> Cir. 1968) *cert. denied*, 395 U.S. 960 (1969)

<sup>423</sup>*Id.* at 824.

<sup>424</sup>United States v. Kent Food Corp., 168 F.2d 632, 634 (2d Cir. 1948)

<sup>425</sup>*Id.* at 634.

<sup>426</sup>*See*, 21 U.S.C. § 334(d)

<sup>427</sup>U.S. v. 1 Dozen Bottles, etc., 146 F.2d 361, 363 (4th Cir. 1944).

the goods shipped in interstate commerce.<sup>428</sup> The Court went on to recognize that the reverse was also true: An FTC finding that the statements made by a manufacturer are not false or misleading, has preclusive effect on a libel action seeking to condemn goods on the grounds that they are misbranded under the FDCA.<sup>429</sup> The Second Circuit has held that a penalty for the violation of a cease and desist order issued under the Federal Trade Commission Act<sup>430</sup> does not preclude further remedies for violation of the FDCA. The court stated that “the remedies are plainly cumulative and not exclusive.”<sup>431</sup>

## **CONCLUSION**

The FDCA and all its amendments have continually increased the substantive and enforcement powers of the FDA over the years. FDA’s mission as recognized by congress, is to protect the public health by ensuring that “foods are safe, wholesome, sanitary and properly labeled; human and veterinary drugs are safe and effective; there is reasonable assurance of the safety and effectiveness of devices intended for human use; cosmetics are safe and properly labeled; and public health and safety are protected from electronic product radiation.”<sup>432</sup> Further, the FDA is charged with reviewing applications for regulated products in a prompt and efficient manner, as well as working with representatives from foreign countries to “harmonize regulatory requirements and achieve appropriate reciprocal arrangements.”<sup>433</sup> These are very momentous responsibilities that require the FDA to be fully equipped both financially and in its ability to enforce its obligations.

With increasing risk to the public health due to technological advances, it is inevitable that Congress will continue to increase the FDA’s responsibilities and to increase its enforcement powers to enable it to meet

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<sup>428</sup> *Id.* at 363, *citing*, *George H. Lee Co. v. F.T.C.*, 111 F.2d 583, 586 (8th Cir. 1940)

<sup>429</sup> *1 Dozen Bottles, etc.*, 146 F.2d at 363, *citing*, *U.S. v. Willard Tablet Co.*, 141 F.2d 141, 143 (7th Cir. 1944).

<sup>430</sup> *See*, 15 U.S.C. § 45(1)

<sup>431</sup> *U.S v. Five Cases of Capon Springs Water*, 156 F.2d 493, 496 (2d Cir. 1946).

<sup>432</sup> Pub. L. No. 105-115, § 406(a)(2) adding § 903(b) (codified at 21 U.S.C. § 393(b), *supra* note 290.

<sup>433</sup> *Id.*

those responsibilities. With this increase in FDA's responsibilities, Congress will also continue to increase its appropriations to the FDA as well as vesting it with authority to assess and collect user fees for other products it regulates, other than drugs and medical devices, to augment its resources.

Courts have generally recognized the importance of the FDA's mission and have construed the FDCA liberally to enable the FDA to carry out its enforcement functions effectively.<sup>434</sup> Additionally, where the Supreme Court interpreted the FDCA in a manner that would have made it difficult for the FDA to carry out inspections, Congress amended the FDCA to overturn that interpretation.

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<sup>434</sup>See, U.S. v. Kordel, at 917 (7<sup>th</sup> Cir. 1947), *aff'd*, 335 U.S. 345 (1948) *reh. denied*, 335 U.S. 900 (1948) *and reh. denied*, 336 U.S. 911 (1949) (noting was passed to protect the public health and should thus be given a "liberal construction" despite the fact that it is for the most part penal and imposes criminal penalties). See also, U.S. v. 7 Jugs, etc., of Dr. Salsbury's Rakos, 53 F Supp 746, 752 (D. Minn 2d Div. 1944) (stating that the FDCA is one of the most important enactments under the Commerce Clause, with its purpose of protecting the public health against adulterated and misbranded foods and drugs, which has led courts to declare with unanimity that food and drug legislation should be given a liberal construction in order to accomplish its remedial purposes).