

# THE FOOD AND DRUG ADMINISTRATION'S POWER TO RECALL A HARMFUL PRODUCT AND OTHER REMEDIAL ACTIONS: THE POWERLESS CONSUMER

## INTRODUCTION

The Food and Drug Administration (FDA) has no mandatory product recall procedures for certain classifications of products under the Food, Drug and Cosmetic Act (FDCA),<sup>1</sup> nor are any established private consumer remedies available to initiate recalls of such products.<sup>2</sup> To illustrate the problem of removing a deleterious product from the market, this Note focuses on the intrauterine device, the Dalkon Shield. The Dalkon Shield was placed on the market in 1970 by A.H. Robins Company. It was subsequently found to be defective and injurious to consumers.<sup>3</sup> The manufacturer has stopped production but it refuses to recall the devices from the marketplace or to notify those consumers with the device still *in situ* of the risks involved.<sup>4</sup> Because the FDA does not have the power, pursuant to the FDCA, to initiate mandatory recalls of such products, this Note explores alternative measures to remove harmful products from the market.

## I. HISTORY OF THE DALKON SHIELD

The Dalkon Shield was designed in 1968 by a doctor and an engineer who incorporated and commercially introduced the device to the medical profession the following year.<sup>5</sup> On June 12, 1970,

---

1. The FDCA provides for recall procedures for products classified by the FDA as drugs. See *infra* note 40 and accompanying text. For an enumeration of the enforcement tools pertaining to products which do not fit within the drug classification, see the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 332-334 (1982). See also Note, *Mandatory Food and Drug Recalls—An Analysis of a Developing FDA Enforcement Tool*, 1980 UTAH L. REV. 809; Note, *The Food and Drug Administration's Recall Power After United States v. C.E.B. Products, Inc.: The Need to Amend the Food, Drug, and Cosmetic Act*, 69 NW. U.L. REV. 936 (1975); see generally H.R. REP. No. 585, 92d Cong., 1st Sess. 5 (1971).

2. See *infra* notes 86-94 and accompanying text.

3. For a discussion of the defects found in the Dalkon Shield and the resulting injuries see generally Van Dyke, *The Dalkon Shield: A "Primer" in IUD Liability*, 6 W. ST. U.L. REV. 1 (1978); Culliton & Knofman, *The Dalkon Shield Affair: A Bad Lesson in Science and Decision Making*, SCIENCE, Sept. 6, 1974 at 839-41.

4. Van Dyke, *supra* note 3, at 2.

5. *In re A.H. Robins Co., "Dalkon Shield" IUD Products Liability Litigation*, 406 F. Supp. 540, 540 (1975).

A.H. Robins Company, Inc. acquired all rights to the Dalkon Shield and sold it on the open market between June 12, 1970 and June 28, 1974.<sup>6</sup> Over 2.2 million devices were prescribed for women in the United States during this period.<sup>7</sup>

After injuries resulting from defects in the Dalkon Shield were reported, the FDA initiated a series of public and private fact finding hearings.<sup>8</sup> Although the FDA did not request a termination of production, A.H. Robins stopped production of the Dalkon Shield on June 28, 1974.<sup>9</sup> In August of 1974, the FDA formally recommended that Robins continue to withhold the Dalkon Shield from the market.<sup>10</sup> In October of 1974, the FDA's Advisory Committee on Obstetrics and Gynecology voted to lift the recommendation and to allow sales to resume.<sup>11</sup> This decision was reversed one month later when new evidence of defects in the product were discovered.<sup>12</sup> However, on December 20, 1974, the FDA, acting contrary to its advisory committee's recommendations, sanctioned the sale of the Dalkon Shield.<sup>13</sup> Despite this approval, A.H. Robins did not market the device again.

The documented injuries resulting from use of the Dalkon Shield include death, pregnancy, septic abortion, tubal pregnancy, perforation of the uterine wall, and pelvic infection.<sup>14</sup> Because of these injuries over 3,000 lawsuits have been filed against Robins in state and federal courts.<sup>15</sup> Not only has Robins failed to voluntarily recall its defective device, but it also refuses to notify the esti-

---

6. *Id.*

7. *Id.* See also Van Dyke, *supra* note 3, at 2.

8. Rheingold, *IUD's: A Federal Loophole*, TRIAL, Nov.-Dec. 1974, at 39.

9. Van Dyke, *supra* note 3, at 2.

10. Rheingold, *supra* note 8, at 39.

11. See The Washington Post, Nov. 8, 1974, § A, at 3, col. 3.

12. *Id.*

13. See The San Diego Union, Jan. 21, 1975, § D, at 3, col. 3.

14. See *supra* note 3 and accompanying text.

15. Zackey, *The Cu-7—A New IUD Risk*, TRIAL, May 1980, at 68. The grounds for these lawsuits include defective production of the tailstring of the Dalkon Shield which physically and chemically deteriorates and erodes in the uterus and becomes an increasingly effective transporter of bacteria into the uterus, thus creating a substantial risk of pelvic inflammatory disease, tubo-ovarian abscess, sterility, fetal death, and wearer death. See generally *In re A.H. Robins Co., "Dalkon Shield" IUD Products Liability Litigation*, 406 F. Supp. 540 (1975) (Judicial Panel on Multidistrict Litigation) (Presents a compilation of Dalkon Shield litigation including the general grounds for these suits). Lawsuits have been founded on Robins's failure to employ adequate assembly or quality control procedures during production and inadequate product labeling. *Id.* The Dalkon Shield package and insert did not mention the possible dangers from use and did not recommend a fixed removal date which is customary manufacturer practice. *Id.*

mated 100,000 women in the United States still wearing the Dalkon Shield of the potential harm from its use.<sup>16</sup>

## II. FDA PRODUCT RECALL POWER

The Food, Drug and Cosmetic Act (FDCA) was adopted in 1938.<sup>17</sup> It replaced the Pure Food and Drugs Act of 1906<sup>18</sup> and broadened the reach of federal law by changing the focus of the Act from a "policeman's" function to a preventive role.<sup>19</sup> The enforcement tools of the FDA under the FDCA are limited to injunctive remedies, criminal prosecution, and seizure of goods.<sup>20</sup> Although seizure was an adequate tool to remove violative products from the market when the FDCA was introduced, today, with increased production and distribution, seizure is both impractical and unreasonable.<sup>21</sup>

The use of voluntary manufacturer recalls has become the FDA's principal mechanism of enforcement.<sup>22</sup> Although recall is not an FDCA mandated procedure, it has been used by the FDA as an informal enforcement procedure since the mid 1950's.<sup>23</sup> The FDA's recall policy assumes that potential liability will provide an incentive to manufacturers to ensure that their products do not present an unreasonable risk of injury to consumers.<sup>24</sup>

The FDA will request a manufacturer recall when it deter-

16. See *supra* note 3 and accompanying text.

17. The Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392 (1982).

18. The Pure Food and Drugs Act, ch. 3915, §1, 34 Stat. 768 (1906) (current version at 21 U.S.C. §§ 301-392 (1982)).

19. Engdahl, *Consolidation by Compact: A Remedy for Preemption of State Food and Drug Laws*, 14 J. PUB. L. 276, 276 (1965); Address by Richard Schweiker, Secretary of the Department of Health and Human Services, 37 FOOD DRUG COSM. L.J. 10, 13 (1982).

20. The Food, Drug and Cosmetic Act, 21 U.S.C. §§ 332-334 (1982). See generally *United States v. C.E.B. Products, Inc.*, 380 F. Supp. 664 (N.D. Ill. 1974); Note, *The Food and Drug Administration's Recall Power After United States v. C.E.B. Products, Inc.: The Need to Amend the Food, Drug and Cosmetic Act*, *supra* note 1, at 936.

21. To effect a seizure of a distributed product, the FDA would incur great expense in procuring the entire product and maintaining a staff large enough to complete the task effectively and efficiently. Note, *Mandatory Food and Drug Recalls*, *supra* note 1, at 810 n. 13.

22. Note, *Mandatory Food and Drug Recalls*, *supra* note 1, at 810-11. See also *United States v. K-N Enterprises, Inc.*, 461 F. Supp. 988 (N.D. Ill. 1978).

23. H.R. REP. NO. 585, 92d Cong., 1st Sess. 3 (1971). See also Kasperson, *Food, Drug and Cosmetic Law Section Recall Panel*, 27 FOOD DRUG COSM. L.J. 349, 349 (1972).

24. See Bozeman, *Recalls—On Making the Best of a Bad Thing*, 33 FOOD DRUG COSM. L.J. 342, 345 (1978); Note, *The Food and Drug Administration's Recall Power After United States v. C.E.B. Products, Inc.*, *supra* note 1, at 942.

mines: "(1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception; (2) That the firm has not initiated a recall of the product; (3) That an agency action is necessary to protect the public health and welfare."<sup>25</sup> Most manufacturers will implement a recall after a request from the FDA or upon their own initiative. The FDA has been content with this voluntary method of enforcement, even though it cannot legally enforce its demand for a recall should the manufacturer refuse to comply.<sup>26</sup> During hearings on the proposed Drug Regulation Reform Act of 1978, the FDA expressly opposed specific legislation creating mandatory recall procedures, claiming they are unnecessary and impractical.<sup>27</sup>

Under the current enforcement system, not only may a manufacturer refuse to cease production, it may refuse to recall products on the market and refuse responsibility for products already in use.<sup>28</sup> This result contradicts the FDCA's objective of protecting the "public from products not proven to be safe and effective for their alleged uses and the safeguarding of the public health by enforcement of certain standards of purity and effectiveness."<sup>29</sup>

One federal court has argued that the purpose of the FDCA will not be realized unless the FDA has implied recall powers under the Act.<sup>30</sup> The FDA has noted that the seizure method of enforcement is unmanageable in today's world.<sup>31</sup> Without seizure, recall is the only viable alternative available to the FDA to remove deleterious products from the stream of commerce. Recall most closely resembles seizure as both procedures remove products from the market. With seizure deemed infeasible, mandatory recall is impliedly necessary under the FDCA to "safeguard the public

---

25. The Food, Drug and Cosmetic Act, 21 C.F.R. § 7.45(a) (1984).

26. See H.R. REP. No. 585, 92d Cong., 1st Sess. 5 (1971).

27. See Drug Regulation Reform Act of 1978: Hearings on H. R. 11611 Before the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce, 95th Cong., 2d Sess. 948 (1978) [hereinafter cited as *Hearings*]. (Report by the Commissioner of Food and Drugs on the findings and recommendations of the review panel on new drug regulations).

28. For example, manufacturers need not warn consumers of the documented or possible harms associated with the use of their products.

29. *United States v. Diapulse Corp. of Am.*, 457 F. 2d 25, 28 (2d Cir. 1972); *Accord* 62 Cases of *Jam v. United States*, 340 U.S. 593, 596 (1951); *United States v. Dotterweich*, 320 U.S. 277, 280 (1943).

30. *United States v. K-N Enterprises, Inc.*, 461 F. Supp. 988, 990-91 (N.D. Ill. 1978).

31. House Committee on Gov't Operations, *Recall Procedures of the Food and Drug Administration*, H.R. REP. No. 585, 92d Cong., 1st Sess. 5 (1971).

health." In support of this notion, it has been argued that FDCA section 701(a)<sup>32</sup> is a license for expansion of the FDA's regulatory authority when broader powers are necessary to protect the public health and safety.<sup>33</sup> This expansion of authority would necessarily include the power to effect a mandatory product recall.

In 1976, Congress amended the FDCA in an attempt to strengthen the FDA's authority to regulate "medical" devices.<sup>34</sup> Pursuant to these amendments, the FDA may order manufacturers, importers or distributors to replace, repair or refund the purchase price of a hazardous or falsely presented product.<sup>35</sup> Of course, in order to replace or repair a product, by definition, the manufacturer must first remove the item from the marketplace. If the FDA may "order" a manufacturer to replace or repair a product, in order to effectuate these mandates, a recall "order" is necessarily implied.

### III. RECLASSIFICATION OF ALL INTRAUTERINE DEVICES AS DRUGS

The FDA classifies most intrauterine contraceptives as devices, not as drugs.<sup>36</sup> In the FDCA's written definitions of "drug" and "device," the only difference is that the word "articles," used in defining a drug,<sup>37</sup> is replaced by the words "instruments, apparatus, or contrivances"<sup>38</sup> in defining a device.<sup>39</sup> Device controls

32. 21 U.S.C. § 701(a) is currently codified at 21 U.S.C. § 371(a) (1982) which reads as follows: "The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in the section, is vested in the Secretary."

33. Note, *Mandatory Food and Drugs Recall*, *supra* note 1, at 828. *Contra* National Confectioners Ass'n v. Califano, 569 F.2d 690, 695 (D.C. Cir. 1978) ("Section 701(a) is not a license for expansion of the FDA's regulatory authority based on fanciful interpretations of the substantive portions of the Act.")

34. Janssen, *The U.S. Food and Drug Law: How It Came; How It Works*, 35 *FOOD DRUG COSM. L.J.* 132, 142 (1980); *See also* Bozeman, *supra* note 24, at 358.

35. Bozeman, *supra* note 24, at 358.

36. *See* 21 C.F.R. § 310.502 (1984).

37. The term 'drug' means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph; but does not include devices or their components, parts, or accessories.

21 U.S.C. § 321(g)(1) (1982).

38. The term 'device' . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, in-

under the FDCA are not nearly as extensive as drug restraints. After the FDA gives approval to an article classified as a drug, it retains continuing jurisdiction to review and to recall the product.<sup>40</sup> This is not true with substances deemed devices. Once the FDA reviews a product and classifies it as a device, the FDA relinquishes its powers of control over the product and waives continuing jurisdiction to review it.<sup>41</sup>

During the review process, the manufacturer submits data to the FDA so that the FDA can determine whether the product is a drug or a device. The manufacturer has complete control over what data is submitted, and the FDA has no staff facilities to check the validity of any submitted information.<sup>42</sup> In a California birth control methods study, the researcher emphasized that the FDA has a "lackadaisical" attitude towards clearly insufficient data and inaccurate claims of safety made by manufacturers to the FDA and consumers.<sup>43</sup>

In response to the FDA's lack of involvement in the regulatory process, Congress enacted the Medical Device Amendments of 1976 which gave the FDA slightly more authority to regulate devices.<sup>44</sup> Pursuant to these amendments, if a product is classified as a medical device, the FDA has discretionary authority to require that the manufacturer prove that its product is safe and effective before it is marketed.<sup>45</sup> However, no standards of proof are enumerated in the amendments; the FDA still must rely on the information submitted by the manufacturer for this "proof."

---

cluding any component, part, or accessory, which is (1) recognized in the Official National Formulary, or the United States Pharmacopoeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principle intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principle intended purposes.

21 U.S.C. § 321(h) (1982).

39. For a general discussion of the difference in the two definitions, see Note, *The Intrauterine Device: A Criticism of Governmental Complaisance and An Analysis of Manufacturer and Physician Liability*, 24 CLEV. ST. L. REV. 247, 253-57 (1975).

40. See 21 U.S.C. § 355(e) (1976).

41. See 21 U.S.C. § 360(c) (1976).

42. See Williams, *The Pill in New Perspective*, 16 FOOD DRUG COSM. L.J. 53 (1961).

43. *Id.*

44. 1976 U.S. CODE CONG. & AD. NEWS 1070. See Janssen, *supra* note 34, at 142.

45. 1976 U.S. CODE CONG. & AD. NEWS 1070, 1089. See Janssen, *supra* note 34, at 142.

The FDA currently classifies intrauterine devices either as drugs<sup>46</sup> or as devices,<sup>47</sup> basing its determination on whether or not the item is produced from "active" materials<sup>48</sup> which cause local irritation. The use of active materials has been correlated to the efficacy of intrauterine devices in achieving their contraceptive effect. If the product is manufactured from an active material, it is classified as a "new" drug.<sup>49</sup> If the device is manufactured from an inert substance, it is only subject to the limited device review procedures. But the fact remains that all intrauterine devices act as local irritants; this irritation interrupts the reproductive process whether the devices are manufactured from "active" or "inactive" materials.<sup>50</sup> Because all such contraceptive devices act as irritants, they should be classified as new drugs pursuant to the FDA definition. In fact, in 1968, both the FDA's advisory committee and its general counsel recommended that a compelling need for uniform classification of all intrauterine devices as new drugs existed.<sup>51</sup>

In the 1973 hearings on the regulation of medical devices, specifically intrauterine contraceptives, the Commissioner of the FDA stated that the Administration could anticipate extensive litigation if it were to treat as drugs those intrauterine devices which did not possess the characteristics of a drug.<sup>52</sup> The Commissioner noted that classifying medical devices as new drugs would be problematic for three policy reasons: drug authority is inappropriate for many devices; the administrative burden of handling all devices under the new drug provisions of the Act would be overwhelming; and a reclassifying of medical devices as new drugs would raise many dif-

---

46. 21 C.F.R. § 310.502 (1984).

47. 21 C.F.R. § 801.427 (1984).

48. 21 C.F.R. § 310.502 (1984). The term "active" is not defined in the regulations.

49. 21 C.F.R. § 310.502 (1984).

50. Hilgers, *The Intrauterine Device: Contraceptive of [sic] Abortifacient?* in *Hearings on Regulation of Medical Devices before a Subcommittee of the House Committee on Governmental Operations*, 93d Cong., 1st Sess. at 86-89 (1973).

51. Advisory Committee Statements of General Policy, *Regulation of Medical Device Hearings Before a Subcommittee of the Committee on Governmental Operations*, 93d Cong., 1st Sess. at 206, 218 (1973) (Memorandum from William G. Goodrich, Assistant General Counsel for the FDA, to James L. Godard, Commissioner, March 19, 1968) [hereinafter cited as *Device Hearings*]. During these hearings, the Acting Commissioner of the FDA, Sherwin Gardner, stated that there was a change in command in the Administration shortly after these recommendations were made. The newly appointed commissioner and director have stated that neither can recall seeing these recommendations or having anyone discuss the matter with them. *Id.* at 210.

52. *Id.* at 200. (Statement of Sherwin Gardner).

ficult legal issues.<sup>53</sup> Addressing these policy arguments, one commentator remarked: "To me this is a nonpolitical controversy or issue, because the uterus, quite frankly, is very nonpolitically oriented."<sup>54</sup>

Two recently decided cases were discussed at length during the 1973 regulatory hearings. Both cases addressed the issues of the scope of the statutory definition of a drug contained in the FDCA and the extent of the FDA's regulatory authority under that definition. The first case was *AMP v. Gardner*,<sup>55</sup> in which the Court of Appeals for the Second Circuit held that inasmuch as an item may be defined as either a drug or a device, to protect the public health, a liberal construction of the FDCA warranted classifying the product as a drug.<sup>56</sup> The court noted that the early versions of the current Act did not separately define devices. Moreover, Congress' purpose in enacting both the drug and device provisions was the same: "To keep inadequately tested medical and related products which might cause widespread danger to human life out of interstate commerce."<sup>57</sup> As Judge Learned Hand has so astutely observed, "unless they [Congress] explicitly forbid it, the purpose of a statutory provision is the best test of the meaning of the words chosen."<sup>58</sup>

The second case to be discussed at the 1973 hearings was *United States v. An Article of Drug . . . Bacto-Unidisk*,<sup>59</sup> in which the United States Supreme Court commented in dicta that the word drug as used in the FDCA is a term of art.<sup>60</sup> The Court

---

53. *Id.*

54. Medical Device Amendment Hearing Before the Subcommittee on Health of the Committee on Labor and Public Welfare, 93d Cong., 1st Sess. (1973) (statement of Russel J. Thomsen, M.D.) [hereinafter cited as *Device Amendments*].

55. 389 F.2d 825 (2d Cir. 1968). The manufacturer requested the FDA to classify its products, which included a dispensable applicator, a nylon ligature loop, and a nylon locking device used for tying off blood vessels during surgical procedures. In response the FDA advised that the products were regarded as "new drugs" pursuant to 21 U.S.C. § 355 and thus subject to approval by the Secretary. The manufacturer took the position that its products were devices pursuant to 21 U.S.C. § 321 and brought this appeal.

56. *Id.* at 830.

57. *Id.* at 829.

58. *Cawley v. United States*, 272 F.2d 443, 445 (2d Cir. 1959).

59. 394 U.S. 784 (1969). This laboratory aid was thought to be a device by the industry. When the manufacturer marketed the disks without complying with the drug certification regulations of the FDCA, the government condemned the disks pursuant to 21 U.S.C. § 331 on the assumption that the disks were drugs and thus subject to pre-market regulation. This action followed.

60. *Id.* at 793.

noted that the term should be construed broadly because remedial legislation such as the FDCA has an overriding purpose of protecting the public health.<sup>61</sup> The Court expounded, "without deciding the precise contours of the 'device' classification, we need only point out that the exception was created primarily for the purpose of avoiding semantic incongruity of classifying as drugs (1) certain quack contraceptives and (2) basic aids used in the routine operation of a hospital . . . ."<sup>62</sup> Thus, separate drug and device classifications were created simply for semantic clarity, and not because of any substantive difference between the two classifications.

Despite the apparent concern about certain medical device classifications voiced in both the 1973 House of Representatives and 1974 Senate hearings, the FDA remains reluctant to make medical device controls more exacting or to change the classifications of certain questionable medical devices. In view of these concerns and the court decisions addressing device classification, the FDA may be compelled to reclassify certain medical devices, primarily the intrauterine devices such as the Dalkon Shield, as either drugs or new drugs pursuant to the FDCA's definitions.<sup>63</sup> By reclassifying these devices as drugs, the FDA would retain jurisdiction to review the products and could effect recalls if necessary. Such a reclassification is necessary to realize the objectives of preventing public harm and promoting public health—goals recently expressed by the FDA's Commissioner.<sup>64</sup>

#### IV. COURT ORDERED PRODUCT RECALLS

The FDA has sanctioned the use of court ordered recalls when, during formal legal proceedings, a product has been found to be harmful.<sup>65</sup> Courts, however, have been reluctant to confer equitable jurisdiction over mandatory product recalls. The doctrine of equitable jurisdiction is founded on article III of the Federal Constitution. The United States Supreme Court has stated that:

---

61. *Id.* at 798.

62. *Id.* at 800.

63. This classification could be accomplished under several sections of the FDCA. For example, the procedures to initiate an administrative proceeding are enumerated in 21 C.F.R. § 1025 (1984). These include a petition to the Commissioner from any interested person and actions by the Commissioner. The Commissioner has the power to reconsider a matter at any time on his own initiative or on the petition of any interested person.

64. Address by Arther Hull Hayes, Jr., M.D. at the 75th Anniversary Symposium, printed in 37 FOOD DRUG COSM. L.J. 30, 35 (1982).

65. *Hearings, supra* note 27, at 949.

[T]he comprehensiveness of this equitable jurisdiction is not to be denied or limited in the absence of a clear and valid legislative command. Unless a statute in so many words, or by a necessary and inescapable inference, restricts the court's jurisdiction in equity, the full scope of that jurisdiction is to be recognized and applied.<sup>66</sup>

The FDCA does not address the remedy of court ordered product recalls. The Supreme Court has reasoned that affirmative relief, including product recalls, is properly granted by the courts pursuant to their equitable jurisdiction in accordance with the FDCA because such jurisdiction "may be considered as an equitable adjunct to an injunction decree"<sup>67</sup> and "as an order appropriate and necessary to enforce compliance with the Act."<sup>68</sup> One commentator has noted that "equitable jurisdiction, once granted, is presumed available in its entirety unless unmistakably restricted by Congress, that neither the history nor the language of the FDCA clearly precludes court ordered recalls, and that the public interest presently at stake requires a broad and flexible approach to equity powers . . . ."<sup>69</sup> The exercise of equitable jurisdiction to provide a remedy is thus well established.

Congress has not addressed whether courts may exercise their equitable powers to recall a harmful product. The Act, however, does grant the courts power to restrain violations of the Act. The issue is whether the powers to restrain violations are broad enough to include product recalls. Thus, interpretation of the word "restrain" in the injunction provision of the FDCA<sup>70</sup> is often disputed.<sup>71</sup>

*United States v. C.E.B. Products, Inc.*<sup>72</sup> was the first decision addressing whether court ordered recalls are authorized, either ex-

---

66. *Porter v. Warner Co.*, 328 U.S. 395, 398 (1945).

67. *Id.* at 399.

68. *Id.* at 400-03.

69. Note, *The Food and Drug Administration's Recall Power*, *supra* note 20, at 956.

70. 21 U.S.C. § 332(a) (1982). This provision reads: "The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions . . . [relating to notice to opposite party] . . . to restrain violations of section 331 of this title." *Id.* (emphasis added).

71. *United States v. C.E.B. Products, Inc.*, 380 F. Supp. 664 (N.D. Ill. 1974) ("restrain" in the injunction provision is not broad enough to include product recalls). *Contra United States v. K-N Enterprises, Inc.*, 461 F. Supp. 988 (N.D. Ill. 1978) ("restrain" in the injunction provision includes affirmative or mandatory relief).

72. 380 F. Supp. 664, 664 (N.D. Ill. 1974).

pressly or implicitly, by the FDCA. The court reasoned that the word "restrain" in the provision must necessarily be limited to injunctive relief "in the circumstances of this case . . . ." <sup>73</sup> Thus, the court limited its decision and its use of "restrain" to the facts before it. In a later decision, the same court opined that the word "restrain" is broad enough to cover affirmative or mandatory relief. <sup>74</sup> The court emphasized the judiciary's general equity jurisdiction in concluding that authority existed to order a recall since the statute giving the courts this form of jurisdiction does not preclude the granting of such relief. <sup>75</sup> The court stated that although "[t]here is no specific authority in the statute for requiring recalls . . . [w]e are . . . granted the specific jurisdiction to 'restrain violations of section 331.' 21 USC § 332(a). The word 'restrain' in our opinion is broad enough to cover affirmative or mandatory relief . . . ." <sup>76</sup>

The courts, when deciding whether to exercise their equity jurisdiction, engage in a balancing of the harm to the consumer against the harm to the manufacturer. <sup>77</sup> In *C.E.B. Products, Inc.*, <sup>78</sup> for example, the court found that when balanced against the potential harm to the product manufacturer, the injuries suffered by the consumers were not of the severity and proportion to warrant a court ordered product recall. <sup>79</sup> The court noted, however, that courts must exert their equitable powers when danger to the general public is great. <sup>80</sup> The court in *United States v. K-N Enterprises, Inc.* <sup>81</sup> reasoned that, in the absence of an adequate remedy at law, to prevent public harm, the invocation of equity jurisdiction is appropriate to effect a product recall. <sup>82</sup> Using a balancing of harms analysis, the court stated that the "harm which may be inflicted upon the public by the defendants' continued distribution of these products greatly outweighs the possible damage inflicted

---

73. *Id.* at 666.

74. *K-N Enterprises*, 461 F. Supp. at 990.

75. *Id.*

76. *Id.*

77. *Id.* at 991; *C.E.B. Products*, 380 F. Supp. at 672; *United States v. Lit Drug Co.*, 333 F. Supp. 990, 992 (D.N.J. 1971).

78. 461 F. Supp. 664 (N.D. Ill. 1978).

79. *C.E.B. Products*, 380 F. Supp. at 672 (in determining whether to order a recall the court balanced the rendering of the company insolvent and bankrupt against consumer injuries including nails splitting and falling off, redness, soreness, disfigurement and infection).

80. *Id.*

81. 461 F. Supp. 988 (N.D. Ill. 1978).

82. *K-N Enterprises*, 461 F. Supp. at 989.

upon the defendants"<sup>83</sup> which would result from an injunction stopping production and a recall removing products already in commerce. The court found that all of the requirements necessary for the exercise of equitable jurisdiction to order a recall were satisfied.<sup>84</sup> In so finding, the court emphasized the irreparable damage to the public, which the court has the duty, in restraining violations of the Act, to prevent.<sup>85</sup>

Therefore, in an effort to prevent injury to the consumer, courts would properly exercise equity jurisdiction by ordering product recalls if, in a balancing of harms, the danger to the public far outweighs the harm to the manufacturer. Because the Dalkon Shield has been found to cause serious injuries including death,<sup>86</sup> it is axiomatic that the courts have a responsibility to exercise equity jurisdiction by recalling the product. Such an order would promote the objectives of the FDCA, promote compliance with the Act, and do complete justice.

#### V. PRIVATE CONSUMER REMEDY

The provisions of the FDCA do not make recall a mandatory procedure available to the FDA nor do they make it expressly available to the private individual. Many courts have justified private remedies by reasoning that in the absence of an affirmative congressional restriction, the equitable powers of the courts are both broad and flexible enough for them to grant relief in such actions.<sup>87</sup> The FDCA does not grant or deny such equitable powers. Although an express provision for a private right of action for damages was deleted in the final draft of the FDCA, nothing in the legislative history of the Act indicates that Congress meant to exclude a right to private injunctive relief.<sup>88</sup>

No court has directly held that the provisions of the FDCA

---

83. *Id.*

84. *Id.* These requirements include: likelihood of success on the merits, the lack of an adequate remedy at law, the prospect of irreparable harm, and a comparison of relative hardships imposed on the parties. See *Banks v. Trainor*, 525 F.2d 837, 841 (7th Cir. 1975).

85. *K-N Enterprises*, 461 F. Supp. at 990-91.

86. See *supra* note 3.

87. See, e.g., *Bivens v. Six Unknown Named Agents of Fed. Bureau of Narcotics*, 403 U.S. 388 (1971); *Swann v. Board of Education*, 402 U.S. 1 (1971); *Holmberg v. Ambrecht*, 372 U.S. 321 (1944); *Sprague v. Ticonic Nat'l Bank*, 307 U.S. 161 (1939).

88. Hearings Before a Subcommittee of the Committee on Commerce, S. 1944, 73d Cong. 2d Sess. (1933).

preclude a private right to equitable relief.<sup>89</sup> Indeed, many individual plaintiffs have sought preventive injunctive relief by maintaining products liability suits as class actions on behalf of all consumers of allegedly defective products.<sup>90</sup> Injunctive class actions are appropriate because individual consumers may not yet have suffered any actual physical injuries, while some absentee class members may have suffered only relatively minor injuries not sufficient to justify the litigation expenses required to adjudicate their individual claims.<sup>91</sup>

Before a specific private remedy, either equitable or legal, may be found in a congressional act not expressly granting one, it must appear that:

- (1) the plaintiff is within the class intended to be protected by the Act; (2) private enforcement will further the congressional policy of the Act; (3) the duty breached was created by the Act rather than by state statutory or common law; (4) the violation of the duty affected the plaintiff directly; and (5) no other legal remedy is available to guard adequately the right asserted.<sup>92</sup>

Once a plaintiff has satisfied these elements, courts would be remiss in refusing to acknowledge a private right of action.

The courts have found that a private right of action would further the overall purposes of the FDCA,<sup>93</sup> and is necessary given the lack of other remedies available to the consumer to remove harmful products from the market. Further, the powers of equity must be particularly broad when the public is confronted with the risk of irreparable medical injury.<sup>94</sup> These powers must be exercised in the public interest on behalf of the individual by providing a private right of action in compliance with the purpose of the FDCA.

---

89. See, e.g., *Farmland Industries, Inc. v. Kansas-Nebraska Natural Gas Co.*, 349 F. Supp. 670 (D. Neb. 1972).

90. Note, *Products-Liability Class Suits For Injunctive Relief Under Federal Rule 23*, 47 *FORDHAM L. REV.* 49 (1978).

91. See generally *id.*

92. *Farmland Industries*, 349 F. Supp. at 679.

93. *Kiel v. Eli Lilly & Co.*, 490 F. Supp. 479, 480 (E.D. Mich. 1980); *American Home Products v. Johnson & Johnson*, 436 F. Supp. 785 (S.D.N.Y. 1977); *Pacific Trading Co. v. Wilson*, 547 F.2d 367 (7th Cir. 1976); *Clairol v. Suburban Cosmetics*, 278 F. Supp. 859 (N.D. Ill. 1968).

94. *Friends For All Children v. Lockheed Aircraft*, 87 F.R.D. 560 (D.C. Cir. 1980).

## VI. STATE LEGISLATIVE REMEDIES

States may take legislative action to prevent injury to their residents from the unregulated marketing of defective products, such as the Dalkon Shield, within the state. Such legislation should expand on the FDCA regulations by enumerating controls for device marketing within the state, an area which the federal law does not address. The authority for such legislation comes from the power of a state to protect the health and safety of its citizens and to impose restrictions having a reasonable relation to that end.<sup>95</sup> Such an enactment, however, raises the question of whether the FDCA's failure to regulate in the area would preempt any more exacting state legislation under the supremacy clause in article VI of the United States Constitution. The test for federal preemption of state law has been worded in many ways over the years. In 1912, the United States Supreme Court stated that state law must yield only when the purposes of the federal legislation cannot otherwise be accomplished, if the operations of the federal law are frustrated, or its provisions are rendered non-effective.<sup>96</sup> As recently as 1984, the Supreme Court determined that state law may be preempted if Congress evidences an intent to occupy a given field.<sup>97</sup> Even when Congress has not entirely displaced state regulation, state law will still be preempted if there is an actual conflict with federal law<sup>98</sup> or if the state law stands as an obstacle to the accomplishment of congressional purposes and objectives.<sup>99</sup>

There is no indication that Congress, in enacting the FDCA in 1938, intended to preclude all state regulations affecting interstate commerce.<sup>100</sup> In the 1962 amendments to the FDCA, Congress adopted a provision which preserves state food and drug laws "unless there is a direct and positive conflict between such amendments and such provision of State Law."<sup>101</sup> The 1965 amendments contain an express provision disavowing a congressional intent to

---

95. *Price v. Illinois*, 238 U.S. 466 (1915).

96. *Savage v. Jones*, 225 U.S. 501, 533 (1912).

97. *Silkwood v. Kerr-McGee Corp.*, 104 S.Ct. 615, 621 (1984) *citing with approval*, *Pacific Gas and Electric Co. v. State Energy Resources Conservation & Development Comm'n*, 461 U.S. 190, 203-04 (1983).

98. *Silkwood* at 621, *citing with approval*, *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963).

99. *Silkwood* at 621, *citing with approval*, *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

100. See S. REP. No. 361, 75th Cong., 1st Sess. § 3 (1935).

101. See 76 Stat. 793 (1962); 21 U.S.C. § 321 note (1982) (Effect of the Drug Amendments of 1962 on State Laws Section 202 of Pub. L. 87-781).

exclude state powers.<sup>102</sup>

The early cases addressing differing state and federal legislation in a single area indicate that a state may validly impose requirements additional to those imposed by federal law.<sup>103</sup> Today, many states have general food and drug acts which follow closely and even supplement the federal food and drug act. Therefore, a state regulation which supplements a federal one is not *ipso facto* preempted.

State legislation enacted to prevent injury to its citizens from defective products marketed within the state must not directly conflict with any federal legislation regulating in that area. Such state legislation will be preempted if the intent of the federal legislation is exclusionary.<sup>104</sup> Therefore, congressional intent and purpose must be determined and scrutinized in deciding a preemption question. This intent and purpose is ascertained by considering two factors: First, whether the scheme of federal regulation is so pervasive as to "make reasonable the inference that Congress left no room for the States to supplement it;"<sup>105</sup> and second, whether the "federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject."<sup>106</sup>

The FDCA does not effectively regulate the intrauterine devices classified as devices. Because the FDCA does not provide a comprehensive regulatory scheme in this area there would be no

102. See 79 Stat. 235 (1965); 21 U.S.C. § 321 note (1982) (Effect of Drug Abuse Control Amendments of 1965 on State Laws Section 10 of Pub. L. 89-74).

103. See *Corn Products Refining Co. v. Eddy*, 249 U.S. 427 (1919); *Weigle v. Curtis Bros. Co.*, 248 U.S. 285 (1919); *Armour & Co. v. North Dakota*, 240 U.S. 510 (1916); *Savage v. Jones*, 225 U.S. 501 (1912). But see *McDermott v. Wisconsin*, 288 U.S. 155 (1913). At least one commentator has remarked that these early decisions have relatively no precedential value on the issue of food and drug law preemption today because inferences of congressional intent can only be made from the circumstances of each particular case. See, e.g., Engdahl, *supra* note 19, at 293. Yet it must be noted that

there is not [one] Supreme Court decision that even hints that state food and drug laws, covering the same ground and the same goods, and going further by adding such enforcement devices as the embargo, are invalid because of the federal act . . . [t]he validity of these state laws is so well settled that there is not even a clear Supreme Court decision saying they are valid, it is taken for granted.

Christopher, *State Police Power in Health and Fraud Matters*, 8 UTAH L. REV. 289, 291 (1964).

104. *Reid v. Colorado*, 187 U.S. 137 (1902).

105. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

106. *Id.*

manifest conflict with state-originated intrauterine device legislation. Both state and federal regulations could be enforced without impairing the federal superintendence of the field. There could be no interference with federal enforcement on which to premise preemption of state legislation because there is no federal regulatory program for most intrauterine devices. When Congress limits its prohibitions enumerated in its laws, those left unenumerated are open to state regulation.<sup>107</sup>

Federal preemption of state regulation of device quality and effectiveness is not the necessary result when the FDA reviews devices and then relinquishes control over them. In *Savage v. Jones*<sup>108</sup> the United States Supreme Court stated that:

[T]he intent to supersede the exercise by the State of its police power as to matters not covered by the Federal legislation is not to be inferred from the mere fact that Congress has seen fit to circumscribe its regulation and to occupy a limited field. In other words, such intent is not to be implied unless the act of Congress fairly interpreted is in actual conflict with the law of the state.<sup>109</sup>

As recently as 1983, the Court has reiterated that the police powers of the state are not to be superseded by a federal act unless that is the clear and manifest purpose of Congress.<sup>110</sup> In *Reid v. Colorado*,<sup>111</sup> the Court determined that a state statute is valid although it may relate to the same general subject as a federal regulation, when the two do not cover the same ground and are not inconsistent with each other. In *Florida Lime & Avocado Growers, Inc. v. Paul*,<sup>112</sup> the Court summarized that:

The principle to be derived from our decisions is that federal regulation of a field of commerce should not be deemed preemptive of state regulatory power in the absence of persuasive reasons—either that the nature of the regulated subject matter permits no other conclusion, or that the Congress has unmistakably so ordained.<sup>113</sup>

---

107. *Savage*, 225 U.S. at 532-33.

108. *Id.* at 501.

109. *Id.* at 533.

110. *Rice*, 331 U.S. at 230, cited with approval in *Pacific Gas and Electric Co. v. State Energy Resources Comm'n*, 461 U.S. 190, 206 (1983).

111. 187 U.S. 137 (1902).

112. 373 U.S. 132 (1963).

113. *Id.* at 142.

The United States Supreme Court has posited that when Congress has addressed a topic matter and legislatively spoken, exclusionary intent is implied.<sup>114</sup> The mere existence of congressional power to supersede or to suspend the exercise of the police powers of the states, however, does not imply an intent to do so.<sup>115</sup> The intent to effect such a result must be clearly manifested in the federal legislation.<sup>116</sup> The Court has categorically stated that if Congress wants to preempt state action, it must say so explicitly.<sup>117</sup>

Congress has not, in any FDCA provision, expressed an intent to invalidate any concurrent state legislation. Furthermore, the FDA encourages state involvement in regulation.<sup>118</sup> The fact that state action has been encouraged and assisted by a federal agency may strengthen an inference that Congress did not intend the federal law to be exclusive.<sup>119</sup>

It may be noted that other public safety measures enacted by Congress have specifically provided that federal law preempts any state legislation. For example, the Federal Hazardous Substances Act<sup>120</sup> states, "no State or political subdivision of a State may establish or continue in effect a requirement . . . unless such requirement is identical to the requirement established under such regulations."<sup>121</sup> Other examples include: the 1967 Wholesome Meat Act<sup>122</sup> which reads, "requirements . . . in addition to or different than [sic] those made under this chapter may not be imposed by any State . . .";<sup>123</sup> the Federal Environment Pesticide Control Act of 1972<sup>124</sup> which has a section prohibiting a state from imposing or continuing in effect any differing or additional requirements;<sup>125</sup>

---

114. *Warren Trading Post Co. v. Arizona State Tax Comm'n*, 380 U.S. 685, 691 (1965).

115. *Savage*, 225 U.S. at 537 (citing to *Reid*, 187 U.S. at 148).

116. *Id.*

117. *Pacific Gas*, 461 U.S. at 206; *Savage*, 225 U.S. at 537.

118. Public Administration Service Report on a Study of State and Local Food and Drug Programs to the Commissioner of the Food and Drug Administration, Department of Health, Education, and Welfare, Report No. 235-36, 237, 238 (1965); Engdahl, *Consolidation by Compact*, *supra* note 19, at 297.

119. *Head v. New Mexico Bd. of Examiners in Optometry*, 374 U.S. 424, 432 (1963); *Parker v. Brown*, 317 U.S. 341, 358-59 (1943); *Mintz v. Baldwin*, 289 U.S. 346, 351 (1933).

120. 15 U.S.C. §§ 1261-1276 (1982).

121. *Id.* at § 1261 note (Effect Upon Federal and State Law Section 17(a) of Pub. L. 94-284).

122. 21 U.S.C. §§ 601-695 (1976).

123. *Id.* at § 678.

124. 7 U.S.C. § 136 (1982).

125. *Id.* at § 136(v).

and the Consumer Product Safety Act<sup>126</sup> which prohibits any state requirements which are designed to deal with the same risk of injury handled by the Act unless such requirements are identical to the federal standards.<sup>127</sup> Thus, when Congress intends to exclude state participation, it does so expressly. As discussed earlier, there is no express intent to preempt state action in the language of the FDCA.<sup>128</sup>

Arguably, in the interests of uniformity of standards, federal law should preempt any state attempt to legislate in the same area.<sup>129</sup> But there can be no controversion of uniformity of standards when the FDCA has not established any standards for intrauterine contraceptives classified as medical devices and when the FDA retains no continuing authority to regulate them. If a congressional intent of uniformity is found, the effect will be preemption.<sup>130</sup> If no such intent is expressed or implied, the result will be non-preemption.<sup>131</sup> The need for uniformity of standards has not been addressed in the legislative history of the FDCA.<sup>132</sup> The legislative history of the FDCA does, however, expressly set forth that by enacting the statute, Congress intended to protect the health and safety of the consumer.<sup>133</sup> This express intent to protect the consumer is more persuasive than any argument for uniformity of standards. In fact, the United States Supreme Court has concluded:

The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and

---

126. 15 U.S.C. §§ 2051-2083 (1982).

127. *Id.* at § 2075(a).

128. See *supra* notes 101-03 and accompanying text.

129. *Cambell v. Hussey*, 368 U.S. 297 (1961). For a general discussion see Engdahl, *Consolidating State and Federal Regulatory Power Over Food and Drugs*, 20 *FOOD DRUG COSM. L.J.*, 587, 588 (1965).

130. *Hussey*, 368 U.S. at 300-01.

131. *Florida Lime & Avocado Growers*, 373 U.S. at 147-49. *Cf. id.* at 169 (White, J. dissenting)(the purpose and objective of Congress calls for the application of uniform standards, even absent the total occupation of the field by the federal regulatory scheme).

132. See S. REP. No. 361, *supra* note 101.

133. The United States Supreme Court has noted that the history of the FDCA reveals the express congressional intent of protecting the public health and safety. 62 *Cases of Jam v. United States*, 340 U.S. 593, 596 (1951); *United States v. Dotterweich*, 320 U.S. 277, 280 (1943).

not merely as a collection of English words.<sup>134</sup>

In *United States v. Dotterweich*,<sup>135</sup> the Court determined that when construing the FDCA, "literalism" and "evisceration" are to be avoided.<sup>136</sup> The provisions of the FDCA are directed to the purpose of safeguarding the public and must be construed to effect that purpose.<sup>137</sup> Under the Supreme Court's direction for construing and interpreting this statute, the FDCA does not preclude a state from protecting its own citizens from harm inflicted by products used in the state. Thus, state action in this area should not be preempted if the intent of such action is to foster the FDCA's paramount purpose of protecting the consumer.

State legislation which would foster the goals of the FDCA while running little risk of being preempted by the Act<sup>138</sup> may take several forms. First, a state may require manufacturers who are distributing products in the state to notify the FDA when their products present a threat to safety. Second, the state could mandate that any manufacturer doing business within the state must agree to conduct a product recall should the FDA or the state determine its necessity. Finally, a state could legislate procedures permitting state imposed embargoes on pernicious products to remove the items from the market until a more definitive action is taken either by the FDA or the courts.

## VII. OTHER POSSIBLE SOLUTIONS

Two solutions directly involving the FDA have been suggested. The first proposal calls for an administrative product review which would lead to an administrative change in the standards imposed or to a recall order.<sup>139</sup> An administrative review procedure would reduce the delay inherent in judicial action thus preventing further harm during judicial review. It may also prove more flexible than

---

134. *Dotterweich*, 320 U.S. at 280.

135. 320 U.S. 277 (1943).

136. *Id.* at 284.

137. *United States v. Two Bags, Each Containing 110 Pounds, Poppy Seeds*, 147 F.2d 123, 127 (6th Cir. 1945)(citing to *United States v. Antikamnia Co.*, 231 U.S. 654, 665 (1914)).

138. State legislative action would merely impose requirements additional to those of the FDCA. Federal preemption of supplemental state laws would be precluded if the state legislatures stay within the necessary parameters. See *supra* notes 103-19 and accompanying text.

139. Note, *Mandatory Food and Drug Recalls*, *supra* note 1, at 823-28.

an action brought through the judicial system. The Code of Federal Regulations provides two procedures to initiate administrative proceedings. The Commissioner may act on his own initiative<sup>140</sup> or an interested person may petition the Commissioner to take administrative action.<sup>141</sup> Thus, the FDA need not always initiate the administrative review; the consumer may take a more active role in product regulation.

The second proposal recommends a national reporting system for adverse product effects.<sup>142</sup> This system would entail a compilation and publication of information on product usage, adverse reactions, and other related experience data. In an effort to expand information dissemination on product usage, a joint project by the National Bureau of Standards, the FDA, and the Joint Commission on Prescription Drug Use was initiated to investigate practical techniques of postmarketing surveillance of a product.<sup>143</sup> Although this approach does not solve any of the previously mentioned problems with removing harmful products from the market, it does aid in achieving other goals. By compiling and distributing product information, this approach would promote public health and consumer protection by keeping consumers informed, thus enabling them to make valid purchase choices.

A third solution does not involve the FDA. State legislatures could avoid the preemption problem by effecting a cooperative "compact."<sup>144</sup> A single law would be created by the concerted legislative action of individual states and the federal government. Rulemaking authority would be vested in a single national agency composed of representatives of both the federal and state governments. This "compact" would circumvent the risk of federal preemption because it would create one law which is at the same time both state and federal. A compact would ensure uniformity of regulation, yet it would preserve to the states a more significant role in regulation.<sup>145</sup>

---

140. Initiation of administrative proceedings, 21 C.F.R. § 10.25(b) (1984).

141. *Id.* at § 10.25(a).

142. Note, *The Liability of Pharmaceutical Manufacturers For Unforeseen Adverse Drug Reactions*, 48 *FORDHAM L. REV.* 735, 760-63 (1980).

143. *Id.* at 760.

144. Engdahl, *supra* note 19, at 310-22.

145. *Id.* at 313.

## CONCLUSION

A paramount need exists for an effective and rapid procedure for either preventing harmful products from entering the market or for removing them. This need is exemplified in the narrative of the Dalkon Shield. The device has caused extensive harm and death while remaining virtually unregulated. It is difficult to believe that those in positions to rectify such deficiencies in device regulations have remained complacent in the face of voluminous evidence of harm and various pressures to take action. During the hearings on the Medical Device Amendments of 1973, one physician admonished:

I would like to point out without reservation that it is not only time for regulation of IUD testing, manufacture, and advertising, but it is long overdue. Parenthetically, I must question how 14 years have elapsed since the introduction of the plastic IUDs into women commenced without responsible organizations and experts demanding regulatory standards.

It remains even more astonishing that with the benign silence of these usually concerned parties, the protection of women users of IUDs was neglected for over a decade by one Federal agency which has rather specific obligations to deal with the safety of health-related products. The fact that the Food and Drug Administration has never been given specific legislated authority over medical devices is a matter of record, but that seems a mute excuse for inaction.<sup>146</sup>

Several solutions address the problem of removal of a harmful product, such as the Dalkon Shield, from the market. First, Congress can broaden the FDA's powers to include mandatory product recalls. The FDA, in its preamble to the final procedural recall policy, cautioned, "if experience under these regulations proves that administrative recall authority is needed, the Commissioner agrees that the agency should seek it from Congress."<sup>147</sup> Despite this agreement, the FDA has unequivocally opposed such legislation. To overcome this opposition, Congress would either have to amend the enabling statute and provide the agency with additional resources or create a separate administrative agency to regulate in this area.

---

146. *Device Amendments*, *supra* note 54, at 367.

147. 43 Fed. Reg. 26,202, 26,203 (1978).

Second, the intrauterine devices now classified as devices could be reviewed by the FDA and reclassified as drugs. Although this solution has been repeatedly recommended, the FDA remains reluctant to take such action as it may prove to be "problematic."

The courts may provide a third solution. The judiciary could, through their equitable powers, exercise their discretion and order harmful product recalls. This is a relatively simple solution as personal injury litigation is currently being heard within the various court systems. A recall order could serve as an adjunct to such litigation.

State solutions include enacting laws which provide injunctive relief in the form of private consumer remedies, and finally, state legislative action could supplement the FDCA by enumerating controls for device marketing within the state.<sup>148</sup> This appears to be the most viable solution. The creation of new state regulatory bodies to administer such state action would not be necessary, as regulation could readily be assumed by existing state agencies whose functions are to protect the public health.

The objectives of the FDCA will be met only by pursuing one or more of these solutions. Without change, many harmful products will remain in the market unregulated and the FDCA will remain a mere "collection of English words"<sup>149</sup> ineffective in preventing injury to the consumer from hazardous products currently classified as devices.

*Janice Alexander Forgays*

---

148. An example of supplemental state legislation being upheld against a federal preemption challenge is *American Grain Products Processing Institute v. Dept. of Public Health*, 392 Mass. 309, 467 N.E.2d 455 (1984)(the state department of public health adopted a regulation establishing acceptable levels for ethylene dibromide in food; the pertinent federal scheme did not explicitly set a tolerance level).

149. *Datterweich*, 320 U.S. at 280.