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PRODUCT RECALLS: A REMEDY IN NEED OF REPAIR

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The product recall is an effective tool that protects consumers as well as agencies, if public participation is secured promptly. This Article focuses on the recall programs of NHTSA, the FDA, and the CPSC that recall hazardous or unsafe consumer products. The authors propose specific statutory and administrative changes to make federal recall programs more efficient and to enhance public responsiveness. They conclude that coordination and uniformity among agencies is necessary to achieve these goals.

INTRODUCTION

EACH YEAR, manufacturers recall millions of consumer products—ranging from toys and household appliances to drugs and autos—under an array of federal health and safety statutes.¹ Manufacturers undertake most recalls voluntarily, either on their own initiative or at the urging of a federal agency with recall authority.² Extensive use of recalls began in the mid-1960's at the

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1. Levy, *A Record Year For Recalls*, 113 DUN'S REV., Jan. 1979, at 28. Perhaps as many as 50 million products were recalled in 1978. *Id.* In 1982, 4.5 million cars and over 12 million consumer products were recalled (excluding food, drugs, and medical devices). 1983 PROD. SAFETY & LIAB. REP. (BNA) 3.

2. In addition to the three agencies examined in this Article, the other federal agencies primarily involved in product recalls are the Environmental Protection Agency (under

height of the consumer movement and continues, although somewhat abated, in the deregulatory environment of the early 1980's.

The vitality of the recall as an enforcement tool stems from a number of factors. Agencies tend to prefer the recall over enforcement tools such as product seizure or standard setting because it better protects consumers and requires fewer agency resources. In general, firms are motivated to recall products voluntarily to avoid not only the cost of agency enforcement proceedings and possible penalties, but also adverse publicity and product liability claims.

The recall remedy, although valuable as an enforcement tool, is difficult to use effectively. An agency must implement the remedy very promptly if it is to serve its purpose of preventing injury. Further, the agency must implement it in a way that encourages public response, for public participation is essential to effective recalls.

This Article examines the recall programs of three federal agencies: the National Highway Traffic Safety Administration (NHTSA), the Food and Drug Administration (FDA), and the Consumer Product Safety Commission (CPSC). All have active recall programs in the area of unsafe or hazardous consumer products, where effective use of the recall remedy is most needed—and most difficult.

For purposes of this Article, the term "recall" encompasses a variety of post-sale remedial actions by product manufacturers and sellers. These include notifying consumers of problems with products, offering to repair products, and offering to refund or replace products. Each of the three agencies has authority to order at least one of these post-sale remedial actions. In most other respects, however, the recall programs are quite diverse. The standards for ordering recalls, the scope of the remedy, and the administrative procedures of the programs vary among agencies. Some of the differences are statutorily based; others arise from the variety of methods used to implement the programs.

This Article recommends a number of statutory changes aimed

the Clean Air Act, the Toxic Substances Act, and the Federal Insecticide, Fungicide, and Rodenticide Act), the Federal Trade Commission (under the FTC Act), and the Department of Agriculture (under the Meat and Poultry Inspection Act). Minutes of Interagency Meeting on Product Recalls 2 (Mar. 6, 1979) (on file with the *Case Western Reserve Law Review*) [hereinafter cited as Interagency Meeting]. Other agencies involved in recalls include the Department of Housing and Urban Development (under the National Mobile Home Construction and Safety Standards Act), the Federal Aviation Administration (under the Federal Aviation Act), and the United States Coast Guard (under the Federal Boat Safety Act). See *The Mindless Pursuit of Safety*, *FORTUNE*, Apr. 9, 1979, at 54-55.

at improving the agencies' abilities to negotiate recalls and proceed expeditiously when voluntary recalls are not forthcoming. In addition, it recommends more uniformity and coordination among agencies in implementing recall programs and dealing with the public. The broad goal of these recommendations is making better use of agency resources and enhancing public responsiveness to recalls, thereby increasing the overall effectiveness of federal recall programs.

I. NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION

Among the agencies most actively involved in product recalls is NHTSA. The National Traffic and Motor Vehicle Safety Act of 1966 (the Safety Act),³ which granted NHTSA authority to order recalls of defective motor vehicles, was the first statute to contain a recall provision.⁴

Since the enactment of the Safety Act, an extraordinary number of motor vehicles and equipment have been recalled—roughly 133 million product units to date.⁵ As under other statutes, nearly all the recalls have been undertaken voluntarily by manufacturers. And, as is often the case, return rates in response to recalls have been low.

A. Recall Authority: Background

Long before federal safety statutes mandated the recall of automobiles with safety-related defects, the auto industry recalled and repaired vehicles.⁶ The government played no role in these recalls, which manufacturers did not publicize. During this, the era of the so-called "silent recall,"⁷ manufacturers notified their

3. Pub. L. No. 89-563, 80 Stat. 718 (codified as amended at 15 U.S.C. §§ 1381-1431 (1982)). The Safety Act authorizes the Secretary of Transportation to implement the recall provision. 15 U.S.C. § 1412 (1982). The Secretary, however, has delegated this authority to NHTSA. 49 C.F.R. § 501.2(a) (1983).

4. The FDA obtained product recalls for many years before the enactment of the Safety Act but it lacked statutory authority to order recalls. See *infra* notes 307-13 and accompanying text.

5. COMPTROLLER GEN., GOV'T ACCOUNTING OFF., DEPARTMENT OF TRANSPORTATION'S INVESTIGATION OF REAR BRAKE LOCKUP PROBLEMS IN 1980 X-BODY CARS SHOULD HAVE BEEN MORE TIMELY 3 (Aug. 5, 1983) [hereinafter cited as GAO X-BODY REPORT]. The total includes 101.4 million vehicles, 6.9 million replacement items, and 24.6 million tires recalled from 1966 through April 30, 1983. *Id.*

6. The earliest known recall involved the 1903 model Packard and occurred at the turn of the century. Other early recalls involved the 1916 Buick and the 1924 Maxwell. Levy, *supra* note 1, at 117.

7. *Id.*

dealers of defects and how to repair them, without informing car owners.⁸ They left to the dealers the responsibility for owner notification.⁹ Too often, however, owners neither learned of defects nor had them corrected unless they serviced their cars with dealers.¹⁰

By the mid-1960's, manufacturers had recalled a large number of cars.¹¹ About this time, industry members also began improving their product recall procedures, a move stimulated by congressional hearings on auto safety, growing public awareness of the silent recalls, and the large number of vehicles requiring recall.¹² But the industry initiatives came too late to stave off legislation mandating industry recall procedures.

1. *The National Traffic and Motor Vehicle Safety Act of 1966*

In 1966, several members of Congress introduced bills addressing auto safety; however, neither the major House bill¹³ nor the Senate bill¹⁴ contained a recall or defect notification provision. Only after concerns about the industry's failure to notify customers and repair defects surfaced in committee hearings did Congress consider amendments regarding recalls.¹⁵

The amendment ultimately adopted mandated that manufacturers notify initial purchasers of defects, but was silent regarding the manufacturers' duty to repair defects.¹⁶ Congress thought that publicity accompanying defect notifications would, as a practical

8. See Note, *Auto Recalls and the Pursuit of Safety: A Commonsense Approach*, 33 STAN. L. REV. 301, 303 n.9 (1981).

9. *Federal Role in Traffic Safety: Hearings Before the Subcomm. on Executive Reorganization of the Senate Comm. on Gov't Operations*, 89th Cong., 2d Sess. 78 (1973) [hereinafter cited as *Federal Role in Traffic Safety Hearings*].

10. See Note, *supra* note 8, at 303 n.9.

11. *Federal Role in Traffic Safety Hearings, supra* note 9, at 78. From 1960 to 1966, 426 recalls occurred involving over 8.7 million cars or 18.5% of all American cars manufactured during that period.

12. General Motors (GM), for example, began notifying car owners directly of safety defects and offering repairs at no charge. *Id.*

13. H.R. 13,228, 89th Cong., 2d Sess. (1966).

14. S. 3005, 89th Cong., 2d Sess. (1966).

15. Senator Mondale introduced an amendment requiring defect notification to eliminate secret recalls. See 112 CONG. REC. 14,247 (1966). Other proposed amendments required both notification and repair. See 112 CONG. REC. 18,792 (1966).

16. National Traffic and Motor Vehicle Act of 1966, §§ 113(a), (b), Pub. L. No. 89-563, 80 Stat. 718 (current version at 15 U.S.C. § 1411(a) (1982)). The manufacturer was to send the notice by certified mail to the first purchaser or to the second purchaser in the case of a resale when a warranty had been transferred. The notice was to contain a clear description of the defect, an evaluation of the safety risk, and the measures required to repair the defect. *Id.* § 113(c) (current version at 15 U.S.C. § 1413(a) (1982)).

matter, assure free repairs by manufacturers.¹⁷

Following the statute's enactment, the industry practice was to pay for defect corrections.¹⁸ However, in two notable instances, manufacturers did not offer free defect correction. In one case involving over 625,000 Corvairs with defective heaters, GM refused to pay the \$200-per-vehicle repair costs and only 7.6 percent of the owners returned their cars for repairs in response to the recall campaign.¹⁹ In another case involving Volkswagens manufactured from 1949 to 1969, VW also refused to pay for repairs.²⁰ Moreover, it notified only 220,000 of the 3.7 million owners affected, since its records of first purchasers dated back only to 1966, when the Safety Act's recordkeeping requirements took effect.²¹ While there were smaller recall campaigns in which manufacturers refused to pay for repairs,²² the Corvair and VW cases focused Congress' attention on the need for strengthening the recall provisions of the Safety Act.²³

2. *The 1974 Amendments*

In 1974, Congress amended the Safety Act to require manufacturers to remedy safety defects without charge to the owner.²⁴ Addressing the inadequate notice of the VW recall, Congress also required manufacturers to provide defect notifications to all state-

17. *Auto Safety Repairs at No Cost: Hearings on S. 355 Before the Senate Comm. on Commerce*, 93d Cong., 1st Sess. 103 (1973) [hereinafter cited as *Hearings on No Cost Repairs*].

18. The Administrator of NHTSA testified that the industry offered to repair about 90% of the 40 million vehicles recalled between 1966 and 1973. In 10% of the cases, the cost was borne by the owner or shared by the manufacturer and owner. *Id.* at 8.

19. S. REP. NO. 150, 93d Cong., 1st Sess. 7 (1973). In addition to GM's refusal to pay for repairs, several factors contributed to the low rate of return by Corvair owners. First, owners had no assurance that the repairs would last. *Id.* Second, the market value of many of the recalled vehicles had fallen below \$500 by the time GM sent the defect notice in 1971. Finally, the defect notification letter gave mixed signals because NHTSA allowed GM to include a denial that the Corvair was defective. *See Hearings on No Cost Repairs*, *supra* note 17, at 104-05 (testimony of Ralph Nader).

20. S. REP. NO. 150, 93d Cong., 1st Sess. 7 (1973). A set screw in the windshield wiper system would loosen, causing the system to fail without warning.

21. *Hearings on No Cost Repairs*, *supra* note 17, at 17.

22. *See id.* at 341-42.

23. The Senate viewed the two cases as the most "notable instances" in which the auto industry had reneged on its promise to remedy defects at no charge. S. REP. NO. 150, 93d Cong., 1st Sess. 7 (1973).

24. 15 U.S.C. § 1411 (1982). Congress permitted only two exceptions to the repair-at-no-cost requirement. The requirement did not apply to defective vehicles purchased more than eight years before the defect notification was ordered, *id.* § 1414(a)(4), or to a defect determined by NHTSA to be "inconsequential as it relates to motor vehicle safety." *Id.* § 1417.

registered vehicle owners, not only first purchasers.²⁵ Congress hoped that these provisions not only would eliminate the problems exemplified by the VW and Corvair recalls, but also would improve the average response rate for all recall campaigns.²⁶

The 1974 amendments did not achieve the desired effect. Since their passage, owner response rates have dropped to about fifty percent.²⁷ To understand why the recall remedy has not worked as well as Congress had hoped requires a closer look at the nature of the recall authority and its implementation by NHTSA.

B. *Scope of Recall Authority*

The Safety Act provides for the recall of vehicles that do not comply with an applicable federal motor vehicle safety standard²⁸ or contain a "defect" which "relates to motor vehicle safety."²⁹ The courts, in a handful of cases, have interpreted the latter provision to give NHTSA broad recall authority.

1. *The Meaning of "Defect"*

In the leading case defining defect, *United States v. General*

25. *Id.* § 1413(c). If the manufacturer does not notify the registered owner, it must notify the most recent purchaser known to it. *Id.*

26. The purpose of the 1974 amendments was to make it "as attractive and convenient as possible for a consumer to invest the energy and effort to get his or her vehicle fixed." S. REP. NO. 150, 93d Cong., 1st Sess. 7 (1973). At the time, recall response rates averaged 75%. H.R. REP. NO. 1191, 93d Cong., 2d Sess., reprinted in 1974 U.S. CODE CONG. & AD. NEWS 6050-51.

27. GOV'T ACCOUNTING OFF., CHANGES TO THE MOTOR VEHICLE RECALL PROGRAMS COULD REDUCE POTENTIAL SAFETY HAZARDS 15 (1982) [hereinafter cited as GAO RECALL REPORT]. NHTSA's recall rates for 1975 through 1979 are as follows:

1975	54.2%
1976	51.1%
1977	40.1%
1978	50.4%
1979	54.8%
Average:	50.1%

Id. For the past several years, however, return rates have been above average. *See infra* note 134.

28. 15 U.S.C. § 1412 (1982). Section 103 of the 1966 Safety Act, *id.* § 1392, provides for the issuance of motor vehicle safety standards to protect the public against unreasonable risks. Few recalls, however, are based on noncompliance with safety standards. In 1979, for example, only about 49,000 vehicles were recalled because of noncompliance with standards. NHTSA, U.S. DEP'T. OF TRANSP., MOTOR VEHICLE SAFETY 1979, at 45-46 (on file with the *Case Western Reserve Law Review*) [hereinafter cited as 1979 NHTSA ANNUAL REPORT].

29. 15 U.S.C. § 1412 (1982).

Motors Corp. (Wheels),³⁰ the Court of Appeals for the District of Columbia Circuit ruled that a prima facie case of defect is made upon a showing of a significant number of failures during “normal operations,” which includes circumstances of “reasonably foreseeable” owner misuse.³¹ Proof of a significant number of failures (other than those due to age or expected wear and tear), the court held, creates a presumption that the failures occurred in normal use.³² The manufacturer can only rebut the presumption by establishing an affirmative defense that the failures were due to “gross and unforeseeable” owner abuse or neglect.³³ As thus broadly interpreted by the court, defect means only that the vehicle failures must be systematic and not isolated incidents.

2. *The Meaning of “Motor Vehicle Safety”*

The Safety Act’s requirement that the defect “relate to motor vehicle safety” limits the types of defects which trigger recall to those posing an “unreasonable risk” of accident or injury.³⁴ The concept of unreasonable risk, however, is not defined by the statute, and the legislative history suggests little more than that it requires a “commonsense”³⁵ balancing of safety benefits and

30. 518 F.2d 420 (D.C. Cir. 1975). The case involved the failure of Kelsey-Hayes wheels in GM pickups. At the time of trial 436 wheel failures had been reported to NHTSA. *Id.* at 430. GM argued that the wheels were not defective and the failures were due to owner misuse in overloading the trucks contrary to GM’s instructions. *Id.* at 426.

31. *Id.* at 427. After examining the legislative history, the court concluded that Congress intended the statute to provide protection broad enough to cover even “lackadaisical” car owners who, for example, neglected regular car maintenance. *Id.* at 434.

32. *Id.* at 438. The court did not require the government to pinpoint the cause of the failures. *Id.* at 427. Nor did the court quantify the term “significant,” except to say that it was more than de minimis but need not be a substantial percentage of the total number of units. “Significant” would be determined case by case, based on the failure rate of a component compared to the rates of similar components, and the seriousness of the risk posed by the failures. *Id.* at 438 n.84.

33. *Id.* at 438. The court’s example of an unforeseeable use—loading a ¾-ton truck with 12,000 pounds—indicates the difficulty the defendant faces in proving widespread unforeseeable use. *Id.* at 438-39 n.88.

34. The Safety Act defines “motor vehicle safety” as

the performance of motor vehicles or motor vehicle equipment in such a manner that the public is protected against *unreasonable risk* of accidents occurring as a result of the design, construction or performance of motor vehicles and is also protected against *unreasonable risk* of death or injury to persons in the event accidents do occur, and includes nonoperational safety of such vehicles.

15 U.S.C. § 1391(1) (1982) (emphasis added).

35. *Traffic Safety: Hearings on S. 3005 Before the Senate Comm. on Commerce*, 89th Cong., 2d Sess. 56 (1966). Although ill-defined, the term “motor vehicle safety” was considered one of the “critical” definitions delimiting the bill’s scope. S. REP. NO. 1301, 89th Cong., 2d Sess. 6, *reprinted in* 1966 U.S. CODE CONG. & AD. NEWS 2713.

economic costs. The courts have interpreted the unreasonable risk requirement liberally to promote the statute's safety aims.

In the leading case of *United States v. General Motors Corp. (Pitman Arms)*,³⁶ the Court of Appeals for the District of Columbia Circuit ruled in a brief per curiam opinion that a defect "relating to motor vehicle safety" existed in the steering pitman arm of the 1959-60 Cadillac. The court based its finding on the government's showing that the manufacturer had replaced many more pitman arms for that model year than for adjacent model years, and failures could cause the driver to lose control of the car.³⁷ On these uncontradicted facts, the court reversed a denial of the government's summary judgment motion.³⁸ The government had demonstrated neither injury nor death resulting from pitman arm failures.³⁹ General Motors argued that the defect posed no unreasonable risk because failures only occurred at low speeds and so few 1959-60 Cadillacs were still in use that the risk of injury was minimal.⁴⁰ The court of appeals found that the government's evidence of one pitman arm failure, creating a dangerous situation, plus expert testimony on the danger of a sudden loss of steering even at low speeds,⁴¹ not only established a prima facie case of unreasonable risk, but also overcame GM's evidence as a matter of law.⁴²

The same court of appeals took a similar approach in *United*

36. 561 F.2d 923 (D.C. Cir. 1977), *cert. denied*, 434 U.S. 1033 (1978).

37. *Id.* at 924.

38. *Id.* The district court had denied summary judgment to both parties. 65 F.R.D. 115 (D.D.C. 1974).

39. Sixty-four "confirmed" instances of pitman arm failures and two "reportable accidents" occurred. *Id.* at 937 (Leventhal, J., dissenting in part). However, this could represent a "minuscule sample" of the failures in light of the large number of replacement part sales. *Id.*

40. GM had forecast less than a one percent chance of a fatality and only two possible injuries for those 1959-60 Cadillacs still in use over their remaining three-year life expectancy. *Id.* at 936.

41. The government presented direct testimony of one driver who had experienced a steering loss during a 90-degree turn at 10-15 miles per hour. An expert testified that while the median reaction time to a brake failure was 1.6 seconds, a pitman arm failure during a 5-mile-per-hour, 90-degree turn could cause the car to enter the opposing traffic lane in only 1.5 seconds. *Id.* at 927.

42. *But see id.* at 938 (Leventhal, J., dissenting in part). Judge Leventhal believed that the majority had improperly elevated facts giving rise to a "strong suspicion" of dangerousness to a "conclusive presumption" that the defect posed an unreasonable risk. He would have remanded the case on the grounds that the district court had erred in allocating the burden of proof. On remand, he would have permitted GM to dispel the "strong suspicion" that the defect was dangerous with proof that the failures did not occur in dangerous situations and thus the risk was inconsequential. *Id.*

States v. General Motors Corp. (Quadrajel), which involved risks of underhood fires caused by defective carburetor fuel plugs.⁴³ In upholding the district court's grant of summary judgment for the government, the court ruled that even if GM's risk analysis—showing negligible future failures, less than one injury, and no deaths—was valid, it would not defeat the government's case.⁴⁴ The court found that even an "exceedingly small" number of injuries from this admittedly defective and clearly dangerous carburetor appeared to be "unreasonably large."⁴⁵

In theory, these cases give NHTSA expansive authority to order recalls even where safety-related defects pose minimal risk. In practice, however, the Agency's authority is more limited. An examination of NHTSA's implementation of the recall program reveals some of these limits.

C. Implementing the Recall Authority

1. Finding the Defects

NHTSA learns of possible safety-related defects in a variety of ways. It may discover defects through its own vehicle testing⁴⁶ or through service bulletins that the Agency requires manufacturers to submit.⁴⁷ Perhaps the most important source of information is its Auto Safety Hotline, which receives some 500 calls a day.⁴⁸ To obtain further information, NHTSA sends follow-up questionnaires to callers complaining about possible defects. The Agency

43. 565 F.2d 754 (D.C. Cir. 1977). Six hundred sixty-five incidents of underhood fires had been reported, and GM had conceded the existence of a "defect" in its carburetors. *Id.* at 756.

44. *Id.* at 758. One reason for GM's anticipation of few additional incidents was that the administrative and litigation phases of the case had consumed so much time that many of the cars involved were no longer in use or the problem had corrected itself. *Id.* The court was necessarily reluctant to relieve the manufacturer of its statutory duty on this basis; to do so would "establish a system which encourages manufacturers to delay proceedings whenever possible . . ." *Id.* at 759.

45. *Id.* at 759.

46. NHTSA tests a sampling of vehicles and equipment to determine compliance with safety standards. 1979 NHTSA ANNUAL REPORT, *supra* note 28, at 45. Few recalls, however, result from noncompliance testing. *See supra* note 28.

47. 15 U.S.C. § 1418(a)(1) (1982) requires manufacturers to supply NHTSA with copies of all notices to dealers and purchasers "regarding any defect or failure to comply [with a standard]." NHTSA's regulations require manufacturers to submit all service bulletins and other communications with dealers, distributors, etc., regarding any defect or flaw "whether or not [it] is safety-related." 49 C.F.R. § 573.8 (1983). This requirement provides NHTSA with general information about potential defects that may warrant further investigation.

48. *See* 1979 NHTSA ANNUAL REPORT, *supra* note 28, at 44; GAO RECALL REPORT, *supra* note 27, at 30-31.

stores the responses and complaint letters it receives—which may number 3,000 a month—in a computerized database that can identify trends and give the Agency early warning about possible safety-related defects.⁴⁹ Many defect investigations and subsequent recalls originate with consumer complaints.⁵⁰

Another important source of information about defects is the manufacturer. As in other recall programs, manufacturers are statutorily obligated to report defects and are subject to civil penalties for failing to do so.⁵¹ The reporting requirement, however, has not been as important a factor in initiating recalls under the Safety Act as it has been under other acts,⁵² and the civil penalty provision is largely unused.⁵³ This is because the Safety Act's reporting provision is narrower than others and does not require reporting of potential problems that "could create" a serious hazard.⁵⁴ The reporting obligation arises only when the manufacturer has determined "in good faith" that a defect relates to motor vehicle safety and the statute requires a recall.⁵⁵ Under this standard, manufacturers do initiate numerous recalls,⁵⁶ but these are generally on a smaller scale. The large-scale recalls are initiated primarily by the government on the basis of consumer

49. GAO RECALL REPORT, *supra* note 27, at 30-31.

50. Telephone Interview with David Allen, Office of General Counsel of NHTSA, in Washington, D.C. (July 14, 1983) [hereinafter cited as Allen Interview].

51. Failure to notify NHTSA and recall defective products under 15 U.S.C. § 1411 (1982) are prohibited acts under § 1397(a)(1)(D) (1982), which subjects violators to civil penalties up to \$800,000. 15 U.S.C. § 1398(a) (1982).

52. In the CPSC's program, manufacturers' reports have been key factors in initiating recalls. *See infra* note 209 and accompanying text.

53. Allen Interview, *supra* note 50. Penalties were assessed in the Toyota Hilux Pickup shimmy recall case, however, and NHTSA threatened additional penalties if the manufacturer did not agree to undertake the recall expeditiously. Interview with Raymond A. Peck, Jr., former Administrator, NHTSA, in Washington, D.C. (Oct. 4, 1983) [hereinafter cited as Peck Interview].

54. 15 U.S.C. § 1411 (1982). Compare the Safety Act's requirement with that of the Consumer Product Safety Act, excerpted *infra* note 211.

55. Section 151 of the Safety Act provides:

If a manufacturer—

(1) obtains knowledge that any motor vehicle or item of replacement equipment manufactured by him contains a defect and determines in good faith that such defect relates to motor vehicle safety . . . he shall furnish notification to the Secretary and to owners, purchasers, and dealers . . . and he shall remedy [by repair, refund, or replacement] the defect

15 U.S.C. § 1411 (1982). The provision also calls for reporting noncompliance with safety standards and recalling those products as well. *See id.*

56. Tobin, *Recalls and the Remediation of Hazardous or Defective Consumer Products: The Experience of the Consumer Product Safety Commission and the National Highway Traffic Safety Administration*, 16 J. CONS. AFF. 278, 288 (1982). Between 1966 and 1981, 3,265 auto recalls occurred, 83.4% of which were manufacturer initiated. *Id.*

complaints.⁵⁷

NHTSA may not need to rely as heavily as other agencies upon manufacturer-supplied defect information, inasmuch as vehicle owners do complain and thus provide the Agency with a good database. Nevertheless, Congress should strengthen the Safety Act's reporting requirement. A provision resembling that of the Consumer Product Safety Act⁵⁸ or one imposing an affirmative obligation to report specific data such as warranty claims and product liability suits,⁵⁹ would improve agency efficiency and effectiveness. With a stronger provision, NHTSA would receive information about possible defects that complainants do not report.⁶⁰ Moreover, a more stringent requirement would reduce agency time and resources required to gather defect information.⁶¹ This benefit is especially important if the remedy is to work, because of the need for dispatch in recall cases.⁶² Additionally, the need for agency cost-cutting makes this benefit important.⁶³ Sanctions for failure to report would generate an additional benefit. As the CPSC has learned, an agency can use the threat of substantial timeliness penalties to induce otherwise recalcitrant manufac-

57. *Id.* at 289. Between 1966 and 1981, the number of vehicles in manufacturer-initiated recalls averaged 17,738, compared with 90,306 for government-initiated recalls. Over half of the vehicles recalled were in government-initiated recalls. *Id.*

58. See *infra* note 211.

59. For example, Congress could require manufacturers to notify NHTSA of lawsuits in which a defect is claimed, or to provide information on warranty claims which arise frequently enough to indicate a possible pattern of defect. Interview with Clarence M. Ditlow III, Director of the Center for Auto Safety, in Washington, D.C. (Sept. 29, 1983) [hereinafter cited as Ditlow Interview]. According to former NHTSA Administrator Peck, however, increased reporting requirements would add little additional information, since NHTSA is able to obtain all necessary data regarding warranty claims, consumer complaints, product liability suits, etc., by requesting it from the manufacturer early in the investigation of a potential problem. See Peck Interview, *supra* note 53. One difficulty with this view is that NHTSA may lack sufficient information to prompt it to request data from the manufacturer.

60. Car owners may have no reason to inform NHTSA about problems with products covered by warranty, even though they may indicate a defect, if the manufacturer or dealer satisfactorily and promptly resolves warranty claims. Ditlow Interview, *supra* note 59.

61. Although NHTSA seeks information from the manufacturer early in an investigation, see *supra* note 59, some manufacturers have construed NHTSA's requests narrowly and have failed to provide the necessary information. Additional requests or negotiations are then required. Ditlow Interview, *supra* note 59. This process could be streamlined by expanding the manufacturer's reporting obligation.

62. The longer the delay in issuing the recall notice, the less effective the remedy becomes. See *infra* notes 92-95 and accompanying text.

63. The Reagan Administration has made significant cuts in NHTSA's budget. Funding of NHTSA's defect investigation and enforcement activities, however, has remained at about the same level. Peck Interview, *supra* note 53.

turers to undertake comprehensive product recalls.⁶⁴

2. *The Investigation Stage*

An automobile is a complex product with roughly 14,000 parts.⁶⁵ Thus, NHTSA's investigation of a potential safety defect can be complex and lengthy. While a manufacturer may agree to recall vehicles at any time during an investigation,⁶⁶ in the absence of voluntary recall NHTSA follows certain defect-investigation procedures. When it has grounds to believe that a safety-related defect exists, the Agency first undertakes an "informal inquiry"—a limited investigation consisting of meetings and telephone conversations with the car manufacturer to identify the problem.⁶⁷ If NHTSA decides to proceed further, it then undertakes an engineering analysis of the problem. Early in this stage, it sends the manufacturer an information request letter seeking detailed information about the item in question.⁶⁸ The staff examines other data as well, and may perform tests to determine the cause and scope of the problem.⁶⁹ This stage often takes years to complete. A notorious example is NHTSA's recent analysis of GM's X-body rear brake lockup problem, which spanned nineteen months.⁷⁰ Critics have attributed the overall delay to the Agency's past practice of opening more engineering analyses than were warranted or than it could handle.⁷¹ A broader initial defect

64. See *infra* notes 214-16 and accompanying text.

65. *Recalls: Why They Occur, How to Answer One on Your Car*, NEW REPUBLIC, Dec. 5, 1983, at 6 (General Motors' advertisement) [hereinafter cited as *GM Recall Advertisement*].

66. Diltow Interview, *supra* note 59. The manufacturer may decide to recall before an investigation is begun or in the preliminary stages of an investigation.

67. J. CLAYBROOK, J. GILLAN & A. STRAINCHAMPS, REAGAN ON THE ROAD: THE CRASH OF THE U.S. AUTO SAFETY PROGRAM 62 (Sept. 1982) [hereinafter cited as *AUTO SAFETY REPORT*]. The "informal inquiry" is a recent Agency creation designed to permit informal and prompt investigation of some problems without first undertaking an engineering analysis. Peck Interview, *supra* note 53.

68. GAO X-BODY REPORT, *supra* note 5, at 40.

69. GAO RECALL REPORT, *supra* note 27, at 31. NHTSA staff examines hotline complaints, accident reports, and the manufacturer's service bulletins. *Id.*

70. See GAO X-BODY REPORT, *supra* note 5, at 8-9. The engineering analysis was inactive for 13 months from November 1979 to December 1980. Transmittal of the information request letter, which agency guidelines require during the first two weeks of the engineering analysis, did not occur until May 1980. *Id.*

71. GAO RECALL REPORT, *supra* note 27, at 6-7. The ratio of about one recall to every five engineering analyses undertaken may indicate that the Agency opens analyses on the basis of too few complaints. The use of informal inquiries may reduce the number of engineering analyses that NHTSA must open. See *supra* note 67. *But see* *AUTO SAFETY REPORT*, *supra* note 67, at 63 (favoring engineering analyses as "essential tools for consumer groups and engineering firms interested in getting defects corrected").

reporting requirement, as recommended earlier, might alleviate the problem somewhat, since NHTSA could then employ fewer engineering analyses for purposes of obtaining defect information from manufacturers.⁷²

Following the engineering analysis, an NHTSA review panel composed of staff from the Office of Defects Investigation and the Chief Counsel's Office determines whether a formal defect investigation should be opened.⁷³ If NHTSA chooses formal investigation, it notifies the manufacturer, issues a press release to inform and solicit information from the public,⁷⁴ and collects further data.⁷⁵ It may also conduct additional tests, interview vehicle owners, and gather tangible evidence such as vehicle parts, to establish legally and technically that a defect is safety related.⁷⁶ This stage also may be lengthy, especially when the defect is difficult to uncover.⁷⁷

3. *Administrative and Judicial Proceedings*

At the close of a formal investigation, staff members prepare an investigative report for the Chief Counsel and recommend either making an initial determination of defect or closing the case.⁷⁸ If they recommend a defect determination and the Chief Counsel and Deputy Administrator concur, the NHTSA notifies the manufacturer of the determination and publishes a public notice in the *Federal Register*.⁷⁹ During the final stage of the administrative process, the manufacturer may dispute the initial determination of defect in a public administrative hearing.⁸⁰ If the determination is reaffirmed, the Agency orders the manufacturer to notify vehicle owners and dealers of the defect and provide a remedy without charge.⁸¹ The notice must include a

72. Lack of information has been one impetus for NHTSA's numerous informal inquiries and engineering analyses. Ditlow Interview, *supra* note 59.

73. See 49 C.F.R. §§ 554.1-11 (1983).

74. In a number of recent instances, NHTSA did not issue a press release although the regulations call for one. Ditlow Interview, *supra* note 59.

75. *Id.*; see GAO RECALL REPORT, *supra* note 27, at 32.

76. GAO X-BODY REPORT, *supra* note 5, at 41; see also 49 C.F.R. § 554.5 (1983).

77. See, e.g., GAO X-BODY REPORT, *supra* note 5, at 50-63 (describing some technical problems involved in testing for rear brake lockup in GM's X-body cars).

78. *Id.* at 41-42.

79. *Id.* at 42; see 15 U.S.C. § 1412(a) (1982).

80. 15 U.S.C. § 1412(a)(2) (1982). At the hearing, the manufacturer and interested persons may present data and arguments regarding the initial defect determination or non-compliance with a standard, but no right to cross examination exists. Regulations governing the public hearing are set forth at 49 C.F.R. § 554.10(b)-(d) (1983).

81. 15 U.S.C. § 1412(b) (1982).

description of the defect, an evaluation of the risk, and information on how and when the defect will be remedied.⁸²

If the manufacturer does not comply with the recall order, the government may bring an enforcement action in federal district court.⁸³ Review is *de novo*, with the burden on the government to establish the existence of a safety-related defect.⁸⁴ The district court will order the recall if the government prevails, and in some instances may impose civil penalties on the manufacturer.⁸⁵

If a manufacturer knew of a safety-related defect but failed to recall the affected product, NHTSA may bypass the administrative hearing and seek a court-ordered recall directly.⁸⁶ The government recently took this approach in a proceeding against General Motors. Among the allegations is GM's failure to recall all 1980 X-body cars despite knowledge that the braking system was defective.⁸⁷ GM moved to dismiss, arguing that the government could not proceed in district court without first having conducted an administrative hearing; the court rejected this contention in denying the motion.⁸⁸ Nevertheless, cases of bad faith which would justify bypass of the administrative hearing are likely to be rare and hard to prove.

Generally, NHTSA must resort to a two-tiered procedural

82. *Id.* § 1413(a)(1)-(3) (1982). The notice must also describe consumer complaint procedures in the event the manufacturer fails to remedy the defect without charge. *Id.* § 1413(a)(6).

83. *Id.* §§ 1415(a), 1399(a).

84. *See* *United States v. General Motors Corp.*, 518 F.2d 420, 426 & n.7 (D.C. Cir. 1975). NHTSA may require the manufacturer to issue a provisional notification of defect while the civil action is proceeding. 15 U.S.C. § 1415(b) (1982).

85. 15 U.S.C. § 1415(c)(1) (1982). The manufacturer's failure to comply with an administrative recall order is a prohibited act under the statute which can subject the violator to civil penalties up to \$800,000 for a related series of violations. *Id.* §§ 1397(a)(1)(D), 1398(a).

86. Section 151 of the Safety Act provides that if the manufacturer obtains information that a defect exists and determines in "good faith" that it is safety related, it must notify NHTSA and recall the product. *Id.* § 1411; *see supra* note 55 (text of § 151). Failure to comply with this requirement is a direct statutory violation which a court may enjoin. *See id.* §§ 1397, 1399.

87. Complaint for Declaratory and Injunctive Relief and for Civil Penalties at 3, *United States v. General Motors Corp.*, No. 83-2220 (D.D.C. filed Aug. 3, 1983) (alleging (1) that before beginning production GM knew "or in good faith should have determined" that the braking system on 1980 X-body cars was defective; (2) that GM's 1981 and 1983 recalls were inadequate; and (3) that GM provided false statements to NHTSA during its investigation). The government seeks recall of about 1.1 million 1980 X-body cars and over \$4 million in civil penalties. *Id.* at 10-13. For a further description of the claims, see GAO X-BODY REPORT, *supra* note 5, at 30.

88. *United States v. General Motors Corp.*, [1983] PROD. SAFETY & LIAB. REP. (BNA) 941-42 (D.D.C. Dec. 1, 1983).

scheme requiring both an agency hearing and a trial de novo in district court. The process is time consuming even when it works smoothly, which often it does not. Delays at the investigation stage are not uncommon.⁸⁹ The manufacturer also has an inducement to delay the administrative process, since the statute of limitations on the no-charge repair requirement relieves the manufacturer of the obligation to repair defective vehicles more than eight years old at the time of defect notification.⁹⁰ If a case progresses through both administrative and judicial proceedings, it can easily span five or more years.⁹¹ At that point, an effective recall is unlikely, since most injuries already have occurred. Furthermore, experience has shown that the rate of consumer response to recalls drops as vehicles age. In *Quadrajet*, for example, the court noted that by the time defect notification was ordered, most, if not all, defect-related injuries had already occurred.⁹² The cars at issue in *Pitman Arms* were nearly twenty years old by the time the court of appeals ruled in favor of the government;⁹³ at the time of the *Wheels* decision the vehicles involved were ten to fifteen years old.⁹⁴ Not surprisingly, the response rates to the recalls in NHTSA's litigated cases have been low—ranging from 8 percent to 20.5 percent.⁹⁵

4. *Implementation through Negotiation*

The vast majority of recalls are manufacturer initiated or negotiated by NHTSA without litigation.⁹⁶ The time-consuming

89. See GAO RECALL REPORT, *supra* note 27, at 10-11.

90. See *supra* note 24; see also Ditlow Interview, *supra* note 59.

91. GAO RECALL REPORT, *supra* note 27, at 6, 45-46. NHTSA's litigated cases have taken from 67 to 86 months to complete. Even in relatively uncomplicated cases, the litigation phase alone can take three years, as in the case of defective windshield wipers in Mercury Capris which Ford did not appeal. Affidavit of Lynn L. Bradford, Associate Administrator for Enforcement of NHTSA, Joint Appendix at 335, *Center for Auto Safety, Inc. v. Lewis*, 685 F.2d 656 (D.C. Cir. 1982) [hereinafter cited as Bradford Affidavit]. In *Center for Auto Safety*, the court upheld NHTSA's decision to settle rather than litigate, in part because litigation would have taken at least four years. 685 F.2d at 663.

92. 565 F.2d 754, 758 (D.C. Cir. 1977).

93. 561 F.2d 923, 924 (D.C. Cir. 1977). The case involved 1959-60 Cadillacs. By 1974, an estimated 96% of the model's service life had expired. *Id.* at 935.

94. 518 F.2d 420, 427 (D.C. Cir. 1975) (involving trucks manufactured from 1960 to 1965).

95. See GAO RECALL REPORT, *supra* note 27, at 6, 46.

96. Aside from a few early litigated cases, brought to establish the Safety Act's parameters, NHTSA has seldom used litigation to enforce the statute. GAO RECALL REPORT, *supra* note 27, at 46. The last trial under the recall provision occurred in 1978 and the last suit brought following an administrative hearing was filed in 1980 and settled in 1981. Allen Interview, *supra* note 50. The recent GM X-body case is therefore unusual not only

procedural scheme provides the Agency with a strong incentive to settle its cases.⁹⁷ In addition, manufacturers' concerns about adverse publicity and risks of product liability claims encourage them to seek a prompt accord.⁹⁸

a. *Inducements to Recall.* Adverse publicity is of prime concern to manufacturers.⁹⁹ When a manufacturer resists a recall request and NHTSA pursues its investigation, considerable publicity may occur, causing an adverse effect on sales.¹⁰⁰ Ford Motor Company recently acknowledged that although two recent recalls hurt its image, to have moved slowly or not at all would have been far more damaging to the company's reputation.¹⁰¹ Another inducement to manufacturer-initiated recalls is the risk of product liability claims, another major concern for manufacturers.¹⁰² A prompt recall can prevent injuries and thus reduce, although not eliminate entirely, product liability claims.¹⁰³ Furthermore, if a manufacturer fails to recall a defective product promptly, it may be liable for punitive damages.¹⁰⁴

because of the legal issues raised, see *supra* note 87 and accompanying text, but also because such litigation is rare.

97. Peck Interview, *supra* note 53. In the Fiat premature rust case, for example, NHTSA sought settlement after years of administrative and judicial proceedings, in part because the defective cars were 11 years old and the recall was rapidly becoming an ineffective remedy. In the end, the parties abandoned recall and repair in favor of repurchasing the cars at their retail price on the date proceedings commenced. *Id.*; see also *infra* note 122 and accompanying text (discussing Ford transmission case).

98. See *infra* notes 99-104 and accompanying text.

99. Panel Discussion, Recalls: FDA, CPSC, NHTSA, and Products Liability Considerations, ABA Annual Convention in Atlanta, Georgia (Aug. 2, 1983) (attended by author Schwartz) [hereinafter cited as ABA Panel Discussion].

100. See Brown, *Industry on the Rebound: Detroit Has Learned Some Hard Lessons*, Wash. Post, Mar. 27, 1983, at F1, col. 4 (indicating that publicity surrounding NHTSA's investigation of X-body braking defects had caused sales to drop sharply in a single year). *But see infra* note 109 (recalls may not affect market share). GM recently announced plans to discontinue all X-body cars by 1986. Chicago Tribune, Feb. 16, 1984, at 4-1, col. 1.

101. *Ford Finds Recall a Better Idea for Flaws*, Wash. Post, Mar. 13, 1983, at F1, col. 1.

102. See, e.g., Address by James T. O'Reilly, Proctor & Gamble Co., to Chemical Specialties Manufacturers Association (May 21, 1983), reprinted in [1983] PROD. SAFETY & LIAB. REP. (BNA) 321 (urging manufacturers to recall defective products quickly and efficiently to limit product liability claims).

103. Not all car owners receive the recall notice, and many of those who do fail to respond. Moreover, receipt of a notice may not be adequate proof that an owner assumed the risk. See *infra* notes 151-54 and accompanying text (describing inadequacies of recall letters).

104. A manufacturer who has learned of a dangerous defect and fails to correct it may incur liability for punitive damages. See *Gillham v. Admiral Corp.*, 523 F.2d 102 (6th Cir. 1973).

b. *Inducements Not to Recall.* The same factors that encourage recalls also can work to discourage them. For example, once a manufacturer has recalled a product, its product liability exposure may actually increase. In a product liability trial, evidence of the recall campaign may be admissible to show that the automobile in question was defective when it left the manufacturer.¹⁰⁵ Furthermore, the publicity accompanying recalls often increases the number of claims by informing those who have had accidents involving recalled vehicles that the defect may have caused the mishap.¹⁰⁶ Thus, in situations where a recall would be large and expensive and anticipated product liability suits few, paying the claimants may cost less than a recall.¹⁰⁷ In these instances, the threat of product liability claims provides little inducement to recall. Finally, publicity may discourage recalls by giving a possible edge to competitors—they may use the manufacturer's recall rate to disparage its products, as demonstrated by a recent advertisement touting Chrysler's relatively low recall rate.¹⁰⁸ While manufacturers may overestimate the adverse impact of recall-related publicity,¹⁰⁹ this concern nevertheless deters them from reporting defects and undertaking voluntary recalls.¹¹⁰

105. *E.g.*, *Kane v. Ford Motor Co.*, 450 F.2d 315, 316 (3d Cir. 1971); *Manieri v. Volkswagenwerk A.G.*, 376 A.2d 1317, 1322 (N.J. Super. Ct. App. Div. 1977). *But see* *Vockie v. General Motors Corp.*, 66 F.R.D. 57 (E.D. Pa.), *aff'd*, 523 F.2d 1052 (3d Cir. 1975); *Landry v. Adam*, 282 So. 2d 590 (La. Ct. App. 1973). One court has reasoned that given the millions of recall letters each year, refusing to admit evidence of the recall would be prejudicial to the plaintiff, since "failure to mention the letters might cause jurors to believe the claimed defect was a solitary one and did not in fact exist." *Barry v. Manglass*, 55 A.D.2d 1, 11, 389 N.Y.S.2d 870, 877 (1976).

106. ABA Panel Discussion, *supra* note 99. Firms expect the number of product liability claims involving a recalled product to jump markedly soon after the recall announcement. *Id.*

107. In a pending case involving the potential recall of 5.3 million GM cars with allegedly defective rear axles, the company has estimated that the \$125 million recall would prevent some 16 injury-causing accidents—roughly \$8 million in recall costs for each injury. *Wall St. J.*, May 5, 1983, at 4, col. 2. If these projections are correct, they may suggest to GM that paying the product liability claims would be less costly than recall.

108. *N.Y. Times*, Sept. 27, 1983, at A23, col. 1. Chrysler claimed in a full-page advertisement that it had recalled only 6% of its 1982-83 models compared with Ford's 26% and GM's 12%. GM responded with a full-page advertisement on its recall program, explaining that recalls by the nation's largest auto producer may be more noticeable. *See GM Recall Advertisement*, *supra* note 65.

109. *See* *Wayne & Hoffer, Auto Recalls: Do They Affect Market Share?*, 8 *ECON.* 157 (1976) (concluding that unless recalls are highly concentrated in a short period of time, they have little impact on market share); *see also* *Wall St. J.*, Oct. 5, 1983, at 31, col. 4 (describing Subaru's popularity despite the fact that Subaru has recalled more cars than it has sold).

110. *Cf. infra* note 223 and accompanying text (publicity deters defect reporting).

c. *Resisting Settlement: The Ford Transmission Case.* On the whole, the informal negotiation process yields satisfactory results. If, however, a manufacturer refuses a recall request and exhibits a willingness to avoid recall by fully exhausting available administrative and judicial procedures, NHTSA has, as a practical matter, no satisfactory recourse. Absent recall, existing procedures do not provide an effective remedy.¹¹¹ The Agency can close the case¹¹² or try to negotiate a remedy short of a recall, but these solutions do not effectively further the aims of the Safety Act.

A case in point is NHTSA's recent settlement with Ford Motor Company. The case involved some twenty-three million Ford automobiles equipped with automatic transmissions manufactured between 1966 and 1979.¹¹³ An alleged defect in the transmissions caused them to slip out of park into reverse—which in turn caused sudden, unexpected rearward movement of the cars, commonly when drivers were outside.¹¹⁴

The Ford transmission case began when the Center for Auto Safety forwarded two consumer complaints to NHTSA.¹¹⁵ The Agency conducted a thirty-month investigation¹¹⁶ during which it received over 23,000 reports of park-to-reverse incidents.¹¹⁷ It made an initial determination of a safety-related defect and held a three-day public hearing.¹¹⁸ Ford consistently maintained that its

111. See *supra* notes 89-93 and accompanying text.

112. The Agency has closed several cases after unsuccessfully urging recalls. Wall St. J., June 16, 1983, at 1, col. 6. Former NHTSA Administrator Peck explained, however, that NHTSA often urged manufacturers to undertake recalls before completing a thorough investigation. If the company agrees to recall, the Agency has saved resources; if it does not, further investigation may reveal no grounds for a recall and the case will be closed. Peck Interview, *supra* note 53.

113. N.Y. Times, Mar. 7, 1983, at A11, col. 1. The figure represents nearly 20% of all vehicles on the road. Center for Auto Safety, Inc. v. Lewis, 685 F.2d 656, 660 (D.C. Cir. 1982).

114. 685 F.2d at 657.

115. See Letter from Clarence M. Ditlow III, Director of the Center for Auto Safety, to Joan Claybrook, Administrator of the NHTSA (July 6, 1977) (on file with the *Case Western Reserve Law Review*).

116. The investigation has been characterized as "the largest and most difficult and complex . . . ever conducted by NHTSA." Bradford Affidavit, *supra* note 91, at 333. It encompassed six different automatic transmissions on all Ford makes and models from 1970 through 1979. *Id.* at 333-34.

117. The complaints derived from a variety of sources such as state and local consumer groups, individual vehicle owners, and police reports. They also resulted from NHTSA surveys of vehicle fleet owners (police departments and commercial and government fleet operators) and persons who had called the Agency's hotline. Brief for Plaintiffs-Appellants at 5 n.1, *Center for Auto Safety*, 685 F.2d 656.

118. Brief for Appellees at 7-9, *Center for Auto Safety*. Following the public hearing, NHTSA Administrator Claybrook intended to make a final determination that vehicles

vehicles were not defective and refused to recall them.¹¹⁹ Since over ninety percent of its automatic transmission cars made between 1966 and 1979 were involved, a recall would have cost about \$130 million.¹²⁰ Ford left little doubt that it would fight the recall vigorously at every stage of the lengthy process.¹²¹

NHTSA settled the case without negotiating a recall. Among the prominent factors leading to its decision were the time required to pursue the case¹²² and the drain on agency resources that litigation would create.¹²³ Under the terms of the settlement, Ford was to mail vehicle owners a letter informing them of NHTSA's defect determination, along with a self-sticking warning label to affix to their dashboards. The label reminded drivers to put the gear in park, set the parking brake, and turn off the ignition before leaving the driver's seat.¹²⁴

Consumer advocates unsuccessfully challenged the settlement. The Court of Appeals for the District of Columbia Circuit upheld the settlement, ruling that the Safety Act did not compel the recall

containing four of the six transmission types investigated were defective. This would have required Ford to recall some 10 million vehicles. Memorandum from Joan Claybrook to the Secretary of the Department of Transportation 1 (Oct. 3, 1980), *reprinted in* Joint Appendix at 293, *Center for Auto Safety*. Regarding vehicles equipped with the remaining two types, the Administrator intended to negotiate with Ford before making a final determination because the remedy was simpler and settlement was a possibility. *Id.* at 15, Joint Appendix at 307. Neither the Secretary nor the Administrator had made a formal final determination of defect when the case was settled. *See infra* notes 122-24 and accompanying text.

119. Ford contended that no mechanized defect existed, that the transmission slippage was caused by vehicle operators and occurred no more frequently in Ford cars than others, and that the number of reported failures was exaggerated due to NHTSA's publicizing of the cases. *See* Brief for Appellees at 9 and Joint Appendix at 138-82, *Center for Auto Safety*.

120. N.Y. Times, Mar. 7, 1983, at A11, col. 1.

121. Ford had stated throughout the process that it would seek judicial review of a recall order. During the administrative hearing, it had sought preenforcement judicial review of the investigation. Its suit was dismissed by stipulation. Brief for Appellees at 9, *Center for Auto Safety*.

122. NHTSA estimated that the enforcement action would take at least four years, during which about six million of the defective vehicles would be retired from service. Bradford Affidavit, *supra* note 91, at 335-36.

123. The amount of time devoted by NHTSA's engineering staff to this one case impaired investigations of other defects. In the six months before settlement, six members of NHTSA's professional investigation staff worked full time and 10 spent 30% of their time on the Ford investigation. *Id.* at 334. Another factor was that proof of a safety-related defect was made difficult because drivers' actions were a key factor in the vehicle malfunctions. *Center for Auto Safety*, 685 F.2d at 663. *But see supra* text accompanying notes 30-33 (discussing *Wheels*). A defect may be found where significant failures occur in "normal operations," a term that includes reasonably foreseeable operator misuse.

124. 685 F.2d at 661 n.4.

of the vehicles absent the Agency's final determination that the defect related to motor vehicle safety.¹²⁵ The court also concluded that the settlement was not arbitrary, capricious, or an abuse of discretion in light of the factors that led the Agency to settle the case.¹²⁶

Considerable criticism has followed the settlement and NHTSA's subsequent failure to monitor its effectiveness in preventing further injuries.¹²⁷ Consumer advocates have claimed that since the settlement, transmission failures have caused over fifty fatalities, but NHTSA has refused to reopen the case.¹²⁸

Although the Ford transmission case may be unique,¹²⁹ the problems it typifies are not. The lengthy procedures of the auto recall program frustrate the safety aims of the program when they prevent the Agency from obtaining a recall. An expeditious alternative procedure is therefore needed in serious defect cases. A provision granting NHTSA authority similar to the CPSC's "imminent hazards" authority¹³⁰—allowing the Agency to go directly to federal district court for a recall order—would be useful. Although this remedy probably would be used rarely, its availability could give the Agency an added advantage in the settlement process, one lacking under the current procedural scheme.

5. Recall Effectiveness

The average owner response rate for auto recalls is higher than that for other product recalls.¹³¹ A primary reason is direct notice—most car owners receive a letter notifying them of the re-

125. *Id.* at 662. The Agency had not made a final determination. *See supra* note 117.

126. 685 F.2d at 663.

127. Congressman Timothy Wirth called the dashboard sticker "gibberish." *Wall St. J.*, June 16, 1983, at 23, col. 1. Whether NHTSA has monitored the settlement is disputed. *See N.Y. Times*, Mar. 7, 1983, at A11, col. 1. According to former Administrator Peck, the Agency did follow up on the fatalities reported after the settlement. Peck Interview, *supra* note 53.

128. Ditlow Interview, *supra* note 59. Before the settlement, 98 deaths, 1,700 injuries, and 6,000 accidents had been attributed to the Ford transmission defect. *Wall St. J.*, June 16, 1983, at 23, col. 1. According to former NHTSA Administrator Peck, however, given the low return rates for recalls, it is not at all clear that recall and mechanical correction of the problem would have provided a more effective remedy than the warning sticker. Peck Interview, *supra* note 53.

129. The estimated cost of the requested Ford transmission recall was \$130 million. *N.Y. Times*, Mar. 7, 1983, at A11, col. 1. A recall order might have posed a serious threat to the company's survival at the time. *Wall St. J.*, June 16, 1983, at 1, col. 6. In addition, the parties settled the case near the end of the Carter Administration, giving rise to speculation that the policymakers wanted to secure some remedy in the case before leaving office.

130. *See infra* notes 190-91 and accompanying text.

131. While about 50% of car owners respond to recalls, *see infra* note 134 and accompa-

call.¹³² Such notice is seldom possible in other product recalls because individual owners cannot be identified. Another reason for the higher response rate for autos is their expense. The automobile is a major investment for most owners, who have an interest in its maintenance.¹³³ Even so, the response rate for auto recalls is still quite low. Over the years, the rate has averaged about fifty percent, although an upswing has occurred in recent years.¹³⁴ Vehicle owners fail to respond for several reasons: inadequate notice, perception that the risk of injury is low, and the inconvenience of taking a car in for repairs.

a. *Lack of Notice.* Owners state that lack of notice is a major reason for not responding to recalls.¹³⁵ One study showed that nearly a quarter of those not responding claimed they had not been notified.¹³⁶ The authors of the study concluded that some members of that group probably had received notice but had forgotten, especially if they had perceived the defect as trivial.¹³⁷ In addition, the study theorized that some may have used lack of notice as a socially desirable excuse for not having responded to a recall.¹³⁸ Others obviously had not received notice due to difficulties inherent in using the mail to reach every car owner. Manufac-

nying text, only about 10% of consumers respond to recalls under the CPSC's jurisdiction. See *infra* note 175 and accompanying text.

132. See *supra* note 25 and accompanying text (Safety Act's notice requirements).

133. A CPSC study demonstrated that recalls of costly products are more likely to be effective than recalls of less expensive items. See *infra* notes 283, 285.

134. GAO RECALL REPORT, *supra* note 27, at 15. The overall average return rate between 1966 and 1979 was 53.5%. *Id.* The return rate in 1981 was 67.2% and the 1982 rate is also expected to be well above average. Telephone interview with Bobby Boaz, NHTSA Office of Public Affairs (Sept. 30, 1983).

135. U.S. DEP'T OF TRANSP., STUDY TO DETERMINE WHY VEHICLE OWNERS RESPOND TO OR IGNORE RECALL NOTIFICATIONS 24 (1980) (prepared by Market Facts, Inc. for NHTSA) [hereinafter cited as DOT RECALL STUDY]. The targets of 25 recall campaigns in 1977 and 1978 comprised the sample for the study, during which the authors completed over 6,000 interviews with responders and nonresponders.

136. *Id.* For some campaigns the figures were even higher—more than 50%—and in one case up to 81% of the nonresponding owners claimed they had not received notice. *Id.* at 23.

137. For example, in one recall involving merely the replacement of a label, 46.2% of those who had returned their cars for service claimed not to have received a recall notice. *Id.* at 20. Undoubtedly they had received the notice and forgotten.

138. Indirect evidence of this phenomenon is found in cases in which nonresponders thought the defect was serious. Of this group, 24% claimed they had received no notice. Only 8.8% of the nonresponders who thought the defect was trivial cited this excuse. Since it is unlikely that actual receipt would depend on the seriousness of the defect, a plausible explanation is that the nonresponders sought a socially acceptable justification for their inaction.

turers send notices based on state vehicle registration information which is never completely up to date when the manufacturers obtain it.¹³⁹ In recalls of older cars, notification is especially difficult because of the likelihood that the cars have changed owners.¹⁴⁰

In any event, lack of notice is not always an important reason for a low response rate. In the well-publicized Pinto recall, for example, nearly half the owners did not respond¹⁴¹ and only 0.8% gave lack of notice as their excuse.¹⁴² A large percentage (22%) failed to respond because of the time or inconvenience involved.¹⁴³ Although a certain percentage of owners might ignore a recall notice under almost any circumstances, the low response rate nevertheless casts doubt on whether the notice does an adequate job of informing owners of the risk.

b. *Inadequate Notice.* Current regulations carefully prescribe the contents of recall letters,¹⁴⁴ thereby eliminating NHTSA's practice of allowing manufacturers to draft their own recall letters, which sometimes included denials that a defect existed.¹⁴⁵ The regulations cover all recall letters, whether NHTSA ordered or manufacturer initiated.¹⁴⁶ The letter must describe the defect,¹⁴⁷ evaluate the risk,¹⁴⁸ specify measures for remedying the defect,¹⁴⁹ and state that owners may file a complaint with NHTSA if the

139. Ditlow Interview, *supra* note 59.

140. *Id.*

141. GAO RECALL REPORT, *supra* note 27, at 44.

142. DOT RECALL STUDY, *supra* note 135, at 25. The Pinto recall was among those examined in the study.

143. *Id.* Other reasons given for not responding were that the car was sold before the recall (29.4%), the parts were not in stock or service was bad (7.6%), there was nothing wrong with the car (1.7%), or the car already had been serviced (23.5%). *Id.*

144. See 49 C.F.R. § 577.1-9 (1983).

145. Believing that the disclaimers would not "normally" affect owner response to recalls, NHTSA had allowed the practice to continue for a number of years. See 38 Fed. Reg. 22,126 (1973). The Agency later reversed itself, finding that such disclaimers might effectively discourage owner response. 41 Fed. Reg. 56,815 (1976); see also *supra* note 19 (providing example of effects of this practice).

146. 49 C.F.R. §§ 577.5(c), .6(a) (1983).

147. *Id.* § 577.5(e). The description must identify the vehicle system or item affected and describe the potential malfunction, the conditions that may cause the malfunction, and the precautions the owner should take before repair. *Id.*

148. *Id.* § 577.5(f). If a crash without warning is a risk, the letter must so state; if a warning may occur before a crash the letter must describe it, along with an admonition that failure to heed the warning may result in a crash. If the risk does not involve a crash, the manufacturer must describe the type of injury that may result. *Id.*

149. *Id.* § 577.5(g)(1). The letter must indicate that the remedy will be provided without charge, give the earliest date when repair or replacement will be available, describe the necessary work, and estimate the amount of time required to correct the defect.

defect is not corrected.¹⁵⁰

Although the requirements for the recall letters are detailed and exhaustive, they have not substantially increased owner response rates. Indeed, a GAO study attributed some lack of response to the style used in drafting recall letters.¹⁵¹ Not only do manufacturers write the letters at reading levels too advanced for most adults,¹⁵² but they also fail to highlight safety risks to impress the reader.¹⁵³ GAO concluded that owners fail to respond to recalls because they underestimate the importance of having the defect corrected.¹⁵⁴ To remedy the inadequacy, GAO recommended lowering the reading level of the letter,¹⁵⁵ highlighting the safety consequences of the defect,¹⁵⁶ and mailing a postcard reminder shortly after the first recall letter is sent.¹⁵⁷ In response to the first recommendation, NHTSA has begun making the letter more understandable.¹⁵⁸ This is a positive development which should help increase response rates. The increase may not be marked, however, because even when owners fully understand the risks many do not return their vehicles for repair.¹⁵⁹

c. *Risk Perceptions.* Many vehicle owners fail to perceive the safety-related defect as serious or likely to injure them. Often this perception is correct. Even NHTSA concedes that "relatively few recalls in fact represent extremely grave or urgent elements of risk

150. *Id.* § 577.5(g)(1)(vii)(A), (B)(1). The letter must provide NHTSA's name and address and indicate that the owner should file a complaint if the manufacturer did not correct the defect free of charge or within 60 days after the owner first tendered the vehicle for repair.

151. *See* GAO RECALL REPORT, *supra* note 27, at 16-24.

152. An analysis of 11 recall letters demonstrated that the letters were written at levels requiring between 12.4 years of education (December of 12th grade) to 16.4 years (senior year of college). About 54% of the adult population reads at or below the 11th grade level. *Id.* at 18.

153. *Id.* at 19. The information about safety consequences is buried in the last line of a paragraph near the middle of the text.

154. *Id.* at 14.

155. *Id.* at 24. In the study, GAO converted a typical recall letter from 12th grade level to 5th grade level, demonstrating that it could convey the same information more logically and comprehensibly. *Id.* at 20-21.

156. The proposed recall letters would begin with a notice about how the safety defect could cause the vehicle to fail and result in a crash. This notice would be printed in capital letters and boxed for emphasis. *Id.* at 21.

157. The GAO based this recommendation on the successful use of follow-up postcards to increase response rates in public opinion surveys. *Id.* at 14.

158. The Agency hired a private firm to write a readable letter, provoking criticism for being unable to write one itself and for paying the firm approximately \$23,000. *See Why Uncle Sam Can't Write*, Wash. Post, Mar. 5, 1983, at A22, col. 1.

159. *See supra* notes 141-43 and accompanying text (discussing Pinto recall).

or exposure.”¹⁶⁰ Recalls for windshield wiper failures exemplify the nonurgent case.¹⁶¹ Moreover, in some cases only a few of the thousands of cars recalled actually contain a defect.¹⁶² Owners who return their cars for repairs only to be told that no defect exists may be less likely to respond to future recalls.¹⁶³ Owners who do not respond and never encounter the problem described in the recall letter also may be less likely to respond to future recalls.

GAO’s recommended approach to the risk perception problem is increased emphasis in recall letters on the safety consequences of the defect.¹⁶⁴ This approach, however, involves the risk of exaggerating the danger and ultimately diminishing the overall impact of recall letters. Another suggested approach is reducing the number of recalls by raising the threshold of risk which warrants a recall.¹⁶⁵ Using the recall remedy to address only the most serious defects would give individual recall campaigns more force. This approach, however, deprives consumers of a benefit they currently enjoy under the Safety Act—free repair of less serious safety-related defects.

A compromise approach is preserving the broad scope of NHTSA’s recall program while developing a recall classification system to identify high-risk, imminent hazard recalls. This would aid owners in assessing the danger of a defect. NHTSA would thus follow the example of the FDA, which for years has classified recalls by risk in order to communicate the seriousness of a problem to the public.¹⁶⁶ Although the classification system does have drawbacks, especially during the recall negotiation phase,¹⁶⁷ if it could improve response rates in serious defect cases (even if it reduced them in the less serious cases), it would be worth the effort.¹⁶⁸

Aside from the defect notification letter, NHTSA imposes no

160. GAO RECALL REPORT, *supra* note 27, at 43.

161. *See* DOT RECALL STUDY, *supra* note 135, at 20.

162. Peck Interview, *supra* note 53. Most autos are recalled for flawed or improperly manufactured components, although some are recalled for defective designs as well. The manufacturer may find the flaws in only a small number of the cars it recalls. *Id.*

163. *Id.*

164. *See supra* note 156 and accompanying text.

165. *See generally* Note, *supra* note 8.

166. *See infra* notes 409-13 and accompanying text.

167. The FDA’s classification system has inhibited settlement, and the Agency has considered abandoning it. *See infra* notes 448-51 and accompanying text.

168. The FDA has never evaluated its classification scheme. *See infra* note 453. Other agencies need to test the system to determine whether its implementation would be practicable and whether it would improve recall response rates in serious defect cases.

obligation to improve owner response even when the response rate is low and the risk high.¹⁶⁹ Fortunately, manufacturers do take extra steps to encourage owners to return their cars for repairs.¹⁷⁰ Nevertheless, NHTSA should experiment with other devices for improving return rates in high-risk recalls. The Agency might further publicize recalls where owner response has been low, or require manufacturers to send follow-up mailgrams or pay for notices sent by NHTSA.¹⁷¹ Notice from a government authority can have extra clout with consumers, impressing upon them the importance of responding to a recall.¹⁷²

Some owners will not respond to a recall even when the notice is received, adequately informs the owner of the risk, and reveals that the risk is high.¹⁷³ For these owners, little, if anything, can be done short of an enforcement scheme penalizing the failure to respond. Such a scheme is technically possible—for example, federal law could prohibit states from registering vehicles that have been recalled but not repaired.¹⁷⁴ This scheme certainly would improve recall response rates; it might be even more effective if applied only to high-risk recalls so as not to burden the states unduly.

169. NHTSA monitors all recalls but imposes no additional requirements on manufacturers when the return rate is low. In some cases, however, the Agency encourages manufacturers to mail out additional notices. Peck Interview, *supra* note 53.

170. Ditlow Interview, *supra* note 59. Concerns about product liability claims partially motivate manufacturers to achieve high return rates. See *GM Recall Advertisement*, *supra* note 65 (GM goes beyond federal requirements by sending follow-up letters to owners not responding to initial recall notice).

171. Ditlow Interview, *supra* note 59. NHTSA could also require manufacturers to offer prospective used car buyers data on whether individual cars have been recalled and repaired. This information is readily available to manufacturers. GM's Computerized Recall Identification System (CRIS), for example, can reveal instantly based on the vehicle identification number whether recall work has been performed. *GM Recall Advertisement*, *supra* note 65. Publicizing the availability of this information might provide another incentive for owners to respond to recalls.

172. For example, the Attorney General of Indiana aids auto dealers in their recall efforts by sending his own letter, which urges vehicle owners, "[P]rotect yourself and your family by taking [your] vehicle to your dealer as soon as possible." The letter stresses that failure to have the vehicle repaired "could have an effect on your auto liability insurance." Since this assistance from the Attorney General's Office became available in January, 1982, many dealers have utilized it and customer response rates have improved substantially. Letter from Eric M. Cavanaugh, Deputy Attorney General of Indiana, to Sam Zagoria, Commissioner of the Consumer Product Safety Commission (Nov. 5, 1982) (on file with the *Case Western Reserve Law Review*).

173. The Pinto recall best exemplifies this phenomenon. See *supra* notes 141-43 and accompanying text.

174. Based on manufacturers' records kept according to vehicle identification numbers, the state could determine whether a car had been repaired. Ditlow Interview, *supra* note 59.

D. *Recommendations*

The auto recall program should continue to operate largely on a voluntary basis. However, three statutory amendments would help to reduce delays in the negotiation process, thereby enhancing recall effectiveness. The first is to add a provision similar to that contained in the Consumer Product Safety Act, requiring manufacturers to notify NHTSA of defects that could create hazards. This provision would give the Agency early warning of a problem and reduce its information-gathering burden. The second is to revoke the eight-year statute of limitations on no-charge repairs, which can encourage dilatory tactics in the investigation of defects. The third is to add a provision granting NHTSA authority to bypass the administrative hearing and seek court-ordered recalls in cases of serious, imminent hazard.

To increase recall effectiveness, NHTSA should improve its notification letter and consider classifying recalls according to risk, tailoring the recalls' requirements to meet that risk. This approach might help consumers more accurately assess the risks of safety-related defects, without limiting NHTSA's use of the recall remedy or the opportunity for no-cost repairs afforded under the Safety Act.

II. THE CONSUMER PRODUCT SAFETY COMMISSION

The CPSC is the newest and smallest of the three Agencies with recall authority. Since its establishment in 1972, it has participated in roughly 3,000 recalls involving approximately 300 million product units.¹⁷⁵ These figures reflect the Agency's

175. TABLE I			
FISCAL YEAR	NUMBER OF RECALLS*	NUMBER OF PRODUCTS INVOLVED	PERCENTAGE RETURNED
1982	91	2,570,117	17.4%
1981	40	2,475,455	25.6%
1980	132	23,310,834	15.6%
1979	198	53,555,927	8.3%
1978	128	35,112,116	16.6%
1977	89	27,281,798	4.2%
1976	162	12,289,631	15.5%
1975	124	12,186,228	25.4%
1974	145	12,205,799	18.9%
1973	3	49,999	99.8%
Total	1,112	181,137,904	12.5%**

* Under § 15(a)(2) of the Consumer Product Safety Act, 15 U.S.C. § 2064(a) (1982).

** Average percentage

preference for the recall as an enforcement tool, as well as the diversity and breadth of the Commission's jurisdiction.¹⁷⁶ Recalls by the CPSC generally address many products, are undertaken voluntarily by manufacturers, and yield low consumer return rates.

A. Recall Authority

The CPSC enforces five federal statutes: the Consumer Product Safety Act (CPSA),¹⁷⁷ the Federal Hazardous Substances Act (FHSA),¹⁷⁸ the Flammable Fabrics Act (FFA),¹⁷⁹ the Poison Prevention Packaging Act (PPPA),¹⁸⁰ and the Refrigerator Safety Act (RSA).¹⁸¹ The latter four are often referred to as the "transferred acts" because other agencies had enforced them before creation of the CPSC.

1. The Transferred Acts

Of the four transferred acts, only the FHSA contains specific

TABLE II

FISCAL YEAR	NUMBER OF RECALLS*	NUMBER OF PRODUCTS INVOLVED	PERCENTAGE RETURNED
1982	72	830,197	22.7%
1981	251	906,810	35.6%
1980	456	3,189,775	19.3%
1979	347	4,478,863	6.6%
1978	149	4,652,293	15.4%
1977	58	16,222,526	10.4%
1976	85	78,083,419	0.5%
1975	67	353,270	33.0%
1974	124	1,640,679	42.1%
1973	394	—	—
Total	1,899	109,809,648	4.5%**

* Under CPSA, FHSA, and FFA regulations

** Average percentage

The average return rate for all products is 9.8%. By excluding fiscal year 1976, an aberrational year, the average rises to 13.1%. Interview with David Thome, Director of the Division of Corrective Actions, Directorate for Compliance and Administrative Litigation, CPSC, in Washington, D.C. (Sept. 22, 1983) [hereinafter cited as Thome Interview].

176. Estimates of the number of products under the Agency's jurisdiction range from 10,000 to 15,000. H.R. REP. NO. 114, 98th Cong., 1st Sess. 3 (1983).

177. Pub. L. No. 92-573, 86 Stat. 1207 (1972) (codified as amended at 15 U.S.C. §§ 2051-2083 (1982)).

178. Pub. L. No. 86-613, 74 Stat. 372 (1960) (codified as amended at 15 U.S.C. §§ 1261-1276 (1982)).

179. Ch. 164, 67 Stat. 111 (1953) (codified as amended at 15 U.S.C. §§ 1191-1204 (1982)).

180. Pub. L. No. 90-601, 84 Stat. 1670 (1970) (codified as amended at 15 U.S.C. §§ 1471-1474, 1476 (1982)).

181. Ch. 890, 70 Stat. 953 (1956) (codified at 15 U.S.C. §§ 1211-1214 (1982)).

recall authorization.¹⁸² Until 1981, the Act included a rigid recall provision mandating repurchase of *every* noncomplying product, no matter how insignificant the hazard or degree of noncompliance.¹⁸³ In 1981, Congress replaced the provision with one modeled on the CPSA's recall requirements.¹⁸⁴

For a number of years, the Commission had maintained that the FFA implicitly authorized recalls as part of the injunctive relief available to restrain ongoing violations of the Act.¹⁸⁵ In *Congoleum Industries, Inc. v. Consumer Product Safety Commission*, however, the United States Court of Appeals for the Ninth Circuit ruled that absent specific authorization by the FFA, no recalls could be ordered.¹⁸⁶ In the staff's view, however, section 15 of the CPSA empowers the Commission to recall dangerously flammable products.¹⁸⁷

2. *The CPSA*

Congress enacted the CPSA in 1972, at the end of the "consumer decade"—a decade marked by high expectations about the government's ability to correct safety problems and passage of numerous health and safety statutes.¹⁸⁸ The CPSA gave the Commission enormously broad jurisdiction over consumer products

182. The CPSC's authority to recall under the RSA has never been tested because virtually all refrigerator manufacturers have complied with the statute. Interview with Robert Poth, Director of the Division of Regulatory Management, Bureau of Compliance, CPSC, in Washington, D.C. (Sept. 19, 1983) [hereinafter cited as Poth Interview]. Likewise, neither the PPPA, the FHSA nor the FFCA contains recall authority; however, CPSC staff have argued that in an appropriate case involving a severe hazard, the Commission could seek the recall of noncomplying PPPA packaging under § 15 of the CPSA since the packaging would be a consumer product. The Commission has not yet attempted to use this section because in the few instances where it might have applied, companies recalled voluntarily. Normally, however, the CPSC does not seek consumer-level recalls for noncomplying packaging under the PPPA. Interview with Michael Gidding, Staff Attorney for the CPSC, in Washington, D.C. (Nov. 10, 1983).

183. 15 U.S.C. § 1274 (1982).

184. See Consumer Product Safety Amendments of 1981, Pub. L. No. 97-35, § 1211(f)(1), 95 Stat. 703, 721 (1981) (codified at 15 U.S.C. § 1274 (1982)). As amended, the FHSA authorizes the recall of banned hazardous substances after a hearing similar to that mandated by § 15 of the CPSA.

185. The FFA authorizes the CPSC to enjoin future violations by issuing cease and desist orders under the Federal Trade Commission Act, 15 U.S.C. § 1194 (1982).

186. 602 F.2d 220 (9th Cir. 1979).

187. Interview with Philip Bechtel, Director of the Division of Administrative Litigation, Directorate for Compliance and Administrative Litigation, CPSC, in Washington, D.C. (June 16, 1983) [hereinafter cited as Bechtel Interview]. The staff's recall theory for the FFA is the same as its theory for the PPPA. See *supra* note 182.

188. See Schwartz, *The Consumer Product Safety Commission: A Flawed Product of the Consumer Decade*, 51 GEO. WASH. L. REV. 32, 33-34, 42-45 (1982).

and an equally broad range of enforcement tools,¹⁸⁹ including the most expansive recall powers authorized at the federal level.

a. *Imminent Hazards—Section 12.* The CPSC may seek recall under two provisions of the CPSA. Under section 12, it can proceed directly to federal district court in the case of an “imminently hazardous” consumer product.¹⁹⁰ An imminently hazardous product is one presenting an “imminent and unreasonable risk of death, serious illness, or severe personal injury.”¹⁹¹ Since its inception, the CPSC has filed only four imminent hazard actions. Three of the cases—which involved a “trouble light” posing an electrocution hazard,¹⁹² an amusement park ride with defective door latches,¹⁹³ and an automatic pitching machine that activated without warning even when turned off¹⁹⁴—were settled before final court rulings. The fourth, involving aluminum wire, was dismissed on jurisdictional grounds after years of litigation and appeals.¹⁹⁵

One writer, noting that courts have insisted on lengthy, full-fledged evidentiary hearings in imminent hazard cases, has suggested that section 12 is not the emergency procedure envisioned by Congress.¹⁹⁶ However, this judgment is probably premature. In three of the four cases, the Commission obtained either an immediate temporary restraining order or an informal agreement by the defendants to halt further distribution of the allegedly hazardous products pending the outcome of the case. Moreover, the satisfactory settlement of three of the four cases commends the process,¹⁹⁷ suggesting that court action expedites settlement and

189. *See id.* at 43-44 (describing CPSC's administrative powers and authority to seek various forms of judicial relief).

190. 15 U.S.C. § 2061 (1982). The Commission may bring an imminent hazard case in its own name, and need not use Justice Department lawyers, who may lack knowledge about the facts of a case or the applicable law.

191. *Id.* § 2061(a).

192. CPSC v. A-K Elec. Co., No. 74-1026 (D.D.C. filed Sept. 9, 1974).

193. CPSC v. Advance Mach. Co., No. 77-1323 (D.D.C. consent judgment May 8, 1978), *discussed in* PRODUCT HAZARDS: A CASE HISTORY GUIDEBOOK 93-97 (S. Coffin ed. 1981) [hereinafter cited as PRODUCT HAZARDS].

194. CPSC v. Chance Mfg. Co., 441 F. Supp. 228 (D.D.C. 1977) (consent decree signed Nov. 30, 1978), *discussed in* PRODUCT HAZARDS, *supra* note 193, at 107-11.

195. CPSC v. Anaconda Co., 3 CONSUMER PROD. SAFETY GUIDE (CCH) ¶ 75,284 (D.C. Cir. Jan. 7, 1982). The court held that since branch circuit aluminum wiring systems are not customarily sold or distributed to consumers as distinct articles of commerce, they are not “consumer products” within the CPSA.

196. *See* Madden, *Consumer Product Safety Act Section 15 Substantial Product Hazards*, in PRODUCT HAZARDS, *supra* note 193, at 5, 27.

197. Bechtel Interview, *supra* note 187.

thereby produces the desired result—prompt recall of the products.

b. *Substantial Product Hazards—Section 15.* The authority most often used for recalls under the CPSA is section 15.¹⁹⁸ The provision has become the Commission's favorite enforcement tool, its use far eclipsing the issuance of safety standards and product bans.¹⁹⁹ Section 15 authorizes the CPSC to seek recall of "substantial product hazards," products that create a "substantial risk of injury to the public" either because they fail to comply with a consumer product safety rule or because they contain a defect.²⁰⁰

Congress offered scant guidance as to what constitutes a defect under section 15 and no court has interpreted its meaning. In 1978, the Commission promulgated a detailed interpretive rule codifying its view of the recall provision.²⁰¹ The rule broadly defines defect to include design deficiencies as well as product flaws due to quality control problems.²⁰² It also provides examples of defective products, including those that fail to perform as advertised, those made dangerous by inadequate warnings about foreseeable product use and misuse, and those exhibiting a pattern of failure even though the specific cause of the problem cannot be pinpointed.²⁰³ The Commission indicated that it would determine defectiveness under a balancing test, weighing the risk of injury against such factors as the product's utility, necessity, and type of risk presented.²⁰⁴

Not every safety rule violation presents a "substantial product hazard," nor does every defective product. To present a substantial product hazard, the defect must create a "substantial risk of

198. 15 U.S.C. § 2064 (1982).

199. See Schwartz, *supra* note 188, at 69.

200. 15 U.S.C. § 2064 (1982). Although this provision limits recalls to products posing substantial risks and thus precludes recalls for minor violations of consumer product safety rules, the CPSC may seek a court order permitting it to seize offending goods or to prevent their further manufacture or distribution. *Id.* § 2071. The Commission may also seek civil penalties for knowing violations of consumer product safety rules. *Id.* § 2069. In the rare case where the Commission proves a knowing and willful violation after notice of noncompliance, criminal sanctions are available. *Id.* § 2070.

201. 16 C.F.R. § 1115 (1984).

202. *Id.* § 1115.4. For an example of a design defect case, see *infra* note 260 and accompanying text.

203. 16 C.F.R. § 1115.4 (1984). For an example of a case where a defect could not be pinpointed, see *infra* note 259 and accompanying text.

204. 16 C.F.R. § 1115.4 (1984).

injury to the public”²⁰⁵ because of the “pattern of the defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise.”²⁰⁶ The Commission views these factors as disjunctive, only one need be demonstrated to prove a substantial product hazard. Thus, a product presenting the risk of minor injury with great frequency could pose a substantial product hazard, as could a product presenting a severe but infrequent hazard.²⁰⁷

B. *Implementing the Recall Authority*

1. *Identifying Defects*

The CPSC learns of potential hazards from many sources, including agency inspections and accident investigations, news reports, and complaints from consumers and manufacturers’ competitors.²⁰⁸ Its most important sources, however, are manufacturers of consumer products obliged to report hazards and potential hazards under section 15(b) of the CPSA.²⁰⁹

The reporting obligation under section 15(b) is broader than that under the National Traffic and Motor Vehicle Safety Act.²¹⁰ A company must report under the CPSA not only when it discovers that a product presents a substantial product hazard, but also when it obtains information that “reasonably supports the conclusion” that a product defect “could create” a substantial product

205. 15 U.S.C. § 2064(a)(2) (1982).

206. 16 C.F.R. § 1115.4 (1984). Under the interpretive rule, the “pattern of defect” refers to the source of the defect, i.e., the design, construction, packaging, warnings, etc., and the conditions under which the defect manifests itself. *Id.* In the Commission’s view, the “number of products distributed in commerce” can be miniscule—even one defective product—if injury is likely and/or serious. In judging the “severity of the risk,” the Commission considers the gravity and likelihood of injury, taking into account the number of reported injuries, the intended or reasonably foreseeable use of the product, and the population group exposed to the product (children, elderly, handicapped). *Id.*

207. *See, e.g.*, cases cited *infra* note 258.

208. Memorandum from David Schmeltzer, Director of the Directorate for Compliance and Administrative Litigation, CPSC, to Stuart Statler, Commissioner of the CPSC 2 (May 26, 1983) (on file with the *Case Western Reserve Law Review*) [hereinafter cited as Schmeltzer Memorandum]. A sizeable number of cases of noncompliance with agency regulations begin with “trade complaints” from competitors. Poth Interview, *supra* note 182.

209. 15 U.S.C. § 2064(b) (1982). Roughly 60% of CPSC-conducted recalls of defective products (excluding those involving safety rule violations) result from § 15(b) reports. Many of these reports are stimulated by the Commission’s “pre-section 15(b)” letters, which inform companies of injury or accident reports brought to the CPSC’s attention. Each letter reminds the company of its reporting obligations under the CPSA. Thome Interview, *supra* note 175.

210. *See supra* note 55 and accompanying text.

hazard.²¹¹ Failures to report can subject violators to civil fines up to \$500,000²¹² and possibly to criminal penalties.²¹³ While the Commission has only infrequently imposed civil penalties,²¹⁴ it has used its civil penalty authority more than NHTSA has used similar authority.²¹⁵ The Commission has done so both to deter reporting violations and in some cases to negotiate more effective recalls.²¹⁶

To stimulate reporting and provide guidance to those subject to section 15(b), Congress and the Commission have identified two situations that must be reported immediately²¹⁷—failure of a product to comply with a consumer product safety standard or

211. Section 15(b) provides:

Every manufacturer of a consumer product distributed in commerce, and every distributor and retailer of such product, who obtains information which reasonably supports the conclusion that such product—

(1) fails to comply with an applicable product safety rule; or

(2) contains a defect which could create a substantial product hazard described in subsection (a)(2) of this section,

shall immediately inform the Commission of such failure to comply or of such defect, unless such manufacturer, distributor, or retailer has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

15 U.S.C. § 2064(b) (1982).

212. Failure to report is a prohibited act under § 2068(a)(4), for which civil penalties can be imposed. *Id.* § 2069.

213. Criminal sanctions can be imposed only for knowing and willful violations after notice of noncompliance. *Id.* § 2070. The Commission has yet to confront a case warranting action under this section.

214. As of mid-1983, the Commission had obtained civil penalties from manufacturers for failures to make timely reports in 14 cases. This number reflects the Commission's general inclination not to pursue de minimis violations. *See infra* note 225 and accompanying text. Most assessments have been above \$70,000, with several over \$300,000. Bechtel Interview, *supra* note 187.

215. *See supra* note 53 and accompanying text.

216. *See, e.g., In re* Bassett Furniture Indus., CPSC No. 78-51 (hazard determination Jan. 24, 1978); CPSC No. 78-81 (hazard determination May 3, 1978), *discussed in* PRODUCT HAZARDS, *supra* note 193, at 134-39 (Commission negotiated very effective recall plan and agreed to relatively small civil penalty as part of settlement); *see also infra* note 294 and accompanying text.

217. *See* 15 U.S.C. § 2064(b) (1982). The Commission defines "immediately" as within 24 hours of determining that a reporting obligation exists. While the obligation does not arise when a company has only a vague hint that it may have a problem, it may arise before a company has completed investigating the problem. According to the Commission:

[T]he 24-hour period begins when the subject firm has information which reasonably supports the conclusion that its consumer product fails to comply with an applicable consumer product safety rule or contains a defect which could create a substantial product hazard. Thus, a firm could report to the Commission before the conclusion of a reasonably expeditious investigation and evaluation if the reportable information becomes known during the course of the investigation.

16 C.F.R. § 1115.14(e) (1984).

ban²¹⁸ and a product defect that has caused or could help cause death or grievous bodily injury.²¹⁹ In addition, the Commission has listed a number of circumstances that companies should study and evaluate in determining whether they must report.²²⁰

Although the reporting requirement is broad, only a small number of section 15(b) reports are submitted yearly. The number of reports decreased in 1980, 1981, and 1982, but rebounded in fiscal 1983.²²¹ The decline may reflect a general perception by business that the severe budget and staff cuts following the 1980 election had substantially reduced the CPSC's capacity to enforce the statute, reducing the risk of not reporting.²²² Other factors also discourage reporting. These include the risk of adverse publicity regarding even minor problems²²³ and the possibility that the Commission will view a defect that a firm believes not to be hazardous as serious enough to warrant a recall, or deem a report untimely and impose penalties.

218. A product's failure to comply with a regulation under one of the transferred acts must be reported if it constitutes "a defect that could create a substantial product hazard" under § 15(b). *See id.* § 1115.2(c).

219. *Id.* §§ 1115.12(a), (c). In the latter case, a company need not report if it determines that its investigation does not support the existence of a product defect which could create a substantial product hazard.

220. Under the Commission's rule, companies should make further inquiries when information from the following sources suggests either noncompliance with a safety rule or existence of a potential safety problem: (1) engineering, quality control or production data, (2) safety-related production or design changes, (3) product liability suit(s), (4) independent laboratory tests, (5) complaints from a consumer or consumer group, and (6) information from the CPSC or another agency. *Id.* § 1115.12(e). The Commission takes the position that investigations and evaluations generally should not exceed 10 days. *Id.* § 1115.14(d). If a firm reasonably could conclude that it is obliged to report before the end of the 10-day investigation and evaluation period, it must so report. *See supra* note 217.

221. The number of § 15(b) reports filed with the CPSC since its establishment is as follows:

<u>Year</u>	<u>Number of Reports</u>
1983	131
1982	96
1981	121
1980	147
1979	201
1978	118
1977	74
1976	99
1975	119
1974	120
1973	3

Bechtel Interview, *supra* note 187.

222. *Id.*

223. For years, companies had argued that adverse publicity presented an extremely strong disincentive to § 15(b) reports and urged the Commission to keep all such reports confidential. *See* 43 Fed. Reg. 34,995-96 (1978).

CPSC officials have attempted to minimize these disincentives by giving the benefit of the doubt to firms that report safety problems promptly²²⁴ and by ignoring de minimis reporting violations.²²⁵ Moreover, the Commission has made clear that filing a section 15(b) report is not an admission that a substantial product hazard exists.²²⁶ Finally, Congress virtually eliminated the risk of adverse publicity in 1981, by amending the CPSA to bar release of information submitted under section 15(b) except in very limited circumstances.²²⁷ Despite the paucity of reports filed with the CPSC, section 15(b) has been useful, not only providing the Commission with early information about potential problems, but also giving it additional leverage in negotiating recalls when section 15(b) arguably has been violated.²²⁸

2. *The Investigative Stage*

The CPSC follows different investigative procedures for products violating safety rules than for those containing defects.

a. *Products Violating Safety Rules.* Since determining whether a product violates a rule or ban is generally easy, the Commission has delegated responsibility for these cases to its regional offices.²²⁹ The regional staff makes an initial investigation and, if warranted, collects a sample and forwards it to headquarters for testing. If testing confirms a violation, the regional office sends the firm a "letter of advice" advising it of the violation and

224. Bechtel Interview, *supra* note 187.

225. For example, in *In re McGraw-Edison*, CPSC No. 77-26 (defect reported July 21, 1977), discussed in *PRODUCT HAZARDS*, *supra* note 193, at 82-83, the Commission did not pursue the company for a possible eight-day reporting delay where the company, when alerted by quality control, found a possible problem, immediately embargoed further production, and fully investigated the problem. CPSC staff concluded that the evidence then available to the company indicated the minor nature of the hazard. See *supra* note 214 and accompanying text.

226. The Commission's reporting rule provides that companies need not admit and may specifically deny that the information they report reveals a substantial product hazard or noncompliance with a safety rule. 16 C.F.R. § 1115.12(a) (1984).

227. 15 U.S.C. § 2055(b)(5) (1982). The CPSC may not release any information submitted to it under § 15(b) unless: (1) it files a complaint against the reporting firm; (2) it enters into a written remedial settlement agreement with the firm; (3) the firm agrees to the release of the information; (4) the Commission has filed an imminent hazard case under § 12 of the CPSA; (5) it has reasonable cause to believe that the information concerns a product in violation of § 19(a) of the CPSA, 15 U.S.C. § 2067(a); or (6) the information is revealed in the course of or concerning a judicial proceeding.

228. See *supra* note 216 and accompanying text.

229. Schmelzter Memorandum, *supra* note 208.

requesting that it stop distributing the product.²³⁰ If the regional office in conjunction with headquarters decides that a recall is appropriate, it asks the firm to present a recall plan. Typically, companies have ten days to respond to letters of advice.²³¹ The regional office monitors the corrective action plan until completion, at which time the regional compliance officer closes the case. If the matter is of sufficient magnitude, approval from headquarters may be required.²³²

b. *Product Defects*. Normally, greater judgment is required to determine whether a defective product presents a substantial hazard. Thus, the Commission's decisionmaking process for those cases is more centralized. In a typical case, the CPSC assigns a compliance officer at headquarters to investigate the suspect product. If, after consulting with agency epidemiologists and engineers, the officer determines that a substantial hazard may exist, he sends a letter to the manufacturer (or importer) requesting injury information, production figures, and other pertinent data. In the alternative, the officer can assign an inspector to visit the firm and gather this information.²³³

If the data reveal a substantial hazard, the officer recommends that the Director of the Division of Corrective Actions make a preliminary determination that the product presents a substantial hazard. If the Director agrees, the compliance officer sends a "case opening letter" to the manufacturer indicating the preliminary finding and requesting the firm to submit a proposed corrective action plan.²³⁴

At this stage, the compliance officer, in consultation with the Director of the Corrective Action Division, classifies the product according to the CPSC's three-tiered hazard classification system. This system, designed primarily for internal use,²³⁵ ranks products as A, B, or C hazards based on severity and likelihood of in-

230. *Id.*

231. *Id.*

232. The CPSC devotes resources commensurate with risk in rule-violation cases, but does not use the three-tiered system for hazards described *infra* notes 236-37 and accompanying text. Thome Interview, *supra* note 175.

233. Schmeltzer Memorandum, *supra* note 208.

234. *Id.*

235. Generally, the Commission does not disseminate its product hazard ratings, either to the companies involved or to the public. CPSC staff is reluctant to share its hazard rating judgments because ratings change as information accrues and because firms that know their products have received relatively low ratings might be reluctant to undertake comprehensive recalls. Bechtel Interview, *supra* note 187.

jury.²³⁶ The higher a product's hazard rating, the more likely it is to receive the Commission's attention. As a policy matter, the Commissioners are immediately notified of class A hazards and continuously apprised of developments in those cases. In recalls of products with high hazard ratings, the Commission is likely to require individual notice to consumers, widespread publicity, explicit descriptions of the hazard in recall letters, and close agency scrutiny of the company's progress in implementing the recall.²³⁷

Once the CPSC has approved a corrective action plan, a regional office normally monitors it.²³⁸ Recommendations to close a case must be approved by the Director of the Corrective Action Division and reviewed by the Director of Compliance and the Executive Director.²³⁹ In class A recalls, the Commissioners must approve the closing of the case.²⁴⁰

3. *Administrative Hearing and Judicial Review*

If a case cannot be settled, the Commission must adjudicate the matter. Both the CPSA and the FHSA require a formal administrative hearing to determine whether a recall is warranted.²⁴¹ An administrative law judge presides, cross examination is permitted, and the ruling may be appealed to the Commission.²⁴²

If, based on the hearing, the Commission finds a substantial product hazard under the CPSA, or determines under the FHSA

236. Schematically, the CPSC classification may be depicted as follows:

Hazard Priority Classification

<i>Hazard Priority Class</i>	<i>Class A</i>	<i>Class B</i>	<i>Class C</i>
1. Severity*	● ● ◐	● ◐ ○	○ ◐ ○
2. Likelihood**	● ◐ ●	○ ◐ ●	◐ ○ ○
* ● - Death or grievous injury			
○ - Serious injury or illness			
○ - Moderate injury or illness			
** ● - Very likely			
◐ - Likely			
○ - Not likely, but possible			

Memorandum from David Thome, Acting Director of the Corrective Action Division, Directorate for Compliance and Administrative Litigation, CPSC, to the Commission, attachment A at 4 (Jan. 6, 1981) (on file with the *Case Western Reserve Law Review*) [hereinafter cited as Thome Memorandum].

237. *Id.* attachment A at 4-6.

238. Schmeltzer Memorandum, *supra* note 208.

239. *Id.*

240. Thome Memorandum, *supra* note 236, attachment B at 3-4.

241. 15 U.S.C. § 2064(d) (1982) (CPSA); *id.* § 1274(b) (FHSA). The Commission may seek recalls under the FHSA only for banned hazardous substances.

242. *See generally* CPSC Rules of Practice for Adjudicative Proceedings, 16 C.F.R. § 1025 (1984). At one point, the Commission permitted commissioners to act as presiding officers, but later forbade commissioners from engaging in this practice. *See id.* § 1025.3(i).

that recall of a banned hazardous substance would be in the public interest, it may order the respondent to provide notification of the hazard and/or the recall. It may order various forms of notification, including public notice, notice by mail to those in the distribution chain, and/or mailed notice to consumers.²⁴³ In contrast to NHTSA,²⁴⁴ the CPSC enjoys substantial flexibility as a result of these notification provisions. Since the products under the CPSC's jurisdiction are so diverse, no one method of notification suits all recalls.

The CPSC also may fashion the recall remedy to fit the circumstances. While the respondent must repair, replace, or refund the purchase price of the product,²⁴⁵ it may elect any of the three, provided the Commission approves its recall plan.²⁴⁶ The Commission has yet to order a recall in a case adjudicated under these provisions. It dismissed a group of cases,²⁴⁷ and the handful of others were settled during litigation.²⁴⁸

Neither the CPSA nor the FHSA contains explicit provision for judicial review of an agency recall order following an administrative hearing.²⁴⁹ Thus, the Administrative Procedure Act (APA) governs and its "substantial evidence" standard of review should apply.²⁵⁰ Jurisdiction is under the APA in federal district court with review by a United States court of appeals.²⁵¹ Two levels of judicial review seem unnecessary, given the formal adjudicative hearing at the agency level. Further, this multilevel review is likely to cause delay that can undermine the effectiveness of a recall.²⁵² Thus, Congress should amend the CPSA and the FHSA to

243. 15 U.S.C. § 2064(c) (1982) (CPSA); *id.* § 1274(a) (FHSA). Direct consumer notification goes to those known to have been sold or taken delivery of the product.

244. *See* 15 U.S.C. § 1413 (1982); *supra* notes 144-50 and accompanying text (discussing NHTSA notice regulations).

245. 15 U.S.C. § 2064(d) (CPSA); *id.* § 1274(b) (FHSA).

246. *Id.* §§ 2064(c), 1274(b).

247. *See* cases cited *infra* note 257.

248. Bechtel Interview, *supra* note 187. The CPSC currently is litigating two substantial product hazard cases. *Id.*

249. In the absence of appeal by the respondent, the Commission may sue in federal district court seeking either civil penalties or criminal sanctions for noncompliance with a final order. *See* 16 C.F.R. § 1025.57(c) (1984).

250. Judicial review likely would be in accordance with § 706(2)(E) of the Administrative Procedure Act, 5 U.S.C. § 706(2)(E) (1982). Interview with Alan Schoem, Assistant General Counsel of the CPSC, in Washington, D.C. (Sept. 27, 1983).

251. *See* 5 U.S.C. § 702 (1982).

252. Delay makes locating products and notifying owners more difficult. In general, recall rates are lower for old products than for recently purchased products. *See infra* note 283 and accompanying text.

provide for direct review of CPSC recall orders by a United States court of appeals. This approach would assure fairness to the parties and better serve the safety aims of these acts.

4. *The Settlement Process*

a. *Background.* Since its creation, the CPSC's use of recalls as an enforcement tool has far exceeded the level anticipated by Congress.²⁵³ In its early years, for example, the CPSC was criticized for failing to implement the standard-setting provisions of the CPSA,²⁵⁴ but its use of section 15 recalls was considered a great "success story."²⁵⁵ By the early 1980's, when rulemaking had come into general disfavor, the CPSC touted its use of section 15 as an efficient and effective alternative to rulemaking.²⁵⁶

Over the years, the CPSC has broadly interpreted its authority under section 15. In case after case, the Commission has obtained recalls before a single injury has occurred.²⁵⁷ It also has obtained recalls when the number of injuries is small but the type of potential injury is severe or widespread.²⁵⁸ Furthermore, the CPSC has

253. Most observers anticipated that the CPSC's activities would be concentrated on standard setting—the "heart of the CPSA." Scalia & Goodman, *Procedural Aspects of the Consumer Product Safety Act*, 20 U.C.L.A. L. REV. 899, 906 (1973).

254. Schwartz, *supra* note 188, at 62, 71.

255. *Regulatory Reform—Volume IV Consumer Product Safety Commission, National Highway Traffic Safety Commission, Federal Trade Commission: Hearings Before the Subcomm. on Oversight and Investigations of the House Comm. on Interstate and Foreign Commerce*, 94th Cong., 2d Sess. 63 (1976) (testimony of Richard O. Simpson, former Chairman, CPSC).

256. *Consumer Product Safety Commission Reauthorization: Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 97th Cong., 1st Sess. 22 (1981) (testimony of Susan King, former Chairman, CPSC).

257. See, e.g., *In re Mylar Star Kites*, CPSC No. 75-16 (Sept. 16, 1977), discussed in *PRODUCT HAZARDS*, *supra* note 193, at 47. The case involved long-tailed aluminized polyester kites that could cause (but had not) an electric shock to the user if it became entangled in high-voltage power lines. The Commission ruled that the action should have been brought under the Federal Hazardous Substances Act. Subsequently, it promulgated under the FHSA a rule banning long-tailed aluminized polyester kites. See 16 C.F.R. § 1500.18(c)(1) (1984).

Other cases involving recalls but no reported injuries include *In re Parkway Fabricators*, CPSC No. 78-41 (file opened Dec. 19, 1977) (defective scuba regulator that could cut off diver's air supply); *In re Nevco*, Div. of U.S. Indus., CPSC No. 78-16 (file opened Nov. 11, 1977) (hot pot for heating water that could cause electric shock due to corrosion of wires in heating element); and *In re Wham-O Mfg. Co.*, CPSC No. 77-1 (filed Mar. 11, 1977) (crossbow with defective latch that could release arrow unintentionally).

258. See, e.g., *In re Hillerich & Bradsby Co.*, CPSC No. 75-9 (filed Nov. 5, 1975); *In re Pepsico, Inc. & Wilson Sporting Goods*, CPSC No. 75-10 (filed Nov. 5, 1975); *In re Lannom Mfg.*, CPSC No. 75-11 (filed Nov. 5, 1975); *In re Reynolds Metals Co.*, CPSC No. 75-12 (filed Nov. 5, 1975); *In re Aluminum Co. of Am.*, CPSC No. 75-13 (filed Nov. 5, 1975); *In re Eaton Corp.*, CPSC No. 75-14 (filed Nov. 5, 1975). All six cases involved aluminum

obtained recalls when neither it nor the manufacturer could pinpoint the injury-causing product defect.²⁵⁹ Finally, the Commission has claimed that industry-wide design defects can present a substantial product hazard warranting industry-wide recall.²⁶⁰ Responding to contentions that it has used section 15 improperly as a "standard-setting" tool in such cases,²⁶¹ the Commission argues that it is within its discretion to proceed by adjudication.²⁶² Most courts would agree that an agency has such discretion.²⁶³

b. *Inducements to Settlement.* All recall programs entail similar inducements to settlement. Like NHTSA, the CPSC wants a prompt recall agreement so that consumer response is maximized.²⁶⁴ Because of difficulties in recalling products at the consumer level, this incentive is particularly strong for the CPSC.²⁶⁵ Moreover, the Commission wants to avoid litigation to conserve agency resources. Since the CPSC is a small agency with a limited

bats with rubber grips that could deteriorate and detach, possibly causing the bat to fly from the swinging batter's hand. Two injuries and one death from roughly 4.8 million bats had been reported when the recalls were undertaken.

259. *In re North Am. Sys.*, CPSC No. 77-19 (file opened Jan. 24, 1977). Neither the CPSC nor the company could pinpoint the cause of several fires and mechanical failures in automatic drip coffeemakers. Due to the vast number of complaints, the CPSC nevertheless insisted that the company recall the product and redesign it to minimize future problems. In targeting those coffeemakers to be recalled, the parties relied on the pattern of complaints filed with the company to estimate the period during which the bulk of defective items were produced.

260. For example, during 1981 CPSC staff wrote to every known manufacturer of electric clamp lamps, informing them of its conclusion that lamps without certain safety features constituted a substantial product hazard. Although the Commission's action prompted a horde of angry protests, most manufacturers agreed to redesign their lamps.

261. See Letter from James N. Pearse, Group Vice President of Engineering of Leviton Manufacturing Co., to Linda Glatz, Division of Corrective Actions of the CPSC (June 8, 1981) (on file with the *Case Western Reserve Law Review*). Mr. Pearse wrote, "We believe it is inappropriate for the Commission to threaten Section 15 action on the basis of not complying with a generic, design standard imposed by the staff without complying with traditional notice and comment procedures and without reviewing any substantive facts concerning a manufacturer's particular product." *Id.* at 2.

262. The issue is currently being litigated in a CPSC action against manufacturers of mesh-sided cribs. See *infra* note 300; see also R. David Pittle, Standards-Setting: Section 15 v. Section 7. Remarks at the Seminar on the Federal Regulatory Process (sponsored by Law and Business, Inc.), in Washington, D.C. (Feb. 10, 1981).

263. Cf. *NLRB v. Bell Aerospace Co.*, 416 U.S. 267 (1974); *SEC v. Chenery Corp.*, 332 U.S. 194 (1941); *Saavedra v. Donovan*, 700 F.2d 496, 499 (9th Cir.), *cert. denied*, 104 S. Ct. 236 (1983); *Montgomery Ward & Co. v. FTC*, 691 F.2d 1322, 1329 (9th Cir. 1982). *But cf.* *Ford Motor Co. v. FTC*, 673 F.2d 1008 (9th Cir. 1981), *cert. denied*, 103 S. Ct. 358 (1983).

264. Delays reduce response rates under the recall programs of both agencies. See *supra* notes 91-95 and accompanying text (NHTSA); *infra* notes 283-86 and accompanying text (CPSC).

265. See *infra* note 286 and accompanying text.

budget to carry out its very broad mandate,²⁶⁶ this incentive may be even more compelling for the CPSC than for NHTSA.

Recall incentives for consumer product manufacturers are the same as those for auto makers. To avoid litigation, consumer product firms have agreed to recalls even though they did not believe their products created a substantial hazard.²⁶⁷ The threat of product liability suits prompts them to avoid the formal agency finding of "substantial product hazard" that may be admissible in such suits.²⁶⁸ Negotiated corrective actions are not equivalent to an admission that a defect or hazard exists.²⁶⁹ Further, the cost and delay of defending a lawsuit can be very high. Most companies faced with the uncertainty of litigation and the opportunity to negotiate the terms of a voluntary recall opt for the latter approach.²⁷⁰ Companies also are induced to recall promptly to avoid negative publicity that can stigmatize not only the recalled product, but also the company's entire product line.²⁷¹ Finally, the wide range of enforcement tools available to the Commission may have an important impact on the settlement process. Two of the tools—section 12 actions for imminent hazards and civil penalties for reporting violations²⁷²—have been used infrequently, but their availability may give the Commission extra clout in negotiating effective recalls.

These inducements have resulted in even less recall litigation

266. The CPSC is the smallest of the health and safety agencies and has only a fraction of most agencies' budgets. See Schwartz, *supra* note 188, at 44 n.81. Nevertheless, Congress has charged the CPSC with the major responsibility of "[protecting] the public against unreasonable risks of injury associated with consumer products." 15 U.S.C. § 2051(b)(1) (1982).

267. For example, to avoid litigation Sears agreed to recall seven-year-old fans that overheated, although it did not believe the fans posed a substantial hazard. Hollerman & Couric, *Consumer Agencies Fretting About Poor Product Recalls*, *Legal Times of Wash.*, Mar. 3, 1980, at 1.

268. Madden, *supra* note 196, at 22.

269. In any subsequent litigation, companies can claim that they recalled a product out of an abundance of caution and not because it posed a serious hazard.

270. For example, in the Sears recall of overheating fans, *supra* note 267, Sears was able to negotiate a recall by advertisement rather than notice sent to credit card customers with monthly bills. Hollerman & Couric, *supra* note 267, at 1.

Although the CPSC's recall provision has not been judicially interpreted, NHTSA's requirement, which resembles the CPSC's, has been very broadly interpreted. See *supra* notes 30-47 and accompanying text. This also may discourage legal challenges by manufacturers.

271. Madden, *supra* note 196, at 22.

272. See *supra* notes 190-95, 214, 216 and accompanying text.

at the CPSC than at NHTSA.²⁷³ In a 1980 report, a Commission task force on recalls was critical of this reliance on negotiated settlements.²⁷⁴ It recommended that the Commission bring more test cases “to push recall authority to its limits of creativity and effectiveness,” and that it step up litigation “to make clear that it will seek formal remedies if negotiations break down”²⁷⁵ The first recommendation seems misplaced, since the Commission already enjoys expansive recall authority.²⁷⁶ The second recommendation has more merit²⁷⁷—there is some indication of a general correlation between an agency’s willingness to take enforcement actions and the amount of voluntary cooperation an agency receives from the private sector.²⁷⁸

5. Recall Effectiveness

The average response rate for recalls at the CPSC has been about thirteen percent.²⁷⁹ Return rates vary markedly from recall to recall, however, depending on a wide range of variables.²⁸⁰ A 1978 Commission study found the most significant variables to be: (1) the price of the product, (2) the expected useful life of the product, (3) the number of units in distribution, (4) the age of the product, (5) the type of corrective action—repair or re-

273. The CPSC has never issued a recall order following an administrative hearing. See *supra* notes 246-48 and accompanying text.

274. Consumer Prod. Safety Comm’n, Report of the Recall Effectiveness Task Force 3 (Aug. 25, 1980) (available from the Office of the Secretary of the CPSC) [hereinafter cited as Task Force Report].

275. *Id.*

276. See *supra* notes 257-60 and accompanying text for a sampling of defective products recalled at the CPSC’s urging. In fact, the Commission never adopted this recommendation. See *Consumer Product Safety Commission Reauthorization: Hearings Before the Subcomm. for Consumers of the Senate Comm. on Commerce, Science, and Transportation*, 97th Cong., 1st Sess. 336 (1981) (statement of Stuart Statler, acting Chairman of the CPSC).

277. CPSC staff opinion is split on whether the Commission has been sufficiently aggressive in its recall program. The current compliance director, although generally satisfied with the CPSC’s program, believes that the Agency must be prepared to litigate more quickly when hazards are life-threatening. Moreover, while recognizing that some firms will not agree to corrective action programs until their liability for timeliness violations has been resolved, he is reluctant to trade reduced civil penalties for corrective action agreements. Interview with David Schmeltzer, Associate Executive Director for Compliance and Administrative Litigation, CPSC, in Washington, D.C. (Nov. 10, 1983).

278. In 1981, the number of voluntary recalls under the FDA’s program dropped sharply when the number of enforcement actions did the same. See *infra* notes 440, 441 and accompanying text.

279. See *supra* note 276.

280. Consumer Prod. Safety Comm’n, Office of Strategic Planning, Recall Effectiveness Study 6 (May 1978).

fund—offered by the manufacturer, and (6) the level of direct consumer notification.²⁸¹ The study was unable to correlate recall effectiveness with another variable that common sense might suggest is important: the severity of the hazard.²⁸²

The study concluded that recalls are least effective when the product costs under two dollars, its useful life is less than two years, the number of recalled units exceeds 100,000, or the product has been in distribution for over five years.²⁸³ It indicated that recalls which entail direct consumer notice are generally effective, and that the most effective recalls involve repairs made in consumers' homes.²⁸⁴ Recalls with limited or no direct notification are normally less than twenty percent effective, unless the recall involves a very expensive unit or is geographically limited.²⁸⁵ Finally, recalls of products still in the distribution chain are far more effective than recalls of products in consumers' hands.²⁸⁶

Several of the most important variables determining recall effectiveness are beyond the Commission's control—the price of a product, its useful life, and the number of products distributed. However, the Commission has some influence over other variables. Product age and the percentage of units in consumers' hands can be controlled by negotiating a prompt and effective recall.²⁸⁷ The Commission has considerable control over the variables of notice and type of corrective action.

a. *Notice.* Notice is a critical issue for the CPSC and manufacturers alike. The Commission generally seeks to have recall notices drafted in stark, direct, and dramatic terms and disseminated widely. Manufacturers fear that unduly strong notices will cause consumers to overreact and discourage future sales. Thus, much of the controversy in recall negotiation centers on notice.²⁸⁸

For some consumer products, especially durable goods, notice

281. *Id.*

282. The data showed that median case effectiveness remained similar at all hazard severity levels. The most likely explanation is that consumers' risk perceptions did not coincide with the CPSC's. *Id.* at 20.

283. *Id.* at 3.

284. *Id.* In cases of home repairs, 90% of the units will be repaired.

285. *Id.*

286. Task Force Report, *supra* note 274, at 19.

287. The recall must occur before the product is distributed widely to consumers. *Id.*

288. For example, in the Sears recall, *see supra* note 270, the CPSC wanted recall notices sent to credit card holders along with monthly bills. Sears successfully resisted, arguing that the notices would undermine other bill-stuffer advertisements. *See Hollerman & Couric, supra* note 267, at 1.

can be mailed to consumers who have returned warranty cards, but many consumers fail to return them.²⁸⁹ For products whose purchasers cannot be identified, notice of the recall must be directed to the general public with the hope that the purchasers will see it.

The Commission has been innovative in its approach to notice. Early in its existence, the Commission sought a court order requiring paid advertising to notify the public in an imminent hazard case.²⁹⁰ Although the district court refused because, in its view, sufficient publicity had been generated,²⁹¹ the CPSC subsequently obtained paid advertising agreements in numerous recalls.²⁹² Gradually, however, the Commission discovered that general media notice often costs more and produces less effective results than "targeted" media notice. The Commission has thus sought notice in diving magazines for allegedly defective scuba gear and gardening magazines for an allegedly dangerous rototiller.²⁹³ In cases involving severe risks, the Commission has obtained multiple forms of targeted notice. For instance, the manufacturer of two crib models alleged to present a strangulation hazard agreed to place warnings in magazines directed to parents of newborns, to mail notice to every United States household known to have children up to the age of twenty-one months, and to mail warning posters to all known pediatric clinics and maternity wards in the country.²⁹⁴ As a result, recall rates improved significantly.²⁹⁵

The CPSC has developed other techniques to alert the public to product hazards. One is the use of bounties or rewards to motivate consumers, as well as distributors and dealers, to participate in the recall. For example, in the recall of an allegedly defective smoke alarm that had been factory-installed in mobile homes, the manufacturer offered mobile home park owners three dollars for

289. To counter this failing, one manufacturer rewards consumers for returning warranty cards. Letter from Robert I. Yeoman, Vice President of Worthington Industries, Inc., to Sam Zagoria, Commissioner of the Consumer Product Safety Commission (October 25, 1979).

290. See CPSC v. A-K Elec. Co., No. 74-1026 (D.D.C. filed Sept. 9, 1974).

291. *Id.*

292. For a listing of cases, see PRODUCT HAZARDS, *supra* note 193, at 271.

293. *In re Roper Corp. & Sears, Roebuck & Co.*, CPSC No. 82-1 (file opened Feb. 24, 1982) (rototiller); *In re Parkway Fabricators*, CPSC No. 78-41 (file opened Dec. 19, 1977) (scuba gear).

294. *In re Bassett Furniture Indus.*, CPSC No. 78-51 (file opened Jan. 24, 1978); CPSC No. 78-81 (file opened May 3, 1978). The Commission accepted a comprehensive consent order against the company. See *id.*, CPSC No. 80-CO-002 (Feb. 7, 1980).

295. The response rates in the two recalls ranged from 24% to 45% and from 77% to 86%. PRODUCT HAZARDS, *supra* note 193, at 139.

every alarm returned.²⁹⁶ A lawn and garden tractor manufacturer offered an "early completion allowance" to dealers who found and corrected allegedly defective products in inventory.²⁹⁷ Similarly, the manufacturer of allegedly defective thermostats for gas water heaters offered dealer's bonuses both for locating and for replacing the thermostats.²⁹⁸ In the mesh-sided crib case, the manufacturer offered a reward to *anyone* identifying an unmodified crib.²⁹⁹

The press conference is another form of notice used by the CPSC, albeit infrequently. Such publicity enables the Commission to illustrate visually the hazard potential of a product, and indicates strong agency concern regarding the danger.³⁰⁰ In several instances, the Commission has determined to hold a conference whether or not the company agrees. This right was recognized in a case involving an imminent hazard.³⁰¹

b. *Consumer Resistance.* Consumers do not always respond to recalls. In a survey of hairdryer owners following a highly publicized recall of hairdryers containing asbestos, CPSC staff found that while eighty-five percent of the owners were aware of the recall, only one-third of those whose hairdryers contained asbestos stopped using them. Of the latter group, only four and one-half percent took advantage of the repair, refund, or replacement remedy offered by the manufacturers.³⁰² Of those consumers surveyed who believed asbestos presented a serious or somewhat serious problem, only slightly more than half (53.6%) had attempted to determine whether their hairdryers contained the sub-

296. *In re* BRK Elec., CPSC No. 76-155 (file opened Aug. 24, 1976).

297. *In re* International Harvester, CPSC No. 77-40 (file opened May 2, 1977).

298. *In re* Emerson Elec., CPSC No. 80-66 (file opened Mar. 7, 1980).

299. *In re* Bassett Furniture Indus., CPSC No. 78-51 (file opened Jan. 24, 1978); CPSC No. 78-81 (file opened May 3, 1978).

300. CPSC staff held a press conference to announce its view that manufacturers of mesh-sided cribs had not warned sufficiently about the dangers of suffocation if a side is left down and the child rolls between the mattress and the loose mesh side. Wash. Post, Oct. 15, 1983, at A3, col. 1.

301. Subsequent to filing a complaint in the automatic pitching machine case, *see supra* note 193, the Commission indicated that it planned to hold a press conference warning of the machine's hazards. The manufacturer objected that a press conference during the pendency of litigation was unfair. In a bench ruling, District Court Judge Thomas Flannery refused to bar the press conference, indicating lack of judicial authority. Interview with Catherine Cook, former Director of the Division of Administrative Litigation, CPSC, in Washington, D.C. (Oct. 16, 1983).

302. Task Force Report, *supra* note 274, at 20-28. The survey sample consisted of 600 nationwide telephone calls.

stance.³⁰³ Thus, as in the case of auto recalls, a certain level of "recall resistance"³⁰⁴ cannot be overcome, despite the best efforts of the Commission and manufacturers to publicize a problem and provide generous relief. Some consumers may believe that the injury associated with the recall will not happen to them. Others may have adopted a fatalistic attitude, having become "saturated" with news of hazards.³⁰⁵

C. Recommendations

Few changes in the CPSC's broad recall authority are necessary to make it work more efficiently and expeditiously. However, some modifications in the transferred acts and minor revisions in the CPSA would be beneficial. In addition, the Commission should consider at least one change in its own procedures. First, the Commission should be granted specific recall authority under the Federal Hazardous Substances Act, the Flammable Fabrics Act, and the Poison Prevention Packaging Act similar to that under the CPSA.³⁰⁶ This would promote uniformity and reduce delay by enabling the Commission to address the risks posed by all products within its jurisdiction under its section 15 authority. Second, Congress should correct the absence of a judicial review provision for recall orders under the CPSA and FHSA. It should provide for judicial review in United States courts of appeals under the "substantial evidence" test, thereby eliminating the duplicative, two-tiered review procedure. Third, as a means of improving consumer response to serious hazard recalls, the CPSC should consider publicly classifying its recalls according to risk, either by employing its internal classification system or by devising a simpler, perhaps two-tiered system. This approach would enable the Commission to inform consumers of the relative risk of recalled products, thus helping them to make more informed decisions on how to respond to recalls.

303. Those who perceived the risk as serious were, however, far more inclined to determine if their hairdryers contained asbestos, and to discard them or seek corrective action if they did. *Id.* at 22.

304. See *Recalls, Why So Many Are Flops*, 34 CHANGING TIMES 29, 32 (Oct. 1980).

305. See *The Failure of Product Recalls*, 46 CONSUMER REP. 45 (1971); *Adequate Notice, But Not Many Returns*, 13 QUALITY PROGRESS 11 (1980); *Product Recalls, How Many Listen?*, Louisville Times, Sept. 2, 1982, at B1, col. 1.

306. 15 U.S.C. § 2079(a) (1982). To conduct recalls under the transferred acts, the Commission must promulgate a rule under § 30(d) of the CPSA, *id.* § 2097(d), reflecting its determination that the risk should be addressed under the CPSA. It then may initiate an action for a recall in accordance with § 15 of the CPSA. See *supra* notes 190, 195 and accompanying text.

III. THE FOOD AND DRUG ADMINISTRATION

The FDA, a part of the Department of Health and Human Services (HHS), has been involved in product recalls longer than any other federal agency, and boasts perhaps the most elaborate recall program. Each year, it conducts many hundreds of recalls of products within its jurisdiction.³⁰⁷ Ironically, the FDA lacks statutory authority to order most of these recalls. It relies largely on voluntary recalls by manufacturers, sometimes using its authorized enforcement mechanisms, such as seizures, to encourage recalls.³⁰⁸ The recall has become one of the FDA's major tools for enforcing the statutes it is charged with administering.³⁰⁹

A. Recall Authority: Background

Although FDA product recalls date back to the 1930's,³¹⁰ the Agency did not encourage voluntary recalls as part of its law enforcement program until the 1950's.³¹¹ Initially, manufacturers only recalled products posing serious hazards. Later, they began recalling products that posed less serious risks, and eventually those that posed no risk at all but were in violation of the statute.³¹² Recalls burgeoned from fewer than 100 per year in the early 1960's to over 1,000 recalls per year by the end of that decade.³¹³

In the early 1970's, Congress criticized the FDA for its failure to establish guidelines or procedures to govern what had become an enormous yearly volume of recalls.³¹⁴ In the late 1970's, the FDA instituted procedural guidelines.³¹⁵ Congress also consid-

307. Off. of Pub. Affairs, Food & Drug Admin., Talk Paper 2 (Dec. 6, 1982) (data collected by FDA's Emergency and Epidemiological Operations Branch for fiscal years 1977 to 1982).

308. See *infra* notes 427-30 and accompanying text.

309. H.R. REP. NO. 585, 92d Cong., 1st Sess. 3 (1971) [hereinafter cited as HOUSE RECALL REPORT]. In 1945, the FDA had relied mostly on seizures—over 3,000 a year—to enforce its statute; by 1969 the yearly number of seizures had fallen to 383, and the agency was relying largely on the recall remedy. *Id.* at 3, 8.

310. One of the earliest recalls, involving "elixir sulfanilamide," occurred in 1937. The drug contained poison and had caused over a hundred deaths. The tragedy led to the 1938 amendments to the Food, Drug, and Cosmetic Act, requiring that manufacturers prove their drugs are safe before marketing them. Levy, *supra* note 1, at 117-18.

311. HOUSE RECALL REPORT, *supra* note 309, at 3.

312. *Id.*

313. *Id.* From January 1962 to June 30, 1964, the FDA participated in only 43 recalls, compared with 1400 in 1970.

314. *Id.* at 17, 20. The FDA also was criticized for overusing the recall tool and neglecting its statutory sanctions such as seizures and injunctions.

315. See 21 C.F.R. §§ 7.40-.59 (1984).

ered but never enacted legislation granting the FDA broad recall authority.³¹⁶ Instead, Congress has addressed the issue on a piecemeal basis, giving the FDA limited recall authority under three different statutes enacted between 1968 and 1976.

B. *Statutory Authority*

1. *The Radiation Control for Health and Safety Act*

a. *Scope of Authority.* The broadest recall provision is contained in the Radiation Control for Health and Safety Act (RCHSA).³¹⁷ It authorizes recall of radiation-emitting products which "fail to comply with an applicable standard . . . [promulgated under the Act or] have a defect which relates to the safety of use of such product. . . ."³¹⁸ Under the FDA's interpretation, defective products are those that create a risk of injury, including genetic injury, when the emissions are unintended or unnecessary, or fail to meet the manufacturer's own emission standards.³¹⁹

b. *Implementing Procedures.* The RCHSA's broad reporting requirement obligates manufacturers to inform the Secretary immediately upon discovering a defect or failure to comply with a standard.³²⁰ The FDA may also uncover defects or noncompliance through its own inspections or testing.³²¹ If, after studying the problem, the FDA finds the product to be defective or not in compliance, it notifies the manufacturer and gives it an opportunity to contest the finding.³²² The manufacturer may obtain an informal administrative hearing on request.³²³ In the case of non-

316. See H.R. 5170, 94th Cong., 1st Sess., 121 CONG. REC. 7407-09 (1975) (statement of Rep. Koch).

317. 42 U.S.C. §§ 263b-263n (1982).

318. *Id.* § 263g.

319. 21 C.F.R. § 1003.21 (1984).

320. 42 U.S.C. § 263g(a)(1) (1982). Manufacturers also must submit copies of service bulletins to the Secretary. *Id.* § 263g(d). This requirement resembles that imposed by NHTSA. See *supra* note 47 and accompanying text. When the manufacturer notifies the FDA, simultaneously it may seek an exemption from the notice requirements. 42 U.S.C. § 263g(a)(2) (1982). To obtain an exemption the manufacturer must show that the product does not create a significant risk of injury. *Id.*

321. See FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL pt. 5, at 2 (1982) [hereinafter cited as FDA MANUAL].

322. 42 U.S.C. § 263g(e) (1982). The FDA must supply the manufacturer with its findings and the data on which they are based. *Id.* In cases involving a defective product, a health hazard evaluation committee assesses the significance of the public health hazard; in cases involving violation of a standard, the health hazard is presumed. FDA MANUAL, *supra* note 321, pt. 5, at 2.

323. Interview with Thomas Moore, Special Assistant to the Director of Compliance

compliance, the manufacturer must rebut the presumption that deviation from a standard presents a significant risk.³²⁴ The FDA has the burden of proof in cases of alleged defects.³²⁵ Since enactment of the RCHSA, only one administrative hearing has been requested and held.³²⁶

When recall is required, the manufacturer must notify its dealers, distributors, and consumer purchasers and their transferees who are known or identifiable through reasonable inquiry.³²⁷ Under the Act, the manufacturer must remedy the problem at no cost by repair, replacement, or refund.³²⁸ The FDA permits the manufacturer to design its own corrective action plan, subject to FDA approval.³²⁹ The implementing regulations detail the contents of the notification letter³³⁰ and specify a warning to appear on the mailing envelope.³³¹

If the manufacturer fails to implement an FDA-ordered recall, the government may sue in federal district court to restrain the manufacturer's violation of the order.³³² As in the case of auto recalls, trial is *de novo*, with the burden on the government to establish that the product is defective.³³³ The court may likewise

Operations of the National Center for Devices and Radiological Health, FDA, in Silver Spring, Md. (Nov. 6, 1983) [hereinafter cited as Moore Interview].

324. *Id.* Since the FDA had found the safety risk to exist during proceedings to establish the standard, noncompliance with the standard is presumed to create a risk unless the manufacturer can show otherwise under the circumstances.

325. *Id.*

326. *Id.* The case involved microwave ovens manufactured by General Electric. GE contested the FDA's measurement of microwave emissions, but ultimately agreed to recall the ovens. *Id.*

327. 42 U.S.C. § 263g(a)(1), (b) (1982) (implementing regulations at 21 C.F.R. § 1003.10(b) (1984)). The manufacturer must notify the consumer by certified mail. 21 C.F.R. § 1003.21(c) (1984).

328. 42 U.S.C. § 263g(f) (1982) (implementing regulations at 21 C.F.R. § 1004.1(a) (1984)).

329. *Id.* § 263g(f) (implementing regulations at 21 C.F.R. § 1004.1(b) (1984)); *see also* FDA MANUAL, *supra* note 321, pt. 5, at 3.

330. The letter must identify the product, describe the problem, provide an evaluation of the hazard in clear, nontechnical terms, and include prescribed language that the remedy will be without charge. *See* 21 C.F.R. § 1003.21(a) (1984).

331. The envelope must bear the legend "IMPORTANT—ELECTRONIC PRODUCT RADIATION WARNING." The regulation also specifies the size, print, and location of the legend. *Id.* § 1003.21(b).

332. 42 U.S.C. § 263j(a)(2) prohibits the failure to furnish defect notifications or provide repair, refund, or replacement of noncomplying or defective products. The federal district courts have jurisdiction to restrain such prohibited acts. *Id.* § 263k(a).

333. Both the RCHSA and the National Traffic and Motor Vehicle Safety Act grant jurisdiction to the district courts "for cause shown" to restrain statutory violations. *See* 15 U.S.C. § 1399(a) (1982); 42 U.S.C. § 263k(a) (1982); *see also supra* text accompanying notes 83-84.

impose civil penalties for failure to carry out the recall.³³⁴

The FDA's recall program, like those of NHTSA and the CPSC, operates almost entirely on a voluntary basis.³³⁵ This is due not only to broad statutory recall standards, which the other agencies share, but also to the fact that the FDA has promulgated performance standards for every major category of radiation-emitting products, thereby easing identification and proof of recall cases.³³⁶ Moreover, the FDA has readily taken these cases to court, seeking recalls and penalties when negotiation has failed.³³⁷ In every case, the parties reached a recall agreement before trial.³³⁸

2. *The Medical Device Amendments of 1976*

a. *Scope of Authority.* The Medical Device Amendments³³⁹ contain a recall provision that is narrower than that of the RCHSA. It does not require repair, replacement, or refund in every case and mandates notification only when a device presents an "unreasonable risk of substantial harm to the public health"³⁴⁰ and "no more practicable means is available" under the statute to minimize the risk.³⁴¹ Before the FDA may require notification, it must consult informally with the obligated party.³⁴² The Agency may require that notice be given to health professionals who use or prescribe the device, distributors and sellers of the device, and device users (unless notice poses greater danger to the individual

334. A penalty of \$1,000 for each product involved in the violation may be assessed, up to a maximum of \$300,000. 42 U.S.C. § 263k(b)(1) (1982). Similar civil penalty authority should be provided under the other FDA-administered statutes. *See infra* note 436 and accompanying text.

335. Moore Interview, *supra* note 323. The FDA's nine performance standards cover such products as televisions, diagnostic X-ray machines, microwaves, and sunlamps. *Id.*

336. *Id.* Since the burden in noncompliance cases shifts to the manufacturer to show absence of a health risk, the FDA's job is simplified in such cases. *See supra* note 324 and accompanying text.

337. Moore Interview, *supra* note 323. Approximately 20 complaints have been filed under the RCHSA. *Id.*

338. *Id.* The parties have settled during discovery, obviating a court-ordered penalty or recall under the Act.

339. Pub. L. No. 94-295, § 2, 90 Stat. 539, 540 (1976) (codified at 21 U.S.C. § 360c (1982)). Devices are to be classified by risk into three categories and regulated accordingly. Class III devices present the greatest risk and require premarketing approval. *Id.* § 360c(a)(1)(C). Class II devices require performance standards to assure their safety and effectiveness. *Id.* § 360c(a)(1)(B). Class I devices involve the least risk and require only general controls to prohibit misbranding and adulteration. *Id.* § 360c(a)(1)(A).

340. *Id.* § 360h(a)(1).

341. *Id.* § 360h(a)(2).

342. *Id.*

than no notice).³⁴³

The FDA also may order the manufacturer to repair, replace, or refund the price of defective devices.³⁴⁴ It may do so only if after providing for an informal hearing it finds that: (1) the device presents an unreasonable risk of substantial harm to the public health; (2) the device was improperly made "with reference to the state of the art" at the time of manufacture; (3) the unreasonable risk is not created by the user; and (4) notification alone is insufficient to eliminate the risk.³⁴⁵ Since these findings are difficult to make in some cases, the Amendments thus substantially limit the Agency's recall authority. For example, devices that complied with the state of the art when made but subsequently are found to be dangerous are not subject to recall.³⁴⁶ Improper use, the source of many device failures, also prevents the FDA from pursuing the full recall remedy.³⁴⁷

b. *Finding the Defects.* The Medical Device Amendments require that manufacturers report product defects to the FDA.³⁴⁸ Nevertheless, for years after their passage, the Agency failed to propose regulations to implement this requirement.³⁴⁹ The FDA has been criticized for this delay and for long relying on an inadequate system of voluntary reporting supplemented by agency inspection of manufacturers' complaint files.³⁵⁰ Predictably, the

343. *Id.* When notification might be harmful to the user (for example, in cases of defective pacemakers), the notification order should require that the health professional who prescribed the device inform the user of the problem and the steps necessary to reduce or eliminate the risk.

344. *Id.* § 360h(b)(2).

345. *Id.* § 360h(b)(1)(A).

346. For example, tampons which complied with the state of the art when made but later were suspected of causing toxic shock syndrome may not have been subject to a recall order. Since the manufacturer agreed to a comprehensive recall plan, the FDA's authority was not tested. Consent Agreement 2-11, *In re Procter & Gamble Co.* (consent agreement Sept. 26, 1980) (on file with the *Case Western Reserve Law Review*).

347. Two leading causes of device failure are improper use and inadequate maintenance. COMPTROLLER GEN., GOV'T ACCOUNTING OFF., REPORT TO THE CONGRESS OF THE UNITED STATES, FEDERAL REGULATION OF MEDICAL DEVICES—PROBLEMS STILL TO BE OVERCOME 30-31 (Sept. 30, 1983) [hereinafter cited as GAO DEVICE REPORT].

348. 21 U.S.C. § 360i(a).

349. The FDA first proposed regulations to implement the reporting provision on November 18, 1980. 45 Fed. Reg. 76,183 (1980). These were withdrawn and new ones proposed on May 27, 1983. 48 Fed. Reg. 24,014 (1983).

350. SUBCOMM. ON OVERSIGHT & INVESTIGATIONS OF THE HOUSE COMM. ON ENERGY & COMMERCE, 98TH CONG., 1ST SESS., MEDICAL DEVICE REGULATION: THE FDA'S NEGLECTED CHILD 21-27 (Comm. Print 1983) [hereinafter cited as DEVICE OVERSIGHT REPORT]. In a 1982 survey, FDA staff inspected 40 manufacturers' complaint files and found that 60% were either "poor or unusable." *Id.* at 25. FDA staff discovered that the files

voluntary system has generated reports of only a small percentage of manufacturer-initiated recalls.³⁵¹ Many reports reach the FDA months after manufacturers have conducted the recalls.³⁵² The Agency has acknowledged that few device manufacturers report problems with their products³⁵³ and that they often delay reporting until after completing recalls or taking other remedial action.³⁵⁴

The legislative history of the Amendments indicates that Congress intended to pattern the reporting requirements after those of the Motor Vehicle Safety Act, the CPSA, and the RCHSA.³⁵⁵ However, the reporting requirements under these statutes vary—from the broad provisions of the CPSA and the RCHSA to the more restrictive provision of the Motor Vehicle Safety Act.³⁵⁶ In its first proposed reporting rule in 1980, the FDA set forth broad requirements³⁵⁷ similar to those under the CPSC's reporting regulations.³⁵⁸ Responding to criticism that the proposed rule was overbroad and unduly burdensome on manufacturers, the following year the FDA placed it in abeyance for further study.³⁵⁹

contained accounts of 3 deaths, 20 injuries, and 48 hazards that had not been reported under the Agency's voluntary system. *Id.*

351. Perhaps only 15% of recalls are reported. *Id.* at 22; see also *FDA Oversight: Medical Devices: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 97th Cong., 2d Sess. 147 (1982) (testimony of Sidney M. Wolfe, Director of Health Research Group, Public Citizen) [hereinafter cited as *FDA Oversight Hearing*] (FDA systematically has failed to implement reporting requirements of Medical Device Amendments).

The low reporting rate is not surprising, given the possible adverse consequences—recall, adverse publicity, and increased product liability claims. See *supra* note 223 and accompanying text. Even when reporting is mandatory, manufacturers are reluctant to comply. See *supra* note 221 and accompanying text.

352. *FDA Oversight Hearing, supra* note 351, at 147. Public Citizen's Human Research Group found that an average of three months elapsed between the time a manufacturer notified its customers of a recall and publication of the recall in the FDA's Weekly Enforcement Report. *Id.*

353. Problems reported by manufacturers often concern competitors' products, not their own. 48 Fed. Reg. 24,014 at 24,016 (1983) (FDA statement accompanying repropoed reporting regulation).

354. *Id.*

355. H.R. REP. NO. 853, 94th Cong., 2d Sess. 21 (1976).

356. See *supra* notes 55, 211, 319-20 and accompanying text.

357. 45 Fed. Reg. 76,183 (1980). The proposed rule would have required device manufacturers and distributors to submit reports to the FDA concerning devices (1) that may have caused death or injury; (2) that may have a deficiency that could cause death or injury or give misinformation resulting in improper treatment; or (3) that are subject to remedial action. Remedial action included all steps by a manufacturer to correct any suspected or confirmed device deficiency. *Id.*

358. See *supra* note 211 and accompanying text.

359. 46 Fed. Reg. 57,568 (1981). The Agency explained that it needed to review com-

The FDA did not propose a new reporting rule for public comment until May 1983.³⁶⁰ The repropoed rule is narrower than the first, requiring reports only when the manufacturer becomes aware of an allegation, or has information that "reasonably suggests,"³⁶¹ that a device "has caused or contributed to a death or serious injury or has malfunctioned, if recurrence of the malfunction is likely to cause or contribute to a death or serious injury."³⁶² "Serious injury" is broadly defined to include not only life-threatening and permanent injury, but also "unanticipated temporary impairment" of a bodily function or structure.³⁶³

Under the statute, failure to report a device defect renders the device misbranded³⁶⁴ and subject to seizure or condemnation.³⁶⁵ The FDA can also enjoin a failure to report³⁶⁶ and criminally prosecute those responsible.³⁶⁷ The proposed rule indicates that the FDA will use these enforcement tools to ensure compliance with the reporting requirements.³⁶⁸

c. *Implementing Procedures.* The recall procedures under the Device Amendments may be the most cumbersome of any enacted. If the FDA wishes to invoke the notification requirement, it need merely consult with the manufacturer before ordering notification. If it wishes to order both notice and corrective action, however, it must hold an informal hearing³⁶⁹ and make the four

ments on the proposal, to review the proposal in light of an executive order requiring cost-benefit and regulatory impact analyses, and to complete an inspection of company complaint files to determine if inspections adequately could replace some of the proposed reporting requirements.

360. 48 Fed. Reg. 24,014 (1983).

361. *Id.* at 24,015.

362. *Id.*

363. *Id.* at 24,018. This category of injuries would include "electrical shocks, severe lacerations, or broken bones"—injuries that are "not generally accepted as part of the risk of using a device and are avoidable." *Id.*

364. 21 U.S.C. § 352(t) (1982).

365. *Id.* § 334.

366. *See id.* §§ 331(k), 332; *see also id.* § 331(q)(1) (making failure to report a violation of the FDA Act which may be enjoined under § 332).

367. *Id.* § 333. A civil penalty provision, which the Device Amendments lack, might be useful, especially in cases in which criminal prosecution seems unduly severe. *See infra* note 436 and accompanying text.

368. 48 Fed. Reg. 24,014 at 24,022 (1983).

369. An informal hearing requires, inter alia, that the parties be given (1) "reasonable notice of the matters to be considered at the hearing," (2) a comprehensive explanation of the basis for the proposed action, (3) a "summary of the information which will be presented," and (4) the opportunity to conduct questioning and present relevant oral and written information. 21 U.S.C. § 321(y) (1982).

findings discussed previously.³⁷⁰ If the FDA affirms its findings following the hearing, it must permit the manufacturer to submit a corrective action plan for its approval,³⁷¹ and hold another informal hearing before it may disapprove the plan.³⁷² If the Agency does disapprove, it cannot mandate its own plan until it has allowed the manufacturer to submit a revised plan and has provided yet another informal hearing.³⁷³

If the manufacturer fails to comply with a recall order, the FDA may bring an action in federal district court for an injunction compelling the recall³⁷⁴ or initiate criminal proceedings.³⁷⁵ The FDA also has authority to obtain court-ordered seizures of adulterated or misbranded devices,³⁷⁶ and to retain the devices administratively for a short time until a court action can be instituted.³⁷⁷

d. *Voluntary Settlements.* If the procedures for securing a recall under the Device Amendments were widely used, they would render the scheme unworkable. But they were not intended to be used often—Congress designed the agency-ordered recall as a remedy of last resort, to be used only when voluntary actions would not eliminate device risks.³⁷⁸ Indeed, the FDA's use of recall orders has comported with congressional intent. The Agency has relied extensively on voluntary recalls—roughly 1,500 of them since the Device Amendments were enacted.³⁷⁹ Seldom has the FDA used its administrative authority, ordering defect notification only three times, although it threatened administrative procedures in another twenty-one cases, thereby inducing voluntary recalls.³⁸⁰ It has ordered no-cost repair only once.³⁸¹ The FDA,

370. See *supra* notes 344-46 and accompanying text.

371. 21 U.S.C. § 360h(b)(1)(A) (1982). The Agency may direct that a combination of persons, such as the manufacturer, importer, and distributor, devise the plan, and may even designate the person to make the final decision regarding the plan. *Id.*

372. *Id.* § 360h(b)(1)(B).

373. *Id.*

374. Failure to give the required notification or remedy is prohibited under 21 U.S.C. § 331(q) and can be enjoined under § 332(a).

375. *Id.* § 333.

376. *Id.* § 334(a)(2)(D).

377. *Id.* § 334(g).

378. DEVICE OVERSIGHT REPORT, *supra* note 350, at 11 (citing Bureau of Medical Devices, summary of regulatory activities from fiscal year 1976 through the first quarter of fiscal year 1982).

379. *Id.* at 11-12.

380. *Id.* at 11.

381. *Id.* at 12. In 1978, the FDA ordered the manufacturer of a defibrillator to repair a switch on the device.

like the CPSC, has had far more success with its recall authority than with its standard-setting authority under the Device Amendments.³⁸²

3. *The Infant Formula Act of 1980*

Following widely publicized recalls of several chloride-deficient infant formulas in 1979,³⁸³ Congress passed the Infant Formula Act of 1980.³⁸⁴ The Act lists the nutritional ingredients that infant formula must contain³⁸⁵ and requires manufacturers to certify compliance with the Act before processing a formula.³⁸⁶ The Act does not give the FDA authority to order recalls of infant formula. However, it anomalously includes provisions usually associated with recall authority, requiring manufacturers to report product defects to the FDA and prescribing procedures to be followed once a manufacturer decides to recall.

The reporting obligation arises when a manufacturer has "knowledge which reasonably supports the conclusion" that a formula either does not provide the statutorily required nutrients or is adulterated or misbranded and, as such, presents a risk to human health.³⁸⁷ "Knowledge" is defined as actual knowledge or knowledge that a reasonable person would have had or obtained in the exercise of due care under the circumstances.³⁸⁸ Once a manufacturer files a report, the FDA decides, under its general voluntary recall guidelines,³⁸⁹ whether the manufacturer should recall the formula; since the Infant Formula Act itself does not establish criteria for initiating a recall. If the manufacturer voluntarily undertakes a recall, however, the Act prescribes certain requirements that it must meet and authorizes the Secretary of Health and Human Services to prescribe others by regulation.³⁹⁰

382. The FDA has not promulgated any performance standards under the Device Amendments. GAO DEVICE REPORT, *supra* note 347, at 40; *see supra* notes 253-56 and accompanying text (CPSC experience).

383. As a result of consuming the formulas, over 130 infants suffered injury from a rare chemical imbalance with unknown long-term effects on their growth and development. H.R. REP. No. 936, 96th Cong., 2d Sess. 4 (1980). For a discussion of events leading up to the enactment of the Infant Formula Act, see Note, *Food and Drug Law: The Infant Formula Act of 1980*, 15 AKRON L. REV. 752 (1982).

384. 21 U.S.C. § 350a (1982).

385. Pub. L. No. 96-359, § 2, 94 Stat. 1190 (1980) (codified at 21 U.S.C. § 350a(g) (1982)). The Secretary of Health and Human Services may revise the list. *Id.*

386. *Id.* § 350a(b)(2).

387. *Id.* § 350a(c)(1).

388. *Id.* § 350a(c)(2).

389. *See infra* notes 409-12 and accompanying text.

390. 21 U.S.C. § 350a(d)(1) (1982).

During a recall, the manufacturer must report bi-weekly on its actions, and the Secretary must review such actions every fifteen days until the recall is terminated.³⁹¹ The regulations outline the steps manufacturers must take in their recalls, giving them leeway to tailor recalls to fit the circumstances.³⁹² The regulations also require that if a recall is to be undertaken, the manufacturer promptly notify the FDA by telephone.³⁹³ The manufacturer must assess the seriousness of the human health hazard posed by the formula, devise a recall strategy appropriate to the risk, and promptly notify consignees to return the products.³⁹⁴ It must furnish the FDA with copies of its hazard evaluation, recall strategy, and all recall notifications it has distributed.³⁹⁵ If the Agency finds the strategy inadequate, it requires that further steps be taken, such as a broader recall or more effectiveness checks.³⁹⁶ After the recall has begun, if the FDA finds that consignees did not receive recall notifications or disregarded them "in a significant number of cases," it may require additional notifications.³⁹⁷ The Agency must approve the termination of the recall efforts.³⁹⁸

The recall provisions of the Infant Formula Act seem at odds with the goals of the Act. By not requiring recalls and imposing additional obligations on companies that undertake voluntary recalls, the statute creates a disincentive to voluntary recall. It is not clear, however, that giving the FDA authority to order recalls would add significantly to the current incentives to recall under the FDA's general recall program.³⁹⁹

391. *Id.* § 350a(d)(1)(A) & (B). *Id.* § 350a(d)(1). These requirements stem from findings that the FDA did not monitor adequately the recall of chloride-deficient formulas. H.R. REP. NO. 936, 96th Cong., 2d Sess. 5 (1980).

392. 21 C.F.R. §§ 7.70-.75 (1984). Congress intended that the "FDA . . . develop necessary flexibility into their regulations to permit the tailoring of recall requirements to the appropriate degree of risk." H.R. REP. NO. 936, 96th Cong., 2d Sess. 9 (1980).

393. 21 C.F.R. § 7.72(a) (1984).

394. *Id.* § 7.71(a)-(c). The recall communication to consignees must be distinctive and reflect the degree of hazard. It must instruct the consignees to report whether they possess the recalled product, and must explain how the products may be returned to the manufacturer or otherwise disposed of. A follow-up communication must be sent to consignees that do not respond to the first one. *Id.* § 7.71(c).

395. *Id.* § 7.71(d).

396. *Id.* § 7.74. On the basis of its own or the firm's hazard evaluation, the FDA also may conclude that the extent of the recall is inadequate.

397. *Id.* § 7.74(c).

398. *Id.* § 7.73.

399. See *infra* notes 426-30 and accompanying text.

C. *The Voluntary Recall Program*

1. *Background*

The FDA's general recall program was prompted by a series of poisonings in the mid-1950's. After issuing a public warning, the FDA permitted the company to remove the product from the market.⁴⁰⁰ Although initially the FDA limited its activities to hazardous products, in the 1960's it expanded its activities to products that posed no health risk or other serious problem but nevertheless violated the Food, Drug, and Cosmetic Act.⁴⁰¹ The Agency made no distinction between recalls involving trivial problems and those addressing serious hazards. Inevitably, recalls became so numerous that they could not be monitored properly, drastically undercutting the effectiveness of all recall efforts.⁴⁰²

In the mid-1960's, the FDA began publishing a weekly list to provide regular public notification of recalls.⁴⁰³ Until 1971, however, the FDA's recall program functioned without published regulations governing its operation. Following congressional hearings critical of the program,⁴⁰⁴ the FDA published its first recall policy,⁴⁰⁵ establishing two categories of recall. One contained products posing an imminent health risk, and the other products posing a potential risk.⁴⁰⁶ The FDA's monitoring procedures varied according to the risks posed.⁴⁰⁷ When congressional critics deemed this policy inadequate, the FDA reevaluated its recall program. As a result, it instituted a three-category system and classified recalls by degree of product hazard.⁴⁰⁸ The three-tiered program, which remains in effect, is unique among the major agency recall programs.

2. *Recall Guidelines*

Under the FDA guidelines, Class I recalls are reserved for

400. *Recall Procedures of the Food and Drug Administration: Hearing Before a Subcomm. of the House Comm. on Government Operations*, 92d Cong., 1st Sess. 30-31 (1971) [hereinafter cited as *FDA Recall Hearings*].

401. *Id.* at 5-6. Products misbranded as to the weight of their contents, for example, were covered by the recall program, although they presented no health risk or other serious problem. *Id.* at 6. See also H.R. REP. No. 585, 92d Cong., 1st Sess. 6 (1971).

402. *FDA Recall Hearings*, *supra* note 400, at 6-8.

403. HOUSE RECALL REPORT, *supra* note 309, at 4. Unfortunately, the Weekly Enforcement Report often lists recalls after they have occurred. See *supra* note 352.

404. See *supra* note 314 and accompanying text.

405. 36 Fed. Reg. 11,514 (1971).

406. *Id.*

407. *Id.*

408. 21 C.F.R. §§ 7.40-.59 (1984).

products that pose a "reasonable probability" of causing serious adverse health consequences or death.⁴⁰⁹ Class II recalls cover products that may cause temporary or medically reversible adverse health consequences, and those presenting a remote risk of such harm.⁴¹⁰ Class III recalls involve products not likely to cause adverse health consequences.⁴¹¹ The classification system applies to medical devices as well as to products over which the FDA lacks specific recall authority.⁴¹² The FDA publicizes all recall classifications in its weekly report, which explains the classification system and lists recalls by class. The Agency's Public Affairs Office originated the classification scheme as a means of informing the public of the relative hazard posed by recalled products.⁴¹³

The FDA requests recalls only in "urgent situations" when the manufacturer has not initiated one.⁴¹⁴ FDA-requested recalls are usually Class I,⁴¹⁵ and require high-level Agency approval.⁴¹⁶ The FDA develops an overall recall strategy for each case and invites the firm to do likewise.⁴¹⁷ The plan is tailored to the severity of the risk and the product's distribution level. It specifies the depth of the recall (*i.e.*, whether to the wholesale, retail, or consumer level),⁴¹⁸ the necessity for public warning (usually reserved for urgent situations),⁴¹⁹ and the level of effectiveness checks, which ranges from level A (100% of consignees contacted) to level E (no effectiveness checks).⁴²⁰

The FDA guidelines include general directives regarding the

409. FDA MANUAL, *supra* note 321, pt. 5, at 6.

410. *Id.*

411. *Id.* The FDA assesses the health risk on the basis of a number of factors and assigns the recall classifications. 21 C.F.R. § 7.41 (1984).

412. 43 Fed. Reg. 26,202 (summary statement of basis and purpose).

413. Interview with Gary Dykstra, Special Assistant to the Associate Commissioner for Regulatory Affairs of the FDA, in Washington, D.C. (Oct. 5, 1984) [hereinafter cited as Dykstra Interview]. The Agency, however, never has studied whether the classification system has had an impact on recall responsiveness. *Id.*

414. FDA MANUAL, *supra* note 321, pt. 5, at 2.

415. Dykstra Interview, *supra* note 413. Only about 5% of the recalls of products under FDA's jurisdiction fall into the Class I category.

416. The Associate Commissioner for Regulatory Affairs approves most FDA recall requests. FDA MANUAL, *supra* note 321, pt. 5, at 2.

417. *See* 21 C.F.R. §§ 7.45(b), .46 (1984); Dykstra Interview, *supra* note 413.

418. FDA MANUAL, *supra* note 321, pt. 5, at 6.

419. *Id.* at 8. Although recall actions are published in the FDA Weekly Enforcement Report, the FDA or the recalling firm may release additional warnings to the general public when serious health hazards or other circumstances dictate that such publicity is in the public interest. *Id.*

420. *Id.* at 7-8.

format and contents of recall notices.⁴²¹ Often only consignees, not ultimate consumers, need be notified because the recall has been initiated before the products reached the consumer.⁴²² The format and method of notification vary with the seriousness of the risk.⁴²³ The firm must report its recall activities to the FDA at specified intervals⁴²⁴ until the recall has been terminated.⁴²⁵

3. *Inducements To Recall*

Like those regulated by NHTSA and the CPSC, manufacturers subject to the FDA's jurisdiction undertake recalls to avoid or minimize product liability claims and adverse publicity.⁴²⁶ The FDA also boasts an array of enforcement tools, in addition to administrative recall authority, for use in obtaining voluntary recalls. For example, the FDA may seek court-ordered seizure of misbranded or adulterated products to remove them from the market.⁴²⁷ It may also obtain injunctions prohibiting the distribution and sale of such products,⁴²⁸ and criminal penalties for statutory violations.⁴²⁹ To obviate these proceedings, the manufacturer may agree to a recall.⁴³⁰

In practice, the FDA's statutory enforcement tools have not always been effective. Seizure is frustrated because the products are frequently distributed by the time the action is filed,⁴³¹ and

421. 21 C.F.R. § 7.49 (1984).

422. Dykstra Interview, *supra* note 413.

423. Notice may be by telegram or first class letter. The envelope must bear notice in bold red type that the letter concerns a recall, and also must be marked "URGENT" in Class I and Class II recalls. 21 C.F.R. § 7.49 (1984).

424. The reporting interval is from two to four weeks, depending on the recall's urgency. *Id.* § 7.53(a).

425. The recall is completed when "the firm has actually retrieved and impounded all outstanding product that could reasonably be expected to be recovered, or has completed all product corrections." FDA MANUAL, *supra* note 321, pt. 5, at 9.

426. For example, the prompt recall of Tylenol capsules after criminal tampering with their containers had caused several deaths, helped reduce adverse publicity and allowed the manufacturer to regain its market share—although at considerable expense. BUS. WK., Nov. 29, 1982, at 36; ABA Panel Discussion, *supra* note 99.

427. 21 U.S.C. § 334 (1982).

428. *Id.* § 332.

429. *Id.* § 333. This is strict criminal liability without proof that the violation was committed knowingly or willfully. *See* HOUSE RECALL REPORT, *supra* note 309, at 7-8.

430. The FDA has made clear its intent to use seizure or other court action when a company refuses an FDA recall request. *See* FDA Recall Policy, 21 C.F.R. § 7.40 (1984). Strict criminal liability can be a powerful incentive to voluntary recalls. Interview with Leonard Stauffer, Chief of the Recalls and Notification Branch, National Center for Devices and Radiological Health, FDA, in Silver Spring, Md. (Nov. 6, 1983).

431. *See* GOV'T ACCOUNTING OFF., LEGISLATIVE AND ADMINISTRATIVE CHANGES ARE NEEDED TO IMPROVE REGULATION OF DRUG INDUSTRY 12-13 (Apr. 5, 1983) [herein-

because several actions may be required when distribution is nationwide.⁴³² While it may be procedurally superior in cases of nationwide distribution, the injunction is inferior to seizure because of its prospective application—the decree normally restrains further sale or distribution and does not remove products from the market. The government has sought injunctive relief in the form of court-ordered recall, but its statutory authority to do so is unclear.⁴³³ It has used criminal penalties infrequently.⁴³⁴

More effective enforcement devices would indirectly serve to improve the recall program. Useful additional tools under the Food, Drug, and Cosmetic Act include: (1) specific authorization for the FDA to seek court-ordered recalls in injunctive actions,⁴³⁵ (2) civil penalties for violations now subject only to criminal penalties,⁴³⁶ and (3) authorization for the Agency to issue ex parte detention orders against products until a seizure action can be filed.⁴³⁷ If these tools are provided, giving the FDA general recall authority would be unnecessary and perhaps counterproductive. Following the example of the Medical Device Amendments,⁴³⁸ Congress might require cumbersome administrative hearing procedures before the Agency could exercise its recall authority,

after cited as GAO DRUG REGULATION STUDY]. In a survey of 35 FDA-recommended seizures, the study found that products were seized in only nine cases. By the time the FDA had approved the actions (an average of 61 days), the U.S. Attorney's Office had brought them, and the court orders had been issued (an average of 34 days), the products already had been shipped. *Id.*

432. See generally Schwartz, *Protecting Consumer Health and Safety: The Need for Coordinated Regulation Among Federal Agencies*, 43 GEO. WASH. L. REV. 1031, 1037-38 (1975) (discussing disadvantages of seizure action).

433. Courts are split on whether they may order recalls under the injunction provision of the Food, Drug, and Cosmetic Act. See *United States v. C.E.B. Prods.*, 380 F. Supp. 664, 667-68 (N.D. Ill. 1974) (statute contemplates "only negative injunctions," not affirmative recall remedy). But see *United States v. K-N Enters.*, 461 F. Supp. 988, 990 (N.D. Ill. 1978) (statute's injunction authority is broad enough to include affirmative relief; court's general equity power is sufficient to order recalls since statute does not preclude it).

434. From 1977 to 1981, the yearly number of criminal prosecutions averaged 23, compared with over 450 yearly seizures. Off. of Pub. Affairs, Food & Drug Admin., Talk Paper 3 (Aug. 25, 1982) [hereinafter cited as Talk Paper].

435. See *supra* note 433.

436. Criminal penalties, a harsh sanction, are pursued infrequently. See *supra* note 434. Civil penalties, however, can be effective. See *supra* notes 214, 216 and accompanying text (CPSC experience). The FDA can seek civil penalties under the RCHSA. See *supra* note 334 and accompanying text.

437. The power to detain products pending seizure would make the seizure action more effective and a viable alternative to recall in more cases. See GAO DRUG REGULATION STUDY, *supra* note 431, at 15 (recommending that FDA be given administrative detention authority over drug products).

438. See *supra* notes 369-73 and accompanying text.

thereby lengthening the time involved in obtaining a recall under the voluntary program. The administrative recall authority contained in the Device Amendments and the RCHSA has not greatly enhanced the FDA's ability to negotiate recalls under those statutes. Given the long history and maturity of the FDA's voluntary program, administrative recall authority is currently unnecessary.⁴³⁹

Recall effectiveness demands more than mere availability of an array of statutory enforcement tools. The FDA must use its tools with sufficient frequency to convince manufacturers that voluntary recalls are warranted. Nevertheless, FDA enforcement actions have become less frequent,⁴⁴⁰ apparently signaling manufacturers that they may avoid adverse consequences if they do not report or agree to a recall. A sharp drop in the number of voluntary recalls has accompanied the FDA's decreased enforcement efforts.⁴⁴¹ The Agency must utilize its enforcement powers to enhance the effectiveness of its voluntary recall program. A wider range of enforcement options would assist in that attempt.

4. *Reporting Defects*

Aside from the specific reporting requirements under the RCHSA,⁴⁴² and the Infant Formula Act,⁴⁴³ manufacturers have no general statutory obligation to report product hazards and defects to the FDA. Although there is an adverse reaction reporting

439. The FDA has been deterred from seeking administrative authority to order recalls, partly by the fear that additional administrative procedures could delay recalls. Interview with Linda R. Horton, Deputy Chief Counsel for Regulations and Hearings of the FDA, in Rockville, Md. (July 22, 1983) [hereinafter cited as Horton Interview].

440. See PUBLIC CITIZEN HEALTH RESEARCH GROUP, REPORT ON DECREASED FDA LAW ENFORCEMENT DURING 1981 (1982). In 1981, there were 577 enforcement actions, compared with an average of 1,041 for the years 1977 to 1980, a decrease of 45%. *Id.* at 1; see also Talk Paper, *supra* note 434, at 3-4 (showing similar drop in enforcement actions).

441. See Talk Paper, *supra* note 434, at 4. From 1977 to 1980, the number of recalls averaged over 1,000 a year; in 1981 there were 658 recalls. The FDA has attributed the decrease to long-term trends such as improved manufacturing practices, greater industry cooperation in complying with the law, and clarification of the legal requirements by the FDA. See *id.* Critics maintain that these factors do not explain the sudden, sharp drop in FDA enforcement actions and recalls during 1981. Interview with Allen Greenberg, Staff Associate of the Public Citizen Health Research Group, in Washington, D.C. (Oct. 12, 1983). Since 1981, however, the number of enforcement actions has risen steadily. Dykstra Interview, *supra* note 413.

442. See *supra* note 320 and accompanying text.

443. See *supra* notes 387-88 and accompanying text. Reporting requirements also have been proposed for the Medical Device Amendments. See *supra* note 349 and accompanying text.

provision for prescription drugs,⁴⁴⁴ items such as cosmetics and foods are not covered. A general reporting requirement should be imposed to provide the Agency with early notice of problems and enable timely publicity of recalls.⁴⁴⁵ Without such a requirement, companies lack the incentive to report,⁴⁴⁶ and fail to do so.⁴⁴⁷

5. *Classifying Recalls*

The FDA's recall classification system has been recommended for adoption by NHTSA and the CPSC to improve public awareness of the relative risks of recalled products. Ironically, the FDA has considered abandoning the system because it makes negotiating recalls more difficult.⁴⁴⁸ Companies resist Class I designation because of the potential impact on product liability suits and the possibility of adverse publicity.⁴⁴⁹ Companies view the designation as punitive, prompting agency concern that it discourages voluntary reporting and product recalls.⁴⁵⁰ When the classification issue prolongs recall negotiations, it delays and diminishes recall effectiveness.⁴⁵¹ In fact, classification may be less important for the FDA than for the CPSC and NHTSA—unlike those of the other two Agencies, FDA recalls do not often reach the consumer level,⁴⁵² where a classification system would be most useful. Nevertheless, before abandoning classification, the FDA should study its effect on recall response rates.⁴⁵³

6. *Recommendations*

The FDA should continue operating under its voluntary recall program but with additional statutory enforcement tools for use when voluntarism fails. Congress should authorize the Agency to

444. See 21 U.S.C. § 335(i), (j) (1982).

445. Recalls often appear in the Weekly Enforcement Report after they have occurred. See *supra* notes 352, 354 and accompanying text.

446. The threat of adverse publicity and product liability claims discourages reporting, Dykstra Interview, *supra* note 413; thus firms are unwilling to make reports not required by statute. ABA Panel Discussion, *supra* note 99.

447. See *supra* notes 353-54 and accompanying text.

448. Dykstra Interview, *supra* note 413.

449. *Id.*

450. *Id.*

451. The longer it takes to negotiate a recall, the more likely the products will be distributed and the more difficult it will be to recall them. *Id.*

452. In food recalls, which frequently never reach the consumer level, a 50% return rate is considered very good. In drug and device recalls, institutional users and medical professionals often must be notified instead of consumers. *Id.*

453. The FDA never has studied the impact or importance of its classification system. *Id.*

detain products pending a seizure action, to seek court-ordered recalls, and to pursue civil penalties where only criminal penalties are now available.⁴⁵⁴

Although the FDA administers a hodgepodge of recall provisions under three statutes, this scheme has not created serious difficulties. The one area warranting uniformity, however, is reporting; companies should be obligated by statute to notify the FDA of defects and statutory violations that could create health or safety risks. Finally, the Agency should continue to classify and publicize the classification of its recalls.

IV. CONCLUSIONS AND RECOMMENDATIONS

Although NHTSA, the CPSC, and the FDA make extensive use of recalls to implement their statutes, recalls have inherent limitations as enforcement tools. Consumers can and sometimes do render them ineffective by failing to respond. Moreover, recalls are generally successful only if promptly (*i.e.*, voluntarily) undertaken. Recalcitrant firms can thwart them merely by invoking available administrative procedures and, indeed, have good reason to do so. Companies cannot insure against product liability claims by recalling defective products—to the contrary, recalls can stimulate additional lawsuits and bring adverse publicity. Recalls also can be very expensive, requiring refunds or replacements of products that have already been produced and marketed. Ultimately, what may be most surprising is the frequency with which companies agree to recalls without litigation.

Because of its superior effectiveness, the recall remedy remains the major enforcement mechanism of the three Agencies. Recalls have virtually supplanted standards as the primary regulatory tool of the CPSC, for example. From the agencies' standpoint, their popularity stems from several factors. First, recalls promote safety. Although response rates are lower than agencies would like, consumers in significant numbers do return, discard, or take greater precautions with recalled products. Second, agencies can use recalls to set quasi-standards, establishing precedent for what constitutes an unacceptably hazardous product. Third, recalls are quicker and more efficient than standard-setting—government and industry often share a sense of urgency in removing a hazardous product from the marketplace. This has led agencies to adopt informal, flexible settlement procedures that encourage firms to

454. See *supra* notes 435-37 and accompanying text.

agree to recalls. Industry also may prefer recalls to standards because recalls generally affect only manufacturers of unsafe products. Unlike many standards, recalls do not impose across-the-board certification requirements and may involve less burdensome recordkeeping.

Agencies must reconcile numerous and often competing interests when implementing recall programs. They must take care not to inundate the public with recalls at the risk of creating consumer apathy. They must stress voluntary agreements to achieve prompt and effective recalls, yet be willing to use their enforcement powers when voluntary efforts stall. They must be flexible in negotiating the terms of recalls to encourage voluntarism, yet ensure adequate notice and remedy for product owners.

In addition to the agency-specific recommendations discussed throughout, this Article suggests that agencies work together to develop a more uniform approach to recalls.⁴⁵⁵ Despite vast differences among the agencies' programs, they have common characteristics and goals. All must deal with the general public. Agencies would benefit from sharing their knowledge about recalls, and the public would benefit from more consistency in the recall programs. The following recommendations should help to achieve these goals. First, an interagency recall liaison group consisting of representatives from all agencies with recall programs should be established. Its purpose would be to educate members about each other's programs and to research areas of common interest, such as how to improve consumer response rates and how to use new technology to improve recall notification.⁴⁵⁶ Second, the liaison group could explore the possibility of coordinating the agencies' classification systems. This would permit agencies to use

455. In 1979, the CPSC convened a meeting of representatives from six agencies engaged in product recalls (FDA, EPA, USDA, FTC, NHTSA and CPSC) to explore coordinating recalls and improving interagency communications. See, e.g., Letter from Susan B. King, Chairman of the CPSC, to Donald Kennedy, Commissioner of the FDA (Feb. 15, 1979).

456. There is precedent for such a group. On September 26, 1977, the CPSC, the Environmental Protection Agency, the FDA, and the Occupational Safety and Health Administration established an Interagency Regulatory Liaison Group (IRLG) to pursue cooperative efforts among the Agencies. One of the specific cooperative efforts was compliance and enforcement, although no work on recalls was undertaken. At the expiration of the IRLG's four-year charter, the Reagan Administration substituted a substantially trimmed liaison body called the Regulatory Work Group on Science and Technology. The new group has no compliance and enforcement component. In the interagency meeting on recalls, see *supra* note 455, the participants targeted areas for joint exploration to improve recall effectiveness but established no ongoing working group to pursue them. Interagency Meeting, *supra* note 1; Horton Interview, *supra* note 439.

similar methods of assessing risk and designating risk level. Third, a central hotline switchboard for consumer inquiries and complaints is needed. Consumers do not always know which agency takes complaints or has information about recalls. A central switchboard could refer all calls to the appropriate agency for experienced operators to handle. Fourth, the agencies should publish prompt weekly reports of recalls. Only the FDA regularly publishes a list of recalls. Each agency should provide this information and distribute it to bodies such as state and local consumer offices and public interest consumer groups.⁴⁵⁷ The implementation of these general recommendations, along with the agency-specific ones, could make the recall a more effective remedial device.

457. The National Association of Consumer Agency Administrators (NACAA) compiles information on the recalls of NHTSA, the FDA, and the CPSC which it publishes monthly in its Recall Clearinghouse Service. Subscribers include state and local consumer offices and agencies. Telephone interview with Claudia J. Sturges, Director of Member Services of the NACAA (Oct. 18, 1983). Data on recalls are not easy to collect from the agencies, even for the knowledgeable staff of NACAA. *Id.* To make this information more accessible, the agencies should publish it on a regular and timely basis.