



Fall 9-1-1988

A Product Safety Agenda for the 1990s

Teresa M. Schwartz

Follow this and additional works at: <https://scholarlycommons.law.wlu.edu/wlulr>



Part of the [Administrative Law Commons](#), and the [Consumer Protection Law Commons](#)

Recommended Citation

Teresa M. Schwartz, *A Product Safety Agenda for the 1990s*, 45 Wash. & Lee L. Rev. 1355 (1988).

Available at: <https://scholarlycommons.law.wlu.edu/wlulr/vol45/iss4/8>

This Article is brought to you for free and open access by the Washington and Lee Law Review at Washington and Lee University School of Law Scholarly Commons. It has been accepted for inclusion in Washington and Lee Law Review by an authorized editor of Washington and Lee University School of Law Scholarly Commons. For more information, please contact christensena@wlu.edu.

A PRODUCT SAFETY AGENDA FOR THE 1990s

TERESA MORAN SCHWARTZ*

INTRODUCTION

In the product safety area the Reagan administration had the same probusiness, antiregulatory attitude it had in other areas. It implemented its philosophy in several ways: it crippled rulemaking by adopting procedures giving industry a greater role and consumer interests a lesser role in the regulatory process; it undervalued human health and safety by using rigid cost-benefit analyses to justify its antiregulatory approach to safety issues; and it cut substantially the budgets of product safety agencies, thereby reducing their ability to promulgate new regulations or to enforce their statutes.

At the same time the administration tried to weaken the regulatory system, it also lobbied for sharp limitations on product liability claims under the tort system—a system that serves as an important adjunct to the regulatory system in providing incentives for companies to comply with safety regulations and statutes.

At the outset, it should be noted that the Reagan administration's tort reform and antiregulatory efforts were not entirely successful. Congress did not adopt the administration's views on product liability reform.¹ Federal safety laws regulating drugs, automobiles, and other consumer products remain largely intact.² In addition, in recent years Congress increasingly has tackled agency laxness by enacting statutory provisions that require agencies to undertake specific regulatory initiatives within certain deadlines.³ Such efforts, however, can never be completely successful in spurring recalcitrant agencies to act.

What is needed in the Bush administration is a complete rejection of the antiregulatory philosophy of the Reagan years. This is not to say that

* Associate Dean for Academic Affairs and Professor of Law, George Washington University.

1. See *infra* notes 117-19 and accompanying text.

2. Early in the administration, for example, the Director of the Office of Management and Budget, David Stockman, tried to have the Consumer Product Safety Commission eliminated—an effort that failed. Kriz, *Leashed Watchdog*, 19 NAT'L J. 2663, 2664 (1987). However, the CPSC's budget was cut so drastically that the agency became a "shadow of its former self." *Id.*; see also *infra* notes 87-90 and accompanying text (discussing budget cuts during Reagan years).

3. See *Regulation: Fragile Change At Best*, NAT'L L.J. Apr. 18, 1988, at 26, col. 1 [hereinafter *Regulation: Fragile Change*]. The 200-page Superfund reauthorization act of 1986 is a good example of recent legislation containing numerous specific deadlines for regulatory action, with penalties for failing to comply. *Id.*; see also *infra* notes 18-20, 33 and accompanying text (examples of legislation that mandate specific regulatory initiatives by safety agencies).

there should be a rush to regulate, as some have urged or forecast.⁴ The appropriate philosophy is one of toughness and fairness in the enforcement of the safety laws, and principled decisionmaking in the issuance of safety regulations. It is important that the Bush administration—at the outset—establish this approach to product safety.⁵

To implement this approach, the administration should reintroduce fairness into the regulatory process. It should avoid the “behind the scenes,” one-sided communications with business interests that marked the Reagan administration’s proceedings. It should avoid the devaluing of human life and safety that occurs when decision making is reduced to a rigid cost-benefit analysis. Further, it should allocate sufficient resources to safety agencies to allow them to carry out their statutory responsibilities. Finally, the Bush administration should recognize and support the role of the tort system as an important adjunct to the federal regulatory system in providing incentives for product safety.

Part I of this Article assesses the weaknesses of the Reagan administration in regulating consumer product safety. It focuses on three federal agencies that have responsibility in this area: the National Highway Traffic Safety Administration (NHTSA), the Food and Drug Administration (FDA) and the Consumer Product Safety Commission (CPSC). It discusses agency laxness in enforcing safety laws and the primary reasons for the laxness, including severe budget constraints and increased oversight by the Office of Management and Budget (OMB). Part II then considers the related issue of tort reform. It explores the importance of the tort system to the functioning of the regulatory system, as well as the Reagan administration’s proposals to weaken the tort system by cutting back on the common law rights of injured consumers. Finally, part III provides an overview of the direction the Bush administration should take in the product safety area.

I. LAX ENFORCEMENT OF PRODUCT SAFETY LAWS IN REAGAN YEARS

A. *Brief Overview of the Reagan Safety Record*

President Reagan came into office promoting “regulatory relief” for business.⁶ The clear aim of the new administration was to reduce regulations

4. See Kriz, *supra* note 2, at 2664 (quoting Republican government official who predicts a regulatory “backlash” after the Reagan years, resulting in “doubling budgets and bringing things back” because conservatives have been “overzealous”); see also *infra* notes 139-40 and accompanying text.

5. The importance of establishing the tone of the new administration—at the earliest possible time—was not lost on the Reagan administration. One of the President’s first acts was to issue Executive Order 12,291, which gave the Office of Management and Budget enormous control over executive agency rulemaking. See Morrison, *OMB Interference with Agency Rulemaking: The Wrong Way to Write a Regulation*, 99 HARV. L. REV. 1059, 1062 (1986); see also *infra* notes 47-85 and accompanying text (discussion of Executive Order and OMB oversight).

6. Costle, *Environmental Regulation and Regulatory Reform*, 57 WASH. L. REV. 409 (1982).

across the board, including health and safety regulations. In the three product safety agencies considered in this article, the antiregulatory philosophy was pervasive.

1. The Natural Highway Traffic Safety Administration

An early regulatory relief initiative, which was to set the tone of the new administration and was "[p]robably the most significant single regulatory event during the administration's first year," was the announcement that the government would reduce or eliminate thirty-four safety and environmental regulations governing the auto industry.⁷ Essentially, the administration's "auto package" was the industry's "wish list."⁸

Not all of the proposed relief measures in the auto package were successful, however. Among the regulations to be reconsidered was NHTSA's passive restraint ("air bag") rule.⁹ The administration first delayed and then rescinded the rule.¹⁰ Later, the United States Supreme Court overturned the rescission in *Motor Vehicle Manufacturers' Association v. State Farm Mutual Auto Insurance Co.*¹¹ on the ground that NHTSA's action had failed to meet even the minimal "arbitrary and capricious" standard of review.¹² In retrospect, *State Farm* may have been crucial in slowing down somewhat the deregulation efforts of the administration.¹³

But there were many other regulations in the auto package that the administration did succeed in delaying, diluting, or abandoning.¹⁴ NHTSA's rulemaking efforts came almost to a standstill. In the first four years of the Reagan administration, the agency issued only one safety standard.¹⁵ Critics identified an array of safety concerns that the agency failed to address, for example, concerns about side impact strength, the adequacy of heavy vehicle brake standards, and the lack of crashworthiness standards

7. See G. EADS & M. FIX, RELIEF OR REFORM? REAGAN'S REGULATORY DILEMMA 125 (1984).

8. *Id.* at 131.

9. *Id.* at 128.

10. *Id.*

11. 463 U.S. 29 (1983).

12. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 46 (1983).

13. *Regulation Fragile Change*, *supra* note 3, at 26, col. 1. Counsel representing State Farm thought that if the government had won this early case of regulatory rescission, it would have been "no holds barred on deregulation." *Id.*

14. See G. EADS & M. FIX, *supra* note 7, at 126-27. Among the proposed rules that were dropped were safety standards for explosive tire rims, driver field of vision, explosive batteries, and safety belt comfort. Brake test rules were diluted. *Id.*

15. *NHTSA Authorization and Oversight: Hearings on H.R. 2248 Before the Subcomm. on Telecommunications, Consumer Protection and Finance of the House Comm. on Energy and Commerce*, 99th Cong., 1st Sess. 31 (1985) (statement of Hon. Timothy E. Wirth) [hereinafter 1985 NHTSA Authorization Hearings]. According to the Subcommittee Chairman, Congressman Tim Wirth, NHTSA had focused "nearly exclusively on modifying consumer behavior" and had "largely ignored" the statute's mandate to set automobile safety standards. *Id.*

for the increasingly popular minivans and light trucks.¹⁶ In 1987, in the face of NHTSA's lethargy, the Senate passed legislation mandating action on these and other matters.¹⁷ Then in the 1988 appropriations bill, Congress earmarked certain funds for the regulation of multipurpose vehicles¹⁸ and directed NHTSA to expedite rulemaking on side impact safety¹⁹ and rear seat lap/shoulder belts.²⁰ As a result of such Congressional pressures, there was an increased number of regulatory initiatives underway at NHTSA by the end of the Reagan administration.

In addition to NHTSA's laxness in setting safety standards during the Reagan years, the agency also was lax in enforcing the recall provisions of its statute.²¹ It proceeded at a "snail's pace" in investigating defects,²² and the number of recalls fell off sharply in the Reagan years.²³

16. Actions in these areas "could save thousands of additional lives each year." *Id.* at 91 (statement of Joan Claybrook, President, Public Citizen, and former Administrator, NHTSA). The agency either rescinded advance notices of these rules or took no action. *Id.* at 96-98.

The concern about the safety of multipurpose vehicles, such as light trucks and minivans, is based on the fact that they have been exempt from many of NHTSA's passenger vehicle standards. In recent years, however, the use of multipurpose vehicles has increased dramatically, as have fatalities associated with their use. Between 1971 and 1985, the market share for such vehicles nearly doubled. *Outlook for Product Safety Liability in 1987*, 15 Prod. Safety & Liab. Rep. (BNA) 49 (1987). Between 1984-85, fatalities increased by 15.8%. Corrigan, *Squeeze on Safety*, NAT'L J., Feb. 14, 1987, 359-60. In 1987 NHTSA did issue an advance notice of proposed rulemaking to strengthen standards for light trucks and vans. *NHTSA Advance Notice of Rulemaking on Vehicle Classification*, 15 Prod. Safety & Liab. Rep. (BNA) 801 (1987). A proposed rule is projected for 1988, but a final rule may be several years after that. *NHTSA Priorities*, 16 Prod. Safety & Liab. Rep. (BNA) 105 (1988).

17. S. 853, 100th Cong., 1st Sess. (1987), discussed at *Comparison of House and Senate CPSC Reauthorization Bills*, 16 Prod. Safety & Liab. Rep. (BNA) 105 (1988). Among other things, the bill would have required the agency to act on side impact protection, lap-shoulder belts in rear seats, and standards for minivans and light trucks.

18. CONFERENCE REPORT TO ACCOMPANY H.J. RES. 395, H. REP. NO. 498, 100th Cong., 1st Sess. 1135 (1987). Funds appropriated for minivan and light truck initiatives were \$1.68 million. *Id.*

19. *Id.* at 1137.

20. *Id.*

21. See 1985 NHTSA Authorization Hearings, *supra* note 15, at 29.

22. *Id.* (remarks of Congressman Wirth).

23. *Id.* at 109 (testimony of Clarence M. Dittlow III, Director, Center for Auto Safety). Mr. Dittlow testified that public investigations of safety defects were down by 80% and that numerous agency requests for voluntary recalls had been refused by manufacturers but NHTSA had failed to pursue them. *Id.* Indeed, in 1987 the Center for Auto Safety reported that over the previous eight years, NHTSA had made requests—which were unheeded by manufacturers—for the recall of one out of every five cars sold. Corrigan, *supra* note 16, at 360.

One of the most notorious of NHTSA's failures to order a recall involves the Ford Motor Company which marketed millions of vehicles with automatic transmissions that can slip out of "park" into "reverse" and which have caused over 200 deaths. 1985 NHTSA Authorization Hearings, *supra* note 15, at 109 (testimony of Clarence Dittlow). For a detailed discussion of the Ford transmission case, see Schwartz & Adler, *Product Recalls: A Remedy in Need of Repair*, 34 CASE W. RES. 401, 418-20 (1983-84).

2. The Consumer Product Safety Commission

Another agency with a poor safety record during the Reagan administration was the CPSC—an agency that also had a great many internal management problems.²⁴ It was an extremely reluctant regulator, willing to defer completely to industry's unmonitored development of voluntary safety standards,²⁵ and willing to allow industry's efforts to continue even when the efforts had been quite minimal. Such was the Commission's approach to the manufacturers of all-terrain vehicles (ATV's), who were allowed to continue with voluntary standard setting even though they were "dragging [their] feet"²⁶ and the number of injuries and deaths associated with ATV use was skyrocketing. In early 1985 the Commission knew of 125,000 injuries requiring emergency room treatment and 161 deaths related to ATV use, with children under 16 years of age accounting for half the deaths.²⁷ By early 1988 the industry still had not produced a safety standard; the death toll had mounted to 977 and the injury toll to 330,000.²⁸

The handling of the ATV matter has been cited as "a typical example of agency inaction."²⁹ Another example, also typical, involved lawn darts. Again, the Commission hesitated to act—in this case by refusing to ban the products, which are responsible for about 680 serious injuries a year (80% of which occur to children under 15 years of age) and have killed 3 children.³⁰ Even conservative newspaper columnist George Will criticized the agency's

24. See *GAO Report Shows Scanlon's Reassigning of Employees Has Damaged CPSC, Florio Charges*, 16 Prod. Safety & Liab. Rep. (BNA) 391 (1988) (describing many disruptive transfers of staff members within agency that have delayed CPSC regulatory activities, including work on safety standard for dangerous all-terrain vehicles (ATV's)); see also *Outlook for Product Safety & Liability in 1987*, 15 Prod. Safety & Liab. Rep. (BNA) 47 (1987) (revealing internal dissension in agency and discussing recent proposals to restructure agency to make it more effective).

25. Kriz, *supra* note 2, at 2664. Critizing the current CPSC for excessive reliance on voluntary efforts, Robert Adler, associate professor of legal studies at the University of North Carolina and former CPSC staff member, has pointed out that the CPSC too often allows the voluntary standards process to proceed even though industry does not allow CPSC staff to monitor the process. *Id.* Then, after years of delay, industry presents the voluntary standards, "only to have CPSC staff members declare them inadequate." *Id.*

26. In 1985 the CPSC turned to the ATV industry to develop a voluntary standard, but two and one-half years later the CPSC Chairman reported the industry was still "dragging its feet with respect to ATV safety" and had not met in several months. *Scanlan Accuses ATV Industry Of Stalling on Voluntary Standard*, 15 Prod. Safety & Liab. Rep. (BNA) 815 (1987).

27. *Consumer Product Safety Commission's Response to Hazards of All-Terrain Vehicles (ATV's): Hearings Before a Subcomm. of the House Comm. on Government Operations*, 99th Cong., 1st Sess. 184 (1985) (testimony of CPSC Commissioner Stuart M. Statler) [hereinafter *ATV Hearings*].

28. *CFA Blames Product Safety Agency for "Black Market" in Three-Wheel ATVs*, 16 Prod. Safety & Liab. Rep. (BNA) 242 (1988).

29. Kriz, *supra* note 2, at 2663.

30. Waldman, *Kids in Harm's Way*, *NEWSWEEK*, April 18, 1988, at 47. See also *Wilson Introduces Bill to Ban Lawn Darts, Criticizes CPSA Action*, 16 Prod. Safety & Liab. Rep. (BNA) 242 (1988) (reporting that between 1978 and 1986, over six thousand people were injured by lawn darts).

"reluctance to act decisively about a proven hazard" and characterized the agency's inaction as "hard sell laissez-faire conservatism."³¹ Several weeks after Will's column and several months after the CPSC had first voted against a ban, the CPSC voted to ban the product.³²

After years of agency inaction by the CPSC, Congress—as it did with the NHTSA—began to mandate specific regulatory initiatives. It ordered the CPSC to undertake action with respect to a number of hazardous products, including cigarette lighters, all-terrain vehicles, flammable adult sleepwear, lawn darts, and toys with small parts that pose choking hazards.³³

Another area in which the CPSC, like the NHTSA, was lethargic during the Reagan years was the enforcement of product recalls.³⁴ The recent, highly criticized settlement of the ATV case, in which the Commission and the Justice Department failed to insist that ATV manufacturers recall their products and offer refunds to purchasers, was symbolic of the lack of aggressive law enforcement by the CPSC and by the Reagan administration in general.³⁵

3. The Food and Drug Administration

The FDA's record as an aggressive enforcement agency also suffered in the Reagan years. In the rulemaking area, the FDA revoked the patient package insert rule for prescription drugs that the Carter administration had adopted.³⁶ It unreasonably delayed the issuance of a rule requiring that aspirin labels warn about Reye's Syndrome,³⁷ and the issuance of standards for infant formulas.³⁸ It bowed to pressures from the Office of Management and Budget (OMB) and industry, and delayed taking action to ban food dyes found to be carcinogenic.³⁹ FDA's recall programs also were reduced

31. Will, *Lawn Darts and the Limits of Laissez Faire*, Wash. Post, May 8, 1988, at B7, col. 2.

32. Wash. Post, May 26, 1988, at C4, col. 6. By a vote of 2-1, the Commission voted to outlaw lawn darts with pointed metal tips. The ban could take effect by the end of 1988 if legal challenges do not delay it further. *Id.*

33. In recent reauthorization bills in both the House and Senate, the CPSC was directed to address these products. *Outlook for Product Safety and Liability in 1988*, 16 Prod. Safety & Liab. Rep. (BNA) 102-03 (1988).

34. At the CPSC the number of recalls fell drastically after the Reagan administration began. *Id.* at 426. The number of products recalled went from an average of 34.5 million in the previous administration to an average of 2.5 million in the first years of the Reagan administration. *Id.*

35. See *infra* notes 97-98 and accompanying text further discussing ATV case).

36. 47 Fed. Reg. 39,150 (1982). For a history of the patient package insert rule in the Carter administration and its revocation in the Reagan administration, see Schwartz, *Consumer Warnings for Oral Contraceptives: A New Exception to the Prescription Drug Rule*, 41 FOOD DRUG COSM. L.J. 241, 246-50 (1986).

37. See *infra* notes 58-63 and accompanying text.

38. *Regulation: Fragile Change*, *supra* note 3, at 24, col. 1. Critics charged that deficient formulas remained on the market while OMB reviewed the matter. *Id.*

39. Kosterlitz, *Reagan Is Leaving His Mark on the Food and Drug Administration*, NAT'L J., July 6, 1985, at 1568, 1569.

during the Reagan years. In 1984, for example, the FDA brought half as many cases as the average number brought in the previous administration.⁴⁰

This brief overview of the product safety record of the three safety agencies reflected the pervasive antiregulatory philosophy of the Reagan administration. The next section examines the various means by which this philosophy was implemented, that is, by appointing officials with antiregulatory views, by giving OMB greater authority to impede executive agency rulemaking, and by imposing severe budgetary constraints on safety agencies.

B. Personnel

The Reagan administration recognized the importance of personnel in achieving its antiregulatory aims. It realized that it was not necessary to amend the relevant statutes or revise regulations, as long as agency heads—enjoying broad discretion under most regulatory statutes—were appointed who shared its views of limited government. In short, it could fundamentally alter the regulatory process through its choice of personnel.⁴¹

Thus, the administration brought people into government to head the safety agencies who were from business backgrounds or were business-oriented, and had little or no experience in government. Many, like Reagan, had been critics of the regulatory process.⁴²

While President Carter selected those who believed in regulation and looked for ways to expand the impact of regulations, President Reagan appointed critics of the regulatory process who had been fighting government regulations long before they arrived in Washington. The Reagan appointees echoed their boss's view that most regulation was burdensome, inflationary, and unneeded.⁴³

An unusual degree of politicization of the agencies also occurred. At the CPSC, the staff became so top heavy with noncareer, political positions the Congress reduced their number in the 1988 appropriations bill.⁴⁴ At the FDA, some of the most experienced, high level civil servants who left the agency were replaced with appointments based more on political background than expertise.⁴⁵ A former FDA Commissioner from the Nixon administra-

40. *Id.* at 1569. FDA brought 260 actions in 1984, compared to an average of 542 actions between 1977-80.

41. S. TOLCHIN & M. TOLCHIN, *DISMANTLING AMERICA: THE RUSH TO DEREGULATE* 96 (1983) (quoting from article by Murray Weidenbaum that "People do matter and, given the tremendous amount of discretionary power vested in the regulatory bureaus, the people who run them can exert great influence.").

42. *Id.* at 85-109.

43. *Id.* at 85.

44. Congress apparently found that these appointees were contributing to the turmoil in the agency and interfering with the agency's safety mission. *Final Budget for CPSC in FY 1988 Means Cuts in Personnel, Operating Funds*, 16 *Prod. Safety & Liab. Rep. (BNA)* 4 (Jan. 1, 1988); H.R.J. Res. 395, 100th Cong., 1st Sess. (1987); H.R. REP. NO. 498, 100th Cong., 1st Sess. (1987).

45. Kosterlitz, *supra* note 39, at 1571.

tion complained that in the Reagan era there has been "more politicization of the [FDA] than is . . . warranted by rational politics or good for the American people."⁴⁶

C. OMB Oversight

At the outset of the administration, President Reagan issued Executive Order 12,291,⁴⁷ which greatly increased OMB's oversight of executive agency rulemaking.⁴⁸ The order also established a cost-benefit test for all major executive agency rules.⁴⁹ The order became a major tool for delaying and diluting regulations in order to implement the antiregulatory philosophy of the administration.⁵⁰ Its implementation by OMB has been widely criticized.⁵¹

1. Procedures Favoring Industry Influence

One of the greatest objections to OMB's oversight was the lack of a fair and open process. Industry was given secret and frequent access to OMB, enabling it to influence OMB's evaluation of proposed rules.⁵² Early in the Reagan administration, high level officials actually encouraged industry representatives to seek assistance from OMB whenever they felt that they could not obtain the desired regulatory relief from the agency in question.⁵³ Needless to say, industry was delighted with the prospect of an

46. *Id.*

47. Executive Order No. 12,291, 3 C.F.R. 127 (1982), *reprinted in* 5 U.S.C. § 601 app. at 431-34 (1982) [hereinafter E.O. 12,291].

48. Under the Order, OMB reviews rules when they are first proposed and before the agencies publish them for comment; it later reviews the final rules and may delay their issuance until receipt of agency responses to OMB's views. *Id.* §§ 3(f)(1), (2).

In 1985 President Reagan again expanded OMB's control over rulemaking by giving OMB authority to review agency proposals to undertake rulemaking and to decide whether they may proceed. Executive Order No. 12,498, 3 C.F.R. 323 (1986) *reprinted in* 5 U.S.C. § 601 App. at 40-41 (Supp. II 1984).

49. The Order requires executive agencies to prepare a "Regulatory Impact Analysis" detailing the costs and benefits of proposed and final "major" rules. E.O. 12,291, *supra* note 47, at § 3(c)(2). No rule is to be undertaken "unless the potential benefits to society . . . outweigh the potential costs," and in choosing among alternatives, agencies must choose "the alternative involving the least net costs to society." *Id.* § 2(d).

50. OMB's influence over the FDA has been documented on a number of occasions. OMB was responsible for (1) staying FDA's proposal to ban certain dyes found by scientists to cause cancer in laboratory animals, (2) delaying and changing quality control standards for makers of infant formula, and (3) holding up implementation of reporting requirements for medical device makers. Kosterlitz, *supra* note 39, at 1568-70.

51. See generally Costle, *supra* note 6; Morrison, *supra* note 5; see also S. TOLCHIN & M. TOLCHIN, *supra* note 41; OMB INTERFERENCE WITH OSHA RULEMAKING, H.R. REP. NO. 583, 98th Cong., 1st Sess. (1983) [hereinafter H.R. REP. NO. 583].

52. Kosterlitz, *supra* note 39, at 1569 (industry influenced OMB to delay banning certain color additives found by FDA scientists to be carcinogenic after more than 20 years of study).

53. S. TOLCHIN & M. TOLCHIN, *supra* note 41, at 59-88. The Executive Order has been characterized as a "back door, unpublicized channel of access to the highest levels of political authority in the Administration for industry alone." H.R. REP. NO. 583, *supra* note 51, at 11.

alternative agency—and particularly one as sympathetic to business as OMB—to which they could turn to get around the regulatory agency.⁵⁴ As counsel to one company said, “[a]nybody representing a client who did *not* use that [OMB] route would be negligent.”⁵⁵ Nonbusiness groups had no similar access.⁵⁶ Their recourse was to challenge administrative action and inaction in court—a time-consuming and costly process.⁵⁷

In the product safety area, one of the most widely cited examples of industry influence over OMB involved the FDA’s proposed rule to require labels on aspirin products that would warn about the risks of Reye’s Syndrome. In 1982 the FDA proposed such a warning on the basis of a number of scientific studies and recommendations by the Centers for Disease Control and the American Academy of Pediatrics.⁵⁸ In response to requests from industry members, however, OMB officials asked the FDA to withdraw the proposal until additional scientific studies could be completed.⁵⁹ In short, OMB was second-guessing an expert agency’s scientifically based determination—an entirely inappropriate role for OMB. However, even after additional scientific proof was gathered confirming the association between Reye’s Syndrome and aspirin use, the FDA resisted issuing a mandatory regulation.⁶⁰ It chose instead to educate the public through public service announcements about the risk, and to encourage manufacturers to do voluntary labeling.⁶¹ The FDA Commissioner resisted issuing a regulation until evidence “unequivocally establish[ed]” the link between Reye’s Syndrome and aspirin⁶²—an extraordinarily high standard of proof to require before mandating a warning. Although eventually the FDA did promulgate

54. As one industry official characterized the advantage: “Whenever we disagree with the FDA, it’s nice to have another shot at it”—not only at HHS but also at OMB. Kosterlitz, *supra* note 39, at 1571 (statement of John T. Walden, Senior Vice President of the Proprietary Association and former Associate FDA Commissioner).

55. Wash. Post, Nov. 26, 1982, at A5, col. 3 (emphasis added).

56. See H.R. REP. No. 583, *supra* note 51, at 11 (documenting instances where OMB met with industry representatives but ignored requests for similar meetings with union representatives).

57. See, e.g., *Environmental Defense Fund v. Thomas*, 627 F. Supp. 566 (D.D.C. 1986) (ruling that OMB had unlawfully delayed agency regulation); *Public Citizen Health Research Group v. Tyson*, 796 F.2d 1479 (D.C. Cir. 1986) (same).

58. See Novick, *Use of Epidemiological Studies to Prove Legal Causation: Aspirin and Reye’s Syndrome, A Case in Point*, 23 TORT & INS. L.J. 536, 544-45 (1987).

59. *Id.* at 545. In September 1982, the Secretary of Health and Human Services Department (of which FDA is a component) signed the proposed regulation; in October, HHS delayed publication pending OMB review; and in November “under intense pressure from the drug industry,” HHS withdrew the regulation and announced another study of the link between aspirin and Reye’s Syndrome. *Id.*

60. *Emergency Reye’s Syndrome Prevention Act: Hearings on H.R. 1381, Before the Subcomm. on Health and the Environment, of the House Comm. on Energy and Commerce*, 99th Cong., 1st Sess. (1985).

61. *Id.* at 334-35 (testimony of FDA Commissioner detailing agency’s extensive education efforts and voluntary labeling program).

62. *Id.* at 345.

a regulation requiring a warning label,⁶³ the Commissioner's reluctance to issue a rule and the agency's willingness, in the meantime, to rely on uneven voluntary efforts by manufacturers to regulate themselves, was symptomatic of the Reagan administration's approach to product safety.

Although in the case of the aspirin manufacturers industry influence became known, often the role of industry influence on the OMB remained hidden. OMB did not keep records of its contacts with private parties, so there was "no paper trail" to uncover what has happened during the oversight process.⁶⁴ What may never be known is what subtle "chilling" effect OMB had on regulatory initiatives that should have been pursued.⁶⁵

The secretive nature of the process was criticized sharply by a wide array of OMB observers, including the Government Accounting Office,⁶⁶ public interest advocates,⁶⁷ legislators,⁶⁸ and academics.⁶⁹ The process eroded confidence in the fairness of the process⁷⁰ and undermined judicial review of agency decisions.⁷¹

2. Cost-Benefit Analysis Favoring Industry Interests

The Executive Order required that, to the extent consistent with statutory requirements, agencies should not issue rules unless their benefits to society

63. 21 C.F.R. § 201 (1988). The mandatory warning went into effect June 5, 1986.

64. Schultz & Vladeck, *An Obstacle to Public Safety*, Wash. Post, May 10, 1988, (Health Supp.) at 20.

65. *Id.* A recent case involved the FDA's handling of the chemical urethane, a carcinogen that is found in many alcoholic beverages. Canada has had mandatory limits on urethane levels since 1985, and many products in the United States exceed the Canadian limits. While FDA seriously considered proceeding with a regulation to limit urethane levels, it hesitated because it anticipated OMB opposition. *Id.* In the end, FDA entered into a voluntary (and unenforceable) agreement under which industry will meet the Canadian limits by 1995.

66. GENERAL ACCOUNTING OFFICE, IMPROVED QUALITY, ADEQUATE RESOURCES, AND CONSISTENT OVERSIGHT NEEDED IF REGULATORY ANALYSIS IS TO HELP CONTROL COSTS OF REGULATION 53-54 (Nov. 2, 1982):

The result of [OMB's] nondocumented approach to rulemaking is that the public cannot determine at whose initiative a rule was issued. While the agency formally remains accountable for its rules, the record does not show whether the agency made its decisions primarily on the basis of its interpretation of the evidence available to it or in response to OMB directives. . . .

Because OMB's influence is potentially great, its apparent openness to *ex parte* communications . . . about pending rules raises similar disclosure concerns.

. . . The public cannot determine either who made the regulatory decision, or on what basis it was made.

67. *Regulatory Reform Act: Hearings on H.R. 2327 Before the Subcomm. on Administrative Law and Government Relations of the House Comm. on the Judiciary*, 98th Cong., 1st Sess. 107-108 (1983) (testimony of Joan Claybrook, President, Public Citizen) [hereinafter *Hearings on H.R. 2327*]; see also Morrison, *supra* note 5, at 1064 (Morrison is Director, Public Citizen Litigation Group).

68. H.R. REP. NO. 583, *supra* note 51, at 12-13.

69. See McGarity, *Regulatory Analysis and Regulatory Reform*, 65 TEX. L. REV. 1243, 1309 (1987).

70. See Morrison, *supra* note 5, at 1064.

71. See *id.* at 1072 (arguing that OMB's oral and written communications to agencies should be put on record to assure adequate judicial review).

were shown to outweigh their costs.⁷² Further, agencies were required to pick the alternative regulatory approach that imposes the least cost.⁷³

While cost-benefit analysis is properly one factor to be considered in making regulatory decisions in the health and safety area,⁷⁴ it has serious weaknesses that the Reagan administration failed (or did not desire) to take into account. The analysis seldom is neutral, but is instead biased *against* safety regulation.⁷⁵ The benefit side tends to be underestimated and the cost side tends to be exaggerated. There is a number of reasons for this. Costs to industry associated with regulatory compliance usually are more immediate in their effect and more readily quantifiable⁷⁶ than health and safety benefits, which accrue over time and are more difficult to assess in monetary terms.⁷⁷ Further, industry itself frequently is the primary source for the cost estimates,⁷⁸ and too often its estimates are inflated.⁷⁹ Thus, if used in an uncritical fashion, cost-benefit analysis inevitably leads to results that favor government inaction over regulation and industry interests over consumer interests.

The inherent bias in the cost-benefit approach was exacerbated under OMB's implementation of the Executive Order. Cost-benefit analysis was not applied evenhandedly, but instead was used to reach antiregulatory results favored by the administration.⁸⁰ For example, OMB was willing to waive cost-benefit analyses occasionally, but only for proposals that would *reduce* regulatory requirements.⁸¹ The message to the agencies was clear: OMB's purpose was not objective cost-benefit analysis, but regulatory relief.

OMB also was criticized for seriously undervaluing benefits. It did not required agencies to assess indirect benefits, although it urged them to

72. See *supra* note 49 and accompanying text.

73. *Id.*

74. See S. TOLCHIN & M. TOLCHIN, *supra* note 41, at 141. ("Although cost-benefit analysis can be useful in determining the most cost-effective alternative among competing regulatory devices, it should be laid to rest as a dominant policy tool—as inadequate, inequitable, and subject to excessive political distortion in its application").

75. See, e.g., Clark, *Do the Benefits Justify the Costs? Prove It, Says the Administration*, NAT'L J., Aug. 1, 1981, at 1382.

76. Costle, *supra* note 41, at 415.

77. This is especially true when the benefits do not become manifest immediately upon implementation of a rule but occur in the future when the rule has had time to take effect. S. TOLCHIN & M. TOLCHIN, *supra* note 41, at 419-20; see also McGarity, *supra* note 69, at 1283.

78. See D. BOLLIER & J. CLAYBROOK, *FREEDOM FROM HARM: THE CIVILIZING INFLUENCE OF HEALTH, SAFETY AND ENVIRONMENTAL REGULATION* 193 (1986); Cramton, *The Why, Where and How of Broadened Public Participation in the Administrative Process*, 60 GEO. L.J. 525, 529-30 (1972).

79. Costle, *supra* note 6, at 415 n.20 (giving examples of overestimating costs of environmental regulations).

80. *Id.* at 417. Mr. Costle concludes that under Executive Order 12,291, "cost-benefit analysis has decidedly shifted from using cost-benefit concepts as an analytical tool to make regulation *better* to requiring cost-benefit analysis to justify a particular regulation, and thus to regulate *less*." *Id.*

81. See McGarity, *supra* note 69, at 1315-17.

calculate indirect costs.⁸² In considering the calculation of long term health benefits that might be gained by a proposed regulation, OMB encouraged agencies to discount such future benefits to their present value by using a high discount rate of ten percent. At that rate, their present value was reduced to a very low sum—a sum “likely to be outweighed by even modest costs.”⁸³ Consider, for example, the case of the EPA’s 1984 proposal to phase out asbestos over a period of five to fifteen years. In reviewing the proposal, OMB started from the premise that a life is worth \$1 million and then, taking into account that asbestos deaths would not occur until well into the future because of the long latency period for asbestos-related diseases, OMB discounted the figure to \$208,000 to represent the current value of a human life.⁸⁴ Using the reduced figure, OMB sent the proposed regulation back to EPA as not justified under cost-benefit analysis.⁸⁵

In sum, OMB’s general approach to cost-benefit analysis, plus the orientation of OMB’s oversight staff who begin their regulatory review with a presumption *against* regulation,⁸⁶ made the regulatory process one-sided indeed.

D. Budget Cutbacks

During the Reagan years, budget cutbacks at some product safety agencies, such as the CPSC and the FDA, were so significant that the workforce was cut drastically and the enforcement of the safety laws fell off sharply. The FDA lost nearly 1,000 employees, or 12% of its workforce.⁸⁷ Among those leaving were some of its most experienced employees.⁸⁸ Even more drastic reductions occurred at the CPSC, which suffered a 38% reduction in staff since 1981.⁸⁹ The budget cuts are even more striking if

82. As one critic has suggested, however, the focus in fact should be on indirect benefits not costs: “It is our collective thinking about regulation’s indirect *benefits* that needs stimulation, not the other way around.” Costle, *supra* note 6, at 420.

83. See McGarity, *supra* note 69, at 1296. As Professor McGarity points out, OMB’s use of a 10% discount rate means that “a dollar’s worth of benefits 50 years from now is worth slightly less than a penny today.” *Id.* at 1296 n.293; see also GILLETTE & HOPKINS, *FEDERAL AGENCY VALUATIONS OF HUMAN LIFE* 58-59 (April 1988) (Report to the Administrative Conference of the United States) (indicating that while OMB has continued to urge 10% discount rate, it also has recognized that agencies may use other analyses).

84. Schultz & Vladeck, *An Obstacle to Public Safety*, Wash. Post., May 10, 1988 (Health Supp.) at 20.

85. *Id.*

86. Kriz, *Kibitzer with Clout*, 19 NAT’L J. 1404, 1406 (1987) (interview with Jim J. Tozzi, former deputy director of OMB’s oversight staff).

87. Between 1980 and 1986, FDA’s staff fell from about 8,000 to about 7,000. Kosterlitz, *supra* note 39, at 1571.

88. *Id.*

89. *GAO Report Shows Scanlon’s Reassigning of Employees Has Damaged CPSC, Florio Charges*, 16 Prod. Safety & Liab. Rep. (BNA) 391 (1988) (quoting Congressman Florio). The CPSC’s appropriation for 1988 was approximately \$32.7 million, a reduction of \$1.5 million from the Commission’s request, necessitating a reduction in senior staff and operating costs across the board. *Id.* at 4. The 1989 budget mark of \$32.9 million set by OMB will require further reductions in funding for a number of projects, including ATVs, the bicycle and riding mower projects, and data collection. *Id.* at 75.

measured in constant dollars: from the mid-1970s to the mid-1980s, NHTSA's budget fell by 34% and CPSC's by 52%.⁹⁰

One consequence of the cutbacks is increased deference to industry groups. Agencies that have fewer resources for research and data collection must rely to a greater extent on industry for information. Cutback also mean delays in being able to collect information. At the CPSC, for example, the agency's data collection system was cut in half,⁹¹ so it took the agency twice as long to collect information on product-related injuries in order to determine whether to initiate a regulation or seek a recall.⁹² In the case of ATV's, one CPSC Commissioner estimated that as a result of budget and staff cutbacks, the agency had taken two years longer than it should have to detect the increased injuries associated with ATV use.⁹³ For each year of delay, there were hundreds of deaths and tens of thousands of injuries.⁹⁴

The Commission staff recently estimated that the development of standards also would be slowed by the agency's severe budgetary limitations.⁹⁵ In addition, lower budgets have meant fewer resources for law enforcement and more reliance on voluntary industry efforts—even when such efforts are inadequate.⁹⁶ In the ATV case, although the CPSC did finally seek a recall, it could not afford to litigate the matter when the industry refused to cooperate and voluntarily recall the product.⁹⁷ It was reported that it would have cost the CPSC \$3 million a year (or nearly 10% of its budget)

90. Brown, *The Role of Legislation*, in *PRODUCT SAFETY IN AMERICA* 72-73 (1985) (Final Report of 1984 Chief Justice Earl Warren Conference on Advocacy in United States).

91. The system is half the size it was when the agency was established in 1972. *Decrease in Data Gathering Capability Seen Slowing Down Projects At Safety Agency*, 16 *Prod. Safety & Liab. Rep.* (BNA) 91 (1988).

92. *Id.* The data is needed to support both voluntary and mandatory standards, according to Carl Blechschmidt, CPSC program manager, since industries generally are not convinced that action is needed unless data demonstrates there is a problem.

93. *See ATV Hearings*, *supra* note 27, at 203 (testimony of Commissioner Statler). CPSC Chairman Terrence Scanlon took issue with the notion that budget cuts had affected the ATV case, saying, "I don't think the budget cuts have anything to do with what we have done or what we have not done." *Id.*

94. *See id.* at 184. In the early 1980s the injury rate was about 40,000 a year and the fatality rate about 50 a year. By the late 1980s the figures were much higher. *See supra* notes 27-28 and accompanying text.

95. *Id.* at 91-92.

96. Cutbacks at the CPSC will mean less agency participation in and monitoring of the voluntary standards process, since travel expenses will be among the first items to be cut. 16 *Prod. Safety & Liab. Rep.* (BNA) 104 (1988). The agency already relies heavily on industries to develop voluntary standards; less agency monitoring translates into even greater reliance on industries to regulate themselves.

97. CPSC did ask the Justice Department to bring suit seeking a recall. Nat'l L. J., Jan. 18, 1988, at 9, col. 1. One year later, however, the government accepted a consent decree requiring no recall or refund. Under the agreement, the industry, among other things, must provide warnings about ATV hazards and offer training on their proper use. *See Complaint and Preliminary Consent Decree in U.S. v. American Honda Motor Co., Inc.*, 16 *Prod. Safety & Liab. Rep.* (BNA) 60 (1988) (text of complaint and preliminary consent decree).

for three years to litigate the case.⁹⁸ The small, underfunded agency could hardly afford such a drain on its resources.

CPSC's small budget also gave the agency virtually no leeway to take on new projects. CPSC had to seek supplemental funds from Congress for any major new initiative. Such was the case when the agency decided to proceed with a mandatory safety standard for ATV's—the CPSC sought supplemental funds of \$1.5 million.⁹⁹

In sum, lower budgets for safety agencies has meant less oversight of industry across the board.¹⁰⁰

II. INTERACTION OF TORT AND REGULATORY SYSTEMS

A. A Brief Overview

The product liability system serves as an important adjunct to the regulatory system in promoting product safety in this country. This is because the tort system provides an important incentive for manufacturers to comply with federal standards. The tort system treats violations of federal statutes and regulations as negligence,¹⁰¹ thereby exposing noncomplying manufacturers to substantial tort liability—indeed, liability far greater than the penalties typically provided by regulatory statutes. Consider, for example, that by far the largest fine ever imposed on a corporation for violation of the food and drug act is \$2 million.¹⁰² While it is a sizeable

98. It was reported that the CPSC agreed to the ATV settlement because the Justice Department would have charged the Commission about \$9 million over three years to litigate the claim for a recall and refund. *Settlement on All-Terrain Vehicles Accepted by 2-1 Vote of Commissioners*, 16 Prod. Safety & Liab. Rep. (BNA) 4 (1988) (according to Congressman Doug Barnard (D-Ga), Chairman of the House Government Operations Committee's Commerce, Consumer, and Monetary Affairs Subcommittee).

99. *CPSC To Request 1989 Budget Amendment for \$1.53 Million to Develop ATV Rule*, 16 Prod. Safety & Liab. Rep. (BNA) 390 (1988).

100. For example, due to deregulation of the trucking industry, the number of interstate trucking companies has jumped from 18,000 to over 30,000, and the number of independent truckers has grown to over 200,000. At the same time, the number of safety inspections has been reduced due to budget cutbacks and the prevailing view of a limited role for government. Corrigan, *supra* note 16, at 361.

101. W.P. KEETON, D. DOBBS, R. KEETON & D. OWEN, PROSSER AND KEETON ON THE LAW OF TORTS 230-31 (5th ed. 1984). Although a number of states treat unexcused statutory violations as merely evidence of negligence, a majority treat them as negligence per se. *Id.* at 230. For a general discussion of the use of statutes and regulations to define tort liability, see Morris, *Role of Criminal Statutes in Negligence Actions*, 49 COLUM. L. REV. 21 (1949); Morris, *Role of Administrative Safety Measures in Negligence Actions*, 28 TEX. L. REV. 143 (1949); Schwartz, *The Role of Federal Safety Regulations in Products Liability Actions*, 41 VAND. L. REV. 1121 (1988).

102. The \$2 million fine—which was six times greater than the next largest fine ever imposed—was paid by Beech-Nut Nutrition Corporation in 1987. The company was charged with fraudulently selling "100% Apple Juice" that contained no apple juice and was a mix of cheap ingredients such as sugars, flavoring, and coloring. Wash. Post, Nov. 29, 1987, at H2, col.1.

penalty, it hardly compares with potential tort liability for selling a defectively dangerous drug. Several decades ago, for example, the manufacturer of MER/29 concealed information about the drug's adverse side effects, faced about 500 lawsuits, and paid tort liability of about \$200 million.¹⁰³ For the same conduct, the company pleaded no contest to criminal charges and was fined only \$80,000.¹⁰⁴ A more recent case involved the maker of the arthritis drug, Oralflex. The company was fined only \$25,000 for failing to report overseas deaths associated with the drug,¹⁰⁵ but in one tort action alone a jury returned a verdict against the company for \$6 million.¹⁰⁶ Similar suits against the company numbered in the hundreds.¹⁰⁷

In short, the tort system can have far more clout than the regulatory system. This is true even when the regulatory system is in the hands of far more aggressive law enforcers than was the case during the Reagan years.

Because of the tort system, manufacturers are encouraged to recall their dangerous products to avoid liability,¹⁰⁸ and the possible imposition of punitive damages.¹⁰⁹ Although the threat of product liability suits does not always provide the necessary incentive—as it did not with ATV manufacturers who are facing an increasing volume of tort suits¹¹⁰—it often does have the effect of encouraging such action. On the whole, federal product recall provisions probably work as well as they do because of the tort system.¹¹¹

Finally, the tort system uncovers risks that the government has not yet recognized or acted upon. Such was the case with two notorious products, asbestos and the Dalkon Shield.¹¹² After a risk is uncovered, the tort system

103. J. BRAITHWAITE, *CORPORATE CRIME IN THE PHARMACEUTICAL INDUSTRY* 60-64 (1984).

104. *Id.* at 64.

105. Metzenbaum, *Is Government Protecting Consumers?*, 22 TRIAL MAGAZINE, April 1986, at 22-24.

106. *Borom v. Eli Lilly & Co.*, Wash. Post, Nov. 25, 1983, at D8, col. 1 (D. Ga. Nov. 24, 1983).

107. *Id.*

108. See Schwartz & Adler, *supra* note 23, at 416, 440, 458 (finding that threat of product liability suits and publicity does prod manufacturers to voluntarily recall their products).

109. See e.g., *Lewy v. Remington Arms Co.*, 836 F.2d 1104 (8th Cir. 1988) (failure to recall defective rifle after receiving notice of its dangerousness points to "complete indifference to or conscious disregard for the safety of others," warranting punitive damages).

110. See Kriz, *supra* note 2, at 2665. Former CPSC Commissioner Statler has predicted a "dramatic" increase in product liability suits against ATV manufacturers over the next 5-10 years. *Id.*

111. See Schwartz & Adler, *supra* note 23, at 422, 441-42. To be effective in notifying purchasers of the risks, manufacturers must carry out recalls as quickly as possible, and because court actions to force recalls are extremely time consuming, the government must rely on voluntary compliance to a very great extent. *Id.* at 415-16, 438-39, 456-57. Without the threat of civil liability, such compliance might seldom be forthcoming.

112. See generally M. MINTZ, *AT ANY COST: CORPORATE GREED, WOMEN, AND THE DALCON SHIELD* (1985); D. HENSLER, W. FELSTINER, M. SELVIN & P. EBENER, *ASBESTOS IN THE COURTS: THE CHALLENGE OF MASS TOXIC TORTS* (1985) [hereinafter HENSLER].

also can be an effective prod to the government to act on such products.¹¹³

Conceivably, in the Bush administration the role of the tort system could become even more important in insuring product safety. This could occur, for example, if the staggering deficits from the Reagan years require extremely lean budgets for the safety agencies.¹¹⁴ If so, the tort system could assume an even more important role in detecting hazards in the marketplace, in prodding manufacturers to comply with federal safety standards, and in serving as a general watchdog for consumer safety.

B. The Reagan Administration's View of Product Liability Law

The Reagan administration has been a harsh critic of the product liability system, viewing it as out of control and imposing unwarranted liability on product manufacturers.¹¹⁵ It attributed the recent insurance "crisis" to the tort system and was an advocate for tort and product liability reform that would cut back significantly on victims' rights. Among the most far-reaching reforms urged by the administration were restrictions on lawyers' contingent fees and a \$100,000 limit on noneconomic damages, that is, damages for pain and suffering and punitive damages.¹¹⁶ The administration's package of proposed reforms contained such extreme cutbacks in victims' rights under the common law that it was not considered seriously, and may, in fact, have set back efforts by more moderate and pragmatic reform proponents.¹¹⁷

Although in recent years a number of states have enacted tort reform measures—and the Reagan administration's proposals may have had some effect on this movement¹¹⁸—none of the state enactments contains cutbacks on victims' rights of the magnitude proposed by the Reagan administration. The \$100,000 cap on noneconomic damages, for example, was less than

113. For example, the Consumer Product Safety Commission—after some 40 product liability suits were filed and Congressional pressure was put on the agency—initiated a rulemaking to make cigarette lighters child resistant. Wash. Post, Jan. 12, 1988, at 5, col. 2. In announcing its action, the CPSC said that in a single year, children playing with lighters had caused 120 deaths, 860 injuries, and \$60.5 million in property damage. *Id.*

114. See *supra* notes 87-90 and accompanying text (discussing budget cuts affecting product safety agencies).

115. See generally REPORT OF THE TORT POLICY WORKING GROUP ON THE CAUSES, EXTENT AND POLICY IMPLICATIONS OF THE CURRENT CRISIS IN INSURANCE AVAILABILITY AND AFFORDABILITY (1986) (inter-agency study under auspices of the Attorney General) [hereinafter Attorney General's Report].

116. H.R. 798, 100th Cong., 1st Sess. (1987); see *White House Reform Measure Introduced by Rep. Delbert Latta*, 15 Prod. Safety & Liab. Rep. (BNA) 113 (1987) (discussing bill that was introduced in both 99th and 100th Congresses).

117. According to one industry lobbyist, the administration's proposals encouraged some businesses to abandon a more moderate but "doable" bill, which would have standardized product liability law, and to go after more radical cutbacks in victims' rights. The net result was no legislation at the federal level. Nat'l L.J., April 18, 1988, at 24, 25.

118. A number of leading advocates of tort reform believe that the Reagan administration did play an important role in pointing to problems in the tort system and in offering solutions. *Id.* at 25.

half the amount of even the lowest caps enacted by a relatively few states.¹¹⁹

The administration's radical reform proposals were viewed as a "hasty offshoot" of a 1986 study by Attorney General Meese's Tort Policy Working Group.¹²⁰ The group studied the tort system and the spiraling insurance rates that occurred from 1984-86 and concluded that a "veritable explosion of tort liability in the United States" had caused the crisis in insurance availability and affordability.¹²¹

As other groups began to study the issue more carefully, however, they questioned whether there was in fact an insurance crisis,¹²² and whether the tort system was a major culprit in causing the rate hikes.¹²³ As early as 1987, the insurance crisis had nearly disappeared as a basis for reforming the tort and product liability laws.¹²⁴ Income and profits of the insurance industry had begun to climb.¹²⁵ This took place despite the fact that no fundamental tort reforms had occurred to account for it, again suggesting the absence of any significant linkage between the crisis and tort law.¹²⁶

119. See Farrell, *Virginia's Medical Malpractice Cap and the Doctrine of Substantive Due Process*, 23 TORT & INS. L.J. 684, 688 (1988). A survey of state enactments with damage caps shows the minimum cap is \$250,000, and most caps are well above that amount. *Id.*

120. Nat'l L.J., April 18, 1988, at 24.

121. Attorney General Report, *supra* note 115, at 2. See generally *id.* at 16-59 (acknowledging that industry's pricing practices, as well as general economic conditions, have played role in insurance crisis, and finding that tort law has played central role in crisis).

122. See generally CONFERENCE BOARD REPORT NO. 893, *PRODUCT LIABILITY: THE CORPORATE RESPONSE* (1987) (concluding that "[a]t least for major corporations, the so-called twin crisis of liability and insurance have had relatively little impact" *Id.* at 21.); Kindregan & Swartz, *The Assault on the Captive Consumer: Emasculating the Common Law of Torts in the Name of Reform*, 18 ST. MARY'S L.J. 673, 710-11 (1987).

123. *The Liability Insurance Crisis: Hearings Before the Subcomm. on Economic Stabilization of the House Comm. on Banking, Finance and Urban Affairs*, 99th Cong., 2d Sess. 89-90 (1986) (statement of William J. Anderson, Director, General Government Division, General Accounting Office) [hereinafter *Insurance Crisis Hearings*]. The Government Accounting Office found that the cyclical nature and pricing policies of the insurance industry account for its profitability from year to year. *Id.* at 89. In the early 1980s, when interest rates were as high as 20%, insurance companies lowered premiums to sell more insurance to obtain funds to invest. *The Manufactured Crisis*, CONSUMER REPORTS 544 (1986). The high return on investments offset underwriting losses and the industry remained profitable. *Insurance Crisis Hearings, supra* at 86. In 1984, however, when interest rates fell, the industry suffered a loss. *Id.* Underwriting losses were \$19.4 billion and investment gains were \$17.9 billion. In 1985 the situation improved and investment gains were again greater than underwriting losses—by \$7.6 billion. By 1986, the industry's future again looked bright. Salomon Brothers forecast that industry profits would rise annually at a rate of 25% in the period 1985-89. *Id.* at 91.

124. *Outlook for Product Safety & Liability in 1987*, 15 PROD. SAFETY & LIAB. REP. (BNA) 47, 51 (1987). "The insurance industry, which took the lead in promoting [tort and product liability] changes in 1986, will stay behind the scenes this year." *Id.* at 51.

125. Net income in 1986 was roughly \$11.5 billion and insurance costs were leveling. *Id.* at 51 (1987).

126. See Rand Corp. Institute for Civil Justice, *DESIGNING SAFER PRODUCTS, CORPORATE RESPONSES TO PRODUCT LIABILITY LAW AND REGULATION* 121 (1983) (finding similarities in exaggerated insurance "crisis" in mid-1970s and mid-1980s and concluding that "product liability claims have not been an unreasonable cost to most manufacturers").

The Attorney General's Tort Policy Working Group also complained about the explosion in the number of product liability suits being filed, pointing to a 758% increase in the number of such suits filed in federal court between 1974-85.¹²⁷ But again, further study revealed that federal suits, which are a very small percentage of claims nationwide, did not reflect what was occurring in state courts, where no similar explosion of litigation was occurring.¹²⁸ Further, the annual increase in tort filings in federal court since the Attorney General's study has been 2% or less.¹²⁹

The Attorney General's Report also concluded that jury verdicts were outlandishly high, a conclusion that researchers generally have found difficult to accept without further study.¹³⁰ While jury awards have increased in product liability and medical malpractice cases, such increases can be attributed to factors other than irrational juries that are "out of control."¹³¹

C. *The Real Crisis in the Tort System*

The real crisis in the tort system is the high cost of the system.¹³² There are long delays between the time a person is injured and the time compensation is awarded or denied.¹³³ Less than half the money spent in tort

127. Attorney General Report, *supra* note 115, at 45. In 1974 only 1,579 claims had been filed; in 1985 the figure had grown to 13,554. The report speculated that state courts must have experienced "a similar dramatic increase in the number of product liability claims." *Id.*

128. Galanter, *The Day after the Litigation Explosion*, 46 MD. L. REV. 3, 6 (1986). A study of state courts revealed that the rate of increase in tort claims between 1978-1984 was only 1% above the rate of population growth. 1984 STATE COURT CASELOAD STATISTICS ANN. REP. pt. 2, at 182 (1986).

129. GENERAL ACCOUNTING OFFICE, FEDERAL COURTS: PRETRIAL MANAGEMENT OF CIVIL CASES VARIED AT SELECTED DISTRICT COURTS 36 (1988). In 1985 tort filings numbered 41,593; in 1986 the figure was 42,326; and in 1987 it was 42,947. *Id.*

130. D.R. HENSLEY, M.E. VAIANA, J. S. KAKLIK, M.A. PETERSON, TRENDS IN TORT LITIGATION, THE STORY BEHIND THE STATISTICS 12-24 (1987) [hereinafter THE STORY BEHIND THE STATISTICS].

131. *Id.* at 21, 22-24. The report did find that in cases involving the same degree of injury, juries make higher awards for products liability, medical malpractice, and workplace injuries than for automobile injuries. It concluded, however, that more research is needed to determine why and how juries reach their conclusions. *Id.* at 21. The report also found that jury awards often are reduced after trial, either by the court or through settlement, and that such reductions are greatest for awards at the highest end of the scale. *Id.* at 22-24. Further, a Consumer Federation study found that much of the growth in the size of awards is attributable to inflation, higher medical costs, longer life expectations, higher incomes, and so on. Cooper, *Trends in Liability Awards: Have Juries Run Wild?* (1986) (Consumer Federation of America Report).

132. Civiletti, *Zeroing in on the Real Litigation Crisis: Irrational Justice, Needless Delays, Excessive Costs*, 45 MD. L. REV. 40 (1986).

133. *Product Liability Voluntary Claims and Uniform Standards Act, Hearings on S. 1999 Before the Subcomm. on the Consumer of the Senate Comm. on Commerce, Science, and Transportation*, 99th Cong., 1st Sess. 88 (1986) (testimony of Deborah Chalfie, Legislative Director, HALT, An Organization of Americans for Legal Reform). Only about half the tort cases are resolved in less than two years, while about 10% require four years. *Id.*

litigation goes to compensate claimants for their injuries—the rest is absorbed by the costs of the process itself.¹³⁴

To some extent, the Reagan administration's reforms would address the issue of transaction costs, for example, plaintiffs would receive more of their recoveries if the size of contingent fees were limited. However, in the long run, plaintiffs would be seriously disadvantaged by the proposal to limit fees. Lower legal fees would make lawyers less willing to take on the more difficult tort cases, and many injured victims would be without recourse at all in the legal system. The same effect would likely occur if extremely low caps were set for noneconomic losses. Lawyers would shy away from bringing difficult cases, and especially those in which a major component of the damage claim was for emotional distress.

While the system needs reform to reduce costs, it needs to be a balanced reform that involves fair tradeoffs for both plaintiffs and defendants. The administration's proposed reforms, however, are all one-sided. They would make it more difficult for plaintiffs to bring and win suits. In addition, they would curtail sharply plaintiffs' recoveries in successful suits. Defendants, however, would suffer no limits on their current rights. They would be able to defend claims to the hilt, with no restrictions on legal fees, and with damages capped at low levels, they would enjoy an enormous advantage over plaintiffs in settling claims.

The net effect of such reforms would be to weaken greatly the tort system and to reduce markedly its role as an adjunct to the regulatory system, in providing incentives for product safety.

III. A PRODUCT SAFETY AGENDA FOR THE 1990s

The Bush administration should begin immediately to reverse the anti-consumer, probusiness philosophy of the Reagan years. The regulatory system itself has not been dismantled¹³⁵ and can be reinvigorated with new personnel and a new philosophy of government.

The one Reagan legacy that cannot be so easily reversed or ignored, however, is the enormous budget deficit.¹³⁶ Certainly, one of the challenges for the new administration will be to make the most efficient use of its regulatory dollars. This part provides a general overview of the new direction the Bush administration should take in the product safety area, keeping in

134. *The Story Behind the Statistics*, *supra* note 130, at 27-29. In tort cases, other than automobile tort litigation, plaintiff's average compensation is 43% of the total expenditures involved. Defendants' expenses, including time and legal fees, are 30% of the costs; plaintiffs' expenses are 26% of the costs; and court expenses are 4% of costs. *Id.* at 27.

135. *See supra* note 2 and accompanying text.

136. The Congressional Budget Office recently projected a \$230 billion federal deficit in 1993 for that portion of the budget that can be spent on general programs. *Wash. Post*, July 20, 1988, at A13, col. 1. An official testified that CBO expects, absent tax increases or spending cuts, that the deficits "would remain at relatively high levels through the 1990's." *Id.*

mind the fiscal constraints that are bound to affect this area of government activity as they will others.

A. *Rejecting the Antiregulatory Philosophy of the Reagan Years*

Many have predicted a rush to *reregulate* in the new administration in reaction to the "rush to deregulate" that occurred in the Reagan administration.¹³⁷ Whether it is forecast in terms of a regulatory "backlash,"¹³⁸ or a "renaissance of regulatory reaction,"¹³⁹ the widely shared view is that a new era of regulation lies ahead.¹⁴⁰

The Bush administration should indeed reject the zealous antiregulatory philosophy of the Reagan years. Its regulatory philosophy should be based on the premise that government has a positive role to play in protecting the public from unreasonable hazards and that the public *as a whole* is its constituency, not any special interest group.

Safety problems should be investigated and regulatory initiatives explored with an open mind about the final outcome. There should be no working presumption against regulatory solutions, as has been the case in the Reagan years.¹⁴¹ Similarly, there should be no presumption in favor of regulatory solutions. The goal should be to gather the best data available about problems and, to the extent possible, engage in the most open and honest evaluations of data and proposed solutions. This means a "hard look" look at information and data from any self-interested source. It also means affirmatively seeking information from independent sources and seeking out the views of groups affected by proposed actions that are not participating in the regulatory process. No one constituency—business or nonbusiness—should have exclusive or *ex parte* access to any part of the regulatory or regulatory review process. This approach should both assure integrity in the process and improve the quality of the ultimate decisions. In the next sections, the implementation of this philosophy will be discussed in greater detail.

B. *People and Process*

1. Appointments

The key to implementing this approach to safety regulation will be the people who are chosen to lead the agencies. First, of course, they must

137. S. TOLCHIN & M. TOLCHIN, *supra* note 41, at 237.

138. *See supra* note 4.

139. *Regulation: Fragile Change*, *supra* note 3, at 24 (quoting James Fitzpatrick, attorney with Arnold & Porter who has challenged administration in safety and environmental fields).

140. *Id.* During the 1988 political campaign, there was little rhetoric against health, safety, and environmental regulation, unlike the Reagan campaign which opposed regulation across the board. Bruce Fein of the Heritage Foundation noted in the summer of 1988 that not a "syllable" had been uttered by the candidates against such regulations. *Id.*

141. *See supra* note 86 and accompanying text.

share this view of the role of government. But just as important—especially given the expected limits on agency resources—they need to be effective managers. People with good track records in the government or other areas of relevant public or private life should be sought out. Purely political appointments of people with little or no expertise should be avoided. The safety agencies are too important, even the smallest ones like the CPSC, to be a “dumping ground” for unqualified appointees.¹⁴²

2. Process

OMB's role in the regulatory process needs to be redefined and limited. Good appointments to the key agency positions should go a long way toward eliminating any need for exacting OMB scrutiny of the agencies. Experienced, knowledgeable agency heads will assure that the regulatory process is functioning soundly, and regulatory decisions can be left largely to the agencies—which have the expertise and knowledge of the problems at hand—rather than turned over to OMB staffers to second-guess on the basis of an abstract cost-benefit analysis. While OMB should play some role in overseeing the government regulatory system, it should be more limited than in the past.

First, OMB should serve as a clearinghouse for regulations for the purpose of assuring that agency rules are not at cross purposes, overlapping, or inconsistent with one another. Secondly, OMB should serve a quality control function, assuring that the regulatory *process* is sound, that is, that input has been received from all sides, that costs and benefits have been evaluated openly and fairly, that information gaps are acknowledged and dealt with, and so on. In connection with this role, OMB should be involved in training agency personnel in regulatory analysis, the strengths and weaknesses of cost-benefit analysis, and how to use it fairly with respect to health and safety issues. OMB could also provide uniform guidelines on certain recurring regulatory issues.¹⁴³

In performing these functions, however, OMB should not second-guess the merits of agency regulations. If the regulatory process passes muster, OMB should not object to the agency's conclusions. In short, OMB's review should not be result-oriented, as it has been in the Reagan administration.¹⁴⁴ Further, OMB should not permit any off-the-record contacts with outside interest groups during its review process. The ultimate responsibility for regulations should remain in the agencies, and no interest group should be encouraged to go around the agencies in an effort to change the outcome at the OMB.

142. See *supra* note 44 and accompanying text.

143. For example, on the issue of valuing human life, agencies take varied approaches and do not always make explicit their methodologies. This would be an area where OMB could serve a supervisory as well as an educational/training role. See GILLETTE & HOPKINS, *supra* note 83, at 62-64.

144. See *supra* notes 80-81 and accompanying text.

C. Agency Budgets

While it seems likely that budget deficits will, to a considerable extent, "eat . . . up [the] next president's leeway,"¹⁴⁵ the budgets of the safety agencies are not "big ticket" items. Budgetary increases to enable these agencies effectively to carry out their statutory responsibilities are not going to have any major impact on the federal budget.

Nevertheless, given the staggering size of the current federal deficit, the new administration must carefully scrutinize the budgets of all agencies, and particularly those which seek even modest increases. The new administration will need to make many tradeoffs and will not be able to do everything it would like to do, nor will it be able to attend to all areas that the Reagan administration left unattended. What follows is a list of issues that should be considered in order to assure that the safety agency budgets are adequate.

1. Current Expenditures

First, it must be determined whether the agency is effectively using its current resources, that is, whether it is getting the most bang for its regulatory buck. For example, government educational programs—which have been emphasized in this administration as an alternative to mandatory regulations¹⁴⁶—are often costly and are not terribly effective in the product safety area.¹⁴⁷ In considering next year's budgets for safety agencies, funds now used for less effective programs should be reprogrammed into more effective regulatory initiatives. In short, a cost-benefit analysis should be used to allocate agency resources into the best programs.

2. Enforcement Strategies

Second, the enforcement strategies of the agencies need to be reassessed. In an era of limited government resources, there can be relatively few enforcement actions and therefore those few must send a warning to others for the broadest possible effect. Criminal prosecutions or the imposition of large civil penalties can serve this purpose.¹⁴⁸ Agencies need sufficient resources, however, to be able to threaten such actions and then to follow through if voluntary compliance is not achieved. If funding levels are so low that it is apparent that no follow-through is possible—as it has been

145. Wash. Post, July 20, 1988, at A13, col. 1.

146. See *supra* note 61 and accompanying text.

147. See generally Adler & Pittle, *Cajolery or Command: Are Education Campaigns an Adequate Substitute for Regulation?*, 1 YALE J. REG. 159 (1984).

148. A recent study by the nonprofit group, the National Safe Workplace Institute, showed that states which brought more criminal prosecutions involving job safety had markedly lower death rates among construction workers than states which did not bring many criminal cases. N.Y. Times, July 17, 1988, at 15, col. 1. The study faulted the federal government for bringing only two successful criminal cases from 1981 to 1988, while California alone had brought 112 criminal cases.

with the CPSC¹⁴⁹—the agency completely loses its clout to get voluntary compliance. When agencies have neither the will nor the resources to enforce their statutes, there is generally a sharp fall off in voluntary compliance, as has been the case in the Reagan years.

3. Data Collection

Data collection and evaluation is at the heart of a fair and effective regulatory system. It frequently has been cut off by OMB in this administration—perhaps, as one critic suggested, to avoid having to regulate.¹⁵⁰ Certainly, without a good data collection system, the government cannot act, or at least it cannot act in a timely fashion.¹⁵¹ Adequate funding for data collection also should make the government less reliant on business as its primary source of information.

D. Tort Reform

The next administration's attitude toward tort reform should reflect the importance of the tort system to the regulatory system. A strong tort system assists the federal agencies in carrying out their statutory responsibilities, and it should not be weakened in ways that undercut its clout in promoting product safety. Tort reforms that are fair to *both* plaintiffs and defendants and that reduce the transaction costs of the tort system are highly desirable. Such reforms need not and should not, however, undermine the deterrent effect of the tort system and its positive role in promoting compliance with federal safety laws.

CONCLUSION

This Article has been highly critical of the product safety record of the Reagan administration. It has criticized the administration on a number of counts—for appointing officials with zealous, antiregulatory views, for giving OMB the power to undercut agency rulemaking, and for slashing safety agency budgets.

At the same time, the article has pointed out that the Reagan administration has failed to achieve its goal of dismantling the regulatory system—the regulatory agencies and the product safety statutes remain intact. Thus, in fairly short order, the new administration can begin to reinvigorate the system. This Article has offered a number of suggestions for doing so, that is, with new personnel, a new philosophy of government, and better use of resources. The suggestions are practical and doable. None requires large budgets, major restructuring of the regulatory scheme, or other fundamental reforms. Yet they can go a long way toward reversing the Reagan record

149. See *supra* notes 97-98 and accompanying text.

150. Morrison, *supra* note 5, at 1068.

151. See *supra* notes 93-94 and accompanying text.

of inaction and delay and restoring the government to its proper role in providing consumer protection for its citizens.