Deregulation and Private Causes of Action: Second Bites at the Apple

James T. O'Reilly
DEREGULATION AND PRIVATE CAUSES OF ACTION:
SECOND Bites AT THE APPLE

James T. O'Reilly*

I. Introduction

The lowly apple figures frequently in modern political metaphors. Freedom from excessive regulation is as American as apple pie; regulation takes a bite out of American business; and there is something unfair about giving people a second bite at the apple. Private causes of action in federal courts to enforce regulatory requirements are the "second bites at the apple" of modern regulatory control. Private enforcement actions adversely affect the client groups of modern administrative law, including regulated manufacturers, municipalities, and other persons. This Article addresses that set of "second bites" from the viewpoint of the "apples" affected by this new challenge to the regulated communities.

Private cause of action theories are divergent, but in general, a "private cause of action" can be defined as a private person's right to invoke a federal enforcement statute against another private person in a civil suit. The suit has its jurisdictional base in the regulatory command of a particular federal command and control statute.¹ Administrative agencies typically enforce regulatory statutes, as in the case of violations of Rule 10b-5 of the federal securities laws.² The decline in regulatory enforcement, brought on by

---

* Lecturer in Law, University of Cincinnati College of Law; corporate practice, Cincinnati, Ohio. B.A. Boston College, J.D. University of Virginia.

1. Discussion of a "private right of action" in this Article refers to an express or implied power of an individual civil litigant to invoke a statute, which creates or preserves a public regulatory interest, as one of the independent grounds of action in a suit which otherwise would involve traditional tort or other civil law concepts. See generally R. Pierce, S. Shapiro, & P. Verkuij, Administrative Law & Process § 6.4.12 (1985); Hazen, Implied Private Remedies Under Federal Statutes: Neither a Death Knell Nor a Moratorium—Civil Rights, Securities Regulation, and Beyond, 33 Vand. L. Rev. 1333 (1980); Stewart & Sunstein, Public Programs and Private Rights, 95 Harv. L. Rev. 1193 (1982).

2. See 17 C.F.R. § 240.10b-5 (1986) for Securities and Exchange Commission regulations proscribing fraudulent trade in securities. An agency has the power to determine primarily whether a violation has occurred and to conduct an "adjudication." See also 5 U.S.C. § 551
budget considerations and policy changes, however, has shifted enforcement toward private injunctive and tort actions. Private enforcement of federal laws is common in antitrust law and in modern environmental regulation. Gradually, however, private actions are becoming a new subspecies of product liability litigation, with even greater use expected in the future as budget reductions reduce direct enforcement by federal agencies.

Apart from private causes of action, a separate set of “initiation rights” cases have enabled private persons to sue to force government action against regulatory violators. The impact of these court-ordered agency actions has been most noticeable during the deregulation efforts of the Reagan administration. The wisdom and consequences of the initiation cases have been amply debated elsewhere.

II. NEW TRENDS

Two major advances in rule-making policy represent important factors in the private enforcement of federal regulatory standards. Neither is novel, but each is a central theme of current administrative agency enforcement. The first is the rise of performance standards, and the second is mandatory self-reporting of violations.
A. Performance Standards

Performance standards are the less precise federal agency regulations, which prescribe certain policy goals without specifying the means by which regulated entities are to achieve them. These standards can include product, service, or conduct rules governing private sector activity. Performance standards offer flexibility: They allow industry to satisfy a regulation in cost-efficient—albeit less easily monitored—ways with creative, inexpensive solutions.

For example, the directive, “One should check airplane engines appropriately” is a performance approach, in contrast to the specific commands in a Federal Aviation Administration airworthiness directive containing 500 pages of specific directions for parts, repairs, and inspection. Application of the former would encourage creative, cost-efficient solutions crafted by individuals, because regulated entities may employ various means to accomplish identical goals. The Occupational Safety and Health Administration hazard communications standard which became effective in 1985-86 best exemplifies the trend toward the performance standard approach. OSHA consciously opted for a performance approach in the final rule requiring workplace chemical labeling. This approach reversed the Carter administration’s effort to define particularized chemical classifications and label warnings.

The recent expansion of tort plaintiffs’ use of federal regulations will significantly affect judicial interpretation of and deference to administrative policy decisions. Where once regulatory requirements were a shield, they now may be a sword. This Article predicts that future plaintiffs may challenge the adequacy of private sector compliance by asserting violation of agency perform-

7. Several studies of regulation define performance standards well. See, e.g., S. BREYER, Regulation and Its Reform 105 (1982).
ance standards in individual product liability actions, and that plaintiffs also may use novel remedies to enforce standards.

B. Reporting Obligations

The use of mandatory reporting obligations is the second current administrative law trend that intersects with the geometric rise in private suits. This standard requires that regulated entities report detailed, often adverse, information about their products or practices to the government. When a firm is required to reveal to the agency and thereby to the public that the firm has violated the law, failure to do so has significant implications for private tort suits.

Mandatory reporting of product problems has become a requirement in the regulated manufacture of automobiles, aircraft, chemicals, pesticides, medical devices, drugs, microwave ovens, and many other products. Although reporting deficient products serves a social need, it encroaches on traditional privileges against self-reporting of violations to police agencies.

Failure to report can bring civil penalties, and willful nonreporting is punishable by criminal and civil actions. Moreover, courts have upheld mandatory reporting requirements on statutory and


13. For example, it is a violation of the Consumer Product Safety Act for a manufacturer of a product subject to a mandatory safety standard to distribute in commerce a product which does not meet that standard, 15 U.S.C. § 2068 (1982), yet the manufacturer must report such a noncompliance as soon as it is discovered. Id. at § 2064.


16. The duty to report has been upheld against challenges to the agency's regulations. See, e.g., Chemical Specialties Mfrs. Ass'n v. EPA, 484 F. Supp. 513, 517-18 (D.D.C. 1980).
DEREGULATION AND PRIVATE CAUSES OF ACTION

constitutional grounds, despite objections based on the self-incrimination privilege.

Congress has accepted the controversial practice of mandatory self-reporting in several statutes. Agencies also have implied power to compel such reports in several contexts in which the statute failed to give express authority for reporting rules. In either case the requirement has a major impact on the availability of a private cause of action against the regulated entity. Because reporting often is linked to a trigger phrase such as "unreasonable risk" or "defect," the admission of such a risk can have drastic consequences for the firm making the report: Unless an appropriate disclaimer is accepted by the administrative agency, the firm may leave itself open to private product liability suits.

The intersection of private enforcement cases and mandatory reporting has been an interesting development. Several varieties of federal civil actions have arisen in recent years. Litigants have brought traditionally state-based product liability actions into federal courts when the product's manufacturer failed to notify the government about the product's deficiencies. The statute typically allows the agency to penalize the firm which failed to report, but only after the product deficiency met a statutory test of "defectiveness." The proof of defective status has varied with the

---


22. The statutory defect threshold is an integral part of the penalty scheme. Beyond a preliminary finding, the agency is not required to meet the full levels of proof as to the existence of the defect in order to reach the legal threshold for an order compelling the manufacturer to provide notice of the defect. United States v. Ford Motor Co., 421 F. Supp. 1239 (D.D.C. 1976), aff'd in part, 574 F.2d 534 (D.C. Cir. 1978).
particular legislative history concerning a specific product, recognizing qualitative as well as quantitative differentiations. When the private tort plaintiff alleges violation of a reporting rule, the judge's perspective on administrative policy is altered. The federal court views the new reporting obligations from the point of view of the plaintiff rather than from that of the government, which wrote, promulgated, and interpreted the rules. A private tort action in these circumstances gives the plaintiff the luxury of targeting a particular defendant's decision not to report with clear and convincing hindsight. The administrative agency, meanwhile, has its policy rationales argued by persons with little or no involvement in that policy. To make matters worse, a lack of resources may preclude the agency from taking an active part in the dispute to explain its policies.

Arguably, exploitation of agency rules by private parties benefits a resource-constrained agency. In the past several years, many federal courts have found the relatively dormant section 15 reporting duties of the Consumer Product Safety Act and the automobile defect reporting system relevant to product liability plaintiffs' actions. Ironically, these cases produced a level of controversy, deterrent potential, public attention, and widespread industry attention for agency rules which the government could not have achieved on its own.

The recent trend in case law granting private enforcement rights to injured plaintiffs as "private attorneys general" is manifest in parallel enforcement efforts by government and private enforcers


24. For example, defects in automobiles have been developed by a line of judicial cases which have differed from the small number of administrative cases interpreting "defect" under the Consumer Product Safety Act. See, e.g., United States v. Ford Motor Co., 453 F. Supp. 1240 (D.D.C. 1978).

25. In this context the "private attorney general" is enforcing one of the newer statutory protections common to all consumers and citizens. This Article does not address the economic protections of antitrust and securities law which also permit private enforcement rights. The "private attorney general" concept is not new. See Associated Indus. of New
in many product safety contexts. Problem reporting in the drug industry is well established, but regulations revised in 1985 have intensified the effort.\textsuperscript{26} The revised regulations prescribe that sponsors of a new drug product file mandatory product adverse reaction reports with the Food and Drug Administration.\textsuperscript{27}

Two recent cases illustrate the juxtaposition of private and public rights. In 1985, the United States District Court for the Eastern District of Pennsylvania convicted a drug firm of criminal violations for not reporting adverse reactions.\textsuperscript{28} In the second case, the United States Court of Appeals for the Third Circuit awarded millions of dollars in punitive damages for failure to report the same type of adverse reactions to the FDA.\textsuperscript{29} The former case involved an ambiguous duty to report medical case information obtained from other nations.\textsuperscript{30} Plaintiffs in the latter case asserted that failure to report adverse reactions of American patients had been indirectly responsible for one plaintiff's injuries.\textsuperscript{31} The FDA had used its regulatory authority to require reporting in some instances, but had not required reports if a product was in a class for which premarket approval reports were not required. The plaintiff in the tort action asserted that the court should read the ambiguous regulation to compel reporting, and the court agreed.\textsuperscript{32}

Private enforcement of reporting requirements is thriving because of the relative ease with which litigants can bring reporting

---

\textsuperscript{26} York v. Ickes, 134 F.2d 694, 699-700 (2d Cir. 1943), rev'd per curiam on other grounds, 320 U.S. 707 (1943).

\textsuperscript{27} 21 C.F.R. § 314 (1986).

\textsuperscript{28} 21 C.F.R. § 314.80 (1986).

\textsuperscript{29} See United States v. Smithkline Corp., Crim. 84-0227 (E.D. Pa. 1985); cf. United States v. Eli Lilly & Co., No. IP85-53 CR (S.D. Ind. 1985) (similar outcome). Both cases were settled with negotiated pleas for the corporation and individual defendants.

\textsuperscript{30} Stanton v. Astra Pharmaceuticals Inc., 718 F.2d 553 (3d Cir. 1983).

\textsuperscript{31} Allegedly, defendants failed to report to the Food and Drug Administration that a product had caused severe reactions among several patients in Northern Ireland clinical observations. Prior to the 1985 revisions, the regulations on adverse information reporting were ambiguous as to the rapidity and duty of reporting for this particular type of adverse drug information. Smithkline, Crim. 84-0227, _____ (E.D. Pa. 1985).

\textsuperscript{32} See Stanton, 718 F.2d at 555. This case involved severe birth defects alleged to have been associated with the use of a local anaesthetic supplied by defendant.

\textsuperscript{32} Id. at 562-63. On advice of counsel, the Stanton defendants believed that their product was outside the literal coverage of the problem-reporting regulations because of its historical status as an "old" drug rather than the fully reporting set of "new" drugs for which certain mandatory reporting rules applied. Id. at 560-61.
violations into federal court. Although courts customarily accord deference to agencies such as the FDA in their fields of primary jurisdiction, the inclusion of a private right of action in a statute infringes upon the responsible agency’s ability to exercise its primary jurisdiction to enforce the statute.

III. Conceptual Divisions

Conceptually, private rights of action can be subdivided into express statutory rights and implied or judicially created rights. Academic attention has begun to focus on the creation of parallel private rights by the federal courts in their construction of federal statutes. With one exception, the Supreme Court generally has been hostile to such implied rights arguments. Commentators observe that courts will have a difficult time implying new causes of action in the face of such reluctance by the Supreme Court.

Recent congressional grants of private rights are somewhat clearer than the older implied-rights statutes. Proponents of the legislation assert that the suits require no public expenditures and argue that the public benefits from the case precedents. Opponents contend that negotiating restraints on agencies’ own investigatory or prosecutorial powers is difficult enough. The true advantage of creating private rights by statute is avoiding the criticism that courts usurp the legislature’s job when they imply new causes of action. In addition, adopting rights of action in legislative pack-

33. R. Pierce, S. Shapiro, & P. Verkuil, supra note 1, § 6.4; Hazen, supra note 1, at 1333; Stewart & Sunstein, supra note 1, at 1193.
35. "Congress’ decision to withhold a private right of action and to rely instead on public enforcement reflects congressional concern with obtaining more accurate implementation and more coordinated enforcement of a regulatory scheme." Merrell Dow Pharmaceuticals v. Thompson, 106 S. Ct. 3229, 3245 (1986). In earlier cases, the Supreme Court has disfavored the creation of private causes of action without a showing of congressional intent. Cort v. Ash, 422 U.S. 66 (1975). For a good analysis of the Supreme Court’s actual and perceived trends, see Hazen, supra note 1, at 1286, and Stewart & Sunstein, supra note 1, at 1304-07.
36. See generally R. Pierce, S. Shapiro, & P. Verkuil, supra note 1; Hazen, supra note 1; Stewart & Sunstein, supra note 1.
37. Creating an express cause of action eliminates the need to debate the social benefits of the judicially implied rights of action. The protected class of persons probably will pursue the statutory remedy. If a statute protects a limited class, courts will recognize their private right of action, absent clear congressional intent to the contrary. Merrill Lynch, Pierce, Fen-
Deregulation and Private Causes of Action

Ages is simpler for potential plaintiffs than constructing public policy arguments for judicial implication of the rights. The legislative process is inherently one of tradeoffs: Legislatures can "cheaply" insert or remove private rights from a piece of substantive legislation, such as a reauthorization bill for a federal agency. Private rights sections rarely should make or break a bill's prospects for passage.38

Dean Pierce39 and Professors Sunstein, Hazen, and Stewart40 have published excellent articles on private rights of enforcement of regulatory statutes, and have laid the intellectual foundation for analysis of the case law. The Sunstein-Stewart treatment concludes that "entitlements," the specially protected rights of administrative law, are the basis for judicially created private rights.41 Entitlements are minimal levels of a benefit to which a person gains either a statutory or constitutional guarantee. Persons with entitlements enjoy special protection from removal of the benefit.42 Because the case law of entitlements in the context of adjudicatory due process safeguards consumes many pages of administrative law scholarship, an entitlement theory as a basis for private rights of action is relatively easy to understand.43 The courts look at the rights and duties created by the statute in order to find an analogy to common law entitlements. Where this form of entitlement exists, the courts allow the individual to enforce those statutory rights. Sunstein and Stewart conclude, however: "Private lawsuits

38. In a legislative struggle for the creation of a new statutory set of rights, for example rights for consumer product safety or chemical regulation, proponents of the legislation, typically including private rights advocates and adversaries representing an established constituency, advocate inclusion of private enforcement remedies. Because the adversaries usually concentrate their efforts on substantive issues, procedural issues routinely do not attract attention. An exception was the 1980 passage of the Comprehensive Environmental Response, Compensation, and Liability Act ("Superfund"), in which the bill's opponents eliminated a private enforcement provision. See Anderson, Negotiation and Informal Agency Action: The Case of Superfund, 1985 Duke L.J. 261, 270 n.21 (private rights removed before final passage).


40. Hazen, supra note 1; Stewart and Sunstein, supra note 1.

41. Stewart and Sunstein, supra note 1, at 1307-16.


43. R. Pierce, S. Shapiro, & P. Verkuil, supra note 1, § 6.4.
are a poor forum for reconciling the social norms involved in regula-
tory programs . . . it is difficult for courts to know whether crea-
tion of a particular private right of action will promote economic
welfare."\textsuperscript{44}

From the viewpoint of regulated firms facing not only regulatory
agencies but also private litigation challenges, private rights of ac-
tion offer even less benefit to society than Stewart and Sunstein
foresee. Regulation promotes social goals only if it remains predict-
able, well directed, and systematic. An unforeseen precedent estab-
lished in a private case can have a disruptive effect on the ability
of an agency and firms to reach compromise and common under-
standing.\textsuperscript{45} An agency's overall program may suffer because of an
unfavorable court precedent created by ad hoc litigation.\textsuperscript{46} That
precedent may reduce interpretive certainty for the regulated com-
community, particularly if the court is not inclined to defer to an inter-
pretation which an agency previously followed as a matter of infor-
mal "working law."\textsuperscript{47} Loss of predictability imperils the enforcers'
programs. The incentive to cooperate in an anticipatory fashion
decreases.\textsuperscript{48}

\textsuperscript{44} StewaRt \& Sunstein, supra note 1, at 1320. This article was cited with approval in

\textsuperscript{45} For example, the Consumer Product Safety Commission has devoted most of its ef-
torts to negotiating voluntary corrective action plans arising out of defects. See 1985 Con-
liability on top of the settlement remedy threatens the Commission's ability to settle dis-
putes. This additional liability is increasingly prevalent in the new wave of private actions
discussed infra at notes 75-84.

\textsuperscript{46} For example, a judge can determine that a certain number of fires occur before a
refrigerator is considered to have a "defect" either in a Consumer Product Safety Commiss-
ion initiated enforcement case, see, e.g., In re White Consolidated Industries, Inc., 1 Con-
sumer Prod. Safety Guide (CCH) ¶ 75,093 (Nov. 3, 1975), or in a private suit by a purchaser
against the manufacturer to which the Commission is not a party. In the latter case, the
defective nature of the refrigerator would be the basis for a separate cause of action in
which the private plaintiff attempts to show that the manufacturer breached a duty to re-
port the defect.

\textsuperscript{47} A reviewing court customarily accords deference to the factual determinations of the
administrative agency. As the agency decision becomes a less formal interpretation matter,
devference decreases.

\textsuperscript{48} Typically, a private entity adapts to the regulatory system and conforms without the
governmental expense of enforcement actions. The regulator, in turn, makes small adjust-
ments in the regulatory scheme to suit the needs of the regulated firm. S. Breyer, Regula-
tion and Its Reform (1982), provides a good insight into this accommodation.
The Sunstein-Stewart article favors private rights of action when the relationship between rights and duties in the administrative program is similar to those established by common law entitlements. Courts may then "ordinarily provide private remedies without exceeding their competence, subverting legislative control of regulatory policy, or contradicting any of the reasons for the creation of an administrative enforcement system." Courts, however, may not be able to create and police these private rights of action without significantly displacing administrative certainty. Deterrence through certainty is a key reason for the operational success of this nation's administrative enforcement system.

IV. SEEKING CERTAINTY

"Interpretive certainty" is nothing more than one's best guess, as counsel to a regulated client, that an agency will act in a certain way under a given set of facts. Today's administrative law practitioners, who must watch the agencies' internal movements for signs of enforcement trends, are the descendents of the Romans who read the future in the entrails of a fowl. Although the process is not exact, experienced agency watchers can predict with some accuracy how a given agency will regulate. An attorney's value to the client is much diminished if he or she loses this ability to forecast agency behavior. Private rights of action make prediction more difficult.

Interpretive certainty is important because government agencies rely heavily on voluntary compliance by regulated entities in order to implement regulation. The primary agency leverage is persuasion and common long-term interests in cooperation. An agency also may utilize occasional prosecutions and other forms of deterrence to maximize the reach and effectiveness of a statute. Regulated firms must be able to predict what an agency's interpretation of a statute will be so that they can operate within its terms. Regulated firms or persons generally plan their construction, operation, marketing, or other activities to stay within the boundaries of permissible conduct. The persuasiveness of agency interpretations is diminished when private litigants cause courts to interject their in-

49. Stewart & Sunstein, supra note 1, at 1307-16.
50. Id. at 1321.
interpretations of regulatory statutes. The more fluid the meaning of a regulatory standard, the less easily affected firms can live within its bounds.

The private cause of action substitutes for agency inaction or supplements weaker action. In so doing, private enforcement permits the courts to interpret regulatory statutes, wholly apart from the intentions of the regulatory managers to whom the statute delegated rule-making or adjudicative powers. The private action plaintiff invites the courts to eschew the delegation of “primary jurisdiction” to agencies and to resist norms of deference to agency interpretation.

Loss of administrative certainty, on the other hand, is attractive to those who oppose a status quo of accommodation between the regulator and the regulated firm. Critics who assert a “capture” theory in which agencies operate so as to accommodate their regulated constituents would almost certainly hail a decrease in agency certainty. Private causes of action can lead courts to reverse or modify “captured” agency policy. In this way litigants can break down a pattern of accommodation between an agency and regulated firms.

Although private causes of action may reduce complicity between regulated entities and captive agencies, the cost is too high.

51. Because of the relatively slow pace of civil litigation, an agency may construe a statute itself between the time the private action is filed and the time that an appellate court reaches a final decision. In the interim, the agency could seek deferential acceptance of its interpretation. The agency is not guaranteed such acceptance because of the different status of the private plaintiff and the private litigation’s separate goals. As a non-party, the agency presumably would have to intervene in order to articulate its position unless the court exercised its discretion to grant an amicus status.

52. In the case of inaction, the private enforcer theoretically will pursue the same result as the agency would, although such an assumption remains open to debate. In the case of weak agency action, supplementary private litigation may nudge the agency toward control of the errant private entity.

53. The delegation of power to interpret statutes to an administrative agency is a significant legislative decision. Recognizing private causes of action forces an agency to share that power with individual litigants and the courts.

54. In the first instance, primary jurisdiction recognizes the agency’s authority to determine questions of statutory construction within its realm of expertise. United States v. Western Pac. R.R., 352 U.S. 59 (1956).

55. The “capture” of a regulatory agency by its constituency is a recurring theme in the academic scholarship of administrative law. See, e.g., R. PIERCE, S. SHAPIRO, & P. VERKUL, supra note 1, § 1.7.2 (1985).
Conflicting administrative and judicial interpretations of regulatory statutes create too much uncertainty and confusion for those who must abide by the statutes. In particular, this interpretive uncertainty discourages the voluntary cooperation by regulated parties on which the effectiveness of the administrative system depends.

V. RIGHTS OF ACTION V. RIGHTS OF INITIATION

In their study, Professors Sunstein and Stewart note that courts that deny implied private rights of action nevertheless sometimes will grant rights of initiation. A right of initiation is a mandatory injunction compelling an agency to adopt rules or create a court-supervised timetable for actions.\(^{56}\) For example, plaintiffs have sought orders directing OSHA to regulate certain hazardous chemicals ahead of other items on the agency's list of rule-making projects.\(^{57}\) Other plaintiffs have sued to compel the Environmental Protection Agency to comply with provisions of the Toxic Substances Control Act\(^{58}\) and to demand that the FDA clear the marketplace of untested drugs within a certain period of time.\(^{59}\) These initiation actions have become more and more common; Public Citizen and other advocacy groups are often successful with initiation suits in the United States Court of Appeals for the District of Columbia Circuit. These groups have earned significant press attention by using initiation suits as political statements.\(^{60}\) The common elements in initiation suits are a policy disagreement between the advocacy group and the agency, a statutory directive, and a program which has been less rapid or less complete than the plaintiffs originally envisioned.

Initiation actions against agencies differ in some important respects from private suits against regulated entities. Initiation suits...
affect the government agency directly, while private actions only indirectly affect agency policy." An initiation suit may force an agency to put aside scheduled business to comply with court-ordered action, while it may take longer for the effects of a private suit to be felt by the agency. The private suit is not directed against an agency, but against an individual who has not followed agency directives. An initiation case, on the other hand, questions whether an agency has met its statutory duty. A successful initiation suit can deplete agency resources and wound the pride that agency managers have in control of agency policy.

Private initiation suits cost agencies more time and money than do private rights of action. A successful initiation plaintiff can compel an agency to reverse direction, alter its priorities, and undertake actions which the court finds more meritorious. In one rule-making case, for example, the court ordered submission of a list of other projects so that the agency could identify the opportunity costs of time spent on the court-ordered project instead of the agency's list of priority projects.

An initiation action also has more political impact than a private right of action. The latter results only in payment of money damages, while the former compels an agency to reshuffle its budget or enforcement schedules. The typical private enforcer wants only a cash award, while the private initiation plaintiff typically seeks a policy shift. By definition, the agency begins its defense of an initiation case with a wholly different political view than that of the challenger. A Public Citizen-type or other advocacy group is likely to have its own view of the priorities an agency should have. The initiation suit is a natural outlet for conflicts between advocacy groups and government agencies resulting from this divergence of

---

61. Private actions sometimes impact the government indirectly. For example, an action determining that the FDA and regulated drug firms had not considered adequately the safety of certain vaccines would result in a damage award, but also would affect the FDA's ability to encourage beneficial development of a regulated vaccine market.


63. Id.

64. Initiation cases may affect the appropriations process, refocus attention on the weaknesses of an ambiguous statute, or be a basis for statutory revision by Congress. None of these consequences would necessarily flow from a private damages remedy.
views. This ideological controversy is generally absent in the private tort cases enforcing regulatory statutes.

Initiation cases suffered a setback in 1984. In *Heckler v. Channey*, the Supreme Court addressed the problem of how the FDA could control the non-approved uses of FDA-approved drug products. Plaintiffs sought and obtained relief in the circuit court compelling the FDA to initiate certain drug enforcement actions. The Supreme Court reversed, however, stating a "general presumption of unreviewability of [agency] decisions not to enforce." The language in *Chaney* put strong limits on court-ordered enforcement demands in initiation cases, at least those affecting the FDA. Recognizing that the agency's decision whether to institute enforcement proceedings was "a decision which has long been regarded as the special province of the Executive Branch," the Court blocked the plaintiff's attempt to force initiation of administrative civil enforcement litigation.

In *Chaney*, the FDA confronted an unusual use of normally safe drugs: execution of condemned convicts by lethal injection. The statutory scheme of the Food, Drug, and Cosmetic Act allowed the agency to challenge the use of otherwise acceptable drugs if the execution-size doses were unapproved under the statutory criteria for "safe and effective" uses of drug products. The FDA, however, opted not to bring enforcement actions against states which used prescription drugs for lethal injections. In the United States Court of Appeals for the District of Columbia Circuit, death row inmates won an order which would have compelled the FDA to take enforcement action, halting execution by lethal injection. The Supreme Court, however, rejected the claim that private individuals can compel the FDA to enforce an informal policy by man-

---

66. *Id.* at 1657. Other agencies recently have won similar arguments. See, e.g., Investment Co. Inst. v. Federal Deposit Ins. Corp., 728 F.2d 518 (D.C. Cir. 1984). In its most recent pronouncement on private rights of action, the Court's rejection of implied rights would support a parallel rejection of the implied rights of initiation plaintiffs. Merrell Dow Pharmaceuticals Inc. v. Thompson, 106 S. Ct. 3229, 3234 (1986).
68. *Id.* at 1652.
dating specific enforcement actions.\textsuperscript{70} The \textit{Chaney} opinion thus cut back on private rights of initiation, limiting the class of cases in which individuals can force an agency to regulate.\textsuperscript{71}

The regulated community must respond to this increasing exposure to private enforcement of regulatory statutes. One possible response could be to challenge the standing of private plaintiffs more frequently\textsuperscript{72} and therefore expand judicial controls on privately-enforced actions. Another response would be to work toward statutory changes by building understanding among businesses and other target groups about the consequential damage done to their interests by a proliferation of statutory rights of action.

The business community should devote legislative efforts to revising the several statutes from the 1970's which have provided for private enforcement. Regulated businesses have overlooked their individual cost of defending private enforcement actions, as well as the cost to businesses generally of the attendant loss of regulatory predictability.\textsuperscript{73}

An understanding of how these new civil actions impact on insurance and tort exposure is also important. Most injury cases can be resolved with traditional common law remedies for negligence and nuisance. Statutorily created torts and remedies, however, place an added burden on insurers and manufacturers because these potential defendants must now plan for the wider range of recovery available to the enterprising challenger. Affected businesses should seek a congressionally imposed standing requirement that would limit the capacity of private plaintiffs to bring suit.

\begin{footnotes}
\item[70] \textit{Chaney}, 105 S. Ct. at 1659. The Court stated, “[W]e essentially leave to Congress, and not to the courts, the decision as to whether an agency's refusal to institute proceedings should be judicially reviewable.” \textit{Id}.

\item[71] The Court stated that “[t]he general exception to reviewability provided by [the Administrative Procedure Act] remains a narrow one, . . . but within that exception are included agency refusals to institute investigative or enforcement proceedings, unless Congress has indicated otherwise.” \textit{Id}.

\item[72] The question of “standing” concerns a particular plaintiff's right to assert a public right as the basis of a civil suit. \textit{See, e.g.}, Association of Data Processing Serv. Orgs., Inc. v. Camp, 397 U.S. 150 (1970).

\item[73] With the exception of the 1980 Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. §§ 9601-9657 (1980), Congress has paid relatively little attention to private causes of action during debates over the adoption of regulatory legislation.
\end{footnotes}
VI. Case Studies

A. Consumer Product Safety Act

Recent Consumer Product Safety Act cases illustrate the problems created by the casual inclusion of citizen suit provisions in safety legislation. The 1972 CPSA requires that manufacturers notify the Consumer Product Safety Commission when the manufacturers discover information concerning substantial product hazards. The government then decides whether to initiate a product remedy, such as a recall.

In practice, the reporting requirements of section 15(b) of the CPSA have worked well, entailing informal notification and informal agreements to voluntarily repair or recall. The Consumer Product Safety Commission has had to challenge a firm for failure to report in only a handful of cases. In those cases, however, the parties usually reached settlements for reduced penalties with little difficulty. More recently, however, private plaintiffs have used section 15(b) to obtain pendent jurisdiction. Although manufacturers have won a few cases, most federal courts have granted jurisdiction, and found significant damage liability as well, on the rationale that a consumer has a right to enjoy the benefit of the manufacturer's notification to the Commission and a cause of ac-
tion to enforce that right as well. The theory is that had the manufacturer reported the defect, the government's remedial action would have prevented the injury. Under this reasoning, the consumer is the principal and the Commission the agent for purposes of consumer protection.80

Such suits have both positive and negative implications. On one hand, when a consumer plaintiff brings a section 15(b) action, the Consumer Product Safety Commission expends none of its own resources for enforcement, the consumer obtains a second opportunity for damages, and the non-reporting penalty's deterrence power expands. On the other hand, however, a single failure by a manufacturer to report can result in multiple private tort actions.81 In addition, state rather than federal law governs both punitive damage awards and statute of limitations issues.82

B. Food, Drug, and Cosmetic Act

A more potent regulatory system, the Food, Drug, and Cosmetic Act, has been the subject of repeated attempts at private enforcement in recent years. No private right of action has been established.83 If one were created, however, thousands of new federal district court cases would result. The FDA's sweeping jurisdiction touches thousands of tort and contract actions now fought under common law tort principles. A small claims action over a sale of

---

stale popcorn—an “adulterated food” subject to seizure—might be litigated in federal district court. The prospect of defending tort, sales, financing, and contract claims that assert noncompliance with FDA standards would threaten hundreds of food packaging and processing firms' ability to reasonably comply with regulatory standards. A circuit court finding for a plaintiff would create an interpretation of the FDA binding on regulated entities even though the FDA itself had taken no action and had shown no interest in accepting the offer of private “help” in enforcing its statute.

C. Federal Trade Commission Act

The Federal Trade Commission Act is another statute which would be altered radically by allowing implied private rights of action. Antitrust actions under the federal antitrust laws often supplement the Federal Trade Commission’s antitrust mission. If, however, the FTC’s regulation of “unfairness” of advertising becomes the subject of private civil suits, for example, the avalanche of case law, as Acting FTC Chairman Calvani recently suggested,

86. The Supreme Court has denied federal jurisdiction for a product liability action based on violations of FDA requirements. See Merrell Dow Pharmaceutical Inc. v. Thompson, 106 S. Ct. 3229, 3244-45 (1986). The FDA has not been receptive to the creation of a private right of action. The agency fears challenges to its priorities similar to the challenge attempted in Heckler v. Chaney, 470 U.S. 821 (1985). Critics have noted that the FDA may settle for too little activity, and some critics have recommended more private rights. See, e.g., Note, The Food and Drug Administration’s Power to Recall A Harmful Product and Other Remedial Actions: The Powerless Consumer, 10 Vt. L. Rev. 129 (1985). In the FDA’s defense, one may argue that multiple private actions with contradictory proposed solutions would impair uniform enforcement of FDA regulations nationwide.
89. A recent news report quoted Calvani as encouraging private litigation over allegedly deceptive advertising claims. “If Pepsi-Cola believes Coca-Cola is running an unfair ad,
would increase geometrically employment among Washington lawyers. When Congress narrowly defeated a bill to create a new Consumer Protection Agency, its choice not to adopt an institutional "master enforcer" of private rights through interventions in the administrative process had far-reaching effects. Although private antitrust actions occur frequently, Congress has been reluctant to authorize the expansion of private causes of action into the purely economic policing role of "supporting" governmental economic regulation. As a result, regulated plaintiffs with economic disputes are limited to "initiation" actions or to special unfair competition remedies such as the Lanham Act. Congress apparently has been more willing to permit private suits in environmental and safety legislation because it perceives these statutory actions as entirely new remedies for traditional nuisance, personal injury, or negligence wrongs, rather than alternate forms of economic regulation.

VII. NEW WAVE

The newest wave of private causes of action might be called "hybrid section 1983 actions." These civil rights actions against state or local government officials, which arise under the "laws" of the federal regulatory scheme, include challenges to a state's failure to properly implement regulatory or beneficiary statutes. Plaintiffs

Pepsi is fully capable of bringing its own case." See Quote of the Week, FTC Watch No. 226, Jan. 24, 1986, at 16, col. 2.

90. The Consumer Protection Agency legislation ultimately failed in the House by a vote of 227-189. See H.R. 6805, 95th Cong., 2d Sess. (1978). The role of the proposed Consumer Protection Agency would have been to intervene in regulatory agency proceedings to effectuate consumer interests. The bills had been alive, but extremely controversial, since the first passage of such a bill in 1970. The chronology of defeat of the measure during 1970-78 is detailed in 5 CONGRESSIONAL QUARTERLY INC., CONGRESS AND THE NATION 255-56 (1981).

91. Antitrust litigation serves purposes which can be quantified and measured by standard commercial and statistical indicators. The questions of safety involved in "defectiveness" include cost-benefit choices and other complex issues better suited to expert analysis by agencies.


93. The Civil Rights Act of 1866, 42 U.S.C. § 1983 (1982), has generated a great deal of civil rights enforcement litigation asserting that injury to the civil rights of the plaintiff occurred under color of state action.

94. Stewart & Sunstein, supra note 1.
have claimed federal statutory bases for section 1983-style actions as they challenge unenforced seat belt laws, disregarded environmental requirements, and improperly administered welfare benefits. The cause of action is a hybrid of an individual civil rights remedy and state enforcement of a federal protective measure. The private right of action is not against the federal agencies themselves but against the state implementers.

The Occupational Safety and Health Act of 1970, for example, delegates enforcement of certain safety requirements to the states. Certain states adopt federal requirements for chemical labeling and documentation pursuant to the OSHA Hazard Communication standard. Civil plaintiffs who oppose federal regulatory restraints get another bite at the apple with these quasi-section 1983 challenges to these state-adopted standards. If the states are slow to enforce the OSHA hazard communication rule, plaintiffs can employ these derivative section 1983 suits as private causes of action. Workers or their unions who object to a federal OSHA policy decision can act against both state government and employer defendants by pursuing these actions. A successful lawsuit might induce the court to construe the state-adopted OSHA final standard to suit the purposes of the private plaintiff. Such an outcome would raise interesting issues of federalism and precedential effect, which would require the attention of the Supreme Court.

95. A section 1983-style action challenges a state agency and a private party for violating the plaintiff's rights under the "constitution or laws of the United States," 42 U.S.C. § 1983. In this context, emphasis is on the violation of "laws," particularly regulatory statutes.


In his dissent in *Maine v. Thiboutot*, Justice Powell listed the many federal regulatory and beneficiary statutes that permit private rights of action for inadequate local or state government performance, including the urban mass transit program, small business investment legislation, historic building preservation, and outer continental shelf legislation. Using section 1983 causes of action to compel enforcement of these statutes, private litigants could force a state administering a federal program to be the vehicle for changing the nationwide program. A civil injunction compelling one state to operate the program as the private litigant demands would be a difficult precedent for other states to ignore. Such an order would take on a hybrid nature, not unlike initiation cases, to the extent that the remedial order might compel the federal program to adapt to the state case precedent. This poses fascinating supremacy clause and preemption issues which go well beyond traditional uses of section 1983 for welfare and food stamp denial cases.

**VIII. Three New Examples**

Three examples of private rights of action recently have caused controversy; each offers intriguing insights into the federal litigation of the future. For example, Congress enacted the Comprehensive Environmental Release, Compensation, and Liability Act of 1980 (Superfund) in an atmosphere of uncertainty and great controversy. During the final stages of debate, Congress eliminated a private right of action which would have allowed residents around a hazardous waste site to enforce a right to have the area

---

100. *Id.* at 34 (Powell, J., dissenting).
101. *See id.* at 32-34.
102. The indirect compulsion would come as potential state government defendants press the federal agency to modify its requirement in order to eliminate the newly “discovered” theory of liability. The exposure to liability should be removed through rule-making changes, which both allow interested parties to participate and provide for public notice, 5 U.S.C. § 553 (1982), than by relitigating that same liability in subsequent product liability cases.
103. Traditional § 1983 litigation has not involved worker occupational rights issues or other broad-reaching regulatory commands.
In a conscious decision made in light of various uncertainties, Congress decided that the EPA should lead a single federal enforcement effort.

The 1986 version of Superfund, by contrast, created private rights of action against governments, entities, or persons in violation of the act. Congress included the right in direct response to arguments that the government had not been sufficiently aggressive in normal enforcement channels. Whether and to what extent a government challenge to a waste site will preclude private persons from challenging the same site or company remains unclear at this point. At a minimum, however, the priorities for cleaning up sites must change as more rapid and aggressive private litigants take part in the development of judicial precedent under Superfund. The private rights which Congress rejected in 1980 and then accepted in 1986 will be extremely unpredictable as they play out in the courts.

The same Superfund legislation permits initiation suits, in which plaintiffs could charge the EPA with inaction if it fails to perform a non-discretionary act. The barrier to initiation suits is higher than the barrier to individual suits asserting private rights, yet the private suits frequently seek more profound changes in the EPA's interpretive boundaries. Private suits against regulated entities often seek to ultimately restrict the agency's freedom of action or

---

105. Superfund proponents acceded reluctantly to the removal of the private cause of action as the bill passed during the last days of the 97th Congress. Anderson, Negotiation and Informal Agency Action: The Case of Superfund, 1985 DUKE L.J. 261, 270 n.21 (history of Superfund legislation).


107. Proponents of the insertion argued for a private supplement to governmental enforcement priorities. See Anderson, supra note 105, at 270 n.21.


109. Under the 1986 legislative revisions to Superfund, litigation will be less predictable because of the many changes in the program.


111. See id. This proposition assumes that the private litigant has been unable to get the government agency to deal directly with the enforcement issue, often because of a disagreement about the scope or interpretation of the agency's authority.
prioritization. Although an initiation suit against the agency itself might reach the same goal, private actions can do the same job.\textsuperscript{112}

The Justice Department faces increased problems in opposing private parallel enforcement actions in this time of fiscal constraint. The Land and Natural Resources Division, for example, which prosecutes Superfund cases, and the Civil Division's Consumer Affairs Section, which prosecutes safety and auto cases, might have 4.3 percent fewer attorneys after the Gramm-Rudman budget legislation goes into effect.\textsuperscript{113}

Superfund's new private rights will be a poor substitute for a national enforcement system administered by federal regulators. Federal legal managers, such as EPA enforcement directors, ultimately may enforce statutes themselves less often than watch from the sidelines as private plaintiffs bring tort and other actions under statutory enforcement powers. If the Justice Department cuts back on the participation of government counsel in civil actions affecting agency programs, removing the government as a "silent partner" in the plaintiff's action, then regulatory precedents will be shaped by default. More significantly, those precedents are likely to bear little relation to established agency policy; private plaintiffs, after all, cannot be expected to promote the government's priorities for toxic waste disposal.\textsuperscript{114}

The OSHA hazard communication standard on chemical labeling illustrates a second, indirect impact of private causes of action. This standard became final in 1983 and first was enforced in 1986.\textsuperscript{115} The Occupational Safety and Health Act did not include an express right of action for workers or other private plaintiffs, and courts have refused to imply a direct private cause of action.

\textsuperscript{112} If we assume that sovereign immunity will not bar direct actions against the agency because the government will not be a party, the plaintiff has an easier burden of enforcing private rights than in an initiation suit. The initiation suit's relatively greater burden of establishing a mandatory duty under the statute, and then enforcing that duty with standing and other jurisdictional prerequisites, will pose significant barriers for the plaintiff.


\textsuperscript{114} Superfund operates from a National Priority List. Private plaintiffs could sue to clean up a lower-ranked waste site without regard for the greater risks posed by other sites higher on the EPA's list. The EPA has tried to accommodate conflicting demands for scarce resources. See, e.g., EPA Allows Otherwise Unqualified Sites on Priority List If They Pose Health Threat, 9 Chem. Reg. Rep. (BNA) 640 (Sept. 20, 1985).

Nonetheless, private litigants often have used the reports and findings of OSHA as weapons in tort liability cases. In the twenty-one states that enforce the act's requirements under "state plan" jurisdiction, private plaintiffs could assert that individual workers or unions have a section 1983 right to enforce protections against injury which could be regulated under the act by the designated state agencies. The hazard communication rule-making program is significant because each affected firm determines which of its chemicals is "hazardous." Consequently, each regulated firm—and potential defendant—makes its own decisions about the chemical safety labeling and data sheets for the firm's products. If a potential litigant alleging injury from chemical exposure disagrees with the OSHA policy decision about a performance standard, the litigant might use a section 1983-type action in a state which has enforcement authority. Alternatively, the plaintiff could urge the court to imply a civil right of action from the Act.

In a novel third type of action, the maker of a chemical pesticide sued the agency which regulated its product for factual flaws in the agency's risk assessment. Great Lakes Chemical Corporation had been named as a defendant in a private action alleging that its EPA-registered pesticide had damaged the plaintiff. Great Lakes challenged the EPA risk assessment upon which the private litigant sued arguing that the EPA's faulty risk finding, which gave rise to the plaintiff's theory of injury, was based on a poorly done EPA study. This flurry of cross-complaints and challenges asserting regulatory "malpractice" should serve as a warning to pesticide manufacturers, and, by analogy, to regulated manufacturers in general. The uncertainty inherent in such expanding theories of liability almost certainly will make investors reluctant to invest in firms subject to private suits. In addition, litigation frequency, ex-

118. Implying a private right to enforce the Occupational Safety and Health Act is a formidable task because of the contradictory legislative history arising out of the debates on passage of the Act in 1970. See Donovan v. Occupational Safety & Health Review Comm'n, 713 F.2d 918, 926 (2d Cir. 1983).
pense, and loss rates are all factors that determine business liability insurance costs. Civil actions to enforce rights such as those arising under the pesticide law may be a major source of insurance premium increases for American industry.

IX. Future Role of Counsel

Lawyers working in the administrative law field should become more attuned to the consequences of private causes of action. The private or corporate attorney's role as counsel to agencies and to companies is to assess how product liability, telecommunications, advertising, or other conflicts are best handled in light of the investment which rides on the decisions to be made. If private rights of action continue to appear more frequently, counsel must obviously provide advice about such private rights of action so that their clients will be able to better anticipate the uncertainties such rights can create.

The first step in serving the client is to understand the terms of the relevant statute. The attorney must determine whether the statute provides initiation rights or private rights; that is, whether the statute creates powers to force government to act, or powers to enforce the statute with a private civil complaint.120 Second, counsel must examine the case law surrounding the statute to learn whether private rights of action have been implied judicially. Courts have implied private rights for a wide variety of statutes.121 The broad extent to which some courts have been willing to imply private rights of action may surprise the private sector counsel accustomed to dealing with one decision point at one agency, but that surprise perhaps illustrates the particular importance of this step in the counsel's task. The third step is to outline for the client

120. The statute usually includes a separate paragraph or subsection creating such a private right of action, see, e.g., 15 U.S.C. § 2073 (1982), or implies such a power in reasonable terms relating to civil enforcement actions.

the conditions that might precipitate a private suit. The attorney should assess the prospects that a third party will sue the client for the conduct which a government agency has found acceptable. As recent private action cases demonstrate, agency acceptance does not necessarily estop private plaintiffs, who may be expected to create novel causes of action as the stakes of the litigated question become greater.

X. Conclusion

Statutes empowering private plaintiffs to bring civil actions to enforce federal requirements for product safety and environmental health are not prudent, even in light of diminishing federal enforcement budgets. The availability of such actions is likely to flood the courts with private suits. The marginal benefit of more frequent policing of violators will be offset by the high cost of less predictable regulatory outcomes—predictability that is essential to a stable regulatory system.

Private sector opposition to the private cause of action has been slow to develop. Regulated firms should do more to challenge the rationale for judicially implied rights of action. These firms also should direct more creative arguments toward seeking legislative limitations of those statutes which now expressly grant private causes of action when the statutes come up for reauthorization. Finally, firms should encourage judicial limitations by seeking to dismiss private enforcers' challenges for lack of standing.

Ultimately, we must ask what “problem” we “fix” when we allow uncontrolled private enforcement of regulatory standards. If the problem is regulatory inactivity, the legislative branch should correct the agency's internal or external enforcement problems or increase its enforcement budget. Society should not expect ad hoc litigants to do the work of regulatory agencies without carefully considering the consequences of such privately directed precedents.


123. Reauthorization offers the best legislative forum for presenting Congress with a rationale against private rights of action.
and private reinterpretation of agency priorities on national regulatory policy. As tight budget years narrow the agencies' power to police their domain, private litigation offers a facially attractive alternative means to enforce agency policies. The risks, however, of inconsistent results, curious lines of case authority suited to private rather than public goals, and variable objectives should be significant drawbacks. Regulatory uncertainty will adversely affect society. From the point of view of the apple—the regulated person—just one bite of regulatory sanctions is enough.