THE THIRD ANNUAL DISTINGUISHED LECTURE ON ADMINISTRATIVE LAW AND REGULATORY PRACTICE

THE NEED FOR OVERSIGHT OF AGENCY POLICIES FOR SETTLING ENFORCEMENT ACTIONS

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INTRODUCTION

The vast majority of enforcement actions by federal agencies against public companies and other major institutions in our society end in settlements, not in contested proceedings. Enforcement officials develop policies of general applicability and standard forms of agreement for shaping such settlements. Although there is some tailoring of agreements

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to the facts and circumstances of individual cases, enforcement officials generally demand—and obtain—settlement agreements that contain certain types of provisions dictated in advance by their enforcement policies and forms of agreement.

Such provisions can be quite onerous; for example, they can require payment of hundreds of millions of dollars and significant changes in organizational operations. Yet, enforcement officials adopt their settlement policies and forms of agreement without notice-and-comment rulemaking, or any other opportunity for public participation in their formulation. The officials implement these policies in case-by-case agreements without judicial review. Some kind of effective and independent review is needed. That review should be provided by administrative oversight, and, better yet, by congressional oversight.

Enforcement policies are exempt from the Administrative Procedure Act's requirement of notice and comment.[1] In my experience, it is not the general practice of agencies voluntarily to subject their enforcement policies or forms of agreement for settling enforcement actions to any formal (or even informal) public process for scrutiny and comment. Except in rare circumstances, such as the outpouring of opposition to the demands by the Department of Justice (DOJ) for waivers of the corporate attorney-client privilege as part of settlements of criminal investigations, private parties not actually involved in an investigation or other enforcement proceeding generally do not comment on such policies and forms of agreements.

Although under presidential executive orders, some administrative review of major actions by executive branch agencies occurs, as far as I am aware, such review has not extended to general enforcement policies or the terms of settlement agreements. Generally, within regulatory agencies, senior enforcement officials and lawyers, not the most senior officials with agency-wide responsibilities beyond enforcement, perform the internal review of enforcement matters—including review of general policies and forms of agreement and settlement terms in individual cases.

This paper will focus on three types of agreements that federal agencies use to settle potential enforcement actions against public companies and other types of institutions. The first consists of non-prosecution and deferred-prosecution agreements entered into by the U.S. Attorneys' Offices, the Criminal Division in the DOJ, and occasionally other Divisions in the DOJ. The second includes agreements for consent decrees entered into by the Food and Drug Administration (FDA). The third includes

1. 5 U.S.C. § 553(b)(A) (2000).

corporate integrity and institutional compliance agreements entered into by the Office of Inspector General in the Department of Health and Human Services (OIG).

Many other federal agencies with enforcement authority close investigations with settlement agreements. The issues raised by the examples discussed here may be similar to those raised by the settlement policies of other agencies as well.

I. DOJ NON-PROSECUTION AND DEFERRED PROSECUTION AGREEMENTS

The DOJ's Principles of Federal Prosecution provide that a non-prosecution agreement is essentially a grant to a party of immunity from prosecution in return for the party's cooperation in furthering the prosecution of some other party or parties.[2] The cooperation an organization can provide may include, in addition to production of documents, information learned in an internal investigation protected by the organization's attorney-client privilege, and information about possible crimes unknown to the government, and by placing pressure on the organization's employees to cooperate with prosecutors. Receiving the results of such internal investigations is particularly valuable to prosecutors because it effectively expands their investigative resources.

One example of a non-prosecution agreement with a business organization is a settlement in June 2006 that resolved an investigation by the Office of the U.S. Attorney for the Southern District of New York of an Austrian bank known as "BAWAG P.S.K."[3] The bank agreed to forfeit to the United States $337.5 million to be used to compensate claimants in the Refco matter.[4] The DOJ press release stated that BAWAG and its parent company would pay "at least $675 million in connection with the non-prosecution agreement and to settle . . . [certain] claims against them."[5]

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2. *See* U.S. DEP'T OF JUSTICE, U.S. ATTORNEYS' MANUAL, PRINCIPLES OF FEDERAL PROSECUTION § 9-27.600 (2007), *available at* http://www.usdoj.gov/usao/eousa/foia_reading_room/usam/title9/27mcrm.htm#9-27.600.

3. *See* Press Release, Office of the U.S. Attorney for the Southern District of New York, Austrian Bank "BAWAG" To Pay $337.5 Million For Restitution to Victims of Refco Fraud (June 5, 2006), *available at* http://www.usdoj.gov/usao/nys/pressreleases/June06/bagwagnon-prosecutionagreementpr.pdf [hereinafter BAWAG Press Release] (noting the government's use of a non-prosecution agreement in settling the case).

4. For a summary of the Refco matter, see Emily Thornton, *Commentary: Refco: The Reckoning*, BUS. WK, Nov. 7, 2005, *available at* http://www.businessweek.com/magazine/content/05_45/b3958095.htm. *See also Ex-Owner at Refco Charged in Fraud Case*, N.Y. TIMES, Jan. 17, 2007, *available at* http://query.nytimes.com/gst/fullpage.html?res=9F0DE2D61030F934A25752C0A9619C8B63.

5. BAWAG Press Release, *supra* note 3, at 1.

The bank and its parent had provided "full cooperation with [the government's] investigation" and they agreed "to continue that cooperation in the future."[6]

A deferred prosecution is one in which, pursuant to a written agreement, the government files criminal charges but, with the approval of the court, agrees to defer proceedings on the charges for a specified period (commonly twelve, eighteen, twenty-four, or thirty-six months). During the deferral period, a defendant is to fulfill certain commitments stated in the agreement. If, at the end of the deferral period, the defendant has fulfilled all of those commitments, the charges are dismissed.

Deferred prosecution agreements began as a means of avoiding prosecution of individuals by deferring the filing or processing of criminal charges so as to give the individuals an opportunity to show that they had reformed. Such arrangements commonly included social services to promote reform and sometimes included restitution by the defendant to victims. In the mid-1990s, and much more frequently during the last several years, the DOJ has extended the technique, with modifications, to public companies and other institutions.

A deferred prosecution agreement commonly includes provisions in which an organization:

- accepts and acknowledges its responsibility for the conduct described in an appended statement of facts, which the organization agrees not to contradict in any public statement (the statement of facts amounts to an admission of all the elements of the crimes alleged in the complaint or information [filed in court with the deferred prosecution agreement]);
- agrees to cooperate fully in the ongoing investigation(s) relating to its conduct, including waiver of the organization's attorney-client privilege and work product protection;[7]
- agrees not to commit further violations during the deferral period;
- agrees to provide specified compensation to victims and/or to pay to the government a specified amount as a penalty;

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6. *Id.* at 3.

7. It remains to be seen whether, and to what extent, the DOJ policy of obtaining waivers of the organizational attorney-client privilege in deferred prosecution agreements will change as a result of the Memorandum issued by Deputy Attorney General Paul J. McNulty on December 12, 2006, to replace the Thompson Memorandum. *See* Memorandum from Paul J. McNulty, Deputy Attorney General, Dep't of Justice, to Heads of Department Components and U.S. Attorneys (Dec. 12, 2006), *available at* http://www.usdoj.gov/dag/speeches/2006/mcnulty_memo.pdf [hereinafter McNulty Memorandum]; Memorandum from Larry D. Thompson, Deputy Attorney General, Dep't of Justice, to Heads of Department Components and U.S. Attorneys (Jan. 20, 2003), *available at* http://www.usdoj.gov/dag/cftf/business_organizations.pdf) [hereinafter Thompson Memorandum].

> • agrees to implement specified remedial actions (in addition to those already implemented) to prevent future violations, including measures affecting organizational governance and compliance with applicable laws, and engagement of an independent examiner or monitor with wide-ranging authority to assess compliance with the agreement and applicable laws and to issue reports thereon to enforcement agencies; and
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> • agrees that, if the government initially determines that the organization has committed a willful material breach of the agreement, the government will notify the organization in writing of that determination, the organization will have two weeks to show that no such breach occurred, and the government's final determination as to breach shall not be reviewable by any court.[8]

An example of a deferred prosecution agreement is one in 2005 that resolved a criminal investigation of Bristol-Myers Squibb Company (BMS) by the Office of the U.S. Attorney for the District of New Jersey.[9] BMS agreed to be charged with securities fraud and to pay $300 million to compensate shareholders (beyond the $539 million it had already paid or committed to pay shareholders).[10] In a settlement with the Securities Exchange Commission (SEC), BMS had also previously agreed to pay a civil penalty of $100 million and $50 million to a shareholder fund.[11]

Under the BMS agreement, prosecution was deferred for twenty-four months.[12] The agreement described extensive remedial actions the company had already taken.[13] BMS further agreed, among other things, "to continue to cooperate fully" with the U.S. Attorney's Office and other governmental agencies conducting investigations, and to waive its attorney-client privilege and work-product protection as to requests by governmental investigators for information.[14] The company also agreed to significant organizational changes, including creating a non-executive chairman of its board of directors, adding a new independent director,

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8. The foregoing list is excerpted from Richard M. Cooper, *Deferred Prosecution: An Added Technique for Resolving Federal Criminal Investigations of Organizations*, BRIEFLY. . .PERSPECTIVES ON LEGISLATION, REGULATION, AND LITIGATION, Aug. 2006, at 11-12, which includes general discussions of non-prosecution and deferred prosecution agreements.

9. *See* Press Release, Office of the U.S. Attorney for the District of New Jersey, Bristol-Myers Squibb Charged with Conspiring to Commit Securities Fraud; Prosecution Deferred for Two Years (June 15, 2005), *available at* http://www.usdoj.gov/usao/nj/press/files/bms0615_r.htm [hereinafter Bristol-Myers Press Release]. For a copy of the Deferred Prosecution Agreement, see Deferred Prosecution Agreement between Christopher J. Christie, U.S. Attorney for the District of New Jersey, and Bristol-Myers Squibb Company (June 15, 2005), *available at* http://www.usdoj.gov/usao/nj/press/files/pdffiles/deferredpros.pdf [hereinafter BMS Agreement].

10. Bristol-Myers Press Release, *supra* note 9.

11. BMS Agreement, *supra* note 9, at 1-2, ¶ 5(b).

12. *Id.* at 1, ¶ 4.

13. *Id.* at 1-3, ¶ 5.

14. *Id.* at 8-9, ¶¶ 31, 32.

adding mandatory training programs for employees to foster compliance, and hiring an independent monitor to report to the government on its compliance with the agreement.[15] The agreement also included provisions as to internal meetings and reports involving the non-executive chairman of the board and provisions as to financial disclosures.[16]

As part of the price for avoiding prosecution, the company also agreed to endow a chair at Seton Hall University Law School, which happened to be the alma mater of the U.S. Attorney.[17] BMS further agreed that "the determination whether BMS has breached this [a]greement rests solely in the discretion of the [U.S. Attorney's] Office, and the exercise of discretion by the Office under this paragraph is not subject to review in any court or tribunal outside the Department of Justice."[18]

II. FDA CONSENT DECREES

The Federal Food, Drug, and Cosmetic Act (FDCA) provides for a range of enforcement actions, including an injunction in federal district court.[19] A consent decree is an injunction to which the defendant consents. The FDA has no written statement of general policy for its consent decrees. Typically, it seeks an injunction or consent decree when multiple inspections of a manufacturing facility or other interactions between the agency and a regulated company show, in the agency's view, continuing or seriously inadequate compliance with regulatory requirements. Common provisions of an FDA consent decree include:

- cessation of some or all shipments from the facility until an independent outside expert certifies, and an FDA inspection confirms, that the facility has achieved compliance with regulatory requirements;
- permission for the company to continue to ship "medically necessary" products, subject to payments to the government of amounts of money intended to deprive the company of any profit from the sale of such products until compliance is achieved;
- periodic reports by the outside expert to the company and to FDA on progress at the facility toward achievement of compliance;

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15. *Id.* at 1-2 ¶ 5(a), (d), (f), 3-4, ¶¶ 8-13, 5-6, ¶¶ 18-19.
16. *Id.* at 4, ¶ 13, 7, ¶ 25.
17. *Id.* at 6, ¶ 20; *see Big Pharma Gets Its Hooks Into Seton Hall Law School*, 21 CORP. CRIME RPTR. 19 (May 7, 2007), *available at* http://www.corporatecrimereporter.com/setonhall050107.htm.
18. BMS Agreement, *supra* note 9, at 10, ¶ 37.
19. The provision for injunctions is 21 U.S.C. § 332 (2000). *See also id.* § 333 (penalties), § 334 (seizure), § 335a (debarment, temporary denial of approval, and suspension), § 335b (civil penalties), and § 335c (withdrawal of approval of abbreviated drug applications).

- payment to the government of a specified amount of money per day as "liquidated damages" if specified milestones for corrective actions are not achieved or other violations of the decree, the FDCA, or regulations under the FDCA occur during the life of the decree;
- a grant to FDA of authority, not otherwise provided by the FDCA, to order the company to take certain types of action if FDA determines that the company has not complied with the decree; and
- limitations on the record the company may present to the court for review of actions by FDA under the decree, and specification of a lenient standard of review (the "arbitrary and capricious" standard of 5 U.S.C. § 706(2)(A)).

A representative example of an FDA consent decree is one entered against Schering-Plough Corporation (Schering) in 2002.[20] Among numerous other provisions, that decree bars Schering from shipping human and veterinary drugs from each of four facilities until certain requirements are met; the requirements differ among the facilities.[21] The decree identifies certain products as medically necessary and permits their continued shipment.[22] It provides for Schering to pay the United States $500 million in equitable disgorgement.[23] The decree further provides that, if FDA determines that Schering has failed to comply with certain provisions of the decree and is still distributing drugs from the affected facilities, FDA has "the sole and unreviewable discretion" to order Schering to pay, from the proceeds of the sales of such products, $15,000 per day for each business day of continuing noncompliance with any of multiple obligations, up to a maximum of $175 million.[24] In certain circumstances, the payments of $15,000 per day stop, and FDA can order Schering to pay the United States a percentage of the net sales of certain drugs.[25]

A more recent FDA consent decree involving GlaxoSmithKline, Inc. (through its U.S. subsidiaries) utilizes similar non-compliance penalties. In addition, it provides for payments of $10,000 per day for each day of noncompliance, up to a maximum of $10 million, as "liquidated damages."[26]

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20. Consent Decree of Permanent Injunction, United States v. Schering-Plough Corp., No. C-02-2397 (JAP) (D.N.J. May 20, 2002).
21. *Id.* at 2-6, ¶ 4.
22. *Id.* at 15-17, ¶ 7.
23. *Id.* at 23, ¶ 15.
24. *Id.* at 24-25, ¶ 16.
25. *Id.* at 26-28, ¶ 17.
26. Consent Decree of Condemnation and Permanent Injunction at 17, ¶ 32, United States v. Undetermined quantities . . . PAXIL CR™ PAROXETINE HCl CONTROLLED-RELEASE TABLETS, No. 5:05-CV-141-FL(1) (E.D.N.C. May 5, 2005).

III. HHS OIG INSTITUTIONAL COMPLIANCE AND CORPORATE INTEGRITY AGREEMENTS

The Office of Inspector General (OIG) in the Department of Health and Human Services (HHS) has authority to seek permissive exclusion of health care providers from Medicare, Medicaid, and other federally funded healthcare programs. The principal basis for such exclusion is a determination by HHS that, in connection with a federal healthcare program, a provider has culpably submitted a false claim or has otherwise committed fraud, and thereby has violated the anti-kickback law,[27] or has committed some other prohibited act.[28] It is not necessary for a court to make an original determination. As an alternative to exclusion, the OIG may agree with a provider to enter into a Corporate Integrity Agreement (CIA) or an Institutional Compliance Agreement (ICA).

OIG summarizes the common provisions of its comprehensive CIAs as including requirements that the provider:

- Hire a compliance officer or appoint a compliance committee;
- Develop written standards and policies [to prevent further violations];
- Implement a comprehensive employee training program;
- Review claims submitted to federal health care programs;
- Establish a confidential disclosure program;
- Restrict employment of ineligible persons; and
- Submit a variety of reports to the OIG.[29]

Provisions for monetary penalties—payments of specified amounts of money per day for violations—are also common in CIAs. For certain types of "material breach," exclusion from federal healthcare programs is a possible remedy. Thus, even if the daily penalties do not accumulate to a large amount, exclusion could be a very drastic sanction. Under another common provision, OIG decisions under the agreement, including decisions on penalties and on exclusion from federal healthcare programs due to a violation of the CIA, are reviewable within HHS, but not by the courts.

An example of a CIA is one entered into in 2003 with GlaxoSmithKline.[30] Among other things, the agreement provides for monetary penalties ranging from $1,000 to $2,500 per day for different

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27. *See* 42 U.S.C. § 1320a-7b(b) (2000).
28. *See id.* § 1320a-7b.
29. HHS Office of Inspector General, Fraud Prevention & Detection, Corporate Integrity Agreements, http://www.oig.hhs.gov/fraud/cias.html (last visited Aug. 7, 2007).
30. *See* Corporate Integrity Agreement Between the Office of Inspector General of the Dep't of Health and Human Services and SmithKline Beecham Corporation d/b/a GlaxoSmithKline (Apr. 15, 2003), *available at* http://www.oig.hhs.gov/fraud/cia/agreements/SmithKline_Beecham_Corp_dba_GlaxoSmithKline041503.PDF.

kinds of violations.[31] It also precludes judicial review of decisions by OIG or HHS under the agreement.[32]

IV. THE PROBLEM

Public companies and other organizations enter into these types of settlement agreements to avoid the prospect of going to court or suffering an administrative sanction, such as exclusion from Medicaid, Medicare, and other federal healthcare programs. Organizations commonly view the prospect of civil litigation against the government and administrative sanctions as far worse than settling on the government's terms. Settling is attractive when the likelihood of prevailing in a contested proceeding does not justify the risks and costs of the proceeding or when even a certainty or near-certainty of prevailing would involve unacceptable costs and/or collateral risks.

The settlements described above impose on the organizations the certainty or possibility of very large costs, significant contractual obligations, and significant curtailment of procedural rights. Because organizations almost always accept such settlements rather than litigate, it is reasonable to infer that they have little bargaining power. Their bargaining power may be weak because the enforcement officials develop strong cases; because the organizations are highly averse to the risks of governmental enforcement litigation; or because the mere pendency, process, and uncertainty of such litigation impose unacceptable costs, regardless of the ultimate outcome.

Settlements of many similar cases may stifle development of the law.[33] Even when enforcement officials may very well be exceeding their statutory authority or invading constitutionally protected rights (e.g., commercial free speech), organizations almost always prefer to settle. In doing so, they give up an opportunity to obtain a judicial ruling on the agency's enforcement theories. In addition, if and when a case is later litigated, the prior settlements may be cited as precedents.[34]

It is unclear whether the common settlement provisions described above are statutorily authorized or good public policy. For example, although the courts have held that the FDCA authorizes courts to award disgorgement of profits and restitution,[35] there has been no judicial decision either way as to

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31. *Id.* at 23-25, ¶ X. A.
32. *Id.* at 27-29, ¶ X. E.
33. I thank Dan Troy for suggesting this point.
34. *See* United States v. Lane Labs-USA Inc., 427 F.3d 219, 234 (3d Cir. 2005) (discussing prior consent decrees between pharmaceutical companies and FDA).
35. *See* United States v. Rx Depot, Inc., 438 F.3d 1052, 1058 (10th Cir. 2006) (disgorgement), *cert. denied*, 127 S. Ct. 80 (2006); *Lane Labs-USA, Inc.*, 427 F.3d at 220 (restitution).

whether the FDCA authorizes daily penalties masquerading as "liquidated damages." More generally, did Congress intend FDA injunctions to become money-making machines for the Treasury Department, with no statutorily prescribed method for determining appropriate amounts? Did it intend the HHS OIG to impose daily penalties on providers? Did Congress intend that settlement agreements provide for unreviewable agency decision-making? Did it intend that allegations of violations of consented-to court injunctions and other settlement documents filed in court be adjudicated not by the judiciary but by federal agencies, with no judicial review or only limited review? Did it intend enforcement officials to dictate how corporations and other institutions would organize themselves for compliance, and what the elements of compliance programs would be?

In *Federalist No. 48*, James Madison wrote: "It will not be denied, that power is of an encroaching nature, and that it ought to be effectually restrained from passing the limits assigned to it."[36] The insight is ancient: in *The Furies* by Aeschylus, Athena says to citizens of Athens: "Here awe and fear must press on the heart, for untouched by fear no man is just."[37] Where are the effectual restraints on the power of federal enforcement officials to dictate settlements? Where are the awe and fear that press upon their hearts to make them just?

For lawyers, the obvious leading candidate is judicial review. A court asked to "so order" a proposed consent decree under a statute certainly may review the decree to determine whether it furthers the objectives of the statute.[38] As a practical matter, however, judicial review is unavailable. Some settlement agreements, such as non-prosecution agreements and CIAs, do not involve any judicial proceeding, and are not filed in any court. Even where settlement agreements are filed in court, as are deferred prosecution agreements and consent decrees, judicial review does not occur because neither party to such an agreement seeks it and because it is not evident that any third party could obtain review. Case-by-case review would deprive a settling defendant of a settlement it wants, even if the government is overreaching.

A company facing an FDA demand for an injunction could admit liability and litigate only the terms, or only a few of the terms, of the injunction. Companies do not do that, however, presumably for several reasons. Admission of violations could collaterally estop a company in

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36. THE FEDERALIST NO. 48, at 256 (James Madison) (George Carey & James McClellan eds., 2001).

37. AESCHYLUS, *The Furies, in* THE ORESTEIA OF AESCHYLUS 93, 119 (Robert Lowell trans., Farrar, Straus & Giroux 1978). For an alternate translation, see AESCHYLUS, *The Eumenides*, *in* 1 THE COMPLETE GREEK TRAGEDIES 1, 178 (Richmond Lattimore trans., David Grene & Richard Lattimore eds., 1942).

38. Sys. Fed'n No. 91, Ry. Employe[e]s' Dep't v. Wright, 364 U.S. 642, 651 (1961).

other litigation; by contrast, resolution by consent decree typically involves no admissions and no judicial findings of fact. In addition, if no agreement on the outcome exists when the government files its complaint, the complaint is likely to contain more graphic detail than it would if it were part of an agreed disposition of the case. During the litigation of the remedy, even though the defendant has admitted the prior violations, the government presumably would introduce evidence of the violations to support arguments for strong relief. The filing of the complaint and the presentation of such evidence are likely to generate publicity adverse to the defendant; such publicity would aid its competitors and possibly other litigants against the defendant. As to the final outcome, the defendant would also face prolonged uncertainty, which could depress its business prospects and its stock price.

Third parties are unlikely to be able to intervene because they would lack standing. There is no analogue here to the Tunney Act, which provides for a public proceeding to determine whether a settlement under the antitrust laws is in the public interest.[39] These are not class actions, where hearings on proposed settlements occur for the protection of the class.[40] Moreover, in all or most cases, both the enforcement office and the company that have entered into a settlement agreement would strongly resist any effort by a third party to inquire into and possibly overturn their settlement. The enforcement office wants no inquiry into its authority to extract concessions from settling defendants, and presumably a settling defendant would rather make all the concessions it has made than see its settlement overturned and have to litigate against the enforcement office. Moreover, even if a settling defendant might benefit from a settlement on less onerous terms, a public proceeding to obtain such terms would impose on it some of the most significant costs it presumably sought to avoid by settling: potentially prolonged uncertainty until the completion of the proceeding (including any appeals) and potentially a stream of adverse publicity (in contrast to stories in one news cycle resulting from press releases announcing the initial settlement).

In some circumstances where the government obtains in a settlement with one defendant a concession that it later uses to disadvantage a second defendant in a separate proceeding, the second defendant may be able to obtain judicial review of the lawfulness of the concession. Such a strategy has succeeded thus far in *United States v. Stein*, where the District Court for the Southern District of New York held that the provision in a deferred prosecution agreement that barred an organization from advancing

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39. *See* 15 U.S.C. § 16(f) (2000).
40. *See* FED. R. CIV. P. 23(e).

attorneys' fees to its former employees under investigation violated the former employees' rights under the Sixth Amendment and the Due Process Clause of the Fifth Amendment.[41]

Nevertheless, not all questionable provisions in settlement agreements disadvantage third parties; and not all disadvantaged third parties become involved in a separate proceeding in which they can seek relief from their disadvantage. Moreover, the kind of collateral attack that has succeeded thus far in *Stein* is a limited, delayed, burdensome, and roundabout way to challenge settlement policies of general applicability.

Judicial review, therefore, appears not to be an effectual restraint on the power of enforcement officials to extract concessions in settlements. Moreover, what is needed much more than case-by-case post hoc review of individual settlements is advance review of the policies and forms of agreement that shape an enforcement agency's settlements generally.

Next, one might turn to the Executive Branch to police itself; however, such self-policing simply has not happened. Agency heads generally avoid imposing any constraint on enforcement tactics, so as not to be distracted from the substantive programs that are their main concern, and so as not to incur criticism for weakening enforcement. Also, why should they risk having to spend political capital for the benefit of organizations that have gotten—or may in the future get—into trouble due to noncompliance?

Furthermore, review under Executive Orders has never reached policies for settlement of enforcement actions. Such policies slip through the cracks in the Executive Orders' definitions. For example, as amended by later amendments, including by President Bush's Executive Order 13,422 of January 18, 2007, Executive Order 12,866 defines the key terms "regulation," "regulatory action" and "guidance document" in ways that would not, without considerable stretch and strain, reach the unwritten but real policies that shape settlements of enforcement actions.[42] The Executive Order's definition of the term "significant regulatory action" includes one that "is likely to result in a regulation that may . . . [h]ave an annual effect on the economy of $100 million or more."[43] Several FDA consent decrees and DOJ deferred prosecution agreements have involved

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41. *See* United States v. Stein, 435 F. Supp. 2d 330, 364-66 (S.D.N.Y. 2006). The court later dismissed the indictment against thirteen of the sixteen defendants, and the government has appealed. United States v. Stein, 495 F. Supp. 2d 390 (S.D.N.Y. 2007), *appeal docketed*, No. 1137 (2d Cir. July 16, 2007).

42. *See* Exec. Order No. 12,866, § 3(d), (e), & (g), 58 Fed. Reg. 51,735 (Sept. 30, 1993) (as amended by Exec. Order No. 13,258, 67 Fed. Reg. 9,385 (Feb. 26, 2002) and Exec. Order No. 13,422, 72 Fed. Reg. 2,703 (Jan. 18, 2007)), *available at* http://www.whitehouse.gov/omb/inforeg/eo12866/eo12866_amended_01-2007.pdf.

43. *Id.* § 3(f)(1).

payments of more than $100 million,[44] and the policies that lead to such settlements result in payments averaging more than $100 million annually; however, the policies are not "regulations," and they and the settlements do not "result in a regulation."

Could the Executive Branch police itself in this area? Yes, of course. To do so, it would have to be willing to risk criticism from groups that see it as part of their mission to make enforcement as tough as possible. To be willing to incur that political risk, agencies or the Executive Office of the President would have to be persuaded that the current lack of effectual restraint on settlements of enforcement proceedings is a serious problem worthy of attention. Somebody, or better, somebodies would have to take up that task of persuasion.

Our last resort for effectual restraint is Congress. The committees that have legislative jurisdiction over agencies have legislative jurisdiction over their enforcement policies and practices. So, too, does the House Committee on Oversight and Government Reform.[45] Thus, there is no question of congressional authority to review such policies and practices.[46]

Oversight and the threat of remedial legislation can also be effectual. The uproar over the Thompson Memorandum and DOJ's routine demands for waiver of the corporate attorney-client privilege as part of the price for settlement of a criminal investigation of a corporation led to an oversight hearing on September 12, 2006.[47] On December 8, 2006, Senator Arlen Specter, who had been Chairman of the Senate Judiciary Committee and, after the 2006 elections, was about to become the ranking minority member, introduced his proposed Attorney-Client Privilege Protection Act.[48] On December 12, 2006, DOJ issued the McNulty Memorandum to modify its policy on demands for waivers.[49] Awe and fear at work? Maybe.[50]

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44. *See, e.g.*, BAWAG Press Release, *supra* note 3; BMS Agreement, *supra* note 9, at 1-2, ¶ 5(b).

45. *See* About the Committee on Oversight and Government Reform, http://oversight.house.gov/about.asp (last visited Sept. 27, 2007) ("The Committee on Oversight and Government Reform is the main investigative committee in the U.S. House of Representatives. It has jurisdiction to investigate any federal program and any matter with federal policy implications.").

46. For a general introduction to the law of congressional oversight, see Morton Rosenberg, *Investigative Oversight: An Introduction to the Law, Practice and Procedure of Congressional Inquiry*, CRS Report for Congress No. 95-464 (Apr. 7, 1995), *available at* http://www.ncseonline.org/nle/crsreports/government/gov-3.cfm.

47. *The Thompson Memorandum's Effect on the Right to Counsel in Corporate Investigations*: *Hearing Before the S. Comm. on the Judiciary*, 109th Cong. (2006), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_senate_hearings&docid=f:34117.pdf.

48. S. 30, 109th Cong. (2006).

49. *See* McNulty Memorandum, *supra* note 7.

50. On August 1, 2007, the House Judiciary Committee reported H.R. 3013, the proposed Attorney-Client Privilege Protection Act, out of committee. A companion bill is

Samuel Johnson said: "Depend upon it, Sir, when a man knows he is to be hanged in a fortnight, it concentrates his mind wonderfully."[51] The ritual hangings we call congressional oversight hearings concentrate the minds of heads of federal agencies. The prospect of a congressional hearing on an agency's settlements of enforcement actions might, for the first time, acquaint the agency's head with what the agency's enforcement officials have been doing. The experience could well prove salutary.

Bringing about focused congressional committee oversight, however, requires the same kind of political mobilization as is needed to stimulate Executive Branch review. Individual organizations will not want their own interactions with enforcement officials to be highlighted in news accounts. Consequently, trade associations, lawyers' associations, and other groups should take the lead in seeking oversight of settlement policies, particularly those that arguably have extended their demands beyond appropriate limits. Although congressional oversight may not be included in some law school courses on administrative law, officials at federal agencies know that it can be a very potent influence on administrative proceedings. Sometimes, it can provide a speedier and more effective remedy than judicial review could provide.

Not all oversight will produce action as promptly as did the oversight of the Thompson Memorandum. If, however, the concern regarding governmental overreaching in settlement agreements continues, such oversight will be a good place to begin. Generally, administrative lawyers should consider administrative and congressional oversight (as well as the press) among the potentially available sources of remedies for inappropriate policies or actions of federal agencies.

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pending in the Senate. DOJ argues that the bill improperly interferes with its prosecutorial decision-making. *See DOJ Attorney Objects to House Bill as Interfering with Prosecutorial Discretion*, 5 CORP. ACCOUNTABILITY REP. (BNA) 860 (Aug. 24, 2007).

51. James Boswell, *The Life of Samuel Johnson LL.D.*, *in* 44 GREAT BOOKS OF THE WESTERN WORLD 351 (Robert Maynard Hutchins ed., 1952) (1791).