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Ashutosh Bhagwat

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by
ASHUTOSH BHAGWAT*

Consider the following examples of regulatory regimes:

In 1976, Congress enacted the Hart-Scott-Rodino Antitrust Improvements Act ("HSR"),[1] which fundamentally altered existing practice regarding the application of antitrust law to corporate mergers. Interestingly, however, HSR made no changes to the *substantive* antitrust rules regarding mergers.[2] Instead, HSR created a new procedural requirement for major corporate mergers, an agency preclearance (or more precisely, prenotification) requirement which firms must comply with prior to consummating a merger. This seemingly minor procedural change, however, has fundamentally altered the nature, scope, and content of substantive antitrust merger law over the past two decades. In particular, commentators and industry participants have noted that the procedural changes enacted by the HSR have resulted in an enormous shifting in discretionary and lawmaking power from the courts to the regulatory agencies who implement the HSR preclearance regime.

In the United States, both tobacco and alcohol products are subject to strict labeling requirements. In particular, both types of products must be sold in packages containing specific health warning labels, the contents of which are set by federal law. The warning requirements for the two industries are quite similar, both in terms of content, and in terms of physical requirements of prominence and so forth. There is, however, a difference between the two regulatory

* Associate Professor of Law, University of California, Hastings College of the Law <bhagwata@uchastings.edu>. B.A. 1986, Yale University; J.D. 1990, The University of Chicago. I would like to thank Marsha Cohen, Fred Lambert, Reuel Schiller, and Bill Wang for extremely helpful comments and suggestions, and Matt Borden for excellent research assistance.

1. Pub. L. No. 94-435, 90 Stat. 1390 (codified at 15 U.S.C. § 18a (1976)).

2. The key antitrust provision regulating mergers is section 7 of the Clayton Act, 15 U.S.C. § 18, which was enacted in its present form (with minor subsequent amendments) in the Celler-Kefauver Act of 1950, 64 Stat. 1125 (1950).

regimes. Tobacco labeling regulations, which are enforced by the Federal Trade Commission ("FTC"), specify the type and content of warnings which must appear on cigarette packaging and advertisements, but no special enforcement procedures are imposed, so that enforcement is left to agency supervision and prosecution.[3] In contrast, alcohol labeling regulations provide that not only must alcoholic beverage packaging contain the requisite warnings, but the labels on which such warnings are printed must be preapproved by the Bureau of Alcohol, Tobacco, and Firearms in the Department of the Treasury ("BATF").[4] Accompanying and associated with this difference in procedure are very different regulatory cultures. The FTC is a relatively quiescent agency, with little day-to-day interaction with the tobacco industry so long as basic labeling rules are followed. The BATF, in contrast, has ongoing interactions with alcohol producers through the preclearance requirements, and members of the industry appear to hold high levels of resentment towards the perceived arbitrariness and improper uses of power by the BATF.[5]

In 1990, Congress enacted the Nutrition Labeling and Education Act of 1990, which provides among other things that statements regarding health claims may appear on a food label only if they have been preapproved by the Food and Drug Administration ("FDA").[6] Congress, however, entirely exempted health claims regarding dietary

3. *See* 15 U.S.C. § 1333 (1994). The Food and Drug Administration (FDA) has recently sought to exercise regulatory authority over cigarettes as a "medical device" under 21 U.S.C. § 352(r) (1994), including preclearance authority over cigarette labeling, in part because of the alleged inadequacy of FTC regulation. *See generally* Lars Noah & Barbara A. Noah, *Nicotine Withdrawal: Assessing the FDA's Effort to Regulate Tobacco Products*, 48 ALA. L. REV. 1 (1996). That effort, if successful, will of course fundamentally change the nature of tobacco regulation. *Cf.* Brown & Williamson Tobacco Corp. v. FDA, 153 F.3d 155 (4th Cir. 1998), cert. granted 119 S. Ct. 1495 (1999)(striking down FDA regulations of tobacco).

4. *See* 27 U.S.C. §§ 205(e), 215 (1994); 27 C.F.R. §§ 4.50, 5.55, 7.41 (1998). It should be noted that unlike tobacco, the BATF's preapproval authority over alcohol labels is not limited to oversight of health warnings, but also extends to labeling rules regarding the contents of the beverage, appellation rules for wine, and so forth. These latter rules have no equivalent in the tobacco context.

5. *See, e.g., Consultant Renews Attack on BATF Label Approval Delays*, FOOD LABELING NEWS, (Oct. 26, 1995).

6. 21 U.S.C. § 343(r)(5)(D) & (r)(6). *See* 21 U.S.C. § 343(r)(3) (1997 Supp.). The FDA has a practice of granting blanket authority for specific health claims, so that once approval is given firms may make that particular claim regarding that food item, and using the FDA's preferred language, without prior approval. However, if a firm wishes to make any health claim which has not been already approved by the agency, preclearance is required (which if successful will typically create a new category of blanket approval). Prior to 1990, if a firm sought to make health claims regarding food, the FDA then treated the food as a drug, subjecting it to very strict procedural preapproval requirements and an onerous substantive standard, as a result of which no such claims were made.

supplements from this regulatory regime, so that such claims are subject only to subsequent enforcement actions brought by the FDA.[7] The consequence of this regulatory dichotomy is a vastly greater number of health claims being made with respect to food supplements than with respect to food, combined with far stronger agency authority over the food industry, and allegedly, greater amounts of fraud in the food supplement industry.[8]

What do the above examples have in common? In each instance, a particular substantive regulatory regime has been implemented through two different procedural modes of enforcement—one of the modes being a system of *ex post* enforcement actions brought by agencies, and the second being a requirement of *ex ante* preapproval, or preclearance, by the agency of regulated conduct. In the latter two examples (cases of tobacco and alcohol labeling laws, and food health claims and dietary supplement health claims regulation), we see parallel substantive regimes with different enforcement mechanisms; while with the antitrust merger laws we see an alteration in enforcement mechanisms over time, without any change in substantive rules. What is striking about the examples is that they reveal that similar substantive regulatory regimes can in practice operate in entirely different ways when implemented through *ex post* versus *ex ante* enforcement systems. What is affected by the choice of enforcement mechanism is not only the relative positions and authority of the agency and regulated entities, but also the actual, practical scope and substance of the regulatory regime, as well as the locus of power among agencies, courts, and Congress. In short, the granting of preclearance authority to an agency can substantially increase the discretionary power and lawmaking authority of an agency without any change in the agency's formal jurisdiction or substantive authority. On the other hand, there also exist some very strong, practical rationales for granting agencies such authority. This article seeks to explore the reasons why particular administrative agencies have been granted different modes of enforcement authority, and to explore the practical consequences of those choices, both for regulated entities and for broader regulatory policy.

In presenting the topic of this article, it is useful to begin by laying out what this article is *not* about, i.e., the areas which it will not examine. In discussing modes of administrative enforcement, I will draw upon examples from the practices of a number of administrative agencies, including the FTC, FDA, the BATF, the Federal

7. *See* 21 U.S.C. § 343(r)(5)(D), (r)(6) (1994).

8. *See e.g.*, Gina Kolata, *Ideas & Trends: The Unwholesome Tale of the Herb Market*, NEW YORK TIMES, sec. 4, p. 6 (April 21, 1996); Steven Pyat, *Melpor Mindranic; FDA Loosens its Grip on Vitamin Supplement Chains*, CHICAGO TRIBUNE, p. 3 (May 17, 1995).

Communications Commission ("FCC"), and the Antitrust Division of the Department of Justice ("DOJ").[9] I do not, however, intend to examine in any great detail the efficiency or prudence of the substantive policies pursued by any of these agencies. Also, I do not intend to enter the law-and-economics debate over the advisability of regulating primary conduct through a regulatory apparatus versus regulating end results only.[10] Rather, I will assume that a decision has been made to regulate certain kinds of primary conduct within the economy and an administrative agency has been created to implement that regulation. I am also not primarily concerned about the choice—identified by previous commentators—between *public* enforcement of regulatory rules (generally by administrative agencies) and *private* enforcement (through lawsuits filed by individuals),[11] though I will draw on this commentary and spend some time discussing the public/private distinction.

Once a decision has been made to regulate conduct, and to create a regulatory agency with primary responsibility for creating and enforcing that regulation, however, one must still decide *how* the agency should be authorized to enforce the regulatory policies chosen by the legislature and/or the agency. That question is the primary topic of this paper. I wish to consider different possible *modes* of public enforcement, different ways in which agencies are authorized to proceed against private citizens. In particular, I identify a basic dichotomy between ways in which agencies enforce standards: certain agencies are authorized to engage in prior, *ex ante* review of regulated conduct, generally through some sort of licensure or preclearance system, while other agencies may proceed only through *ex post* enforcement, either through civil or criminal prosecution (or its equivalent), after a regulatory violation has occurred. Of course, this dichotomy is not a clean one; a variety of enforcement procedures exist along a spectrum between pure *ex post* and *ex ante* enforcement, and particular agencies may possess a number of different powers which vary along the spectrum. Nonetheless, I argue that this distinction is an important one.

The ultimate question I pose in this article is what are the consequences, for agency power, discretion, and substantive

9. On whether the Antitrust Division can properly be considered a regulatory agency, see E. Thomas Sullivan, *The Antitrust Division as a Regulatory Agency: An Enforcement Policy in Transition*, 64 WASH. U. L.Q. 997 (1986).

10. *See, e.g.*, STEVEN SHAVELL, ECONOMIC ANALYSIS OF ACCIDENT LAW 277-90 (1987); Donald Wittman, *Prior Regulation Versus Post Liability: The Choice Between Input and Output Monitoring*, 6 J. LEGAL STUD. 193 (1977).

11. *See* Richard B. Stewart & Cass Sunstein, *Public Programs and Private Rights*, 95 HARV. L. REV. 1193 (1982) (discussing the relationship between a private right to initiate administrative enforcement, and a private right of action against regulated firms).

policymaking of the mode of enforcement which an agency is authorized to implement. I also examine why particular agencies in particular substantive areas may need one or the other type of enforcement power. My basic thesis is that granting an agency the power to engage in *ex ante* review of private behavior, through licensure or the equivalent, may sometimes be desirable for practical reasons, but it should be recognized as having significant, negative consequences. The power of *ex ante* review provides an agency with an enormous amount of substantive discretion to shape the policies it implements, as well as a great deal of power to coerce or otherwise hold-up private, regulated entities. Most importantly, *ex ante* enforcement often enables agencies to avoid judicial review of their regulatory decisions by making it impractical or exorbitantly expensive for regulated firms to challenge those decisions, and so enhances agency discretion and power in ways both subtle and unsubtle. In pursuing this analysis, some fundamental points emerge and will be discussed regarding the nature of administrative discretion, and why precisely such discretion is of concern to students of the administrative state. Finally, I will conclude by identifying various factors which policymakers—primarily the legislature—should take into account in determining what kinds of enforcement powers particular agencies should be granted, and by then applying these factors to evaluate the wisdom and efficiency of some current regulatory systems.

I. Modes of Regulatory Enforcement

A. A Basic Typology

Let us begin with a typical regulatory problem. Suppose that because of growing health concerns Congress has made a decision to regulate the contents of baby food to ensure that all baby food meets minimal nutritional standards. Once the decision has been made to regulate, the first step in designing such a regulatory regime is of course to choose the substantive contents of the regulatory scheme—the rules. Let us assume that Congress does so by specifying particular content and/or nutrients which all baby food must contain; or alternatively, Congress adopts a broad substantive standard (*e.g.*, that all baby food must be "healthy and efficacious"), and delegates to a federal agency (let us call it the FBFC, the Federal Baby Food Commission) the power to adopt specific, substantive rules implementing that standard, which the agency does. All of these decisions—the decision to regulate, the choice of substantive standards, and the decision of whether or not to create a new agency—are likely to be the source of great public debate and

attention. Once these basic questions have been answered, however, a further decision must be made: How to enforce the substantive rules that have already been chosen? The latter decision—which is one of enormous practical import—is not likely to command nearly the same level of attention from the public or from the legislature as the former decisions. Nonetheless, it is crucial, and raises many difficult questions.

The first question one might ask is whether enforcement of the new baby food regulations should be purely private, purely public, or some combination? One might imagine a regime where FBFC's authority is limited to adopting substantive rules, but enforcement of those rules is entrusted to damages actions by consumers of baby food who have been injured by noncompliant products—actions which might be brought pursuant to existing tort law, or pursuant to a newly created, federal cause of action. Congress might also authorize private injunctive actions in place of, or in addition to, private damages actions. In today's highly regulated world, regulatory regimes which are subject to *purely* private enforcement are almost unheard of, but they are theoretically possible.[12] Alternatively to a purely private enforcement regime, Congress might follow the more common course of authorizing enforcement actions undertaken by the administrative agency, here the FBFC. Such public enforcement can either replace or supplement private enforcement. In a classic article, Professors Richard Stewart and Cass Sunstein have explored the relationship between public and private enforcement of administrative regimes, and reached conclusions regarding the best balance between the two.[13] I will proceed upon the likely assumption that Congress has chosen to authorize public enforcement of the new regulations, either exclusively (by preempting existing private causes of action) or in combination with private remedies.

Once Congress has decided to grant the agency enforcement authority, the question arises, what *kind* of authority? Once again, a basic choice emerges. FBFC might be structured along traditional lines, and authorized to investigate and prosecute either criminally or civilly on an *ex post* basis (meaning after a violation has occurred) any baby food maker who has sold a noncompliant product. In other words, Congress could adopt a "law enforcement model" for the new

12. The closest examples of such purely private enforcement regimes today are probably medical malpractice tort claims and regulation of police misconduct. Of course, both doctors and policemen are also subject to public discipline and enforcement in principle; but in practice, absent egregious misconduct, such enforcement is notoriously lax.

13. *See generally* Steward & Sunstein, *supra* note 11.

regulatory regime.[14] On the other hand, FBFC could be structured along a more "regulatory model," with a greater emphasis on prior oversight and regulation of private conduct.[15] In particular, FBFC could be granted preapproval authority in connection with the new rules, which would require that all baby food makers obtain official approval, or licensure, from the agency before marketing any particular type of food. Failure to comply with such preapproval requirements would of course be subject to punishment (on an *ex post* basis), regardless of compliance with the underlying, substantive standard.

The above discussion identifies two axes along which enforcement methodology can vary: public versus private and *ex ante* versus *ex post.* These two axes, in combination, produce four alternative enforcement methodologies which can be depicted graphically as follows:

	Public	**Private**
Ex Post	Prosecution, either civil or criminal	Private damages actions
Ex Ante	Preapproval or preclearance system/licensure	Private injunctive relief, prior to illegal conduct (perhaps)

Note that these enforcement regimes are distinct but not mutually exclusive; a regulatory scheme might contain any combination of the four choices. Furthermore, the distinction between *ex post* and *ex ante* regimes, as laid out starkly above, is something of an overstatement; in fact, the distinction is more of a spectrum so that enforcement regimes can have varying aspects of a "pure" *ex post* or a "pure" *ex ante* system. Nonetheless, the above typology has value in highlighting the basic choices made by policymakers while constructing regulatory regimes, and in analyzing the consequences of those choices. I will therefore proceed to explicate my basic model by describing in more detail each of the above enforcement options, with particular emphasis on the public enforcement alternatives which are the main focus of this paper.

(1) Public Ex Post *Enforcement*

This is the traditional model for public enforcement of social rules. Under this model, an enforcing government agency is expected

14. *See* A. Douglas Melamed, *Antitrust: The New Regulation,* 10 ANTITRUST 13, 13 (1995).

15. *See id.*

to identify and investigate conduct by regulated parties who have already violated the substantive rules being enforced, and then to bring a judicial action to punish that conduct. In other words, it is the model of the public prosecutor of criminal laws. The model is not limited to criminal penalties, however, but also covers many other possible punishments including civil fines or other adverse actions such as revocation of a license, confiscation of property, loss of government contracts, and so forth. The critical common factor is that this mode of enforcement involves the enforcement agency identifying *prior* violations of law, and then obtaining a judicial order imposing a penalty against the violator.

Examples of *ex post* public enforcement of regulatory regimes are of course common. First of all, the entire criminal law is based on this model. In addition, many regulatory regimes are organized in this manner. Thus the National Labor Relations Board identifies and prohibits unfair labor practices by unions and employers and enforces its prohibitions by seeking a judicial order.[16] Similarly, the FTC regulates advertising of health claims regarding food as well as advertising of over-the-counter drugs, using an *ex post* prosecution system which includes civil fines and cease-and-desist orders.[17] The FDA's regulation of prescription drug advertising is also, in principle, based on a system of *ex post* prosecution as mandated by Congress.[18] The Department of Justice enforces the two primary antitrust statutes, sections one and two of the Sherman Act, entirely through *ex post* criminal and civil prosecutions.[19] Other examples of *ex post* enforcement within the regulatory state are myriad and far too numerous to detail here. As the above list indicates, however, even in today's highly regulated environment the *ex post* "law enforcement" model of regulatory enforcement remains the norm.

(2) Public Ex Ante *Enforcement*

In the above typology, a pure *ex ante* enforcement mechanism is one in which the administrative agency is authorized to review, and must provide *prior* approval for, *all* regulated conduct within a designated category, regardless of whether the conduct violates any rule. Concomitantly, in such a regime regulated firms are absolutely barred from acting within the regulated sphere of activity without first requesting and obtaining regulatory preapproval, or preclearance.

16. *See* National Labor Relations Act, § 10(e), (f), 29 U.S.C. § 160(e), (f) (1994).

17. *See generally* Federal Trade Commission Act, §§ 5, 12-15, 15 U.S.C. §§ 45, 52-55 (1994); Elisabeth A. Sachs, *Health Claims in the Marketplace: The Future of the FDA and the FTC's Regulatory Split*, 48 FOOD & DRUG L.J. 263 (1993).

18. *See* 21 U.S.C. § 352(n) (1994 Supp.); 21 C.F.R. § 202.1(e) (1998).

19. *See* Sherman Act, §§ 1, 2, 4, 15 U.S.C. §§ 1, 2, 4 (1994).

The agency's method of enforcement within such a system is of course to deny approval for conduct, prior to its occurrence, if the agency determines that the conduct would violate the underlying, substantive norms. If such disapproval occurs, the regulated firm is then prohibited from engaging in the conduct unless and until it is able to invoke judicial review and obtain a court order overturning the agency's determination that the proposed conduct is illegal.

The critical differences between *ex ante* enforcement mechanisms and the traditional, *ex post* mechanism described above lie in the timing of judicial review, and in the placement of the burden of inertia and inaction. Under an *ex post* system of enforcement the burden of inertia and inaction operates in favor of the regulated entity, since absent action by the agency the firm may engage in any conduct it wishes (always, of course, with the risk that in the future its conduct will be found to have violated regulatory standards). Furthermore, the burden of *judicial* inaction and the timing of judicial review also favor the firm because a firm is subject to punishment or coercive measures only *after* a court has determined that a substantive violation has occurred.[20] In an *ex ante* regime, by contrast, all of those burdens are reversed. Failure to seek or gain agency approval, or inaction by the agency, preclude the firm from pursuing desired conduct, and therefore the burden of delay and inaction fall entirely on the firm. If the agency eventually disapproves the firm's proposed conduct the firm must seek out judicial review, and once again, the intervening delay operates to the detriment of the firm, which cannot engage in desired activities. If agency decision-making and judicial review were swift and certain in operation, these differences would be minor; but in the real world, of course, they are not, so the shift in the burdens of delay and inaction between the two regimes can be very significant.

Ex ante enforcement regimes within the administrative state are not quite as common as *ex post* regimes, but they are far from

20. Many administrative enforcement schemes permit agencies to impose fines or other coercive measures (such as loss of licensure) upon a regulated entity after a full agency adjudication, but *before* judicial review is completed. As such, these schemes seem to bear some aspects of an *ex ante* system (in terms of the timing of judicial review), even though in most respects they resemble traditional *ex post* enforcement by placing the burden of inertia, investigation, and proof on the agency. In practice, however, such schemes do not appear to operate very differently from pure *ex post* enforcement devices, perhaps because of the generous interim stay provisions of the Administrative Procedure Act, *see* 5 U.S.C. § 705 (1994) (authorizing either agency or reviewing court to stay agency order pending appeal, to preserve status quo), and because agencies do not appear to try and coerce firms into giving up judicial review rights by imposing punitive sanctions while an appeal is pending. For the purposes of this paper, therefore, I will presume that such systems are equivalent to pure *ex post* enforcement regimes.

unknown. As noted above, pursuant to the Hart-Scott-Rodino Act ("HSR"), corporate mergers are effectively subject today to a preclearance regulatory scheme administered by the antitrust enforcement authorities, the FTC and the Department of Justice's Antitrust Division.[21] In addition, as also noted above, alcohol labeling rules are enforced under a preclearance system administered by the BATF and health claims on food labels must be preapproved by the FDA.[22] Many other examples of preapproval regimes can also be identified. For example, the staff of the Securities and Exchange Commission (SEC) reviews all disclosures that an issuer of a new security intends to make in conjunction with the public sale of those securities.[23] All new prescription drugs are subject to preapproval by the FDA, including both the physical composition of the drugs (*i.e.*, the agency must approve the drug's medical effectiveness) and the labeling accompanying the drug when it is sold.[24] Any effluent discharge from a point source into the nation's waterways is subject to a permitting requirement administered by the Environmental Protection Agency;[25] and under the same statutory scheme, the Army Corps of Engineers enforces a preclearance regime for the placement of dredged materials into wetlands.[26] Licensure provisions, such as the rules requiring all commercial broadcasters to obtain licenses

21. *See supra* note 2 and accompanying text. As discussed in the next section, describing HSR as an *ex ante* regulation scheme is a bit of a misstatement, since in principle HSR requires only predisclosure, not preclearance, of mergers. In practice, however, the HSR does in fact operate as a preclearance system, for reasons that will also be discussed

22. *See supra* note 6 and accompanying text. As noted above, FDA preapproval of health claims is generic, so that once a claim has been authorized it may then be made by anyone without further preapproval.

23. *See* Securities Act of 1933, § 5(c), 15 U.S.C. § 77e(c) (1994). To be precise, the Act does not require affirmative preapproval by the SEC, but provides rather that a registration statement will go into effect after a twenty day waiting period unless the SEC disapproves it, by issuing a "stop order." *See* 15 U.S.C. § 77h (1994). Furthermore, in practice, stop orders are apparently almost never used by the agency; rather the agency's true power to preclear emerges from the issuer's need for the agency to accelerate the effective date of a filed registration statement, thus permitting the pricing of offerings to reflect current market conditions. The agency is able to exercise considerable influence over the content and timing of public offerings of securities through its power to withhold acceleration, thereby creating an unwritten preapproval regime over disclosures. *See also* Frederick Schauer, *The Speech of Law and the Law of Speech*, 49 Ark. L. Rev. 687, 690-92 (1997) (discussing first amendment implications of SEC preclearance regulations).

24. *See* 21 U.S.C. § 355 (1994); 21 C.F.R. §§ 314.50, 314.100 (1998); Thomas A. Hayes, *Drug Labeling and Promotion: Evolution and Application of Regulatory Policy*, 51 FOOD & DRUG L.J. 57, 61, nn.43-44 (1996).

25. *See* Federal Water Pollution Control Act, § 301(a), 33 U.S.C. § 1311(a) (1994).

26. *See id.* at § 404, 33 U.S.C. § 1344 (1994); 33 C.F.R. §§ 320.1-320.4, 326.1-326.6, 330.1-330.6 (1998).

from the FCC,[27] operate to enforce qualification rules on an *ex ante* basis even though the agency may still enforce other, substantive restrictions through more traditional *ex post* prosecution. Finally, in many regulated industries, before firms can change the prices they charge for their products they must file a tariff with the responsible regulatory agency and obtain regulatory approval of the new rate.[28]

Preclearance regimes can thus be found in a wide and diverse range of regulatory programs, administered by a broad array of agencies. The question that arises naturally is why certain types of substantive regimes are, or should be, enforced through *ex post* mechanisms while others are enforced through preclearance requirements. Before turning to this question, however, it would be worthwhile to finish filling out the typology of enforcement mechanisms, including private enforcement, and intermediate enforcement mechanisms between pure *ex post* and *ex ante* models.

(3) Private Ex Post *Enforcement*

Private, *ex post* enforcement is in some ways the most familiar and most ubiquitous of enforcement regimes. At its core, it is based on private parties bringing legal proceedings, typically seeking damages, against those who have violated regulatory norms and in the process caused harm to the private plaintiffs. The entire common-law tort system is one of private *ex post* enforcement, and many modern regulatory schemes also incorporate such an enforcement mechanism. Prominent examples include private securities fraud actions under the Securities Exchange Act of 1934;[29] private actions to enforce the antitrust laws, including both the Sherman and Clayton Acts;[30] and private discrimination claims brought under Title VII of the Civil Rights Act of 1964.[31] Such enforcement regimes have as their hallmark flexibility, decentralized decision-making, and uneven (sometimes arbitrary) patterns of enforcement. Furthermore, unlike public enforcement regimes, private enforcement generally has as its primary purpose compensation of victims, with only a secondary purpose of preventing or deterring violations.

27. *See* Communications Act of 1934, § 301, 47 U.S.C. § 301 (1994).

28. *See, e.g.*, 47 U.S.C. §§ 203-204 (1994) (tariffing requirements for communications common carriers).

29. *See* Superintendent of Ins. v. Bankers Life & Cas. Co., 404 U.S. 6 (1971); *see also* SEC Rule 10b-5, 17 C.F.R. § 240.10b-5 (1998); Securities Exchange Act, § 10(b), 15 U.S.C. §78j(b) (1994).

30. Clayton Act, § 4, 15 U.S.C. §15.

31. Civil Rights Act of 1964, Pub. L. No. 88-352, 78 Stat. 241, §§ 703, 706, codified as amended at 42 U.S.C. §§ 2000e-3, 2000e-5 (1994); *see also* St. Mary's Honor Center v. Hicks, 509 U.S. 502 (1993).

In addition to the traditional damages-focused private enforcement regimes, Sunstein and Stewart have identified an intermediate form of private enforcement, consisting of a private right to initiate *public* enforcement.[32] Such an enforcement regime would also typically be *ex post*, since it would presumably only be triggered after the private party suffered damages; and in other respects it would share many of the characteristics of more traditional private actions with the great distinction that the compensatory goals of private damage actions would *not* be advanced by initiation rights. In any event, private rights of initiation are beyond the scope of this paper, and have been analyzed in detail by Sunstein and Stewart.[33]

In conclusion, private *ex post* enforcement regimes, like public *ex post* enforcement, are common and well-established. Also, like public *ex post* enforcement, private enforcement is characterized by a presumption of legality for regulated conduct, with the burden of inertia, inaction, and judicial inaction or delay falling on the plaintiffs, and to the benefit of regulated entities. For the purposes of my analysis, therefore, we may assume that most of the same arguments in favor of, and against, *ex post* public enforcement also apply to the private variant.

(4) Private Ex Ante *Enforcement*

True private *ex ante* enforcement is almost unknown in our legal system, since it would require that a private party be authorized to prevent or coerce the conduct of others, without any prior judicial intermediary. Such a "self-help" rule would be extremely problematic, if not unconstitutional.[34] The closest well-known equivalent to *ex ante* relief for private enforcers would appear to be temporary restraining orders ("TROs"), or preliminary injunctions, obtained in anticipation of conduct by defendants which it is believed will violate a regulatory requirement. Such relief is of course widely authorized and available under both the common law and many regulatory regimes.[35] There is, however, an important distinction between injunctive relief of any sort and true *ex ante* regulation. In the case of injunctive relief, the burden of inaction and inertia fall upon the regulator/plaintiff, and are in favor of the regulated. In other words, injunctive relief does not prevent a regulated firm from acting until the person seeking to prevent the conduct brings a legal

32. *See* Stewart & Sunstein, *supra* note 11, at 1201-12.

33. *Id.*

34. *Cf.* A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495 (1935) (invalidating a broad congressional delegation of rulemaking authority to private groups).

35. *See, e.g.*, Clayton Act, § 16, 15 U.S.C. § 27 (1994) (authorizing private injunctive relief against violations of the antitrust laws).

action, and then the regulated firm is entitled to at least some judicial review *prior* to any coercive force being applied against it.[36] For these reasons, for the purposes of my analysis this last category can fairly be considered to be negligible.

B. Intermediate Modes of Enforcement

The above model of enforcement methodologies sets out two basic distinctions between enforcement modes for regulatory regimes: public versus private enforcement, and *ex post* versus *ex ante* enforcement. In fact, however, these distinctions are not as well-defined as the above discussion suggests; instead, each axis is probably better understood as identifying a spectrum than as establishing two distinct categories. Along the public-private spectrum, for example, we might find many intermediate enforcement systems such as private rights to initiate public enforcement, *Qui Tam* statutes[37], or *parens patriae* actions by the state on behalf of its citizens. The *ex post-ex ante* spectrum is similarly complex—many modes of public enforcement can be identified which have some of the characteristics of one type of regime and some of the characteristics of the other. The goal of this section is to identify and analyze some of those intermediate modes of enforcement. The intermediate enforcement systems discussed below are listed in order, from those sharing more of the characteristics of *ex post* enforcement to those which are more akin to *ex ante* systems.

(1) Shifting Burdens of Proof or Legal Standards

One relatively minor variant on a traditional *ex post* enforcement scheme is a regime in which, once a regulatory agency initiates an enforcement proceeding against a firm, the burden of proof is shifted against the firm, or alternatively, the legal standard is adjusted to favor the agency. For example, under the FTC's regulation of advertising pursuant to the doctrine of advertising substantiation, once the FTC decides to challenge an advertisement, the burden of proof is on the advertiser to show that any claims made in the ad were adequately supported at the time they were made.[38] Similarly, the

36. An exception to this general statement is, of course, the TRO, which can create a temporary judicial order against a defendant prior to its obtaining its day in court. *See* FED. R. CIV. P. 65(b). However, even a TRO is subject to *some* prior judicial oversight, albeit *ex parte*, and furthermore it is of extremely limited scope. *See id.* As such, it cannot be considered an important example of private *ex ante* regulation.

37. Qui Tam statutes permit private citizens to bring suit on behalf of the government, to recover damages for harm caused to the government, generally with some sort of a bounty provided to the private plaintiff.

38. *See* Patricia P. Bailey, *How Advertising is Regulated in the United States*, 54 ANTITRUST L.J. 531, 534 (1985).

Supreme Court has interpreted section 7 of the Clayton Act (the primary antimerger provision of the antitrust laws) to create a presumption of illegality for mergers beyond a certain size as measured by market share, thereby shifting the burden of proof onto the merging entities to rebut the presumption of anticompetitive effects.[39] More generally, any time an administrative agency makes a finding in an administrative adjudication against an alleged violator, a defendant who invokes judicial review under the Administrative Procedure Act ("APA") bears a heavy burden in seeking to set aside that finding;[40] and under the *Chevron* doctrine, which commands judicial deference to administrative interpretations of statutes, a similar shift in favor of the agency occurs with respect to the legal standard governing any particular alleged violation.[41]

Regimes shifting burdens of proof or legal standards are probably understood, for the purposes of my analysis, as mere variants of traditional *ex post* enforcement because in the critical respects noted above—burden of delay or inertia and timing of judicial review—such regimes operate in the same way as simple prosecutions. Along the *ex post/ex ante* spectrum, therefore, we can place such systems almost all the way at the *ex post* end. Of course, any regime which favors one party to litigation over the other will change the dynamic between the parties, increasing the bargaining power of one (here the agency) vis-a-vis the other; but crucially, even when legal standards and burdens of proof have been shifted, regulated entities can still claim their day in court prior to being subjected to coercive state action (except in the rare and constitutionally problematic instances where judicial review has been precluded by Congress).

(2) Preliminary or Accelerated Injunctive Relief

Occasionally, Congress will create an administrative scheme which permits the responsible agency to seek judicial orders on an accelerated basis prohibiting conduct which the agency believes will violate regulatory standards, often in conjunction with special scheduling requirements imposed on the judiciary. A notable example was the original version of the HSR, which required

39. *See* United States v. Philadelphia Nat'l Bank, 374 U.S. 321 (1963); United States v. General Dynamics Corp., 415 U.S. 486 (1974).

40. *See generally* Administrative Procedure Act, § 706, 5 U.S.C. § 706 (1994); Universal Camera Corp. v. N.L.R.B., 340 U.S. 474 (1951). Of course, the APA's burden-shifting provisions apply only on appeal, not to the original adjudication before the agency, where the agency's prosecutorial arm typically does bear the burden of proof.

41. *See* Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-43 (1984).

expedited judicial consideration of motions for preliminary injunctions against pending mergers brought by the antitrust agencies.[42] Furthermore, almost any agency with authority to enforce a statutory scheme can also invoke general preliminary injunction procedures. Such procedures appear to bear some of the hallmarks of *ex ante* regulation, since they permit an agency to regulate and prevent conduct believed to violate substantive norms *before* the conduct occurs. Nonetheless, like shifting burdens of proof, and also because of the reasons set out above in the discussion of private injunctive actions,[43] injunctive relief—even accelerated injunctive relief—is probably best understood as a form of *ex post* prosecution because, once again, the burden of inertia remains with the agency in such situations and judicial review remains available *before* a firm becomes subject to any coercive prohibitions.

(3) Voluntary Preclearance

Certain administrative agencies have adopted procedures (whether because of congressional mandate or, more commonly, their own initiative) whereby regulated firms are permitted, but not required, to obtain prior review by the agency of conduct which the firm is concerned may, in the agency's view, violate regulatory rules. Such a system in principle has the benefits of granting firms more certainty and predictability in their actions, and of permitting agencies to stave off potential violations, without the huge volume and strongly coercive aspects of mandatory preapproval regimes. Probably the best known example of a voluntary preclearance regime is the SEC staff's issuance of "no-action letters" in response to industry requests that the Commission staff clarify whether they would recommend enforcement action against particular conduct.[44] In the antitrust area, the primary antitrust enforcement agencies, the Antitrust Division (of the DOJ) and the FTC, have established procedures to grant upon request "Business Review letters" through which the agency may express its view regarding the legality of proposed behavior.[45] Like SEC no-action letters, business review letters are not technically binding on the agency,[46] but in practice they provide a very strong assurance against action by the responsible

42. This provision was struck out by Congress in 1984. *See* 98 Stat. 3335, 3358 (1984); 15 U.S.C. § 18a(f) (1994).

43. *See supra* Part I.A.4.

44. *See* I LOUIS LOSS & JOEL SELIGMAN, SECURITIES REGULATION 532-36 n.29 (3d rev. ed. 1998); Donna M. Nagy, *Judicial Reliance on Regulatory Interpretations in SEC No-action Letters: Current Problems and a Proposed Framework*, 83 CORNELL L. REV. 921, 936-44 (1998).

45. *See* 28 C.F.R. § 50.6 (1998); 16 C.F.R. §§ 1.1-1.4 (1998).

46. *See* 17 C.F.R. § 202.1(d) (1998); 28 C.F.R. § 50.6(9) (1998).

agencies.[47] The BATF maintains a voluntary preclearance system for alcohol advertising, in parallel with its mandatory preclearance of alcohol labels.[48] Finally, the FDA has enacted a voluntary preclearance system for direct-to-consumer advertising of prescription drugs as a means of enforcing its jurisdiction over false or misleading advertising of such drugs.[49] This procedure is particularly notable because the FDA is specifically prohibited, by statute, from adopting a *mandatory* preclearance system for advertising.[50]

On their face, voluntary preclearance systems appear to offer many benefits to regulated entities, without any obvious downside. Such regimes by definition do not punish firms which fail to seek preapproval (otherwise the systems would not be voluntary), and they do not appear to create any additional enforcement authority on the part of the agency. As such, they appear to be consistent with, and merely a supplement to, traditional *ex post* enforcement. Of course, a voluntary preclearance system might impose a large, even unmanageable administrative burden on the *agency*; but that is a judgment for the agency to make in deciding whether to initiate or retain such a program.

One caveat is necessary here, however, regarding the actual "voluntariness" of a preclearance system of this sort. Most voluntary preclearance systems are truly voluntary in the sense that no untoward consequences flow from a firm's failure to take advantage of preclearance procedures. In some instances, however, an agency may seek to convert a voluntary system into what is in effect a mandatory one by threatening retaliation (generally implicitly) against firms which do not obtain preapproval. Such retaliation might simply be limited to investigation and possible prosecution of the relevant conduct; but it might also extend to other informal actions, expressing general hostility to the offending firm. In heavily regulated industries, where firm/agency interactions are common and necessary, such threats can have an enormous impact, easily converting "voluntary" procedures into required ones. There is some suggestion that the FDA's preclearance system for direct-to-consumer advertisements may operate in this way, though perhaps due more to caution on the part of firms than agency threats.[51] If a

47. *See Hearings on S. 2754 Before the Subcomm. on Foreign Commerce and Tourism of the Senate Comm. on Commerce*, 92d Cong. (1972) (statement of Walker B. Comegys); Spencer Weber Waller, *Prosecution by Regulation: The Changing Nature of Antitrust Enforcement*, 77 OR. L. REV. 1383, 1395-97 (1998).

48. *See* 45 Fed. Reg. 83,530 (1980).

49. *See* Wayne L. Pines, *Some Major Issues in Direct-to-Consumer Advertising*, 49 FOOD & DRUG L.J. 589 (1994); Hayes, *supra* note 24, at 66-68.

50. 21 U.S.C. § 352(n) (1994).

51. *See* Pines, *supra* note 49, at 590; Hayes, *supra* note 24, at 67; *cf.* Lars Noah,

preclearance procedure does operate in this way, then in effect an agency has managed to create, without congressional authorization, what is in practice a thorough-going system of *ex ante* regulation with all of the consequences that flow from it. Notably, under such a regime firms cannot in practice act before securing agency permission; and furthermore, firms in such situations probably face greater barriers to obtaining judicial review than in formal preclearance regimes because failure to provide voluntary preclearance may not qualify as "final agency action" for the purposes of APA review.[52] Voluntary preclearance must therefore be considered on the borderline between an *ex post* and an *ex ante* system of enforcement.

(4) Predisclosure Requirements

Also on the borderline between *ex post* and *ex ante* enforcement regimes are predisclosure requirements imposed on firms by regulatory schemes. Such requirements have characteristics of *ex ante* enforcement because they require action by the firm, *i.e.*, disclosing the details of its proposed course of conduct to a regulatory agency, *before* it engages in that conduct; but it also has characteristics of *ex post* enforcement in that the burden in principle remains on the agency to bring an enforcement action and invoke judicial procedures if it wishes to punish the firm or force it to change its conduct. Examples of predisclosure requirements include SEC filing requirements regarding tender offers or other corporate control transactions[53] and the FDA's "premarket notification" process for medical devices "substantially equivalent" to those in use prior to 1976.[54] In addition, many tariff-filing regimes operate in practice as predisclosure requirements since the governing statutes often permit tariffs to go into effect after a waiting period without agency approval, but require a tariff to be filed prior to any change in charges or terms of service.[55]

Like voluntary preapproval, the proper classification of

Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority, 1997 WIS. L. REV. 873, 892-93 (describing the FDA's use of consent decrees to impose otherwise forbidden advertising preclearance requirements on firms).

52. *See* 5 U.S.C. § 704 (1994); Board of Trade of City of Chicago v. S.E.C, 883 F.2d 525, 529-31 (7th Cir. 1989) (no-action letters not reviewable); Nagy, *supra* note 44, at 945 ("the weight of recent authority" suggests that "no-action letters are not 'final orders'"); *cf.* New York City Employee's Retirement Sys. v. S.E.C, 45 F.3d 7, 12 (2d Cir. 1995). *See also infra* Part II.A (discussing barriers to judicial review under pure *ex ante* regulation).

53. *See* HAROLD BLUMENTHAL ET AL., SECURITIES LAW HANDBOOK 1289-92 (1998 ed.).

54. *See* 21 U.S.C. § 360(k) (1994); 21 C.F.R. §§ 807.81 - 807.100 (1998).

55. *See, e.g.*, 47 U.S.C. § 203(b) (1994).

predisclosure procedures depends critically on how the system operates and is administered by the agency in practice. The HSR presents an excellent example of this reality. In principle, HSR created only a predisclosure regime, combined with a waiting period for consummating covered mergers—the Act requires only that prior to a merger larger than designated dollar thresholds, the merging firms must supply certain designated information to the antitrust authorities regarding the merger and affected markets and then wait thirty days from the date of notification (or fifteen days in the case of tender offers) before consummating the merger.[56] No agency approval is required. In practice, however, the HSR predisclosure requirements, combined with other interim coercive powers created by the Act,[57] operate as a preclearance regime. In particular, HSR explicitly empowers the antitrust agencies to request "additional information" from merging parties after the preliminary notification (known in the parlance as a "Second Request"), and to extend the waiting period for an additional twenty days *after compliance with the additional request.*[58] As other commentators have noted, in practice this power converts the HSR procedures into a preclearance regime because it permits the agency to impose potentially fatal delays on any merger of which it disapproves.[59] As noted above, the SEC's regulation of prospectuses for new issues also operates to some extent in this manner, converting a waiting period into a full preapproval regime through the power of delay.[60] If a predisclosure regime is administered in practice as a preapproval requirement, then like a "voluntary" preapproval regime which is in fact mandatory, such an enforcement scheme has all of the characteristics of a true *ex ante* regulatory system with the added element of greater barriers to judicial review since, unlike formal disapproval, agency manipulation of a waiting period is unlikely to be subject to effective judicial scrutiny.

(5) Interim Coercive Measures

Properly speaking, the enforcement tools described in this

56. 15 U.S.C. § 18A(b), (d) (1994).

57. *See infra* Part I.B.5.

58. 15 U.S.C. § 18A(e) (1994).

59. *See* Sullivan, *supra* note 9, at 1045; Joe Sims & Deborah P. Herman, *The Effect of Twenty Years of Hart-Scott-Rodino on Merger Practice: A Case Study in the Law of Unintended Consequences Applied to Antitrust Legislation*, 65 Antitrust L.J. 865, 881-83 (1997); *contrast* William J. Baer, *Reflections on Twenty Years of Merger Enforcement Under the Hart-Scott-Rodino Act*, 65 ANTITRUST L.J. 825, 849-52 (1997) (denying that HSR creates such undue power on the part of regulatory agencies—author is a senior FTC official).

60. *See supra* note 23.

section are not distinct "modes of enforcement," but rather aspects of broader enforcement schemes. They include such powers as the ability to engage in discovery; the ability to temporarily suspend a tariff or a license pending investigation; or more controversially, the ability to subject a firm to adverse publicity prior to any adjudication. What these steps have in common is that *in practice*, such powers grant agencies great leverage over regulated firms since the threat of interim coercion may present a firm with unpalatable options. One example of such a threat is the Second Request procedure of the HSR, described above. Other notable examples include the power of U.S. Department of Agriculture meat inspectors to close down meat packing lines for violations;[61] the power of agencies such as the Consumer Product Safety Commission to create adverse publicity regarding regulated firms;[62] and the FDA's (admittedly rarely invoked) power to seize misbranded or adulterated food in interstate commerce prior to a hearing (a seizure is a civil *in rem* action brought by the FDA against the offending merchandise, which may be brought with or without notice to the owner).[63]

Many years ago, Kenneth Culp Davis noted the highly discretionary nature of such powers, as well as their great practical importance.[64] For the purposes of this paper, the importance of an agency's ability to undertake such interim coercive measures against a firm is that they can convert any enforcement regime, including a pure traditional *ex post* system, into something more akin to an *ex ante* preclearance requirement. As noted above with regard to HSR, when combined with predisclosure requirements and/or waiting periods, interim coercive measures become *precisely* equivalent to a preclearance regime. Even in other situations, the threat of interim coercive steps gives agencies great leverage in bargaining with

61. *See* Robert A. Anthony, *"Well, You Want the Permit, Don't You?": Agency Efforts to Make Nonlegislative Documents Bind the Public*, 44 ADMIN. L. REV. 31, 36 (1992) (noting enormous coercive effect of this power).

62. The coercive effect of such publicity has been recognized by Congress to be a sufficiently serious concern that it has placed substantial procedural barriers in the path of the CPSC releasing such information. *See* 15 U.S.C. § 2055(b) (1994); Frances E. Zollers and David Barry, *A Regulation in Search of a Rationale: An Empirical Study of Consumer Product Safety Act Section 6(b) and its Effect on Information Disclosure Under the Freedom of Information Act*, 43 ADMIN. L. REV. 455 (1991) (criticizing these barriers).

63. 21 U.S.C. § 334 (1994); Marie A. Urban, *The FDA's Policy on Seizures, Injunctions, Civil Fines, and Recalls*, 47 FOOD & DRUG L.J. 411, 411-12 (1992); Richard L. Waters, *The FDA: It's Not Just About Tobacco*, 52 J. MO. B. 231, 232 (1996). Such pre-hearing seizures without notification to the owner have been held to be consistent with the due process clause. *See* United States v. An Article of Device "Theramatic," 715 F.2d 1339, 1342-43 (9th Cir. 1983).

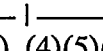
64. *See* KENNETH CULP DAVIS, DISCRETIONARY JUSTICE: A PRELIMINARY INQUIRY 23 (1969).

regulated entities, and as a result can, in practice, enable an agency to constrain a firm to conform to the agency's understanding of statutory requirements without the option of judicial review. Of course, unlike with true *ex ante* regulation, the burden of inertia remains on the agency since it is only in the face of agency action (*i.e.*, interim coercive measures or the threat of such) that a firm will be forced to yield. But such use of interim coercion does share with *ex ante* regulation the crucial characteristic, discussed in more detail in the next part,[65] that it permits the agency to impose on firms rules and obligations of its own creation, shielded from judicial oversight.

(6) Waivers

Many agencies possess legislative authority to grant waivers to regulated entities from their existing rules. Given their ubiquity, a brief discussion is necessary of the place of waivers in my typology of enforcement methods. Most waivers exist as components of other enforcement systems, both *ex post* and *ex ante*, and in principle being unusual and requiring special-circumstances, they usually have no effect on the overall structure of the scheme. If, however, an agency engages in a regular practice of granting waivers based on established criteria, especially in combination with very strict underlying rules, such a system of waivers can in effect operate as a means of *ex ante* policymaking and regulation.[66] This is because if regulations are so strict that they impede regular conduct, then a waiver operates in practice as a license for particular preapproved conduct. Such a use of waivers is presumably unusual, but not unknown, and so must be considered as one way for an agency to implement *ex ante* regulation, even in the face of statutory authorization only to engage in *ex post* prosecution.

In conclusion, regulatory enforcement modes come in many shades and varieties with an almost infinite combination of various enforcement powers being possible. There are, however, some important commonalities that emerge when such powers are viewed through the prism of the typology set forth earlier in this Part. Such commonalities do not of course capture all relevant aspects of enforcement powers, but, as the following part discusses in detail, this perspective has important implications in understanding the shape and practical operation of administrative schemes.



65. *See infra* Part II.A.

66. *See* Martin Shapiro, *Administrative Discretion: The Next Stage*, 92 YALE L.J. 1487, 1504-05 (1983).

II. Agency Discretion and Agency Power: The Consequences of Enforcement Methodology

Up to this point, this paper has focused on identifying and categorizing various methods or procedures through which regulatory agencies are authorized to enforce the substantive rules which they administer. The topic of this section is to consider why that choice might matter. In particular, by looking at some of the practical, pragmatic consequences of granting agencies particular sorts of enforcement powers, I hope to identify policy considerations suggesting why certain kinds of enforcement powers may be preferable in particular contexts, while other contexts may call for other powers. As a starting point, however, we must consider why it matters how an agency enforces its rules.

A. Power, Delay, and Judicial Review

If one begins one's analysis by contrasting pure *ex post* and pure *ex ante* systems of enforcement, basic and obvious distinctions emerge. Most fundamentally, the difference between an *ex post* and an *ex ante* system of enforcement has to do with who, between the agency and regulated firms, has residual control and power. In other words, who is in the driver's seat. As noted previously, in a system of *ex post* enforcement regulated firms remain free to act until, and unless, an agency commences proceedings against it and obtains a judicial decision supporting the agency's position.[67] In an *ex ante* system, by contrast, firms cannot act without agency approval, and if that approval is not forthcoming the firm must await action unless and until it obtains a judicial reversal. *Ex ante* regulation thus shifts the balance of power between an agency and regulated entities towards the agency. But why, one might ask, does that matter? After all, under both systems, firms are entitled to judicial review of adverse agency decisions, and so under both systems the *substantive* legal rules to which a firm is subject should be unchanged. The answer, of course, lies in the practical consequences of delay and inertia.

The great power conferred upon an agency by *ex ante* regulation is the power of delay. In a system where regulated conduct is subject to preclearance by an agency, the period of time when the agency is considering an application and, if the agency disapproves, the time

67. Note that in a true *ex post* system, preliminary agency adjudications do *not* have a legal, coercive effect on firms, since a court order is still necessary to enforce the agency decision. As noted previously, however, *supra* note 20, some agencies can in principle impose effective penalties prior to judicial review; but in practice such systems do not appear to deprive parties of access to judicial review, because of the generous interim stay provisions of the APA, 5 U.S.C. § 705.

spent appealing that decision to the judiciary are equivalent to waiting periods from the point of view of the firm—meaning that during this period, the firm cannot engage in the activities it desires. Furthermore, the power of delay is an extraordinarily potent one. In part, this is simply because time is money—any significant period of time during which firms must delay productive activities is a period when profits are being lost; and when the activity being prevented constitutes an important component of the firm's business, that delay can threaten bankruptcy. In that situation, even the *threat* of delay from the agency is a devastating one to the firm. As examples, consider a threat by a BATF official to refuse to approve a new wine label, thereby indefinitely delaying *all* sales by a winery;[68] or a threat by a USDA meat inspector to close down a meat packing line.[69] In both cases, any significant delay spells ruin for the firm. And even if delay need not mean bankruptcy, any delay in a significant activity means substantial postponed, or even lost, profits, which given the time value of money and compound interest can add up to huge sums as well as a loss of competitive position with respect to other firms. This point has been made about the HSR merger review process,[70] the FDA's drug approval process,[71] and the BATF's approval of alcohol labels,[72] and it applies with equal force to *all* agency-induced delays.

Beyond the financial consequences of delay *simpliciter*, in many circumstances excess delay can result in a collapse of the plans underlying the proposed regulated conduct. Once again, merger review provides an excellent illustration. Many mergers, especially ones involving publicly traded companies, are often extremely time-sensitive since changes in reported profits or stock prices are likely to unravel any deal over time.[73] As a consequence, a regulatory hold-up, if sufficiently long, can derail almost any significant merger. New securities issuances are likely to present similar issues, as is any activity which is time-dependent.

68. *See, e.g.*, Bronco Wine Co. v. United States Dep't of Treasury, 997 F. Supp. 1309, 1317 (E.D. Cal. 1996) (describing injury caused by winery when BATF denied plaintiff label approval).

69. *See* Anthony, *supra* note 61, at 36.

70. *See* Sims & Herman, *supra* note 59, at 885-86.

71. *See* Noah, *supra* note 51, at 878-82 (recounting incidences of FDA delay and their consequences); *see generally* Michael P. VanHuysen, *Reform of the New Drug Approval Process*, 49 ADMIN. L. REV. 477 (1997); C. Frederick Beckner, III, *The FDA's War on Drugs*, 82 GEO. L.J. 529 (1993).

72. *See Consultant, supra* note 5 ("[d]elays in review have resulted in huge financial losses to processors or importers").

73. *See* Sims & Herman, *supra* note 59, at 897 for a discussion of the practical consequences of delay for merger transactions.

One very pragmatic, but ultimately crucial, effect of the power of delay created by *ex ante* regulation and the impact that delay can have on regulated firms, relates to the availability of judicial review. As noted above, in principle *ex ante* regulation is subject to judicial review just as *ex post* regulation is, albeit in the *ex ante* context review must occur *prior* to the firm beginning its proposed conduct. Denial of a permit, license, or other sort of agency approval would certainly qualify as "final agency action" for the purposes of review under the APA.[74] In practice, however, judicial review is a slow and uncertain procedure. Even if successful, the best a firm can generally hope for is often a remand to the agency to reconsider its decision[75]—which of course translates into more delay. The problem is accentuated by the fact that judicial review of agency *delay* as such is difficult to obtain under prevailing standards.[76] As a result, since such long delays are likely to impose large, ruinous costs on firms, in the face of *ex ante* regulation judicial review becomes an impractical option and therefore a nullity. Moreover, even if in any particular case judicial review is a practicable option because delay is tolerable, a firm is often deterred from seeking review because of the fear of agency retaliation in *future* proceedings.[77] As a result, both firms and agencies know that the threat of appeal is a hollow one.

Moreover, there is no other non-judicial recourse in the face of a recalcitrant agency or an unreasonable agency interpretation of law, since congressional action is even more slow and uncertain than judicial action.

It is certainly true that in the modern administrative state legislative oversight is an important check on agency misbehavior - perhaps a more important check than judicial review. At some point, if an agency develops a reputation for abusive behavior or overreaching some corrective is likely to occur (as the IRS's current

74. 5 U.S.C. § 704.

75. *See e.g.*, SEC v. Chenery Corp., 318 U.S. 80 (1943) (holding that a reviewing court may not base its decision upon grounds not considered by the agency below).

76. *See* Noah, *supra* note 51, at 937-38; 5 U.S.C. § 706(1) (authorizing judicial review of agency action "unreasonably delayed"); Telecommunications Research & Action Ctr. v. FCC, 750 F.2d 70, 79-81 (D.C. Cir. 1984) (leading case establishing deferential test for review of agency delay); In re Barr Laboratories, Inc., 930 F.2d 72, 76 (D.C. Cir. 1991), *cert denied* 502 U.S. 906 (1991) (denying mandamus to compel FDA to expedite processing of generic drug approval application); *see also* Landgate, Inc. v. California Coastal Commission, 953 P.2d 1188 (1998) (delays in the granting of a building permit, even unreasonable delay, does not constitute a "temporary taking"), *cert. denied*, 67 U.S.L.W. 3235 (U.S. Oct. 5, 1998)(No. 98-183).

77. For allegations of such retaliatory actions by the FDA, see Noah, *supra* note 51, at 922-23 & nn.183-186. For similar accusations against the BATF, see *Consultant, supra* note 5 ("many members of the industry are reluctant to complain due to 'fear of retribution'").

woes arguably demonstrate). However, Congress is notorious for its inaction, and its lack of speed, so that a very great deal of petty, arbitrary behavior or incremental legal overreaching is possible before Congress gets involved – as again the example of the IRS seems to demonstrate. This is especially true if the regulated industry consists of small firms and lacks political clout. For all of these reasons, the theoretical availability of congressional oversight is not likely to be a substitute from the point of view of regulated firms for judicial review of individual agency behavior.

Basically, *ex ante* regulation and the power of delay that it engenders places the forces of inertia, especially judicial and congressional inertia, at the disposal of the agency. This is a powerful force since, in many situations, it results in the agency being the final unreviewable decision-maker on many regulatory issues. This effect is unquestionably true, though it is hard to prove in the negative since the denial of judicial review is observable primarily through the *lack* of judicial decisions in areas where agencies possess *ex ante* preapproval power. Many commentators have noted that the passage of the HSR, and the coercive Second Requests it authorized, has eviscerated judicial review of merger policy.[78] Other examples are more difficult to document since they are primarily evidenced by the *absence* of judicial decisions, but common sense and casual empiricism suggest that in the face of *ex ante* regulation, judicial review is often utterly impractical from the point of view of regulated firms.[79]

The combination of the threatened financial injury which *ex ante* regulation permits an agency to impose upon a firm, and the loss of judicial review which it often results in, has very practical consequences for an agency's relationship with the firms it regulates. Most obviously, in any situation where the agency and firm are likely

78. *See* Sims & Herman, *supra* note 59, at 897-98 & n.96 (citing examples of mergers failing because of the inability to obtain effective judicial review); William J. Kolasky, Jr. & James W. Lowe, *The Merger Review Process at the Federal Trade Commission: Administrative Efficiency and the Rule of Law*, 49 ADMIN. L. REV. 889, 910-11 (1997); *contrast* Sullivan, *supra* note 59, at 1052-53 (denying that HSR acts as a barrier to judicial review, though conceding that such litigation is rare); U.S. v. Northwest Airlines, No. 98-74611 (E.D. Mich.)(action by U.S. D.O.J. challenging reacquisition of Continental Airlines by Northwest Airlines).

79. For an unusual example of a successful appeal of an attempted BATF revocation of a preapproved label, see *Cabo Distrib. Co., Inc. v. Brady*, 821 F. Supp. 601 (N.D. Cal. 1992), a case which also nicely illustrates the BATF's use of preclearance powers to expand its own substantive authority; *see also* Rubin v. Coors Brewing Co., 514 U.S. 476 (1995); Hornell Brewing Co. v. Brady, 819 F. Supp. 1227 (E.D.N.Y. 1993). For a more common example of a failed attempt to obtain judicial review, which ultimately ended in a settlement, see *Bronco Wine Company v. U.S. Dep't of the Treasury*, 997 F. Supp. 1309 (E.D. Cal. 1996) (denying TRO against BATF denial of label preapproval).

to negotiate or seek settlement, such powers grant the agency a valuable, often overwhelming chit—the ability to end delay—so that the balance of power during negotiation shifts decisively towards the agency. As a result, when the agency and firm are negotiating over any substantive issue—whether it be the terms of a permit, the content of a Consent Decree, or more informal agreements regarding the firm's activities—the agency possesses the ability to impose its will on the firm in ways which may not be authorized by the governing statute, may not have been envisioned by the creators of the agency, and indeed may exceed the agency's formal powers. Lars Noah, in a recent article, has extensively detailed this sort of agency behavior, which he labels "administrative arm-twisting."[80] Noah recounts numerous instances of agencies extracting concessions from firms which exceed, and may even contradict, statutory grants of power; and many of his examples stem from regulatory contexts such as HSR merger review, FERC review of energy mergers, FDA preapproval of drugs, and FCC broadcast licensing, where the agency possesses *ex ante* regulatory authority.[81] Other commentators have made the same point about negotiations to resolve HSR merger investigations—that the "deals" that emerge from such negotiations are not true compromises, but rather are more often the result of a firm concluding that conceding to the agency's demands is the only realistic option.[82] Robert Anthony has made the same point regarding negotiations between USDA meat inspectors and meat packing plants;[83] and firms appear to have similar experiences across a range of industries subject to *ex ante* regulation.[84]

The practical impact of *ex ante* regulation and its effects on negotiating power might be illustrated by contrasting two recent antitrust controversies involving the Microsoft Corporation. In 1994, Microsoft announced its intention to purchase Intuit, the maker of Quicken, the dominant personal finances software. During the subsequent HSR investigation, the Department of Justice announced that it would seek to block the transaction. Ultimately, in the face of DOJ opposition, Microsoft dropped its acquisition plans.[85] Contrast this with Microsoft's response to the Division's efforts to limit,

80. Noah, *supra* note 51, at 874.

81. *See id.* at 876-95.

82. *See* Sims & Herman, *supra* note 59, at 887-88, 896-97; Kolasky & Lowe, *supra* note 78, at 910-11; *cf.* Sullivan, *supra* note 9, at 1051-52 (denying that most HSR settlements are coercive, because merging parties tend to be wealthy, large corporations).

83. Anthony, *supra* note 61, at 36.

84. *See Cabo*, 821 F. Supp. at 604-07 (describing coercive BATF negotiating practices during label revocation proceedings).

85. *See* Lawrence M. Fisher, *Microsoft Scraps a Software Deal that U.S. Opposed*, N.Y. Times, May 21, 1995 § 1, at 1.

pursuant to *ex post* prosecutions under section 2 of the Sherman Act, Microsoft's bundling of its Windows operating system with its internet browser. Microsoft is fighting the Department tooth and nail on this subject, and has already won an important court victory in the first phase of the battle.[86] What is striking about these two examples is that the Antitrust Division's legal position is probably *stronger* in its section 2 case than in its challenge to the Intuit merger, where the anticompetitive consequences were less obvious than what the Division claims the evidence demonstrates in the internet browser cases. Nonetheless, the vastly greater agency power generated by *ex ante* regulation has produced diametrically opposite results.

As Lars Noah points out, the problem with administrative negotiations of the sort described above is that they do not occur "in the shadow of the law."[87] The lack of effective judicial review, and the consequent lack of external constraints on the positions that an agency can take in the course of negotiations means that the results of such a negotiation are not meaningfully limited. In most settlement negotiations, no party will yield more than its worst possible outcome if it chose to litigate. Thus if judicial review were an effective constraint, no firm would agree to more onerous (or at least substantially more onerous, taking into account saved litigation costs) obligations than those imposed by the law. Similarly, no agency during such negotiations could seek, or would obtain, concessions beyond what the agency is authorized to impose under law, and certainly no agency would be able to engage in conduct forbidden by law. When the shadow of the law is lifted, however, such constraints vanish, which creates the potential for grave abuses by regulatory agencies and personnel.

B. Discretion and Supervision

One way of describing the effect of *ex ante* regulation on an agency's power is that such regulatory schemes substantially expand the scope of agency *discretion*. By granting agencies broad and unreviewable authority, such enforcement mechanisms greatly increase an agency's flexibility and latitude. Of course, this is not an entirely bad thing, since discretion is a necessary and important part of any administrative scheme, and indeed, without discretion expert

86. *See* U.S. v. Microsoft Corp., 147 F.3d 935, 956 (D.C. Cir. 1998).

87. Noah, *supra* note 51, at 912 (*citing* Robert H. Mnookin & Lewis Kornhauser, *Bargaining in the Shadow of the Law: The Case of Divorce*, 88 YALE L.J. 950, 997 (1979)); Robert Cooter et al., *Bargaining in the Shadow of the Law: A Testable Model of Strategic Behavior*, 11 J. LEGAL STUD. 225 (1982); Edward L. Rubin, *The Nonjudicial Life of Contract: Beyond the Shadow of the Law*, 90 NW. U. L. REV. 107 (1995)); *cf.* Harry First, *Is Antitrust "Law"?*, 10-FALL ANTITRUST 9, 9 (1995).

agencies would be largely pointless. Nonetheless, since Kenneth Culp Davis's pathbreaking study in 1969,[88] the existence and potential abuse of administrative discretion has been one of the great concerns of administrative law scholarship.[89]

Let us begin by considering a most basic question, which is exactly what we mean by discretion. In an excellent recent article, Edward Rubin has pointed out that there is a fundamental ambiguity in the way we understand the concept of "discretion."[90] Ronald Dworkin's classic study of the problem identified three meanings for discretion: a decision made subject to standards and review, a decision made subject to standards with no review, and a decision subject to no standards at all.[91] The first two Dworkin describes as versions of "weak" discretion, while the last he calls "strong" discretion.[92] Under this model, one might ask what kind of discretion is produced by *ex ante* regulation, and whether it is problematic. However, Rubin demonstrates that at least within the administrative context, Dworkin's model is both inadequate and misleading. First of all, *no one* within the administrative state enjoys true "strong" discretion, meaning authority subject to *no* standards, at least not regarding any important decision. Such a situation would be contrary to the basic premises of a democratic society, and as such is unsupportable.[93] Second, even when monitoring, or review, is absent within an agency structure, this is not typically because the agency affirmatively desires to create "discretion" in the sense of freedom to decide on the part of subordinates. Rather, lack of supervision tends to occur either because of practical constraints, or because the employee is trusted *not* to exercise discretion freely—*i.e.*, she is trusted to act predictably.[94] Once again, therefore, Dworkin's description of discretion does not capture the reality of the

88. *See generally* Davis, *supra* note 64.

89. *See, e.g.*, Edward L. Rubin, *Discretion and Its Discontents*, 72 CHI.-KENT L. REV. 1299 (1997); Timothy A. Wilkins & Terrell E. Hunt, *Agency Discretion and Advances in Regulatory Theory: Flexible Agency Approaches Toward the Regulated Community as a Model for the Congress-Agency Relationship*, 63 GEO. WASH. L. REV. 479, 479-80 (1995) (describing control of discretion as "the central project" of American administrative law); Richard M. Thomas, *Prosecutorial Discretion and Agency Self-Regulation:* CNI v. Young *and the Aflotoxin Dance*, 44 ADMIN. L. REV. 131 (1992); Martin Shapiro, *supra* note 66.

90. Rubin, *supra* note 89.

91. RONALD DWORKIN, TAKING RIGHTS SERIOUSLY 31-32 (1978), *cited in* Rubin, *supra* note 89, at 1301.

92. Rubin points out that in principle, one might have "strong" (*i.e.*, standardless) discretion *with* review, where the reviewer substitutes her own judgment in reviewing the original decision. *See* Rubin, *supra* note 89, at 1311. In practice, however, such a system seems absurd, since the first stage of decision becomes meaningless.

93. *See id.* at 1320.

94. *See id.* at 1306-07.

administrative process.

In place of Dworkin's description of discretion, Rubin proposes two new concepts: supervision and policymaking.[95] As Rubin points out, both of Dworkin's "weak" modes of discretion in truth refer, at least within the administrative context, to the presence of supervision to constrain decisional freedom—review does so for obvious reasons, while standards present an alternative form of supervision, based on instructions from a superior to a subordinate rather than oversight of actual implementation.[96] Strong discretion, on the other hand, translates in the administrative context into policymaking—the power to make choices regarding the content of the substantive standards which will guide the agency's actions.[97] As noted above, "true" strong discretion in the sense of standardless power is unknown in the agency context, but policymaking authority is ubiquitous and unproblematic—the very reason we create agencies is to permit them to make policy within their fields of expertise.[98] Such authority is of course not unlimited, and is subject to supervision through both substantive standards (generally incorporated in governing statutes or Executive Orders) and active oversight (presidential, congressional, and judicial); but it is there, and it is a significant aspect of the administrative state.

Viewed through the lens of Rubin's analysis, the effects of *ex ante* regulation on agency authority begin to be clarified. All of the practical consequences described above of granting agencies preapproval authority relate to *supervision*, to the impact of standards and external overseers on an agency's freedom to decide. Most obviously, *ex ante* regulation has a tendency to denude judicial supervision of agencies as a whole, by stripping firms of practical access to judicial review. In addition, the leverage that *ex ante* regulation grants agencies vis-a-vis regulated entities in negotiations tends in practice to free agencies from the substantive standards which would otherwise constrain their activities. In his study of administrative "arm-twisting," Lars Noah cites examples of such activities, including the FCC's use of licensing powers to control the content of programming, and the FDA's use of "accelerated" drug approval to elicit preclearance authority over advertising, both of which are forbidden by statute.[99] *In toto*, preclearance authority can remove most, if not all, effective supervision over an agency's activities. Policymaking authority, by contrast, exists presumably

95. *See id.* at 1301.
96. *See id.* at 1303-1314.
97. *See id.* at 1314-1324.
98. *See id.* at 1323.
99. *See* Noah, *supra* note 51, at 877-82.

under any enforcement regime and is not directly affected by enforcement mechanisms in any obvious way (though as we shall see, it is profoundly affected in nonobvious ways).

Beyond the reduction of supervision over an agency as a whole, *ex ante* enforcement mechanisms can also have important effects on supervision *within* an agency structure, in particular regarding supervision over line personnel. The power to impose delay is one enjoyed not merely by the agency as a whole but also by the line personnel who are responsible for day-to-day preapproval decisions. Given this power, firms are often placed in a difficult position when faced with seemingly unreasonable (or at least not fully authorized) demands from agency personnel. The option of complaining to higher-level agency officials generally does, of course, exist, but like judicial review, it is uncertain in effectiveness and likely to create further delay. Moreover, such an appeal runs the serious risk of angering the line personnel involved.[100] Note that unreasonable demands by agency personnel need not be the result of corruption or bad intentions, though in some instances lack of effective supervision *can* lead to line personnel acting for illegitimate, personal reasons, and exercising power arbitrarily, or in the extreme case even corruptly (though actual financial corruption seems to be an extremely limited problem, at least within the federal bureaucracy).[101]

Another preapproval context in which popular wisdom suggests the existence of widespread, often unreviewed arbitrariness is in the granting of local zoning and building permits. Once again, the power of delay, which denial of such permits threatens, allows those in authority to impose conditions (for reasons sometimes legitimate,

100. *Cf. Consultant, supra* note 5 ('most members of the regulated industry are afraid to criticize the BATF for fear of retribution. They read stories in the national press about people who fought with BATF and lost their businesses').

101. I was once recounted a story by an employee of a winery (to remain anonymous) about a BATF agent who refused to grant approval to the winery's new label (for a new vintage) because he was offended by a joke on the label. The winery eventually prevailed on the agent to approve the label, but the story illustrates the arbitrary decisions which lack of supervision can make possible. Another winery, Wild Horse Winery & Vineyards, reports that when they sought to name their reserve wine releases "Unbridled Passion," the BATF ("who else?") objected, forcing the winery to rename the releases only "Unbridled." *See* Wild Horse Winery & Vineyard, Club Sauvage Member Newsletter, p. 1 (October 1998) (on file with author). In both these instances, it is hard to believe that the BATF personnel who denied approval to the challenged labels were advancing legitimate regulatory policies. For first-hand, empirical evidence that the BATF is perceived by the industry to behave arbitrarily, see *Consultant, supra* note 5 (an industry focus group revealed that members had "grievances with respect to label review delays, inconsistencies, employee inaccessibility and rudeness," and the author, an industry insider, suggests that one cause for the problems in the BATF's preapproval process is "failure to properly train employees and monitor their performance").

sometimes not) which might well not survive judicial or higher-level scrutiny. But whatever the underlying reasons, regulated entities faced with such demands are often left with little choice but to "swallow hard."[102] The concerns raised by such arbitrary, low-level decision-making should not be underestimated. Cynthia Farina has persuasively argued that one of the greatest threats to democratic legitimacy in the modern state lies precisely in such arbitrariness and mistreatment of citizens by government officials.[103] In so far as *ex ante* enforcement powers expand the opportunities for such arbitrariness, this possibility must at least be taken into account in assessing the social value of such powers.

C. Policymaking and Substantive Standards: "Making Law"

In addition to the problems of generalized arbitrariness and lack of supervision, the existence of *ex ante* enforcement authority also raises substantial issues regarding an agency's *substantive* powers to make and interpret law. Here may lie the greatest danger resulting from the increased discretionary power generated by preclearance authority. An examination of the effects of enforcement procedures on the scope of substantive authority tends to show how the line drawn by Rubin between supervision and policymaking, as well as the distinction drawn earlier in this paper between procedural and substantive agency powers, tend to break down in practice.

The basic substantive concern raised by *ex ante* enforcement powers and the freedom from supervision which they engender is that agencies and agency personnel will use the relatively unfettered authority they enjoy in such regimes in order to coerce compliance from regulated entities with substantive rules and interpretations which are of *their* own creation and are inconsistent with the norms laid out by the legislature or the courts. In essence, the concern is that administrators will use their "discretion," their freedom, to make law. Of course, agencies make law all the time—that is the nature of delegated rulemaking authority in the administrative state. Moreover, agencies make law through adjudications and informal decisions just as they make law through formal rules.[104] In principle,

102. *See* Sims & Herman, *supra* note 59, at 888-89; *see also* William Blumenthal, *Ambiguity and Discretion in the New Guidelines: Some Implications for Practitioners*, 61 ANTITRUST L.J. 469, 488 (1993) (describing agency practice under HSR procedures, and noting the limited supervision of lower-level employees available in typical merger reviews).

103. Cynthia R. Farina, *The Consent of the Governed: Against Simple Rules for a Complex World*, 72 CHI.-KENT L. REV. 987, 1035-36 (1997).

104. *See, e.g.*, NLRB v. Wyman-Gordon Co., 394 U.S. 759 (1969) (upholding agency authority to make rules via adjudication); Ashutosh Bhagwat, *Three-Branch Monte*, 72 NOTRE DAME L. REV. 157, 176-81 (1996) (discussing agencies' ability to make rules

however, all of those instances of lawmaking occur within the constraining bounds of the scope of the agency's delegated authority. In other words, the "law" that an agency can make is limited by the statute which gave it authority as well as by judicial decisions interpreting the statute, and applying the "arbitrary and capricious" standard of judicial review under the APA.[105] However, when an agency is coercing (or to use a less charged word, negotiating) compliance in a context where outside supervision is lacking, those constraints in practice disappear. In that situation, the agency can effectively "make law" which is distinct from, perhaps stricter than, and indeed sometimes flatly inconsistent with governing statutory and judicial standards. If the new "law" that is made merely occupies the gray zone of interpretive uncertainty, it can perhaps be defended as merely an instance of an expert agency filling in gaps in a statutory scheme as it is permitted to do, and to which the *Chevron* doctrine mandates judicial deference. When this law goes *beyond* congressional and judicial authorization,[106] however, serious problems of democratic legitimacy are raised. In terms of Rubin's analysis of discretion, this is the sort of "super strong discretion" which should be impermissible within the administrative state, since it is in effect decision-making power which is subject to neither standards nor review.

Perhaps the best-known instance of an agency making law through its preclearance powers arises in the context of merger review pursuant to the Hart-Scott-Rodino Act ("HSR"), and in particular, in the shape of the various "Merger Guidelines" issued by the antitrust authorities under the Act. These Guidelines, the most important of which are the 1992 Horizontal Merger Guidelines issued jointly by the Department of Justice ("DOJ") and the FTC,[107] are officially only statements of the antitrust authorities' "enforcement policies" regarding horizontal mergers.[108] The Guidelines describe the rules which the agencies will apply in evaluating HSR merger filings, and so the standards under which the agencies will assess the legality of proposed mergers. In practice, however, the 1992 Guidelines constitute what is in effect the "law" of horizontal merger since they state rules which for all practical purposes *must* be

through enforcement policies).

105. 5 U.S.C. § 706(2)(A).

106. Note that the *Chevron* doctrine does not compel deference to agency interpretations inconsistent with prior judicial ones. *See* Lechemere, Inc. v. NLRB, 502 U.S. 527, 536-37 (1992).

107. U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines (April 2, 1992), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,104 ("1992 Guidelines").

108. *See id.*

complied with by merging firms for reasons stated previously. Indeed, in the past decade the 1992 Guidelines have become the dominant tool through which horizontal merger law is applied by practitioners and increasingly taught in law schools. Admittedly, this is not necessarily a bad thing—the 1992 Guidelines are almost certainly a superior body of rules to the confusing and inconsistent case law which they have effectively displaced—nor are the Guidelines necessarily in conflict with current judicial attitudes (and likely interpretations). The 1992 Guidelines are, however, "law" which lack any legislative, democratic pedigree, and which have been passed without the procedural protections and judicial supervision of the APA.

The merger guidelines, moreover, are not the only instance of the antitrust authorities "making law" pursuant to the HSR process. Since 1982, the Antitrust Division has adopted a policy towards proposed mergers called "fix-it-first" (the FTC had already been following a similar policy for many years). Under this policy, if, during the HSR review process the Division concludes that a merger poses anticompetitive problems, it will seek to "fix" the problem by negotiating a consent decree with the merging parties, the terms of which should address the Division's concerns, rather than to simply challenge the merger in court. The decree might require the firms to divest parts of their business, to create barriers between different divisions, or might impose even more detailed regulatory obligations on the merged firm, such as a duty to deal with competitors.[109] Like the 1992 Guidelines, in principle the consent decrees are is not a bad thing—after all, generally negotiation and settlement are superior to litigation as a means of dispute resolution. The problem is that these consent decrees are often not negotiated "in the shadow of the law." As a consequence, the agencies will sometimes extract consent decrees even when there is probably no violation of the statute under judicial interpretations[110] and the consent decrees often impose remedies which are broader and more intrusive than anything the agencies would have been likely to obtain in litigation.[111] As an example, one commentator has noted with disapproval the Clinton Administration's policy of carefully scrutinizing vertical mergers or relying on "the latest incantations of economic game theory" in its decisions to challenge mergers, neither of which positions are likely to

109. For good descriptions of the Fix-it-First policy, see Kolasky & Lowe, *supra* note 78, at 901-03, and Sullivan, *supra* note 9, at 1034-42.

110. *See* Melamed, *supra* note 10, at 13-14.

111. *See id.* at 14; Kolasky & Lowe, *supra* note 78, at 893; Michael L. Weiner, *Antitrust and the Rise of the Regulatory Consent Decree*, 10-FALL ANTITRUST 4 (1995).

gain great judicial support.[112] From the point of view of merging firms and antitrust attorneys, these consent decrees together constitute a new "law" of antitrust distinct from and in addition to the "law" of the merger guidelines. This law sets out substantive rules and theories with which parties, in practice, must comply, and lays out remedial obligations which firms must follow.

Not only have the antitrust agencies been effectively "making law" pursuant to their pre-review powers under HSR, but since the passage of HSR in 1976 the various Guidelines and other agency internal policies have become essentially the *only* law governing such mergers because of the absence of any judicial (or congressional) activity in this area. It has been widely noted that one of the most stunning and apparently unexpected effects of the passage of HSR was the virtual elimination of antitrust merger litigation in the courts.[113] The Supreme Court has not decided any substantive merger cases since 1974,[114] and one commentator reports that in the ten years prior to 1997, there were only ten substantive appellate decisions on mergers—half of which involved hospitals.[115] This paucity of litigation is not particularly surprising given the barriers to judicial relief in the HSR process noted above (an alternative source of merger litigation might have been private antitrust actions against mergers, but the Supreme Court has over the same period of time created substantial, often insurmountable barriers to such litigation in the form of the "antitrust injury" and "antitrust standing" doctrines[116]). The consequences of this, however, is that given a body of Supreme Court precedent that is a quarter-century, and several economic theories, out of date, and given the lack of other case law, the antitrust agencies' "enforcement policies" are in effect *the* law of antitrust mergers today. What is troubling about this situation is that, as noted earlier, the law created by the agencies diverges from, and in

112. Sims & Herman, *supra* note 59, at 899-900.

113. *See* Sims & Herman, *supra* note 59, at 865-66; Malcolm R. Pfunder, *Some Reflections on, and Modest Proposals for Reform of, the Hart-Scott-Rodino Premerger Notification Program*, 65 Antitrust L.J. 905, 907-08 (1997); Kolasky & Lowe, *supra* note 78, at 890-91; Melamed, *supra* note 10, at 14.

114. *See generally* United States v. General Dynamics, 415 U.S. 486 (1974); United States v. Marine Bancorporation, 418 U.S. 602 (1974); United States v. Connecticut National Bank, 418 U.S. 656 (1974).

115. *See* Sims & Herman, *supra* note 59, at 881 & n.57.

116. *See generally* Brunswick Corp. v. Pueblo Bowl-O-Mat, 429 U.S. 477 (1977); Cargill v. Montfort, 479 U.S. 104 (1986); Associated General Contractors v. California State Council of Carpenters, 459 U.S. 519 (1983). Perhaps not surprisingly, the Antitrust Division has supported and encouraged this development, thereby defending its own position as the primary creator of merger law. *See* Thomas Kauper, *The Justice Department and the Antitrust Laws: Law Enforcer or Regulator?*, 35 ANTITRUST BULL. 82, 111-13 (1990).

many respects exceeds what the antitrust statutes, as they would likely be interpreted by today's judiciary, require of firms. The "law" of mergers is thus no longer the Sherman Act, no longer the Clayton Act, and no longer judicial decisions. Instead, it is the current enforcement policies of the Antitrust Division and the FTC, largely unconstrained by outside review or standards.[117]

The above discussion of lawmaking in the shadow of the HSR review process provides an example of agencies who possess congressional authority to interpret and enforce particular statutes utilizing their preclearance powers to extend their lawmaking power, perhaps beyond statutorily permitted limits. The problem of "unauthorized lawmaking" in the context of preclearance authority is not, however, limited to agencies as a whole exceeding their statutory confines. As noted above, preapproval enforcement powers can have the consequence of weakening supervisory structures within an agency, just as they can weaken external supervision of an agency. If a lower level employee who possesses line authority to grant or deny a preapproval request chooses to impose his or her *own* rules or interpretations upon a regulated entity, often those rules can, in practice, have a binding effect no different from duly enacted regulations or statutes. Internal agency review procedures may be too slow or inadequate to provide sufficient protection to firms which are unhappy or disagree with the employee's demands, and so the firm is faced with the unpalatable choice of accepting the huge costs imposed by delay, or yielding to the employee's demands.[118] These demands might simply constitute the employee's own honest (albeit perhaps mistaken or even unreasonable) interpretation of existing statutes and regulations, or they might go well beyond any conceivable

117. Admittedly, the problem of agency enforcement policies becoming an effective source of "law" is not unique to mandatory preclearance schemes. Many commentators have noted that the SEC's *voluntary* "no-action" letter preclearance mechanism has become the source of an enormous body of effectively binding securities regulation, both because of the *in terrorem* effect of a potential agency enforcement action, and because courts often defer to SEC interpretations stated in no-action letters during litigation. *See* Nagy, *supra* note 44, at 924-26. Indeed, it has been suggested that in recent years the SEC has actively sought to employ the no-action procedures to make substantive policy while evading judicial review and the APA's procedural requirements. *See id.* at 949-53. In so far as the SEC is able to make "law" through this mechanism, however, what this suggests is that in some respects the SEC's "no-action" procedures may not be voluntary from the practical perspective of industry participants, and is in effect an *ex ante* enforcement system, though this is probably due more to industry caution than agency coercion.

118. The problem of constraining lower-level employees from abusing their discretion is of course not limited to *ex ante* enforcement regimes. The example of police officers' power to stop or arrest motorists demonstrates that the problem is universal. Nonetheless, the discussion in the text shows that the problem is likely to be *worse* within an *ex ante* rather than an *ex post* enforcement system, all other things being equal.

enacted authority. In this context, however, even the whims of agency personnel constitute "law" in a meaningful sense because they are backed up by the coercive power of the state (*i.e.*, by rules prohibiting firms from acting without preapproval or a license)—a coercive power which in a society ruled by law is and should be of the greatest concern.

One further point should be noted regarding the lawmaking power of agencies that possess preapproval authority. Until now, the above discussion has focused on an agency's use of its discretion to extend the law *beyond* authorized limits. In principle, however, an agency might also use such freedom to *restrict* the law by failing to enforce it as strictly as intended by Congress or the courts. The Reagan Administration, for example, was accused of adopting such a policy towards mergers in the 1980s. There is a significant potential limitation on such power, however, in the form of private rights of action, which can produce adjudicated challenges to private conduct even in the face of agency inaction.[119] Such private challenges are of course a direct threat to an agency's power to effectively limit or repeal regulatory standards—which perhaps explains why the Antitrust Division during the Reagan Administration actively opposed private rights of action under the antitrust laws, regularly urging the Supreme Court to limit their application.[120] The bottom line, however, is that underenforcement is not a particular vice of preapproval authority since, even in an *ex post* enforcement regime, an agency can simply choose not to bring prosecutions.

Ultimately, reasonable people may differ over the wisdom of granting agencies the sort of expanded, unchecked lawmaking authority that often comes with preapproval enforcement powers. Some might applaud the greater shift of power to expert executive-branch agencies from Congress and the courts, neither of whom possess much expertise over the technical areas which tend to be the domains of agency regulation. This same school of thought might generally also support the greater administrative discretion—meaning reduced supervision of agencies—created by preapproval enforcement authority. In this respect, one's views are likely to depend on one's opinion of the value of "expertise," as well as the relative merits of the policymaking potential of the different branches of government. Even if broader agency authority is desirable, however, presumably all would agree that such power must be exercised within the constraints imposed by Congress, and that when agencies are dealing with individual citizens some judicial supervision

119. *See* Bhagwat, *supra* note 104, at 177-78 (discussing the relationship between agency enforcement discretion and private rights of action).

120. *See* Part I.B.5, *supra*; Kauper, *supra* note 116, at 111-13 (1990).

is essential. Protecting citizens from arbitrary exercises of governmental power is, after all, the overarching purpose of judicial review in the administrative area and of the judicial power generally, in part because of the perception that political constraints on agencies are unlikely to provide sufficient protection for individuals. The difficulty with *ex ante* enforcement powers is that they enable an agency to evade even the minimal constraints and supervision provided by statutory restrictions and judicial oversight.

D. Efficiency, Deterrence, and Protecting Society: Benefits of *Ex Ante* Authority

The above discussion has primarily emphasized the concerns and drawbacks of granting an agency *ex ante* enforcement authority. Such authority, however, also has some important advantages which should not be ignored because in the final analysis, the benefits and demerits of *ex ante* authority must be balanced in deciding whether such authority should be granted in any particular circumstance.

Perhaps the most important benefit of preapproval authority involves an agency's ability to impose remedies and avert harm. This is because *ex ante* enforcement occurs *before* the challenged conduct has been undertaken, and so averts violations before they occur. This has two advantages. First, there are certain kinds of violations which are likely to create irreparable harms, which society may consider unacceptable (note that irreparable and unacceptable are not synonymous—it may be considered necessary to tolerate certain irreparable harms in the name of efficiency). *Ex ante* enforcement permits an agency to prevent such harms from occurring in a way that *ex post* enforcement cannot since the latter is not triggered until the violation and harm have already occurred. The leading example of this kind of benefit is certainly the FDA's preapproval authority over prescription drugs and food additives. In this regulatory regime, the averted harm from a violation—serious injury or death to a substantial population of citizens—is considered sufficiently irreparable and significant that the added costs of preapproval, in terms of delay and loss of supervision over agencies, are probably worthwhile. The USDA inspection regime for meatpacking plants described above[121] probably also falls within this category, as do a vast array of local building permitting and health licensing regimes.

In addition to averting irreparable harm, a preapproval regime greatly enhances an agency's ability to impose effective remedies against prohibited conduct. The concern here is that when agencies are limited to *ex post* enforcement actions, the remedial options

121. *See supra* Part I.B.5.

available at the end of such an action are often quite limited. Fines or even criminal penalties are of course always an alternative, but fines do not undo the harm (past and continuing) caused by a violation; and criminal penalties, in addition to not undoing harm, are unlikely to be imposed in a wholesale manner, especially in the absence of *mens rea*. Equitable or behavioral remedies, on the other hand, can be very difficult to impose when a violation is long past and its consequences are largely a *fait accompli*. Such concerns were in fact a major (probably the primary) motivation behind the adoption of HSR pre-review of mergers. Before HSR, the antitrust authorities often discovered that by the time they had successfully concluded a lengthy merger prosecution, the two companies were so intertwined that true divestiture, to restore the *status quo ante*, was impossible.[122] HSR prereview permits the agencies to formulate and impose a remedy *before* the merger has occurred, and thus before such barriers arise—a benefit which is reflected in the Antitrust Division's strong promotion of its "fix-it-first" policy.[123] Similar policies also probably support building permitting requirements, where regulatory officials must approve plans prior to construction—in such circumstances, the costs of curing violations *ex post* by requiring the building to be torn down and rebuilt are so exorbitant that such a remedy is unrealistic and unlikely to be imposed.

Another obvious benefit of preapproval authority is that it severely reduces the investigatory burden on agencies in enforcing the rules they are charged with administering. The problem with *ex post* prosecution schemes is that they place the burden of finding, investigating, and prosecuting violations solely on the agency. The agency must discover the violation, accumulate the evidence needed to prove it, and then engage in protracted expensive litigation before obtaining *any* relief. When violations are difficult to ferret out, the burdens imposed by such a scheme can be overpowering, leading to systematic underenforcement and thus a failure to avert the social harms which the regulatory regime is designed to prevent. Such problems are likely to be particularly severe when the underlying conduct or violations are not visible or are very numerous. *Ex ante* regulation, by contrast, places most of the burden of compliance on firms by requiring them to disclose every potential violation to the agency, and to provide the agency with sufficient information so that a determination can be made whether a violation exists or not. In effect, the firm builds the case against itself before the agency. Of course, to be effective, such a scheme must be reinforced with

122. *See* Baer, *supra* note 59, at 830-31 (recounting remedial difficulties faced by the antitrust authorities before HSR).

123. *See* Sullivan, *supra* note 9, at 1034-40.

penalties and prosecution if a firm fails to obtain the required preapproval before acting; but enforcing such penalties is likely to be less burdensome on the agency since a violation is typically easier to identify and prove.[124] Relieving investigatory burden appears to have been one of the motivations for adopting the HSR prereview process,[125] as it probably was for the BATF's preapproval authority over alcohol labels. The only caveat one might raise regarding the benefit of reduced investigatory burdens and benefits is whether a simple (and true) *predisclosure* regime might not provide many of the same benefits to the agency, without the potential for delay and unchecked power, which true preapproval authority threatens to create.[126]

Finally, it is important to note that preapproval authority may also have some advantages for regulated firms, not just for agencies. Most importantly, *ex ante* enforcement regimes permit firms to obtain information about an agency's enforcement goals, policies, and priorities *before* the firm has engaged in potentially illegal conduct, which enables the firm to avoid a violation. It is important to remember that *ex post* prosecutions are expensive and sometimes embarrassing (especially in certain consumer industries such as food or drugs), so that most firms would rather avoid them if possible, even if it means greater up-front costs. *Ex ante* regimes permit firms to clarify their legal positions and avoid inadvertent violations before they act. As with alleviating investigatory burdens, however it may be that many of the informational benefits of *ex ante* enforcement might be achievable through less intrusive means than full preapproval authority. In particular, most of the benefits to firms might be achieved if agencies established voluntary preclearance programs, or if agencies clearly disclosed their enforcement policies through prior publication, and then adhered to those policies.[127] Therefore, informational benefits to firms are not in themselves likely to be a sufficient justification for adoption of an *ex ante* enforcement

124. *See* William J. Baer, *Reflections on Twenty Years of Merger Enforcement Under the Hart-Scott-Rodino Act*, 65 Antitrust L.J. 825, 828-29 (1997). One exception to this statement might be the FDA's broad, complex enforcement policy regarding "off-label" use, which is simply an enforcement mechanism for its drug preapproval authority. *See generally* James M. Beck and Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71 (1998).

125. *See* Baer, *supra* note 59, at 828-29.

126. As the discussion above, *supra* Part I.B.4, *supra*, suggests, there is admittedly a difficult line to draw here, since to be effective a predisclosure regime must require detailed, timely disclosure, reinforced by the threat of sanctions for noncompliance; but as in the case of HSR, such a strict predisclosure regime has a tendency to mutate in practice into a preapproval regime.

127. *See* Bhagwat, *supra* note 104, at 183-84 (proposing a regime under which agencies are required to publish their enforcement policies).

regime.[128]

E. Summary: Policy Considerations Surrounding the *Ex Post/Ex Ante* Choice

The above discussion examines in some detail the relative merits and demerits of different modes of administrative enforcement. In this section, I will seek to summarize the most important aspects of that analysis and supplement it somewhat by highlighting particular factors which policymakers would wish to take into account in determining whether a particular regulatory regime would be best enforced through *ex post* prosecutions or through a system of *ex ante* agency approval.

(1) Likelihood and Willfulness of Violations

One of the most obvious factors that should be considered in evaluating the optimum enforcement regime is the frequency and likelihood that regulated firms will violate the rules of the regulatory regime, as well as the nature and willfulness of anticipated violations. As the incidence of violations becomes higher, investigatory burdens on the agency multiply sharply, suggesting the need for *ex ante* review and preapproval to reduce that burden. Concomitantly, as violations become less frequent *ex ante* enforcement becomes less necessary, since *ex post* prosecution becomes a more feasible and effective means of punishing violations and deterring future misbehavior.[129] Also of concern is the incidence rate of violations, meaning the number of violations as a fraction of the underlying regulated activity (as opposed to the sheer number of violations). As the incidence of violations rises, the costs of *ex ante* enforcement in terms of "false positives," meaning unnecessary prereview and delay of firm activities, declines and thus the case for *ex ante* regulation becomes stronger. Finally, note that the *willfulness* of violations is also relevant to the analysis. If firms intentionally evade or violate the regulatory regime on a frequent basis, the case for *ex ante* enforcement becomes a powerful one since in such a situation the costs of investigation and detection associated with *ex post*

128. Another potential benefit to firms of preapproval authority is a possible defense to tort actions. *See generally* Richard C. Ausness, *The Case for a "Strong" Regulatory Compliance Defense*, 55 MD. L. REV. 1210 (1996). This benefit, however, could also be made available through voluntary preclearance, though it generally is not.

129. One potential complication here is that the nature of the enforcement regime and the incidence of violations may not be independent – *i.e.*, the adoption of an *ex post* enforcement system may lead to an increase in violations by firms. If, in a regulatory system, such an effect is observed, and it is significant, that is of course an independent argument in favor of *ex ante* enforcement. I am grateful to Reuel Schiller for this insight.

prosecution are likely to be very high.

The only caveat one might raise regarding the above analysis concerns whether some intermediate solution less burdensome than full *ex ante* enforcement might be considered to address these concerns. In particular, predisclosure requirements might provide a reasonable alternative by reducing the investigatory burden on the agency without creating the broad discretionary authority that characterizes preapproval regimes. Furthermore, shifting burdens of proof against regulated firms may reduce the agency's litigation expenses. However, predisclosure alone is not a panacea since under such regimes the costs and burdens of litigation remain on the agency, and so when violations are common underenforcement remains a problem. Also, shifting the burden of proof does little to alleviate the agency's investigatory burden since it retains the responsibility for identifying potential violations and proving a prima facie case. All of which suggests that in the face of a high incidence of violations *ex ante* regulation is indeed an appropriate response.

(2) Ease of Detection

Closely related to the above considerations is another factor obviously relevant to the choice of an enforcement scheme: the ease with which the agency is likely to be able to detect a violation of the regulatory regime, and to determine the identity of the violator. Both of these things are likely to depend on the nature of the regulated activity. Certain kinds of regulatory violations are very public, or cause obvious and prominent injury.[130] Therefore, these violations are easily detected, and the nature of the violation makes the identity of the violator easy to determine. As an example, consider modern health warning requirements for alcohol and tobacco products. Identifying a violation of a labeling requirement is relatively easy since these products are publicly sold, making reporting of a violation quite likely. Identifying the violator is of course trivial. In those circumstances, *ex post* prosecution is likely to be an effective form of enforcement since few violations are likely to escape the attention of the agency and the investigatory burden on the agency is limited. On the other hand, certain types of violations are extremely hard to detect, or even if detected, hard to attribute to a particular perpetrator. Examples might include anticompetitive mergers, where the anticompetitive effects of a merger in terms of higher prices or excluded competitors often appear years after the merger, and are difficult to trace to a particular cause such as the merger; or pollution,

130. Unfortunately, visible, public injuries also tend to be serious and irreparable, which, as the next section indicates, is an independent, strong rationale for *ex ante* regulation. Consider as an example a nuclear accident.

which may be easily detectable, but is often difficult to attribute to a particular polluter. Under those circumstances, *ex post* regulation might be ineffective due to the massive investigatory burdens on the agency, and so *ex ante* enforcement authority may be called for.

(3) Irreparable Harm and Remedial Concerns

As the examples of FDA drug approval and HSR merger review indicate, one of the most powerful justifications for granting an agency preapproval authority is the impossibility of effectively remedying illegal actions through *ex post* prosecutions. Most notably, when a violation is likely to cause injury which is *both* irreparable and of such a serious nature that as a matter of social policy it is considered intolerable, a strong case can be made for *ex ante* enforcement authority. On the other hand, if the injury is correctable after a prosecution through either financial reparations or curative action, or if the injury is not a very serious one even if effectively irreparable, the case for *ex ante* regulation becomes much weaker. In evaluating the feasibility of repairing or remedying a harm *ex post,* it should be noted that the barriers to such a remedy might be inherent, as in the case of death or serious injury to humans; or they might be practical, as in the difficulty of divesting firms many years after a merger, of imposing any effective penalty against a violator who is judgment and punishment proof, or more generally of requiring exorbitantly expensive curative measures when the violation does not threaten immediate injury.

An alternative, but probably less effective, enforcement strategy in the face of remedial concerns might be to grant agencies a combination of a right to predisclosure and an enhanced ability to obtain preliminary injunctive relief from the judiciary (this was in fact the originally intended model for HSR). The benefits of such a regime are that it does interpose judicial review before the agency can coerce citizens, but at the same time it permits enforcement before the harm occurs. In practice, however, especially in the modern era of crowded dockets, obtaining accelerated judicial relief is often very difficult, and can be quite expensive both to society and to the agency in terms of litigation expenses, which suggests that *ex ante* enforcement may indeed be the best response to serious remedial problems.

(4) Costs of Delay

If the regulated activity is of such a nature that delay is likely to be extremely costly to the regulated entity and/or to society at large, this is a strong consideration against granting an agency *ex ante* enforcement authority. The reasons for this are two-fold. First of all,

ex ante enforcement by its nature imposes delay since prereview and approval takes time, and during that time activity must be suspended. This delay is in itself costly to society since the economic (or other) benefits of the regulated activity are foregone or deferred. In addition, the costliness of delay is the primary factor which permits agencies which enjoy preapproval authority to enlarge their discretionary authority, evade supervision, and ultimately expand their effective lawmaking power. Thus the downside risks of *ex ante* enforcement powers are much less likely to materialize in contexts where regulated firms do not face great time pressure and so are able to appeal unfavorable decisions or unreasonable demands without suffering undue loss.

If delay is very costly but an *ex ante* regime seems attractive for other reasons, some alleviative steps might be effective to at least limit the above problems. Most notably, it may be advisable to provide firms access to accelerated judicial review procedures (in so far as this is practical) in the event of agency delay or denial of permission so that the coercive impact of delay is at least limited. Another more controversial possibility is to require an agency to compensate the firm for the costs of delay in the event of successful appeal of an agency decision—though the political and practical barriers to such a solution are substantial.[131]

(5) Nature of Regulated Activity ("Preferred Interests")

One major consequence of *ex ante* enforcement authority is that it tends to weaken the constraining influence of judicial review, and concomitantly, to create wider discretionary authority in agency personnel. Such unconstrained authority should be of concern in all circumstances, but those concerns become especially heightened when the activity being regulated involves interests which are considered by society to deserve special respect and protection. The threat to liberty posed by unconstrained regulation of such activity is far more serious because of the danger that agencies will use their unsupervised power to impose arbitrary restrictions on individual freedoms. This of course suggests that preapproval authority in such circumstances is inappropriate.

The best example of a "preferred interest" raising precisely such concerns is speech. It has long been recognized that the Constitution

131. *Cf. Landgate*, 953 P.2d at 1197 (mere delay in the granting of a building permit, even unreasonable delay, does not constitute a "temporary taking" requiring compensation); Richard A. Posner, *Taxation by Regulation*, 2 BELL J. ECON. & MGMT. SCIENCE 22 (1971) (noting the incentives faced by administrative agencies to pursue distributional goals by imposing regulatory costs on firms rather than through public funding).

strongly disfavors governmentally imposed "prior restraints" on speech or the press;[132] and *ex ante* regulation would certainly qualify as such a prior restraint when the regulated activity is speech. Furthermore, the Supreme Court has indicated that unfettered or standardless discretion in the granting of licenses for speech activities, another common characteristic of preapproval regimes, is also constitutionally suspect.[133] Nonetheless, *ex ante* regulations of speech—for example, the BATF's preapproval of alcohol labels or the SEC's preapproval of securities prospectuses—have not generally been treated as unconstitutional prior restraints or otherwise constitutionally troublesome, apparently because they involve regulations of commercial speech.[134] This analysis may well provide an adequate response to the constitutional argument against *ex ante* regulation of speech, but as the Supreme Court has recently recognized, even commercial speech is deemed worthy of special protection,[135] suggesting that one should at the least be quite concerned as a matter of public policy about authorizing *ex ante* regulation of commercial speech-related activity (to say nothing of non-commercial speech).

Other examples of preferred interests where *ex ante* regulation would be troublesome include religious activities (though regulation of those would raise a host of constitutional issues as well), personal travel, and certain sexual and reproductive activities protected by the constitutional "privacy" right. Of course, not surprisingly these activities (unlike speech) are rarely subject to any *ex ante* regulation. A more controversial question is whether *ex ante* restrictions on property rights, such as those imposed by building and zoning permitting schemes, should be deemed to infringe on "preferred interests."

(6) Clarity of Rules/Benefits of Cooperation

One of the important, practical effects of an *ex ante* enforcement scheme is that it requires communication between firms and the agency prior to regulated activity occurring, and so encourages information exchange, negotiation, and even cooperation. Thus when such behavior seems especially valuable, *ex ante* regulation may be

132. *See, e.g.*, New York Times Co. v. United States, 403 U.S. 713, 714 (1971) (*Pentagon Papers* case); Near v. Minnesota, 283 U.S. 697, 713-14 (1931).

133. *See* City of Lakewood v. Plain Dealer Publ'g Co., 486 U.S. 750, 769-70 (1988); Lovell v. Griffin, 303 U.S. 444, 449-52 (1938).

134. *See generally* Frederick Schauer, *The Speech of Law and the Law of Speech*, 49 ARK. L. REV. 687 (1997). The lack of constitutional scrutiny may also be in part because the regulation is not of the press, unlike many of the prior restraint and licensing schemes which have been struck down.

135. *See* 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 501-04 (1996).

justified. Consider a regulatory regime whose substantive scope and requirements are not well understood by the public. In such a situation, preapproval procedures give guidance and certainty to the regulated public by permitting regulated firms to obtain agency advice regarding the legality of their conduct *before* they overstep the law. However, the advantages of *ex ante* enforcement in this respect should not be exaggerated. Many of the benefits to regulated firms from *ex ante* regulation, in terms of increased understanding and certainty regarding the state of the law and enforcement policy, can be obtained from *voluntary* preapproval regimes (such as the SEC's no-action letter procedures) just as effectively as from mandatory preclearance but without the coercive aspects of *ex ante* regulation. Furthermore, the implications of legal clarity, or lack of clarity, are not entirely straightforward. One might argue, for example, that clear rules actually *support* the creation of *ex ante* enforcement power because clarity tends to leave less scope for agency interpretation or avoidance of judicial review and so limits the danger of agency abuse of discretion,[136] while unclear rules give greater scope to agency overreaching and so increase the threat of abuse.

The crucial consideration, then, in whether to provide for *ex ante* enforcement may be the nature of relationships within the regulated community, more so than the clarity of rules as such. If an administrative system is characterized by friendly relationships between the responsible agency and regulated entities, preapproval authority is less troublesome because the agency and firms are likely to be able to clarify ambiguities and work out disagreements without coercion, and without overreaching by the agency through abuse of its unsupervised authority. On the other hand, where relationships are adversarial *ex ante* authority is more troublesome because it has the effect of stacking the deck heavily in favor of one side, in contradiction to the usual assumptions of our adversarial system of justice. Once again, however, the relevance of this consideration should not be overstated. *Ex ante* regulation may encourage cooperation and negotiation, but it is hardly a prerequisite for such behavior. After all, even most *ex post* enforcement actions are settled through negotiation, many before any charges have even been filed by the agency. Furthermore, even when relationships between firms and the agency are not cooperative, for the reasons noted above *ex ante* regulation may be justified if regulatory violations by firms are particularly frequent and willful.

136. One example of a permitting system where clear rules seem to limit the potential for abuse seems to be the Clean Water Act's regulation, enforced by the EPA, of all point sources of effluent discharges. *See* Clean Water Act, §§ 304(b), 306, 33 U.S.C. §§1314(b), 1316 (1994).

(7) Information Costs: Lack of a Record

One serious disadvantage of *ex ante* enforcement is that because it requires agencies to make enforcement decisions *before* the regulated activity has occurred, it necessitates decisions with a limited, sometimes inadequate record. *Ex ante* enforcement schemes typically operate by having firms, prior to engaging in regulated activity, file an application with the responsible agency seeking permission to proceed. The agency then makes its decision based on the firm's description of its planned conduct, combined with the agency's estimation of the impact or nature of the planned activity. This inquiry is by its nature guesswork, often with very limited data, and is sometimes simply impossible to conduct with any accuracy. Estimating the anticompetitive impact of a proposed merger, for example, is often such a complex undertaking that any *ex ante* analysis is likely to be very speculative.[137] A partial solution to this conundrum is to require full and thorough disclosure by firms of their planned activity as part of their permit application, with strong penalties for intentional nondisclosure. Such disclosure requirements, however, are difficult to enforce since the agency may never know what it does not know, and even if effective they do not eliminate the inherent difficulty of guessing the impact of conduct before it occurs, as *ex ante* enforcement often requires agencies to do. Furthermore, firms do not always know the precise contours of their future conduct in advance. The problem is thus to some extent an insurmountable one.

What all of this suggests is that *ex ante* enforcement may be inadvisable in contexts where a complete record may be especially helpful (or necessary) in identifying violations or determining their nature and severity. This is likely to be true when the regulation being enforced defines violations in terms of the impact of regulated activity (for example, the ban on anticompetitive mergers), or where the regulated activity does not tend to be planned in detail at inception. Under these circumstances, waiting to see what happens, *i.e.*, relying on *ex post* enforcement, may be the least costly and error-prone alternative.

(8) Volume of Regulated Activity

A final important consideration in choosing a mode of administrative enforcement is the simple volume of regulated activity,

137. Regarding the information costs of *ex ante* regulation in slightly different contexts, see STEVEN SHAVELL, ECONOMIC ANALYSIS OF ACCIDENT LAW 281-82 (1987); Richard A. Posner, *The Rise and Fall of Administrative Law*, 72 CHI.-KENT L. REV. 953, 960 (1997); Jon D. Hanson & Kyle D. Logue, *The Costs of Cigarettes: The Economic Case for Ex Post Incentive-Based Regulation*, 107 YALE L.J. 1163, 1266-71 (1998).

and concomitantly, the volume of agency decisions which would be necessary under an *ex ante* enforcement regime. In particular, when the volume of activity is high, use of *ex ante* enforcement becomes quite problematic for two reasons. The first problem is simply one of administrative costs. *Ex ante* regulation by its nature imposes substantial administrative costs since it requires the creation of a decision-making apparatus (*i.e.*, a bureaucracy) to regularly pass on applications for agency approval, and also imposes large social costs on regulated firms which must prepare and submit applications. When the volume of activity and occasions for agency review are limited, however, these costs are likely to be reasonably low, and may well be made up for in saved investigatory costs. When the volume of activity is high, however, administrative costs mount rapidly, to the point where they may overwhelm any social benefits from the regulatory scheme itself. This problem is exacerbated if the regulated activity is not only frequent, but also tends to vary greatly from incident to incident, since this requires increased agency resources to evaluate each individual application. Ultimately, the whole endeavor may well become not worth the cost—though given the self-perpetuating power of bureaucracy, that is of course no guarantee that the system will be dismantled. When volume of activity is high, therefore, authorizing *ex ante* enforcement is a perilous path on which to embark. *Ex post* enforcement, on the other hand, might be effectively employed to deter violations even in high-volume contexts through the imposition of stiff penalties, unless the incidence or willfulness of violations is especially high (see factor 1, above).[138]

Beyond the imposition of high administrative costs, high volume of activity also tends to aggravate the other problems associated with *ex ante* enforcement because it tends to create further barriers to effective supervision of agency personnel. A high volume of activity means that individual agency personnel will be evaluating large numbers of applications, probably fairly quickly and informally. Martin Shapiro designates such procedures as "high volume, low-level" decisions.[139] The pyramidal structure of an agency means that review of such decisions by agency higher-ups is likely to be quite limited. Lack of supervision, however, inevitably grants line personnel a great deal of unfettered discretion, and therefore creates the potential for arbitrariness or "rogue lawmaking" described

138. If an industry is characterized by both a high volume of activity (factor 8) and a high incidence of violations (factor 1), there seems no simple solution to the problem of effective enforcement. In that hopefully rare situation, a more basic reassessment of the regulatory regime seems called for.

139. Martin Shapiro, *Administrative Discretion: The Next Stage*, 92 YALE L.J. 1487, 1501-02 (1983).

previously. As such, a high volume of activity provides quite a compelling argument against *ex ante* enforcement.

The above discussion identifies a number of different factors which policymakers should bear in mind in deciding how to design (or reformulate) an enforcement regime for a particular administrative scheme. Obviously, not all factors will be present or determinable in any particular case, and the different factors that are ascertainable are likely to tug in different directions. The above discussion therefore does not provide a blueprint for decision, it merely provides a framework within which policy judgments can be made. However, the framework can be of great value in guiding analysis, and can be especially valuable in certain situations where a number of factors push heavily in one direction, and no strong countervailing arguments exist. In the next section, I will apply this framework to specific regulatory regimes in an attempt to generate some useful insights and identify needed reforms.

III. Evaluations and Conclusions

In the modern administrative state, *ex ante* enforcement in the form of prereview, permitting requirements, licensure, and the like are quite widespread, and can be found in a variety of substantive areas. Nonetheless, it is a fair statement that *ex post* enforcement in the form of agency-initiated investigations and prosecutions, perhaps supplemented by regular inspections or burden-shifting rules, remains the norm. *Ex post* enforcement comports better with the common law tradition, as well as with traditional American notions of due process and the proper role of the state. The question one might ask, then, is why in particular instances we have chosen to depart from that model and move towards an *ex ante* enforcement regime instead. The answers turn out to be complex and varied. In some instances, such as the FDA's preapproval powers, legislators seem to have been driven by a desire to prevent the irreparable injury that would be caused by the sale of dangerous food additives or drugs.[140] In other situations, such as HSR premerger review, the driving force seems to have been a desire to alleviate the remedial difficulties agencies faced in *ex post* prosecutions.[141] In yet other cases, such as BATF's preclearance of alcohol labels or the SEC's prereview of securities prospectuses,[142] the answer is simply unclear. Whatever the original

140. *See supra* Part II.D.

141. *See id.*

142. Given the historical context, the primary motivation behind the Securities Act of 1933 seems to have been to restore investor confidence in securities markets through a system of predisclosure and agency oversight, rather than any specific enforcement objectives or concerns. *See* THOMAS K. MCCRAW, PROPHETS OF REGULATION 169-85

reasons, the analysis set forth above provides a framework within which a reassessment might be made of the wisdom of these schemes. Many of the current *ex ante* enforcement regimes turn out to be quite defensible under my analysis, though perhaps needing some improvements to address the concerns raised in this paper; but with respect to some regulatory regimes the analysis suggests that Congress should seriously consider eliminating the agencies' *ex ante* authority, and revert instead to a more traditional prosecutorial model.

A. Hart-Scott-Rodino

The twentieth anniversary of the passage of HSR has produced a flood of commentary over the past few years assessing the merits of the legislation.[143] Some commentators strongly support HSR and its consequences,[144] others attack it,[145] while a few fall in the middle, proposing reform but not elimination of merger prereview.[146] HSR is unquestionably a hard case, given the powerful (and vociferously presented) arguments for and against its procedures. My analysis, not surprisingly, confirms that the social value of merger preclearance is open to debate. Ultimately, however, I fall within the third camp, advocating retention of the HSR procedures, but with some important reforms.

The arguments in favor of premerger review are fairly clear. Anticompetitive mergers are difficult to detect, even long after they have been consummated, and even if detected agencies face enormously expensive litigation in trying to challenge them. Furthermore, and perhaps more importantly, even if an *ex post* challenge is successfully brought, agencies then face huge remedial difficulties in trying to "undo" the merger and restore the competitive *status quo* prior to the merger; and during the time period when litigation is occurring, or a remedy is being implemented, the public at large can suffer serious financial injury from supra-competitive prices.

(1984). If so, the justification for continued retention of the preclearance requirement, over 70 years after the Great Crash of 1929, is somewhat unclear, especially in light of the great changes in financial conditions and the operation of financial markets in the intervening period.

143. *See, e.g.*, Kolasky & Lowe, *supra* note 78, at 889 (1997); William Blumenthal, *Symposium: Twenty Years of Hart-Scott-Rodino Merger Enforcement, Introductory Note*, 65 ANTITRUST L.J. 813 (1997); Baer, *supra* note 59, at 849-52 (1997); Sims & Herman, *supra* note 59, at 881-83 (1997); Malcolm R. Pfunder, *Some Reflections on, and Modest Proposals for Reform of, the Hart-Scott-Rodino Premerger Notification Program*, 65 ANTITRUST L.J. 905, 907-08 (1997).

144. *See* Baer, *supra* note 59.

145. *See* Sims and Herman, *supra* note 59.

146. *See* Pfunder, *supra* note 143; Kolasky & Lowe, *supra* note 78.

In addition, the antitrust law of mergers is notoriously vague and unclear so that premerger review probably provides a valuable avenue for merging firms to gain information regarding the relevant agencies' legal views, and in most instances to fix the merger ahead of time through negotiation to avoid any looming legal problems. Indeed, the negotiation and "Fix it First" policies adopted by the agencies towards mergers highlight the prevalence and value of negotiation in this area. Finally, the nature of the regulated activity—corporate mergers—is in no way a "preferred" or protected activity, suggesting that some additional regulatory burden should be tolerable. Thus, among the factors set forth above, factors 2, 3, 5, 6, and to some extent factor 1 (only to some extent though, as we shall see) support retention of the HSR *ex ante* enforcement scheme.

If that were the end of the analysis, reaching a conclusion would be easy—retain HSR. Unfortunately, it is not; there are also substantial arguments that HSR is socially costly. Most notably, the volume of regulated activity, meaning the number of mergers subject to HSR, is very large and, due to the interaction between inflation and the statutory jurisdictional limits, has expanded dramatically over the years from 861 in 1979 to 3,087 in 1996.[147] This expansion has imposed enormous administrative costs on the agencies, and sharply restricted their ability to perform their other duties.[148] Furthermore, the incidence of violations is relatively low—only five percent of reported transactions result in any further agency investigation (through a "Second Request"),[149] and of course not all of those result in any agency action beyond investigation. All of this means a lot of resources spent on prereview, a very large percentage of which is essentially wasted. Moreover, the social costs of HSR review are also substantial, both because filing itself is expensive and because in the context of corporate mergers delay is extremely expensive, indeed often fatal. That delay is costly also raises the danger of arbitrary agency behavior. Agency lawmaking is widely noted to be a particular problem in the merger area.[150] Finally, the complexity of the competitive analysis of mergers means that merger prereview inevitably forces agencies to make difficult judgments based on inadequate records—though this factor is admittedly of limited persuasive force because the facts necessary to properly analyze a merger are difficult to determine even after a merger has occurred. In sum, factors 1, 4, 8, and to some extent 7 push against retention of HSR prereview.

147. *See* Kolasky & Lowe, *supra* note 78 at 891 n.5.
148. *See id.* at 891 n.6; Sims & Herman, *supra* note 59 at 890.
149. *See* Pfunder, *supra* note 143 at 912.
150. *See supra* Part II.C.

Ultimately, the arguments for retention of HSR seem to be compelling, especially because the underlying activity, corporate mergers, is not so inherently valuable that administrative burdens, or even overenforcement by agencies, raise great social concerns, and because pre-HSR experience suggests that the barriers to effective *ex post* enforcement in this area are often insurmountable. Some reforms, however, are indicated. Most notably, the volume of transactions subject to HSR review should be reduced in order to cure the "high volume, low level" problem—probably by raising the jurisdictional limits of transactions subject to HSR to reflect inflation and the rise in financial asset prices since 1976, and then indexing the limits to ongoing inflation. In addition, the agencies' ability to impose delay on mergers through onerous interim procedures such as "Second Request" discovery should be curbed, perhaps by granting firms the ability to challenge such requests on an expedited basis, or more radically, by requiring the *agency* to go to court if it wishes to obtain further discovery.[151] Finally, in combination with reform of the discovery procedures, the existing time limits for agency action under HSR should be enforced strictly to insure as far as possible that the costs of delay are mitigated. Assuming these steps are taken, the HSR premerger review procedures will remain a valuable and important part of the FTC and Antitrust Division's enforcement arsenal, and well worth retaining.

B. FDA Preapproval

The primary justification for the requirements of FDA *ex ante* preapproval of food additives and drugs is unquestionably remedial, and in particular to prevent, as far as possible, the irreparable injuries that would be caused by the public sale of dangerous food or drug products. That overwhelming concern, combined with the fact that the regulated activity does not seem to implicate any "preferred interests," has led to a longstanding acceptance of the FDA's preapproval regime, albeit with some controversy due to the delays imposed by the regime on the release of new drugs.[152] Interestingly, however, the other factors laid out above almost all seem to argue against the FDA's authority, to a greater or lesser degree. The volume of regulated activities is very large, and the likelihood and

151. The latter solution creates the danger that firms will intentionally submit incomplete or deceptive HSR filings, knowing that the agency will be deterred from seeking further information. A possible solution to this problem would be to authorize stiff, prompt penalties for obviously inadequate filings.

152. *See* Noah, *supra* note 51, at 880-81 (noting complaints raised about FDA-imposed delays in release of AIDS treatment drugs, and the expedited approval procedures established by the agency in response).

willfulness of violations is small—after all, few companies would choose to intentionally release dangerous products, given the massive tort liability they would eventually face for such conduct (not to mention any moral qualms the firms may also have). Furthermore, detection of dangerous products is not particularly difficult once a dangerous product has been sold (presumably people would fall ill), and once identified a recall would effectively prevent future harm.[153] Finally, and perhaps most importantly, the costs of delay in this context are huge, particularly with respect to drugs, both to the firms who must forego profits and watch patents expire, and to society which must do without potentially valuable medical treatments while awaiting FDA review (as the AIDS controversy has demonstrated).[154]

How to balance these opposing considerations is ultimately a policy judgment that in a democracy only the elected representatives of the people can make. Congress's decision to retain the FDA's *ex ante* powers thus must be taken as a judgment that the human safety concerns addressed by the FDA preapproval regime outweigh all of the other factors cutting against *ex ante* authority. Nonetheless, some suggestions for revisions to the current system do emerge. Most importantly, all feasible steps should be taken to limit delay in the FDA's review procedures—a suggestion which is surely not radical or new.[155] In addition, the FDA should be encouraged, or in the event of agency obduracy required by Congress, to publish clear statements of its legal interpretations and enforcement policies, both in order to reduce public uncertainty, and more importantly, in order to provide a check against the kind of "private lawmaking" and overenforcement that *ex ante* enforcement authority facilitates. The FDA has in fact been notoriously resistant to such steps,[156] suggesting

153. Admittedly, firms may choose to release *ineffective* drugs sometimes and detection of such drugs would be far more difficult than detection of dangerous drugs. However, ineffective drugs do not pose the same danger of irreparable injury as dangerous drugs. Nonetheless, concern about ineffective drugs (and possible, unwarranted reliance on them by patients) provides another argument in favor of FDA preapproval authority.

154. Factors 6 and 7, clarity of rules and the need for a complete record, seem neither here nor there with respect to FDA preapproval. The current FDA standards regarding food and drug safety are indeed somewhat unclear, but that may be as much a product of as a reason for preapproval authority. And while a record of usage may be helpful to the agency, the other crucial information needed to make safety judgments—primarily clinical trials—may be easier to obtain before rather than after sale, because of the difficulty of obtaining control groups once a medication is available.

155. The details of how such reform would be implemented are, however, controversial, and fortunately well beyond the scope of this article. The difficult judgment, of course, is how far to trade off reduced delay against increased risk to human health.

156. *See generally* Lars Noah, *The FDA's New Policy on Guidelines: Having Your Cake and Eating It Too*, 47 CATH. U. L. REV. 113 (1997) (regarding FDA's arguments against being bound by its own rules); Richard M. Thomas, *Prosecutorial Discretion and Agency*

the need for legislative prodding. This step alone might do a great deal to limit the worst consequences of *ex ante* enforcement, while retaining the important benefits.

In addition to preapproval of food additives and prescription drugs, under 1990 legislation the FDA also has preapproval power over all health claims made on food labeling.[157] Here, the arguments for retention of *ex ante* enforcement powers are far weaker than with potentially dangerous food and drug products. The strongest argument for retaining *ex ante* authority is probably the difficulty of detecting false health claims, since though such claims are by definition made to the public, the accuracy of such claims is not facially obvious, and is very expensive and time-consuming to determine through investigation. In addition, it may be, as some commentators claim, that the incidence of violations is likely to be high in this area absent preclearance.[158] But the arguments against preclearance authority seem more powerful. The harms caused by false health claims which initially escape detection because of the lack of preapproval seem trivial—a little more junk food inadvertently consumed by the American public will hardly threaten the Republic, and the danger of over-reliance on "health foods" by the seriously ill seems a little far-fetched. The volume of regulated activity is potentially huge. Finally, and most critically, the regulated activity here is *speech*, a quintessential preferred interest. In light of these powerful considerations, the arguments for preapproval seem weak indeed, suggesting that Congress should seriously consider amending the 1990 Nutrition Labeling Act to limit the FDA to *ex post* enforcement powers only.[159]

Self-Regulation, 44 ADMIN. L. REV. 131, 153 (1992) (giving an example of when the FDA avoided issuing self-binding enforcement guidelines).

157. *See* Nutrition Labeling and Education Act of 1990, 21 U.S.C. §§ 343(i), (q), & (r) (1994); *supra* note 6 and accompanying text.

158. *See, e.g.*, Elisabeth A. Sachs, *Health Claims in the Marketplace: The Future of the FDA and the FTC's Regulatory Split*, 48 FOOD & DRUG L.J. 263, 268 (1993).

159. Many of the same arguments made here would also seem to apply to the FDA's preapproval of prescription drug *labeling*, suggesting the need to reconsider that power as well. The issues surrounding labeling are more complex, however, because of the difficulty of disentangling approval of the drug itself from approval of the drug's *uses* which labeling promotes (as well as because of the statutory exemption from FDA jurisdiction for the practice of medicine), and because the potential costs imposed on society by mislabeled drugs are probably much higher than those imposed by mislabeled foods. *See generally* James M. Beck and Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71 (1998); *cf.* Washington Legal Foundation v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998) (striking down on First Amendment grounds limitations imposed by FDA on drug manufacturers' provision of information regarding off-label uses of drugs).

C. BATF Preapproval of Alcohol Labels

Most of the arguments set forth in the previous paragraph regarding FDA preapproval of food health claims would also seem to argue against retention of BATF's preapproval authority over alcohol labeling.[160] The injury caused to a consumer in purchasing a few items of mislabeled alcohol seem trivial. In practice, such mislabeling is likely to consist of incorrect or difficult-to-decipher health warnings, or inaccurate or deceptive descriptions of the *precise* content of the beverage.[161] Alcohol warnings, however, are after all ubiquitous, so that one indecipherable label will not have a perceptible impact on consumer knowledge; and while misdescribing the content of a beverage does cause real, financial injury, it is hardly the sort of serious, irremediable injury associated with adulterated foods or dangerous drugs. Furthermore, as with all labeling violations, detection does not seem very difficult. The volume of regulated activity is also enormous,[162] and as discussed previously[163] the costs of delay to alcohol producers whose labels have been disapproved are very high. Furthermore, the BATF is not well known for its cooperative relationships with regulated firms or the general public,[164] suggesting that preapproval powers create a serious potential for abuse in this context, perhaps more serious than with the FDA. Finally, as with food labeling the crucial consideration here is probably that the regulated activity is speech, albeit generally (though not always[165]) commercial speech, so that prior restraints and unfettered regulatory discretion raise particularly serious concerns. It is possible to identify some arguments in favor of preclearance for alcohol labeling, most notably that the incidence and willfulness of

160. For a description of the BATF's authority in this regard, *see supra* note 4 and accompanying text.

161. Gross misrepresentations of contents seems very unlikely, since it is hardly in a manufacturer's interest to trick a consumer who is trying to buy vodka into buying gin. Instead, inaccuracies are more likely to involve subtle gradations such as the exact appellation of a particular wine, or whether a wine which is only 55% cabernet sauvignon may be described on the label as a cabernet.

162. *See Fiscal Year 1999 Treasury-Postal Appropriations: Before the Subcomm. on Treasury, Gen. Gov't, and Civil Serv. of the Senate Comm. on Appropriations*, 105th Cong. (1998) (statement of John W. Magaw, Director, BATF, that BATF has over 1.5 million approved labels on file).; *Consultant, supra* note 5 (BATF reviews approximately 60,000 labels per year).

163. *See supra* note 68 and accompanying text.

164. *See Consultant Renews Attack on BATF Label Approval Delays*, FOOD LABELING NEWS, Vol. 4, No. 4 (October 26, 1995).

165. For an example of noncommercial speech appearing on alcohol labels, consider the current controversy over the wine and industry's efforts to place *accurate* information about the health effects of wine on wine bottles. *See* Gerald D. Boyd, *New Wine Label Causes Uproar*, S. F. CHRON., March 17, 1999, at Food Section 6 (March 17, 1999).

violations here might well be significant, making effective *ex post* enforcement difficult and expensive;[166] but they seem to pale in comparison to the arguments against *ex ante* authority.

As with the FDA's preclearance of health claims therefore, there is a strong argument that Congress should repeal the BATF's preclearance authority over alcohol labeling, and replace it with an *ex post* enforcement regime.[167] If the agency contends that a pure *ex post* enforcement system would place too great an investigatory burden on it, Congress might consider combining prosecutorial authority with imposing a simple predisclosure filing obligation on firms. Such a predisclosure requirement would mandate that firms file with the agency, on or before the date of the first sale, all new labels for products the firm intends to sell to the public, but would deny the agency any power to block sales unless the agency goes to court and obtains an injunction, after proving a statutory violation. Such a scheme would appear to address all of the agency's legitimate concerns, while curbing its ability to engage in arbitrary behavior.

D. SEC Preapproval of Prospectuses

The Securities Act of 1933[168] requires that any documents to be distributed in connection with the issuance and sale of new securities must be submitted for preclearance to the SEC, and the sale may not proceed unless and until the documents are approved by the Commission's staff.[169] The primary justification for this rule would appear to be the prevention of consumer fraud, which was believed to be one of the causes of the financial instability associated with the Crash of 1929 and the Great Depression. Like FDA regulation of

166. The lack of clarity regarding labeling requirements might also seem to support preclearance, but this is a weak argument. As noted previously, tobacco products are subject to similar labeling requirements as alcohol, but with *ex post* enforcement only, and regulators have had little difficulty in devising clear standards. *See, e.g.*, 15 U.S.C. § 1333(b) (1994) (setting out detailed requirements for location and appearance of tobacco warning labels).

167. These same factors also provide a powerful argument against the BATF's resent proposed regulations which would permit the agency to unilaterally *revoke* an already approved label if the agency determined that the regulated firm was attempting to market its product to miners. *See* William S. Morrow, Jr., *Pouring Old Wine Into New Labels*, 24 Administrative and Regulatory Law News 1, 3 (Summer 1999). Such authority would provide the agency with enormous coercive power over what is after all a *speech*-related activity, and also exposes the agency's own understanding of the enormous power inherent in its preapproval power over labels.

168. 15 U.S.C. §§ 77a-77aa (1994).

169. *See* 15 U.S.C. § 77e(c); BLUMENTHAL, *supra* note 53, at 189-94. The actual SEC preclearance system for prospectuses is a bit more complicated than the text implies, and is described in more detail *supra* note 23 and accompanying text; but as noted there, in practice the system appears to operate as a true preclearance scheme.

health claims and BATF regulation of alcohol labeling, this rule constitutes *ex ante* regulation of speech, and therefore would seem to be at least suspect as a matter of public policy. The arguments for and against *ex ante* authority in this context are more complex, however, because of the distinct concerns raised by securities fraud. Unlike labeling violations, securities fraud is not always easy to detect (indeed, it is the source of large amounts of expensive litigation), and the costs imposed by undetected securities fraud are far more serious than mislabeling, since such fraud imposes injury not only on defrauded purchasers, but also on the public at large because of the resulting loss of confidence in financial markets. Individual victims, of course, can be compensated through financial reparations (assuming the violator can be located and is solvent), but the social harm of such violations is difficult to remedy through any *ex post* enforcement. The rules regarding what does, and does not, constitute securities fraud are also necessarily quite vague, so that preclearance provides an attractive avenue for firms to obtain legal advice from the agency. Finally, the SEC is an agency which appears to enjoy the respect of, and quite friendly relationships with the industry it regulates, which substantially mitigates the fear of arbitrariness and overreaching. All of these arguments suggest that the SEC's preapproval authority is distinguishable from the FDA's and the BATF's, and should be retained.

On the other hand, it should be noted that some factors argue powerfully against *ex ante* SEC authority. Most importantly, the costs of delay in the securities industry are of course extremely high, suggesting that the preapproval regime currently in place is expensive, and potentially subject to abuse (though the apparently friendly relationships between the agency and industry alleviate this concern somewhat). In addition, one might question whether the information needed to properly judge the accuracy of a sales document is really available to the agency before the sale has occurred, as required by a preclearance system, since the most controversial statements are likely to be those regarding estimates of future performance.[170] Finally, the high volume of regulated activity also cuts against preapproval, both because of high administrative costs and because high volume inevitably undermines the quality and consistency of decision-making. Balancing these competing considerations is once again a quintessentially legislative task, which at least in 1933 Congress resolved in favor of prereview. Barring constitutional concerns,[171] that judgment must be respected, though it

170. The apparent effect of this uncertainty has been to seriously limit the substantive content of securities sales documents—a result which is surely not socially beneficial.

171. *Compare* Frederick Schauer, *The Speech of Law and the Law of Speech*, 49 ARK.

is probably time for Congress to at least reconsider and perhaps (though not necessarily) reverse the judgment it made in 1933 in light of changed circumstances, including notably the enormously greater public confidence in financial markets, as well as the explosion in private securities litigation which deters violations by issuers.

E. Environmental Permits (Clean Water Act)

Two other *ex ante* enforcement systems that were briefly touched upon in this article were the Army Corps of Engineers' preclearance requirement for placing dredged materials into wetlands, and the Environmental Protection Agency's effluent discharge permitting system for point sources under the Clean Water Act.[172] The use of preclearance or permitting systems in the environmental context appears to be premised on two primary factors: the difficulty of detecting pollution and, even more so, identifying polluters under an *ex post* enforcement regime; and the irreversible harm done to the environment by pollution, which can be better prevented through *ex ante* than through *ex post* enforcement. In addition, the activities that are regulated—generally the operation of industrial facilities, or land development—are not generally considered to implicate any specially favored interests, though that consensus may be changing;[173] and policymakers appear to treat the burden of *ex ante* enforcement as an acceptable price to pay for a clean environment.

In the case of the Clean Water Act, the congressional judgment to authorize *ex ante* enforcement seems a defensible one. The EPA's permitting system has proved to be workable, in part because of the relatively low volume of activity and in part because the relatively clear rules governing effluent discharges[174] permit the EPA and regulated firms to negotiate without great danger of agency overreaching. The wetlands regulations, however, are more open to criticism. First of all, the difficulty of detection is less obvious in the case of filled wetlands, since the responsible party is almost always the landowner involved. If the concern were the agency's inability to detect violations in the first place, given the vast geographic jurisdiction of wetlands regulation, a disclosure requirement would

L. REV. 687, 691-92 (1997) (no constitutional concerns) *with* Aleta G. Estreicher, *Securities Regulation and the First Amendment*, 24 GA. L. REV. 223 (1990) (constitutional concerns).

172. *See supra* notes 25-26 and accompanying text.

173. *See* Dolan v. City of Tigard, 512 U.S. 374, 385 (1994) (striking down land use regulations pursuant to the Takings Clause of the Fifth Amendment); Lucas v. South Carolina Coastal Council, 505 U.S. 1003, 1027 (1992); Nollan v. California Coastal Commission, 483 U.S. 825, 831 (1987).

174. *See* Clean Water Act, §§ 304(b), 306, 33 U.S.C. §§ 1314(b), 1316 (1994); *supra* Part II.E.6.

seem an adequate solution. Concomitantly, the vast jurisdiction of wetlands regulation implies a very high volume of regulated activity, raising a classic "high volume, low-level" problem in supervising individual permitting decisions. Furthermore, filled wetlands are often (though admittedly not always) more easily remediable than polluted bodies of water, also reducing the barriers to *ex post* enforcement. There are also arguably preferred interests at stake here, in the form of property rights. Finally, and perhaps most importantly, the agency in question, the Army Corps of Engineers, has a reputation for actively, and arguably illegitimately, expanding its jurisdiction and powers by relying on the lack of clarity in governing rules.[175] All of this suggests an agency which is willing to wield its enforcement powers aggressively, in a context where agency/regulated relationships are likely to be contentious. In other words, this is precisely the sort of context where *ex ante* authority should be of greatest concern. It may be that Congress has judged that the high social costs of environmental harm outweigh all of these considerations, and that the loss of enforcement efficiency entailed by a move to *ex post* enforcement is therefore unacceptable; but unless such a judgment has explicitly been made, it may be time for Congress to reconsider whether the current balance is really a wise one.

The preceding discussion has provided a mere survey of some major *ex ante* enforcement schemes, as viewed through the lens of this paper's analytic framework. The same sort of analysis might be usefully applied to any number of other such regimes, as well as to administrative systems which are currently enforced through *ex post* prosecution, but might be more effective if converted to *ex ante* enforcement. Finally, it must be acknowledged that the analysis set forth here cannot alone be expected to generate legislative action—in the real world regulatory reform is a complex, political game, where no one argument can drive legislation or results. Nonetheless, it is to be hoped that the perspective, the view of the cathedral,[176] set forth here will yield some valuable prescriptions for change.

Conclusion

In the study of the regulatory state, there exists a great divide

175. *See* Robert A. Anthony, *"Well, You Want the Permit, Don't You?": Agency Efforts to Make Nonlegislative Documents Bind the Public*, 44 ADMIN. L. REV. 31, 39 (1992) (describing Army Corps' expansion of its jurisdiction through an extremely broad interpretation of the term "waters of the United States").

176. *Cf.* Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089, 1128 (1972).

between examinations of the *procedures* followed by regulatory agencies in formulating, enforcing, and defending the policies which they are authorized to implement, which generally fall within the rubric of administrative law; and examinations of the *substance* of the policies and rules implemented by agencies, which fall within the rubric of a myriad of specialized subjects such as antitrust law, environmental law, food and drug law, or regulated industries. There is of course some overlap among the scholars who specialize in these fields, but generally the subjects are taught and written about as distinct areas of the law. Within that framework, this was a paper about procedure, about administrative law. I have sought to identify and analyze the different ways or modes through which administrative agencies enforce the substantive rules and policies over which they have been given authority by the legislature. Far too little attention, either legislative or academic, has been given to this question of enforcement methodologies, which after all represent the operative mechanisms through which agencies are permitted to act against and coerce private citizens. This is unfortunate because, as I have demonstrated, the procedures through which an agency is authorized to implement regulation can have a profound and sometimes unforeseen impact on the power and discretion available to the agency, as well as on the nature of relationships between agencies and the subjects of regulation.

Beyond this fairly traditional administrative law analysis, however, I want to suggest a more basic issue which has emerged from my paper: the artificiality and danger of the traditional dichotomy in regulatory studies between procedure and substance. In fact, my analysis suggests that there is a deep relationship between the procedures through which agencies are permitted to enforce their rules and policies, and the power agencies possess to shape the substance of those rules and policies. As such, ultimately changes in procedure can result in regulated entities being subject *in practice* to profoundly different substantive rules and constraints. In closing I suggest that this close relationship between procedure and substance provides yet another reason why administrative procedure matters a great deal, and needs to be studied in detail; but also why such procedural analysis cannot be conducted in isolation from an awareness of the substantive rules which administrative procedures implement.