REGULATION, LOGIC, AND IDEOLOGY

Jerry L. Mashaw

HIS ESSAY is not another call for deregulation or another defense of some institutional device for reforming the regulatory process. Instead, I want to speculate about the political and legal dynamics of regulation, and to isolate some of the reasons regulatory programs develop as they do. I am not here concerned with stories of regulatory failure brought about by client capture, or with murky conceptions of the public interest, or with undefinable regulatory outputs, or with bureaucratic bungling. Instead, I hope to describe attributes of the post-New Deal perception of social and economic problems that combine with the modes of operation of legal institutions — legislatures, administrative bureaus, and courts—to produce a kind of "progressive logic of regulation."

In my view, the internal problem-response dynamic of the political-administrative-regulatory system tends of itself to produce increasingly stringent and pervasive regulation. But, this progressive logic is not inexorable. Indeed, as we shall see, the logic has been supported by a political ideology—what I call here the ideology of governmental efficacy. But that gets ahead of our story.

The Progressive Logic of Regulation

Step One: The Legislature Defines the Problem. One is often struck by the discontinuity between the evidence of social and economic malaise upon which legislatures operate and the Jerry L. Mashaw is a professor of law at the Yale Law School.

way the legislatures define the problems they address. The evidence is usually specific, limited, even anecdotal, but the problem as defined is general. If a toxic fog appears in Pennsylvania, the problem, as defined, is somehow not that a toxic fog appeared in Pennsylvania, but air pollution control. If Corvairs are unsafe, the problem is motor vehicle safety. If a drug manufacturer in North Carolina markets an otherwise safe compound in a toxic solvent, the problem is pharmaceutical safety.

This kind of discontinuity is not the result of simple stupidity or cussedness on the part of legislators, but reflects the common, "there oughta be a law" reaction of the general population. That reaction has embedded in it the notion that "things like that" (whatever the disaster or crisis of the moment may be) should not, in general, be allowed to happen. The law that "oughta be" is one that would prevent all such mishaps.

It may also be the case that this generality is required by the limits on legislative competence. There are, after all, constitutional prohibitions against specific or retroactive laws (bills of attainder, ex post facto laws); and the awarding of compensation on general common law principles is the function of courts—not of legislatures. If a legislature is to respond to political demand, it is virtually constrained to do so in general ways.

Step Two: The Legislature Formulates a Solution. Legislatures generally appreciate the lack of fit between the events that have occurred and the policy problem as defined. They indeed seem acutely aware that the facts that give

rise to a sense of alarm do not provide an adequate basis for a general solution. The legislative problem, then, is how to act quickly, while avoiding massive legislative error through hasty generalization (or perhaps, merely while avoiding difficult choices). The answer quite often is to move to a higher level of generality—to address the issue not even in general policy terms, but as a problem of institutional design. The need for a policy is redefined as a need for an institution that can focus on the policy question over time and can devise solutions in the light of this experience. The regulatory agency is, of course, such an institution.

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I do not mean to suggest that legislatures move in one giant step from a specific problem to an all-powerful regulatory agency. Indeed, regulatory legislation is almost always a compromise between pro- and anti-regulation forces which results in limited agency jurisdiction and, particularly, limited agency legal powers and physical resources. But, as we shall see, regulatory systems tend, through a kind of innate logic, to surmount early compromises and to move toward more complete regulatory control.

Step Three: The Agency Selects Its Approaches. Once established, the regulatory agency faces the task of implementing the legislative intent. Usually that intent is somewhat problematic regulatory legislation abounds in "public interest" standards and laundry lists of contradictory goals. But core areas are not usually in doubt: the agency is to do something about the general classes of problems that caused the legislature to act in the first place. (Hence, perhaps, the satirical but not implausible agency rule of statutory interpretation: if the legislative history is in doubt, it is permissible to consult the statute itself.) And should there still be grounds for arguing about the boundaries of those problems, a generous definition of what

they are ensures that the agency is not charged with failing to implement the legislature's mandate.

The basic challenge for the regulatory agency is to prevent the occurrences that led to its creation, while staying within the constraints on its fiscal resources and legal techniques. The regulators respond to this challenge at each of the three stages of administrative implementation: (1) data collection. (2) policy formulation, and (3) enforcement.

• Data collection. Obviously the cheapest way for regulators to obtain information about the part of the world potentially subject to their jurisdiction is to require that someone else supply the information, at that someone else's expense. In fact, one finds a substantial number of data collection and reporting requirements in agency regulations. Sometimes these requirements are directly authorized by statute; other times, though not authorized, they are imposed by the agency's threat to use powers that are authorized—and can be exercised or not depending on the cooperativeness of the regulated parties. In addition, regulators can obtain information simply by proposing to adopt certain policies and then waiting for those who favor or oppose the policies to supply the facts and arguments supporting their positions. This private production of public information costs the agency—and the legislature-nothing. And, given the usual demand for a commodity at zero price, it is not surprising to find that recordkeeping and reporting demands are high on the list of complaints by those who claim that regulators overregulate.

• *Policy formulation*. Here too, one should expect agencies to prefer procedures that are least costly to them. The least-cost method is perhaps a single secret meeting, while the highest cost is the evolution of precedent in a series of decisions after trial-type proceedings. Between these extremes lie any number of variations, including the standard method set forth in the Administrative Procedure Act—notice in the Federal Register, opportunity for written comment, and publication of a final rule. What is to be noted is that the methods least costly to the agency are also those most likely to produce general policy rather than limited decisions. The use of general rules both economizes on the resources an agency need commit to policy development (thus permitting more regulatory activity of other kinds) and maximizes the reach of any particular policy. It is not surprising to find that regulators often gravitate toward rulemaking as their dominant regulatory technique and that the regulated complain loudly of overly generalized—and thus to some degree unnecessary—regulations.

Of course, it also costs the agency something to make wrong decisions—that is, to choose wrong policies. And agencies can hardly expect to be right every time. Regulators, therefore, need guidelines for making decisions in the face of uncertainties concerning both the incidence and seriousness of problems on which they have incomplete information and concerning the costs and benefits of deciding now as against waiting for better information. A decision rule that resolves doubts in favor of regulating now, as if the problem were serious and pervasive, has obvious attraction. At the least it tends to ensure that the administrator is not embarrassed by recurrences of the difficulties that led to the legislative scheme in the first place.

A when-in-doubt-regulate rule will obviously entail some costs of overregulation (demands for useless information, unnecessary delays in producing needed goods and services, and so on), but those costs are often difficult to document and complaints about them can be put down to the usual carping of regulated groups. Failure to regulate, on the other hand, smacks of "irresponsibility," perhaps of "corruption." Overregulation does, of course, have political costs of the sort that are important to the agency in its relationships with the legislature—particularly relationships with individual legislators. Yet, the general impression of legislative oversight that one gleans from hearings or from General Accounting Office reports is of agencies subjected to continuous criticism for failure to regulate, not for regulation.

• Enforcement. The regulatory approach here mirrors the general approach to data collection and policy formation. In the best of all possible worlds for administrators—licensing—no potentially detrimental action can be taken without the agency's prior approval. The regulated party must come to the agency, supply all the data the agency deems relevant to decision making, and frequently accede to con-

ditions on its future behavior (reports, inspections, audits) that will make the agency's continuous monitoring and enforcement job easier. Nor is it necessary to have statutory authority for a licensing scheme in order to create one. If the risks associated with other forms of agency enforcement (lawsuits, cease-and-desist orders) are great enough, a "voluntary" licensing system can be created.

Enforcement systems that rely on administrative adjudication of violations are less effective than licensing. But if such systems can be combined with regulatory rules that make proof of a violation relatively straightforward, then regulatory enforcement power remains substantial. If the Federal Trade Commission (FTC), for example, must prove in a protracted adversary proceeding that an oil company's failure to post octane ratings on its pumps is an "unfair or deceptive act or practice," it can undertake few such proceedings and "voluntary" compliance is likely to be low. If, on the other hand, the FTC can adopt a rule that all companies must post octane ratings, then any enforcement action would be limited to proof that the ratings were not posted. Few companies would want to litigate that question, and voluntary compliance should be forthcoming from most or all. In short, regulators who desire to establish an effective enforcement process want to move as far away from judicial and administrative trials, and as near to pervasive licensing requirements, as possible. The movement is, of course, from less regulation to more.

The example of octane posting suggests a particular regulatory move that reduces enforcement problems—that is, the move from general performance criteria to specific directions that can be more easily monitored or enforced. In pollution control, for example, the move has been from ambient water and air quality standards to effluent limitations and finally to equipment specification. Motor vehicle safety regulations, notwithstanding statutory language to the contrary, have moved inexorably from performance toward design criteria. Occupational safety and health regulations reveal a similar pattern. But the move is not without costs. This tendency to trade the compliance efficiencies that might emerge from diverse approaches for the enforcement efficiencies of objective, performance proxies, or design requirements is often criticized as a form of overregulation.

Step Four: The Judiciary Upholds the Agency. The progression we have been describing, from limited problems to pervasive schemes, has not taken account of the fact that judicial review may limit both legislative and administrative policy making. But the record of judicial review of regulatory activity suggests that we need not make much of this-for it is in many ways the record of failed attempts to interdict the progressive logic of regulation. The twin stories of judicial attempts (1) to prevent legislatures from making general regulations to deal with individualized (or arguably nonexistent) problems and (2) to inhibit the adoption of institutional solutions to policy problems are well known. They are the stories of substantive due process and the nondelegation doctrine.

General judicial approval of agency attempts to render regulation more effective, through resourceful use of licensing and rule-making techniques, is of more recent vintage and not yet complete. Courts do not approve all agency exercises of power. Yet the tendency to approve administrative techniques for increasing regulatory power is marked. In case of doubt the operational rule of statutory construction for reviewing courts is to support agency action. The logic of doing so is impeccable. The role of the reviewing courts is to see that the congressional will is done. The agency justifies its actions as ensuring more effective implementation of that will. Q.E.D.

Step Five: Regulation Begets Regulation. Not only is there a progressive logic within regulatory programs, but regulatory activity also helps to identify yet more problems needing regulatory attention. As the United States moves into the regulation of water quality and air quality, we begin to see more and more how these aspects of environmental quality are involved with solid waste disposal and land use planning generally—and we seek to regulate the latter also. As we encounter and regulate toxicity in foods, drugs, and workplaces, we perceive residual categories of danger that can be approached only by regulating toxic substances as a whole. The opportunities for generalizing regulation abound. And the combination of evasive action by regulatees and the desire to motivate staff provide additional reasons for taking new regulatory initiatives. Indeed, given a relatively well-developed administrative state, the primary impetus for new regulatory legislation may come from the results of old programs and the initiatives of old agencies. In the United States today, step five in our process may be—I think it is—more common than step one.

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It is true that the progressive logic of regulatory expansion need not always lead us astray. If what we have been saying is correct, regulation does have a capacity to generate new data that not only identifies new problems, but also might make our subsequent efforts better informed. The bureaucratization of the Congress may have similar effects. But I am not wholly convinced. Trucks were regulated because railroads were, and when airplanes came along, regulating them seemed the natural course. And I find preposterous the extension of the Federal Communication Commission's jurisdiction to cable television. Cable, after all, solves for many television markets the technological problem that motivated the regulation of access to broadcast frequencies in the first place.

The Logic in Action

The story I have told thus far is obviously oversimplified. There are, after all, other stories of hesitant legislatures, timid administrators, agencies that produce their own information, and obstructionist courts. Yet our experience lends support to the simplified outline I have given here. Let me fill in that outline with an example: the federal regulation of pharmaceuticals.

Pure Foods and Drug Act of 1906. Significantly, the "harmful event" that gave rise to the direct

predecessor of the current Food, Drug, and Cosmetic Act was contrived by an already existing agency. (I am not sure how far back we have to go to find a step one uncomplicated by elements of step five.) In the early years of this century, Dr. Harvey Wiley, chief of the Division of Chemistry of the U.S. Department of Agriculture was determined to have Congress deal with the problem of toxic food preservatives. After failing several times to stimulate legislative action, he concocted the idea of forming what he called his "poison squad"-a group of twelve who volunteered to eat meals laced with the common preservatives of the day: borax, boric acid, formaldehyde, sulfurous acids, copper sulfate, salicylic acid, benzoic acid, and benzoates. Analysis of the effects of these chemicals on the "digestion and health" of the volunteers convinced the Congress. It banned interstate shipments of "contaminated" foodstuffs and, somewhat strangely given Wiley's interests, of "misbranded" drug preparations.

The Food, Drug, and Cosmetics Act of 1938. The so-called Wiley Act of 1906 served as the basic statute governing federal drug regulation for thirty-two years—even though the Bureau of Foods and Drugs had thought it inadequate for some time. The bureau could proceed in court against foods that were adulterated (made dangerous by some constituent) and drugs that were misbranded (fraudulently labeled). But proving to the satisfaction of a court that some long-used food preparation was dangerous or some drug fraudulently labeled was a difficult business. Given its resources, the bureau could not make much headway against the ingenuity of entrepreneurs who were busily concocting thousands of new preparations each year and who needed only to be circumspect in the *labeling* of their products to avoid censure. Under the 1906 act the bureau could not require disclosures on the labels, nor could it regulate advertising claims made elsewhere than on the label. Also, it had no way to prevent the marketing of new drugs; it could act only after the damage was done.

As early as 1933, bureau chief Walter Campbell convinced Assistant Secretary of Agriculture Rexford Tugwell that new legislation was needed. But Tugwell could not convince President Roosevelt. Then, in late 1937

came a fortuitous disaster. A drug manufacturer seeking to broaden its participation in the new and growing sulfa drug market developed the first liquid sulfanilamide preparation, using diethylene glycol as the solvent. No tests for toxicity were run before marketing. As events demonstrated, diethylene glycol induced kidney failure. Over 100 persons died before the Bureau of Food and Drugs could track down and seize all of the first forty-gallon batch of "Elixir Sulfanilamide—Massengill." Indeed, it was able to proceed at all only on the theory that "elixir" fraudulently suggested the presence of alcohol in the compound.

Within months of the tragedy, Congress adopted a comprehensive new law covering foods, drugs, and cosmetics. Under the 1938 act drugs were required to be safe, and the newly established Food and Drug Administration (FDA) was given licensing authority over all "new drugs"—that is, drugs not "generally recognized as safe by recognized experts." Such authority obviously could be used—was intended to be used—to require the testing of new drugs for safety before they were marketed.

We might note, of course, that the legislative response somewhat overgeneralized the problem. Not only did the new statute cover foods and cosmetics (where there was, to be sure, plenty of evidence of toxicity problems, although none so dramatic as in the Elixir Massengill case), but it was considerably broader than the facts might have warranted. The failure of a company to test a new product for toxicity was made the occasion, not for a requirement that companies test their products. but for a requirement that they obtain licenses from the FDA approving the safety of their preparations. Rather than specifying the testing that was to be done and sanctioning the failure to test with the traditional judicial remedies of seizure, injunction, or criminal prosecution, Congress gave the FDA the power to develop drug-testing policy through the exercise of its power to withhold licensing approval. Responding both to external events and to the internal logic whereby regulation begets regulation, Congress expanded the agency's power.

The 1962 Amendments. For nearly a quarter of a century thereafter, no major changes were made in the 1938 act. Then amendments passed

in 1962 enormously increased the FDA's impact by requiring not only drug safety but drug efficacy—both to be demonstrated by "substantial evidence" (including "adequate and well-controlled clinical studies").

Curiously, the principal force behind the amendments, Senator Estes Kefauver (Democrat. Tennessee), was primarily concerned with the price of pharmaceuticals. In a series of investigative hearings he came up with evidence showing considerable similarity in pricing on the part of drug firms and what appeared to him to be an astronomical industry-wide profit margin on many drug preparations. Following the hearings. Kefauver introduced a bill (1) to restrict patents on pharmaceuticals and require their compulsory licensing after three years, (2) to limit the profits on brand-name drugs by requiring that the generic name of the drug be disclosed in labeling and advertising, and (3) to reassure the medical profession about the quality of the far cheaper generic drugs by providing for industry-wide inspection. As a further protection against false claims, the bill also provided that new drugs be licensed only if "effective" as well as safe.

The 1962 amendments as passed embodied a twofold irony: they had little to do with what concerned either Kefauver or the public. First, Congress rejected virtually all of Kefauver's price-reducing proposals: and while it accepted the generic name and effectiveness provisions, the senator set no great store on the latter as consumer protection measures. Second, what concerned the public was safety, not efficacy. The Kefauver bill was going nowhere until the thalidomide tragedy generated interest in drug regulation. But neither the generic name provision nor the effectiveness provision would have made any difference in the thalidomide case. Thalidomide, which was an effective but unsafe generic drug, had not been approved for marketing in the United States under the 1938 act.

To be sure, the demand in the 1962 amendments for "well-controlled clinical studies" was germane to the safety issue. But that provision was (and herein lies a third irony) part of a deal with the pharmaceutical industry that was thought, at the time, to *reduce* the amount of proof needed for FDA approval of a new drug application from a "preponderance" of the evidence to "substantial" evidence.

The FDA's Problem. As of 1962, then, the FDA was administering a comprehensive licensing scheme under which drugs had to be tested clinically for safety and efficacy if they were to be admitted to or remain on the market. But to say this seriously overstates the FDA's effective control. More drugs were on the market than anyone realized, with estimates ranging from 100,000 to 250,000. Very few of these had been submitted for safety review under the 1938 act, and manufacturers would be slow to change their practices in this regard. Moreover, the 1962 amendments applied only to "new drugs"—defined in the statute as drugs "not generally recognized as safe and effective." Few manufacturers were willing to concede that their existing drugs were not so recognized and, indeed, some took the position that certain drugs marketed for the first time after 1962 were not new because they were sufficiently similar to pre-1962 drugs. (The peculiar meaning given to "newness" in the statuteone permitting a drug that has been marketed for years to be classified as new-produced understandable confusion on the reach of the 1962 amendments.)

In short, drug firms did not suddenly perceive themselves to be part of a pervasively regulated industry, and did not willy-nilly apply for FDA permission to put or retain all their preparations on the market. Moreover, the FDA's enforcement powers were unchanged. If it thought a new drug was being marketed without an approved new drug application (NDA), it had to pursue the drug or its manufacturers in court. There it would have the burden of proving that the drug was not generally recognized as safe and effective. For all the hundreds of thousands of drugs on the market, this was hardly feasible. Besides, even if the manufacturer submitted to the FDA's jurisdiction, the statute required that the agency give the manufacturer a formal hearing before denying clearance—an important requirement since the agency had, in 1962, only two hearing examiners (one of whom had been tied up for nearly ten years in a formal proceeding on the definition of peanut butter).

In a nutshell, at one and the same time the agency was empowered and rendered impotent by its legislative mandate. It had a mammoth regulatory task, but only time-consuming means of enforcement. In its case the licensing

technique, which in general gives administrators considerable leverage, seemed to confer no appreciable power. The definition of "new drugs" (those not generally recognized as safe and effective) permitted the potential licensees to confer the license on themselves, or at least to believe that they already held one.

Really, the FDA had two problems: (1) convincing manufacturers to submit post-1962 drugs, and pre-1962 drugs never previously submitted, for approval and (2) developing an expeditious procedure for revoking pre-1962 safety approvals for drugs that were not generally recognized as effective. The first problem could be solved only in the courts and then only if the agency could make wholly unrewarding any litigation concerning "newness" (does the drug have current "recognition"?) or "grandfathering" (was the drug generally recognized as safe and effective prior to the 1962 act?). Several courts did award the FDA summary judgment against drugs on the strength of a simple affidavit that no medical literature had been found reporting the results of clinical trials concerning them. But most preparations did not fall into this category.

The problem of revoking pre-1962 approvals posed similar difficulties. The FDA contracted with the National Academy of Sciences-National Research Council for a review of the effectiveness of all its previously approved drugs, based on the existing literature. But when the agency proposed, following NAS-NRC recommendations, to withdraw a prior approval, manufacturers uniformly demanded trial-type administrative hearings—hardly less burdensome than court trials. Indeed in one sense, the administrative hearings were more burdensome: the FDA had to supply the hearing officers.

The FDA's Solution. After false starts and some confusion, the agency devised a solution to its legal problems. The solution involved three somewhat problematic assertions:

• First, that the agency had the power to define by regulation the attributes of "substantial evidence"—including the attributes of an "adequate and well-controlled clinical study"—and to treat as not generally recognized as effective any drug that had not been proved effective by such a study. With this power claimed, the FDA proceeded to define "substan-

tial evidence" to include only evidence of the highest scientific caliber—basically a double-blind clinical study in which neither patients nor doctors know who is receiving the tested drug. And it claimed that "general recognition" and "substantial evidence" were the same question (thereby rendering wholly irrelevant the results of years of clinical use by thousands of physicians who were prepared to attest to a drug's efficacy).

- Second, that satisfaction of the substantial evidence standard was a question within the agency's primary jurisdiction—that is, "newness" not only need not but could not be litigated in court. This assertion of primary jurisdiction to make "newness" decisions was a sharp departure from prior practice.
- Third, that the FDA could refuse a request for a hearing and award itself summary judgment, withdrawing an NDA whenever the evidence submitted in favor of a drug did not measure up to the agency's substantial evidence definition. This summary judgment power seemed to read the hearing provision out of the statute. If the evidence were not substantial, then no hearing would be granted. If it were substantial, no hearing would be necessary, and the drug would simply be approved.

The validity of these claims was ultimately put to the Supreme Court in five companion cases, decided in 1973. The FDA's basic argument to the Court was that Congress had intended in 1962 to institute effective, pre-clearance regulation of drugs. The agency could not, it argued, carry out that legislative mandate except with the powers asserted. Indeed, the agency went further to suggest that any diminution of the powers asserted would undermine not only what the agency had done, but also its future plans. Those plans included standardizing the composition and labeling claims of the tens of thousands of over-the-counter drugs by issuing general regulations that would exempt from NDA approval drugs that satisfied the composition and labeling instructions of the proposed OTC monographs.

The FDA prevailed on every issue. On each interpretive question there was some legislative history or some prior judicial decision concerning the inherent power of some other agency that supported the FDA's position. In cases of doubt—and all the FDA's assertions of power were in some ways doubtful—the propensity to

interpret statutes in ways that would further the general regulatory purpose tipped the balance. Phrases like "only paralysis would result", "the overriding purpose of the 1962 Amendments", "the deluge of litigation that would follow", and "the regulatory scheme would be severely undermined" punctuate the Supreme Court's opinions.

The Ideology of Governmental Efficacy

I do not know whether this tendency to extend and generalize the regulatory posture of the FDA is proof that overregulation is abroad on the land. The question of how much regulation is enough is outrageously complicated. But it does seem clear that there are strong institutional biases—in legislatures, administrative agencies, and reviewing courts-toward resolving ambiguous questions of regulatory policy or regulatory power in favor of the exercise of governmental control. The Federal Trade Commission, the Federal Power Commission, and the Federal Communications Commission would provide a number of further examples -as indeed would the newer health and safety regulatory agencies (though the developments in the latter cases have not had nearly so long to work themselves out).

This progressivity of regulatory systems seems to be tied directly to the ideology of governmental efficacy—that is, the view that government is, and must be, an effective agent for getting things done. Only a legislature committed to that ideology need act to solve problems in the face of pervasive uncertainties about their dimensions and their remedies. Only administrators who view ineffectiveness as the cardinal bureaucratic sin need resolve jurisdictional doubts and surmount budgetary constraints by exploiting techniques for amplifying their power. Only courts that accept, at least implicitly, this dominant political ideology could resolve conflicts concerning private rights and governmental power by invoking the government's need for the power asserted.

It is from this perspective that we should view many contemporary proposals for regulatory reform. Legislative vetoes, sunset laws, regulatory budgets (budgets reflecting the costs of compliance), and regulatory impact statements are all devices for inhibiting the progressive logic of regulation. Each provides some new stopping point for evaluating policy or institutions, and some opportunity for analysis free from the inertial force of an ongoing regu-

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latory system. But, from this perspective, one may doubt that these devices by themselves will have a substantial impact on the amount and kind of regulation. Without an ideological shift of some proportions they seem doomed to ineffectiveness.

Yet, it will be said, surely these proposals and their growing political acceptance suggest that such a shift is in fact taking place. Indeed, I would argue that like most other ideologies in American politics, governmental efficacy is recognizable as such only because we have begun to lose the faith. For years it masqueraded as a functional and pragmatic antidote to the "hidebound" ideology of free enterprise. Now, as we increasingly question the capacity of governmental institutions, the prior era's pragmatism is revealed as only another ideology.

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It is improbable, of course, that we will return to our once-upon-a-time free market ideology, just as it is improbable that we will pass through what President Carter terms our crisis of confidence to embrace once again the ideology of efficacy. We are probably headed somewhere else, toward some new ideology that will work itself out slowly and be fully recognizable only as it is passing away. As that process goes, so goes regulation.