David L. Weimer
University of Wisconsin

Essays on Alternatives to Formal Rulemaking

The Puzzle of Private Rulemaking: Expertise, Flexibility, and Blame Avoidance in U.S. Regulation

David L. Weimer is a professor of political science and public affairs at the University of Wisconsin–Madison. In addition to his long-standing interest in policy craft, his current research focuses on the areas of health and environmental policy. He currently serves as president of the Association for Public Policy Analysis and Management.
E-mail: weimer@lafollette.wisc.edu.

The standard federal regulatory process in the United States involves notice and comment by government bureaus. This traditional agency model of public rulemaking faces difficulties in taking full advantage of the expertise of stakeholders, and it has been criticized as being slow and inflexible; therefore, it is not surprising that alternative institutional forms involving the delegation of rulemaking to stakeholders have appeared. Yet it is surprising that private rulemaking has been used to allocate valuable goods such as transplant organs. Why is private rulemaking used as an allocative institution of governance? The answer recognizes the advantages it offers in certain rapidly changing circumstances in which essential expertise inheres in the stakeholders, as well as the asymmetric political rewards involved in the allocation of highly valued goods, which create incentives for politicians to avoid blame by delegating substantive rulemaking authority to nongovernmental organizations.

Regulatory agencies in the United States face inherent difficulties in responding rapidly, flexibly, and effectively to changing circumstances such as scientific advances and technological change. Procedural requirements that are intended to promote fairness, especially opportunities for dissatisfied stakeholders to challenge rules in court, slow the responsiveness of regulatory agencies to changing circumstances. Civil service rules, which make it hard to hire, retain, and fire, hinder the assembly of staff with sufficient expertise to access fully the implications of innovative scientific research or novel technologies. These difficulties have prompted two types of adaptation in the "agency model" of rulemaking. First, many agencies employ advisory panels to supplement in-house staff with expertise from scientists and practitioners who are involved in cutting-edge research and medical practice. Second, agencies often attempt to involve stakeholders in the development of regulations through the process of negotiated rulemaking. A very different approach involves *private rulemaking,* through which stakeholders exercise explicitly delegated authority over the development and adoption of rules within the framework of a nongovernmental organization (NGO). What potential advantages does private rulemaking offer, and why has it been adopted?

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Although the answers to these questions should be of general interest to students of public administration, they are even more important because private rulemaking is being used in a number of areas in which valuable goods are allocated. For example, the substantive rules governing the allocation of transplant organs, literally a matter of life and death, are made by an NGO. This poses an apparent puzzle: Why have politicians delegated the allocation of such valuable goods to private rather to public rulemakers?

Private rulemaking comprises three essential elements: First, it is carried out by an NGO that includes representatives of the major stakeholders. Second, the NGO has a charter, either under statute or administrative delegation, to formulate the substantive content of rules under a specified voting procedure. Third, the rules have immediate effect because those whose actions are necessary to implement them are members of the NGO, or, if the NGO is accountable to a regulatory agency, the agency generally accepts the substance of the rules through either passive acquiescence or routine approval.

For example, under the National Organ Transplant Act of 1984, the Organ Procurement and Transplantation Network was created to establish rules for the allocation of cadaveric solid organs, items of high value because of their life-saving capacity and scarcity. Transplant centers and organ procurement organizations, among other stakeholders, must be a member of this NGO to

be eligible for participation in federal programs, and they are subject to the rules by virtue of their membership in the NGO. Although the U.S. Department of Health and Human Services must approve the rules though a public rulemaking process in order to make them legally binding, it has yet to issue a rule concerning the hundreds of particular rules that have been made and put into effect by this NGO. Thus, the board of the Organ Procurement and Transplantation Network votes to enact the rules that actually determine the allocation of organs among patients and transplant centers.

The discussion that follows attempts to unravel the puzzle of private rulemaking. The preliminary task is to review public rulemaking, its major criticisms, and the institutional innovations that have attempted to respond to these criticisms. The next task is to present examples of private rulemaking as a basis for induction about the circumstances of their use. The final task is to set out hypotheses about the selection and operation of private rulemaking.

Public Rulemaking

In the United States, executive agencies issue rules that are relevant to health, safety, and environmental quality under authority delegated by Congress through various statutes. Federal agencies exercise this quasi-legislative authority under the general guidelines established by the Administrative Procedure Act of 1946, which was intended to ensure procedural fairness in the regulatory process, as well as under the specific provisions of their enabling statutes. Broadly speaking, the Administrative Procedure Act requires agencies to publish proposed rules and to accept comments from the public for a period of no less than 30 days before publishing their final rules in the *Federal Register,* which are then incorporated into the *Code of Federal Regulations.* Rules may be challenged in federal court if they violate procedural due process or fail to be supported by substantial evidence. As a consequence of these procedural requirements, and the opportunity for disgruntled parties to seek judicial review, the regulatory process often moves slowly.

Federal regulatory agencies, whether they are embedded within the hierarchies of executive departments, such as the regulatory offices of the Environmental Protection Agency (EPA) or the Food and Drug Administration (FDA), or established as independent commissions with appointed boards of directors, such as the Federal Communications Commission and the Federal Trade Commission, hire and fire according to civil service rules administered by the Office of Personnel Management. These rules slow the hiring process, sometimes discouraging qualified people from pursuing federal careers. Efforts to set fair salary structures across all federal executive agencies make it difficult for agencies to compete with the private sector for employees with particularly rare skills that have not been recognized in established job classifications. In the case of active researchers, these factors make it difficult for agencies to convince them to trade laboratory for regulatory work.

Even when effective leadership and favorable organizational cultures help agencies to develop effective in-house expertise that is relevant to their general regulatory missions, the serendipity of scientific research and technological development may thrust new issues that demand specialized expertise onto the regulatory agenda. By their very nature, new scientific and technological claims tend to be controversial, denying agencies the luxury of simply observing a consensus among the relevant experts. When scientific developments raise health and safety concerns, it may not be politically possible or socially desirable for the agency to wait for a consensus to develop on its own. It is not surprising, then, that agencies seek out ways of obtaining the advice of those with the specialized knowledge needed to supplement general intramural expertise.

Tapping Extramural Expertise: Advisory Panels

The federal government has a long history of using advisory panels. George Washington convened a number of commissions, including the Whiskey Rebellion Commission (Smith 1992, 14), and as early as 1842, Congress sought to control executive-branch expenditures on advisory commissions (Croley and Funk 1997, 453). As science and industry became more entangled with executive agencies during World War II and the Cold War, the number of advisory committees grew substantially. Research sponsors, facing the problem of having less information about the integrity and productivity of researchers than about the researchers themselves, came to rely heavily on advisory and peer-review panels in their evaluation of research proposals (Guston 2000). For example, by the mid-1980s, the National Institutes of Health had formed 65 study sections that met thrice yearly to review research proposals (Barke 1986, 83). The role of advisory committees in rulemaking increased with the economic interventions of the New Deal. The demands for scientific and technical advice increased further as the scope of federal health and safety regulation expanded; for example, in 1962, the Kefauver-Harris Amendments to the Food, Drug, and Cosmetics Act required the FDA to assess the efficacy of all drugs approved for marketing between 1938 and 1962 (Friedman 1978, 206). In 1970, a congressional report estimated that approximately 3,000 committees of all types were advising the federal government (Croley and Funk 1997, 460).

As a result of congressional concerns about the large number of advisory committees, their expense, inconsistencies in their use, and the lack of balance in their memberships, the Federal Advisory Committee Act was

passed in 1971 (Smith 1992, 22). It put in place the current legal framework for the establishment and use of groups assembled to offer advice or recommendations to the federal government. Its provisions fall into three broad areas (Croley and Funk 1997, 461–65).

First, provisions of the act address concerns about the unnecessary use of advisory committees. Standing committees of Congress are required to review the advisory committees serving the agencies they oversee and determine whether the roles of the proposed advisory committees could be played by agency personnel or existing committees. To encourage agencies to reassess their need for existing committees, the act requires that committees be rechartered every two years unless otherwise specified by statute. As a result, the number of committees fell from 1,439 in 1972 to 816 in 1978 (Petracca 1986, 85), rising slowly since then to the current 948 (GAO 2004, 64).

Second, provisions of the act address concerns about the formation of advisory committees whose members share particular views, such as committees consisting solely of members drawn from an industry. The act requires Congress to seek fair balance in terms of the points of view represented among the members of committees it authorizes, and it has been interpreted through subsequent regulations as placing the same requirement on agencies. These regulations require agencies to announce their intention to convene an advisory committee in the *Federal Register,* assess potential conflicts of interest, monitor committees closely by maintaining control over committee agendas and meetings, and ensure that an appropriate federal employee is present at every committee meeting. Studies of advisory committees both before (Friedman 1978) and after (Petracca 1986) the passage of the 1972 act raise concerns about undue industry influence relative to that of consumers. Nonetheless, based on a detailed assessment of the National Drinking Water Advisory Council, Steven Balla and John Wright (2001, 811) argue that agencies give weight to interest group endorsements of committee nominees so that the pattern of interest representation on the committee mirrors that in Congress; more generally, public interest group endorsements clearly indicate to members of Congress the policy preferences of appointees, perhaps facilitating fire-alarm oversight.

Third, provisions of the act address concerns about openness. In the spirit of the Freedom of Information Act, enacted in 1966, and the Government in the Sunshine Act, which followed in 1976, the Federal Advisory Committee Act requires that advisory committee meetings not only be announced in advance in the *Federal Register* but also, with few exceptions, be open to the public. Detailed minutes of meetings must be kept and made available to the public for inspection and copying.

Agencies continue to rely heavily on advisory committees. For example, a 1992 study by an Institute of Medicine committee found that the FDA employed 41 standing technical advisory committees to help with the evaluation of specific drugs, biological products, and medical devices and especially with respect to biological products, to help the agency set general guidelines (Rettig, Early, and Merrill 1992). Committees dealing with controversial issues may draw audiences in the hundreds, including representatives of drug sponsors, their competitors, investors, and the media, suggesting that participants view committee recommendations as influential (Rettig, Early, and Merrill 1992, 34).

How well do advisory committees serving regulatory agencies operate within this framework? Sheila Jasanoff (1990) sought to answer this question through case studies of a number of advisory committees used by the EPA and the FDA. Based on her research, she concludes that a strict separation of science from politics is generally impractical (230). Furthermore, attempts to maintain a strict separation often produce more conflict than explicit integration of science into policy making (231). Advisory committees seem to be most effective when they facilitate negotiation among divergent views, both scientific and nonscientific, and when they are successful in drawing sharp boundaries as to which issues are considered scientific and, therefore, not subject to challenge by nonscientists (234–36). The primary challenge in the use of advisory committees, according to Jasanoff, is not guarding against the danger that a narrow scientific view will dominate the regulatory process, but finding better ways for the agencies to "harness the collective expertise of scientific community so as to advance the public interest" (250).

Bruce Smith (1992) reaches similar conclusions based on his study of science advising at the Department of Defense, the EPA, the Department of Energy, the National Aeronautics and Space Administration, and the Department of State. He notes a paradox facing the adviser: "[H]e or she must become a true insider to accomplish anything; but in doing so the adviser may lose the fresh view, detachment, and outsider qualities that are urgently required" (193).

Overall, these accounts suggest that advisory committees play an important, if imperfect, role in supplementing agency expertise. The most effective committees appear to be able to reach at least a partial consensus on clearly delineated scientific or technical questions and to relate those answers to the immediate policy issues facing agencies. Yet integrating expertise into policy requires an understanding of the value trade-offs that confront policy makers. Can committees drawn solely on the basis of their scientific and technical expertise have sufficient understanding of

these trade-offs to shape effective advice? Can committees drawn to include divergent points of view in order to facilitate a sophisticated understanding of value trade-offs (say, through the inclusion of stakeholder interests) enjoy sufficient credibility and possibility of achieving a consensus to have an independent effect on the policy process? If a committee included both credible scientific and technical expertise and representation of all stakeholders, would it be a desirable forum for decision making? The first two questions make clear the tension in the use of expert committees in public rulemaking; an affirmative answer to the third question suggests a more radical alternative—private rulemaking—in which the stakeholders actually determine the content of the rules.

Increasing Rapidity? Co-opting Stakeholders through Negotiated Rulemaking

The increased involvement of the federal government in the economy that began during the New Deal and expanded with the establishment of new regulatory agencies in the early 1970s—such as the Occupational Safety and Health Administration and the EPA in 1970 and the Consumer Products Safety Commission in 1972—has been accompanied by an expansion of procedural protections within administrative law for those affected by agency actions. Specifically, Richard Stewart (1975, 1716) notes four major doctrinal developments that had occurred in administrative law by the mid-1970s: First, the courts adopted an increasingly strong presumption that agency actions should be subject to judicial review; second, the courts recognized a wider range of interests as being entitled to administrative hearings under the due process clause of the Constitution; third, statutes enlarged the classes of interest with legal standing in formal agency processes; and fourth, the courts enlarged the classes of interest with standing to obtain judicial review of agency decisions. In addition to these extensions of recognized interests, the courts gradually abandoned the "rational basis test," which gave a presumption to sustaining agency action as long as it had a rational basis, in favor of the "hard look standard of review," which requires agencies to look closely at the relevant issues involved in the action (Harter 1982, 11). More recently, Supreme Court decisions have signaled somewhat more deference to agency discretion, especially with respect to their interpretation of scientific evidence in risk assessment (Jasanoff 1995, 84–86). Overall, these doctrinal changes in administrative law during the last 30 years have contributed to the emergence of a highly adversarial regulatory process.

Beginning in the mid-1970s, observers of the regulatory process expressed concerns about the disadvantages of adversarial rulemaking. Critics readily acknowledged that an adversarial process could be effective in mobilizing interested parties to gather and present information, as well as to detect errors in the information provided by others. At the same time, however, critics raised concerns about the incentives that an adversarial process gives participants to take extreme positions, conceal information that does not support their positions, make defensive expenditures on gathering factual information that has only marginal value in informing the decision, and rely too heavily on specialists (lawyers) in the regulatory process itself (Harter 1982, 19–22). Furthermore, adversarial processes are best for resolving disputes between pairs of parties, but they are less suitable "for resolving polycentric disputes involving many parties and many possible outcomes . . . [and] require delicate tradeoffs among competing interests," circumstances that characterize much rulemaking (Harter 1982, 20). Adversarial rulemaking was widely perceived as producing poor rules, costing too much, taking too long, and generating too much litigation. Indeed, Gary Coglianese (1997, appendix D) documents that for 20 years, prominent practitioners and academics readily accepted and repeated the apocryphal claim that 80 percent of the rules produced by the EPA had resulted in litigation. There is no empirical basis for the 80 percent figure, and Coglianese (1997, 1296–1301) estimates the actual rate to be between 19 percent and 35 percent, depending on whether the base is all rules or only significant rules under two important statutes. The wide acceptance of the claim suggests that it fit well with observers' perceptions of the highly adversarial nature of the regulatory process.

Concerns regarding adversarial rulemaking led a number of critics, such as John Dunlop (1976), Peter Shuck (1979), and Philip Harter (1982), to offer *negotiated rulemaking* as a supplement to the Administrative Procedure Act. Under negotiated rulemaking, the regulatory agency convenes a committee consisting of stakeholders, citizens, and agency staff to draft a proposed rule. The members negotiate among themselves in meetings that are open to the public. If the members of the committee reach a consensus on a rule, then the agency publishes it in appropriate form as a proposed rule in the *Federal Register,* as specified by the Administrative Procedure Act. The Negotiated Rulemaking Act of 1990 and subsequent presidential executive orders have encouraged agencies to make greater use of negotiated rulemaking. Proponents argued that by involving stakeholders in the drafting process, negotiated rulemaking would produce rules more quickly, with greater legitimacy, and with less likelihood of judicial challenge. How has negotiated rulemaking worked in practice?

Under negotiated rulemaking, the regulatory agency convenes a committee consisting of stakeholders, citizens, and agency staff to draft a proposed rule.

In a study of the EPA's use of negotiated rulemaking, Coglianese (1997) found little difference in either calendar time for completing rulemakings or rates of judicial challenge between conventional and negotiated rulemaking. It appears that the fragility of consensus, especially in the face of subsequent revisions of the rule in formal drafting or as a result of public comments and Office of Management and Budget review, is one source of litigation—even small changes during the process of formalization can unravel the consensus. Another source of litigation is organizations that are excluded from formal participation, either because they were not selected by the agency to participate or because they only became interested in the rulemaking as the negotiations proceeded.

Laura Langbein and Cornelius Kerwin (2000) conducted extensive surveys of participants in eight negotiated rulemakings and six conventional rulemakings by the EPA. Consistent with Coglianese, they found little difference in terms of the rates of judicial challenge between conventional and negotiated rulemaking. They did find differences in the perceptions of participants, however. In particular, those who had participated in negotiated rulemaking showed greater satisfaction with the content of the final rule and the process by which it was produced than those who had participated in conventional rulemaking. Participants in negotiated rulemaking also reported learning more about the issues involved, but at a higher cost to themselves—the overall costs of negotiated and conventional rulemaking appear to be comparable if the personnel costs of the EPA are also taken into account (Freeman and Langbein 2000).

A broader study suggests that, all else being equal, consensual rulemaking (either negotiated rulemaking or the use of advisory committees) delays rulemaking. Steven Balla and John Wright (2003) analyzed 170 major rulemakings completed between March 1996 and June 1999. They found that, taking into account the tendency of agencies to select rulemakings of shorter duration (selection bias), negotiated rulemaking appeared to increase the time between proposed and final rules. Furthermore, they found that the use of advisory committees slowed down rulemaking.

Although negotiated rulemaking produces rules neither more quickly nor with less likelihood of challenge than those produced through conventional rulemaking, it does appear to offer some benefits in terms of participants' perceptions of the regulatory process and their education on the issue at hand and related issues. Like negotiated rulemaking, private rulemaking involves participation by stakeholders. Unlike it, however, private rulemaking involves ongoing interactions among stakeholders and, in its strongest form, produces final rules by voting rather than proposed rules by consensus.

Regulatory Forms: Expertise and Stakeholder Involvement

Table 1 arrays different regulatory forms in terms of how they incorporate expertise and stakeholder involvement in the development of rules. The first column shows the ways in which expertise can be integrated into rulemaking. In conventional agency rulemaking, external expertise is injected into substantive rules through comments submitted to the regulatory docket by interested parties, usually stakeholders, but sometimes by independent researchers. Advisory panels may be established and directly supervised by agencies under the Federal Advisory Committee Act. Alternatively, agencies may commission independent bodies, such as the National Research Council or the Institute of Medicine of the National Academies, to conduct studies on particular topics that are relevant to rulemaking. In such cases, the agency provides the question to be pursued but leaves the composition and oversight of the expert body to some other organization.

The second column indicates regulatory forms that involve direct stakeholder participation in the development of rules through negotiated rulemaking. In negotiated rulemaking, expertise is integrated into rule development through the participation of stakeholders. In effect, the stakeholders become the advisory panel. The agency may also commission independent bodies to provide additional expertise, often to set the larger scientific context of the rulemaking.

The third column indicates full delegation of the substantive development of rules to an organization of stakeholders. Although one could imagine forms in which the organization of stakeholders develops substantive rules in consultation with advisory panels supervised by the sponsoring regulatory agency, the primary form shown in this column, private rulemaking, refers to the delegation of rulemaking to an NGO that has the necessary expertise or can obtain it under its own supervision. It corresponds to what has been labeled *subcontracting* (Huyse and Parmentier 1990, 259), *mandated full self-regulation* (Gunningham and Rees 1997, 365), or *regulated self-regulation* (Knill and Lehmkuhl 2002, 49–51).

My approach to the analysis of private rulemaking as an institutional form, although much less ambitious, follows in the spirit of Elinor Ostrom's study of self-governing common property regimes. Although she is fully cognizant of participants' interests and incentives and therefore adopts a rational choice perspective, Ostrom (1990) looks across common property regimes to make *inductive generalizations* about the elements that contribute to their longevity, a measure of success in the face of the inherent problems of overexploitation and underinvestment that plague and

Table 1 Regulatory Forms

		Stakeholder Involvement in Rule Development		
		Comments Only	Direct Involvement	Full Substantive Delegation
Incorporation of external expertise in rule development	Volunteered comments to regulatory docket	Conventional agency rulemaking	——	——
	Direct agency supervision of panels	Conventional agency rulemaking with advisory panels	Negotiated rulemaking	——
	External supervision of panels	Conventional agency rulemaking with commissioned panels	Negotiated rulemaking with commissioned panels	Private rulemaking

often fully deplete goods that are rivalrous in consumption but not exclusively owned by individuals. I begin by considering the more familiar institution of private standard setting, and then I look at prominent examples of private rulemaking as a basis for rationalizing its choice by politicians.

Private Rulemaking

Private regulation has always had a significant role in U.S. political economy. Many states rely heavily on private organizations in setting the conditions for the certification and licensing of those who wish to practice professions such as law and medicine (Hollings and Pike-Nase 1997). Industries often form organizations to engage in self-regulation in order to weed out firms that attempt to gain market share with low-quality but low-cost products, to head off threats of public regulation, or to establish a defense against legal negligence. Professionals such as industrial hygienists and accountants who work within firms often bring norms of practice that constrain managerial discretion to achieve goals that might otherwise be addressed through public regulation.

Concern about the undesirable consequences of the adversarial nature of agency rulemaking, which prompted calls for negotiated rulemaking, has been matched by concern about the consequences of the adversarial nature of the relationship between the inspectorate that implements regulations and those being regulated. Eugene Bardach and Robert Kagan (1982, 92) analyzed the problems that arise from the standardization required if public regulation is to satisfy requirements of due process and equal treatment before the law in the face of the "diversity, complexity, and fluidity of the real world." Standardization inevitably results in enforcement that appears unreasonable. Reactions to the unreasonableness create a vicious circle: "When regulatory systems seem to act unreasonably, businessmen react defensively. Enforcement officials, when challenged, respond with enhanced mistrust and legalism. Businessmen become still more resentful and retaliate with various forms of noncooperation and resistance" (107). Bardach and Kagan (1982, chap. 8) assert that private regulation circumvents this vicious circle and therefore deserves greater consideration in the choice of policy instruments for achieving regulatory goals.

Private regulation takes many forms. Private rulemaking by stakeholder organization, which has not been extensively studied or explicitly compared to public rulemaking, is an extreme form. Before considering private rulemaking, however, it is useful to consider a less extreme from, private standard setting, which has been explicitly analyzed in comparison to public standard setting. It is less extreme in the sense that it largely solves a coordination problem (agreeing on a common set of standards) rather than a cooperation problem (agreeing on the allocation of things of value).

Private Standard Setting: Displacing and Complementing Public Regulation

A large number of private organizations in the United States, such as Underwriters Laboratories, the American Society for Testing and Materials, and the American National Standards Institute, maintain many thousands of standards. To assess the relative effectiveness of private and public standard setting, Ross Cheit (1990) conducted case studies in four substantive areas in which plausible comparisons could be made: safety standards for grain elevators (the National Grain and Feed Association and the Occupational Safety and Health Administration), standards for aviation fire safety (the National Fire Protection Association and the Federal Aviation Administration), safety and labeling standards for wood stoves (Underwriters Laboratories and the Consumer Product Safety Commission), and safety standards for gas-fired space heaters (American Gas Association Laboratory and the Consumer Product Safety Commission). Although public standard setting appears to enjoy some advantages, such as greater capacity for collecting information about risks from the actual use of products, private standard setting appears to offer a more flexible and adaptive process:

> The case studies suggest that there are significant evolutionary differences between public and private standard-setters, differences that indicate several previously unrecognized advantages of the private sector. In short, private standards-setting

> is prospective and ongoing, while public efforts are usually corrective and singular. Private standards-setters tend to intervene relatively early in the life cycle of an issue, adjusting the standard subsequently over time. Public standards-setters, by contrast, are likely to get involved later, often after a major disaster, adopting a "one-shot" standard without the benefit of subsequent adjustments. (Cheit 1990, 202)

Giandomenico Majone (1996, 23–26) sketches a similar comparison of standard setting by the European Commission and private or semiprivate standardization bodies.

On the surface, the comparison may not seem justified because the private standards by themselves are not legally binding. Private standards gain force, however, in a number of ways: adoption by public regulators, incorporation into private contracts, as a defense against tort, and use in accreditation required for participation in government programs such as Medicare and Medicaid (Havighurst 1994). Additionally, standards may directly inform consumers and thus create market pressures for compliance.

In summary, private standard setting generally involves an open process characterized by evolutionary adjustment. Although private standard setting does not directly regulate in the sense of imposing and enforcing legally binding rules, commercial incentives and government requirements often give standards an effect equivalent to the rules drafted by regulatory agencies. The process by which private standards gain regulatory force generally involves the government tying the requirements of various sorts to certification, accreditation, or compliance to the standards already being developed by private organizations. It certainly displaces public standard setting and supplements public rulemaking, but it generally does not involve an explicit delegation of rulemaking authority.

Private Rulemaking: Substituting for Public Regulation

Private rulemaking does involve an explicit delegation of rulemaking authority to private organizations. The organizations exercise this authority to produce rules that directly affect the allocation of valuable goods. The organizations themselves generally include representatives of major stakeholders. They typically use voting rules rather than consensus to reach decisions. The clearest examples of private rulemaking involve regular decisions about the allocation of such goods as agricultural production quotas, information about securities, Internet address names, and transplant organs.

Agricultural Marketing Orders During World War I, California producers of citrus fruits, nuts, and raisins organized voluntary cooperative associations to limit production and obtain higher prices for their crops. These attempts to form a cartel enjoyed some initial success, but they had largely collapsed by the beginning of the Great Depression. During this period, however, federal policy encouraged voluntary marketing cooperatives by exempting them from antitrust laws and, in 1929, by establishing a revolving fund to give them access to credit (McMenamin 1983). The Roosevelt administration initiated production controls and marketing agreements, and ultimately, in the Agricultural Marketing Agreement Act of 1937, gave the secretary of agriculture the authority to establish marketing orders for fruits, vegetables, milk, and specialty crops (Shepard 1986). Similar policies operate today in Canada and other countries (Green 1983).

A marketing order may involve a variety of mechanisms for restricting supply to the market. Marketing order participants—farmers in a particular region who grow the same crop—may establish maximum annual allotments, prorate production, determine allocation between primary (e.g., fresh fruit) and secondary (e.g., processed fruit) markets, and establish mandatory reserve pools. They may also regulate the quality of products and the specifications of their shipping containers, as well as impose mandatory fees on members to cover administrative costs or to support research and marketing.

The Department of Agriculture works with participants to develop procedural rules for the marketing order, and, if approved by two-thirds of the producers (by number or by volume of production) within a geographic area, these rules become legally binding upon publication in the *Federal Register.* Under these rules, which usually involve decision making through majority voting by an administrative committee that is nominated by the participants and appointed by the secretary of agriculture, the particular volume or quality controls are implemented. The most direct volume control, allocation of annual sales allotments, is still used in a few marketing orders, such as one for spearmint oil produced in the far West. In the past, such direct allotments were used much more frequently. For example, the administrative committee for the lemon marketing order that previously covered California and Arizona voted on the common fraction of inventory that each grower was allowed to sell in a particular period (Cave and Salant 1995, 84). In some marketing orders, allocations were made quite frequently, even on a weekly basis. For example, over a 35-year period, weekly quotas were set by the Navel Orange Administrative Committee and promulgated by the Department of Agriculture (Schoenbrod 1993, 51).

More than 40 federal marketing orders for fruits and vegetables operate, though most are not currently

exercising volume controls. An additional 11 federal marketing orders actively exercise volume controls for milk. When marketing orders do restrict volumes, their desirability from a public policy perspective is highly dubious—they have the effect of transferring wealth from a large number of consumers to a small number of producers, and they result in economic inefficiency and sometimes even physical waste of product. As a regulatory institution, however, they are generally effective in providing a mechanism for producers to make rapid adjustments to changing market conditions in order to increase short-run profits. Indeed, it is hard to imagine the Department of Agriculture being able to set yearly, let alone weekly, production quotas through public rulemaking, for several reasons. First, the regulators would have to rely on the growers for information on production, inventories, and market conditions. It would be much more difficult for the regulators to monitor the quality of the information obtained than it is for the administrative committee, which includes people with knowledge of local conditions and a direct financial interest in knowing such things. Second, producers favoring higher or lower allotments would have an incentive to invest resources in influencing the regulatory process, possibly through legal challenges that might prevent timely decisions. Third, groups representing consumers, both individuals and processors, might seek to affect rulemaking, perhaps challenging the legitimacy of the marketing order itself.

Securities Self-Regulatory Organizations Prior to 1933, the regulation of the securities market was a state function. The 1929 stock market crash focused attention on fraudulent stock issues and other practices that market professionals were using to manipulate stock prices to the detriment of uninformed investors. Adopted within the first hundred days of the New Deal, the Securities Act of 1933 gave the Federal Trade Commission several powers, including the regulation of information provided to the public about new stock issues. The Securities Exchange Act of 1934 expanded regulatory authority to include the stock exchanges and related professions and transferred it to the new Securities and Exchange Commission (SEC). Section 19(b)(1) of the act authorized the creation of self-regulatory organizations (SROs) to participate in the regulatory process.

The stock exchanges, such as the New York Stock Exchange, and the national securities associations, such as the National Association of Securities Dealers and the accounting profession's Public Oversight Board, are all SROs. An SRO must ensure fair representation of its members and develop rules to prevent fraudulent and manipulative practices. It must have the capacity to enforce compliance with its own rules, as well as with federal security laws, and have mechanisms for disciplining members who violate its rules. Its rules may not impose a burden on competition. An SRO must submit proposed changes to its rules to the SEC, which can either reject them or approve them through a notice-and-comment rulemaking process.

Harvard law professor James Landes, who helped draft the 1934 act and served as an SEC commissioner during its first four years, sought to include the securities industry within the regulatory framework for two reasons (Khademian 1992, 39–40): First, he sought to give the industry a stake in the act's success by involving it in the regulatory scheme; second, by involving the industry in the development and enforcement of regulations, the SEC would have a wider regulatory reach than would otherwise be possible with limited staff and budget. Because the SEC oversees a complex market with diverse interests and complicated and arcane rules, its active intervention risks drawing opposition from segments of the industry that may undercut both political support and enforcement cooperation. Active public regulation might also invite legal challenges that could threaten its legitimacy. Furthermore, allowing market participants to develop specific rules is generally consistent with the SEC's primary responsibility as a "disclosure agency"—permissiveness about the rules accompanies strong demands that they facilitate disclosure (Khademian 1992, 86–87). The SEC relies heavily on SROs to develop and propose rules.

Few criticisms have been raised against the SRO approach to stock exchanges, which routinely have their rule changes approved expeditiously by the SEC. Notices of proposed rule changes published in the *Federal Register* rarely receive public comments. The SRO approach to the regulation of the accounting profession, however, has received substantial criticism over the years (Chatov 1975). In 1998, the SEC proposed the Auditor Independence Rule (Securities Act Release No. 33-7870), which would have imposed restrictions on the provision of nonaccounting services by firms to their corporate auditing clients (Palmrose and Saul 2001). The Enron scandal resulted in the Sarbanes-Oxley Act of 2002, which explicitly prohibits nine nonaudit services. Furthermore, it formalized the Public Company Accounting Oversight Board, which the SEC commissioners had previously voted to establish. Thus, although SROs remain generally important in the securities industry, the accounting failures of recent years have prompted more direct regulation of corporate auditing.

ICANN and Internet Domain Name Policy Although the Internet operates as a highly decentralized system, considerable centralized coordination and governance must be provided (Krishnan and Chakravarti 1999). Unique numerical addresses, the four-part numbers that serve as Internet protocol addresses, must be assigned and a record kept of the assignees. Decisions

must be made about allowable domain names, including, most importantly, the top-level domain names (country names, international organization names, and generic names, such as .edu, .gov, .com, .net, and .org), and second-level domain names, which have gained substantial commercial value, must be allocated in the face of conflicting claims. Furthermore, an up-to-date root directory providing the addresses assigned to top-level domain names must be maintained and provided to the 13 legacy root name servers that make this information available to Internet users worldwide.

A brief history of the governance of the domain name system, drawn from the very detailed account provided by A. Michael Froomkin (2000), follows. Until 1998, the governance functions of the Internet were performed by a variety of organizations with contractual relationships to federal agencies. Standards and policy were generally set by the Internet Assigned Numbers Authority, based at the University of Southern California, under contract with the Department of Defense. Beginning in 1993, the National Science Foundation replaced the Department of Defense as the governmental sponsor for the maintenance of the root directory and registration of domain names. It contracted with Network Solutions, Inc. (NSI) to provide these services. The contract gave NSI a monopoly over the allocation of names under the important .com upper-level domain.

Growing controversy over the allocation of the increasingly valuable domain names—between NSI and firms seeking to create their own upper-level domain names and between speculators in domain names and trademark holders—as well as increasing foreign concern over U.S. control of domain name policy led President Bill Clinton to direct the secretary of commerce to take steps to privatize the domain name system in July 1997. An interagency task force headed by Ira Magaziner published a statement of policy providing detailed specifications for a nonprofit organization to take over management of the domain name system (U.S. Department of Commerce 1998). The Internet Corporation for Assigned Names and Numbers (ICANN), which was founded by key personnel from the Internet Assigned Numbers Authority, quickly formed to play the role set out in the policy statement. A series of agreements clinched the role: a memorandum of understanding between the Department of Commerce and ICANN; an agreement between the University of Southern California and ICANN, through which ICANN took over the responsibilities of the Internet Assigned Numbers Authority; and a contract between the Department of Commerce and NSI, according to which the latter recognized ICANN's authority in return for continued control over the .com upper-level domain name. By February 1999, these agreements enabled the Department of Commerce to recognize ICANN officially as the manager of the domain name system.

Because there is no statutory basis for ICANN's rulemaking function, its supporters argue that it is simply setting standards, and the Department of Commerce claims that it retains policy control. Yet Froomkin argues that ICANN activities go well beyond standard setting: "choosing [top-level domains] on the basis of social utility from among multiple qualified providers, fixing the business models of registrars, enforcing dispute-resolution procedures on millions of unwilling businesses and consumers, accrediting dispute-resolution providers, writing substantive and procedural rules for the disputes—not one of these tasks is 'technical' standard setting in any routinely meaningful sense of the word" (2000, 96). More generally, Jonathan G. S. Koppell uses ICANN to illustrate his theory of "multiple accountabilities disorder," the problem that organizations face in responding to transparency, liability, controllability, responsibility, and responsiveness—the often conflicting standards of accountability: "ICANN has swung from responsiveness to responsibility to controllability as its operating principle. It has left constituents, partners, observers, and even its own leaders perplexed" (2005, 105). Some European observers see ICANN as having "a huge concentration of power" and being able "to conduct global public policy" (Holitscher 1999, 139). Regardless of whether ICANN is legally recognized as undertaking rulemaking, it is clearly involved in the authoritative allocation of things of value.

United Network for Organ Sharing and the Organ Procurement and Transplantation Network Experimental kidney transplantation, which began in 1951, had its first real success in 1954 in a case involving a transplant between identical twins (Prottas 1994, 2). With the introduction of immunosuppressive drugs, which provided a way of countering organ rejection, and the development of the artificial kidney, which allowed patients with kidney failure to be kept alive through dialysis while they waited for transplant operations, kidney transplants became common during the 1960s. Kidney transplantation soon became recognized as a medically desirable and cost-effective alternative to dialysis. In 1969, the Public Health Service gave contracts to seven hospitals to establish organizations that would procure cadaveric kidney donations and funded a computerized system for matching donors and recipients in the western states (Rettig 1989, 194). The Social Security Act Amendments of 1972 extended Medicare coverage for dialysis and transplantation to patients with chronic renal disease through the End State Renal Disease (ESRD) program. To reduce the costs of the ESRD program by encouraging more kidney transplants, amendments to the Social Security Act were adopted in 1978 that

extended coverage for immunosuppressive drugs following transplants from one to three years.

The powerful immunosuppressant cyclosporine, which began clinical trials in the United States in 1980, had a significant impact on transplantation generally. Its most immediate impact was to reverse the generally disappointing results of liver transplants. Pediatric liver transplantation was dramatically brought to public attention in 1982 by the ultimately successful efforts of the parents of 11-month-old Jamie Fiske to secure a liver donation (Rettig 1989, 199). President Ronald Reagan, House Speaker Thomas O'Neill, and newscaster Dan Rather all used their influence and media access on behalf of particular families seeking donors or financial support for pediatric liver transplants. A presidential aide who had helped pressure a number of states to cover the costs of liver transplants under Medicaid candidly remarked in a newspaper interview, "Sure, it's politics of the first order. It's whoever can get to the White House, whoever can use the media" (Wehr 1984, 455).

Several members of Congress, including Representative Albert Gore and Senators Orrin Hatch and Edward Kennedy, worked during 1984 to develop legislation to create a privately administered network, the Organ Procurement and Transplantation Network (OPTN), to encourage more effective procurement of cadaveric organs and to coordinate their allocation. The result, the National Organ Transplant Act of 1984, called for the secretary of the Department of Health and Human Services to contract with a nonprofit organization to provide for the establishment and operation of the OPTN, which would, among other responsibilities, maintain a national list of patients awaiting transplants to facilitate matching them with donated organs on the basis of medical criteria.

The contract for administering the OPTN and the Scientific Registry of Transplant Recipients, a database for assessing transplant results, was awarded in 1986 to the United Network for Organ Sharing (UNOS), a nonprofit organization based in Richmond, Virginia. This network evolved from the Southeast Organ Procurement Foundation, an organization established in 1976, which, in turn, evolved from an arrangement involving the Medical College of Virginia, one of the original Public Health Service contractors, and a number of other hospitals (Rettig 1989, 195). By 1983, UNOS was already operating a computerized list of patients awaiting kidney transplants that supported a voluntary system of nationwide sharing (Denny 1983, 26). The UNOS has continued to secure contracts for administration of the OPTN, though in 2000 it lost the contract for analyzing data in the Scientific Registry of Transplant Recipients to the University Renal Research and Education Association, a nonprofit organization based in Ann Arbor, Michigan.

The status of the OPTN was strengthened somewhat by the Omnibus Reconciliation Act of 1986, which required all hospitals performing organ transplants to be members of the OPTN and to abide by its rules in order to receive payment under Medicare and Medicaid. It was further strengthened by Title IV of the Omnibus Health Amendments of 1988, which required the OPTN to "establish membership criteria and medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria" (sec. 403a). Subsequently, the Department of Health and Human Services interpreted the laws as requiring all rules to be approved by the secretary before they became binding among OPTN members (DHHS 1989) and clarified the circumstances of approval in an extended and controversial rulemaking that began in 1994 and was finalized in 2000 (DHHS 2000). Although the secretary must approve all OPTN rules before they become enforceable as federal rules, the OPTN can discipline members who fail to comply. Because the DHHS has yet to accept formally any OPTN rule through a federal rulemaking process, the OPTN effectively retains responsibility for developing the content of the rules themselves, and these rules actually govern cadaveric organ procurement and transplantation.

Why Private Rulemaking?

Private rulemaking involves the delegation of authority to an NGO for the development of rules governing the allocation of things of value. Private rulemaking provides an alternative to public rulemaking for developing the substantive content of rules. What explains the choice of private over public rulemaking? The cases of private rulemaking, especially in contrast to what is known about public rulemaking, suggest three rationales: technical efficiency, blame avoidance, and availability.

Private rulemaking involves the delegation of authority to an NGO for the development of rules governing the allocation of things of value.

Technical Efficiency Much of the contemporary literature on delegation concerns the control of agents such as regulators by legislative principals (Calvert, McCubbins, and Weingast 1989; Epstein and O'Halloran 1999; Huber and Shipan 2002; McCubbins, Noll, and Weingast 1989). For example, legislators may build in procedures to "stack the deck," "put issues on autopilot," or otherwise attempt to constrain future regulatory decisions (McCubbins, Noll, and Weingast 1989, 444). The executive also has resources to shape and control the regulatory process

(Whittington and Carpenter 2003). As Jonathan Bendor and Adam Meirowitz (2004) note, the models underlying this literature employ strong and largely unexamined assumptions that yield equilibrium forms of delegation that emphasize the control of discretion and largely ignore the traditional rationale of delegating to more informed decision makers. Yet some institutional forms provide better prospects for accomplishing goals than others. One reason for the choice of private over public rulemaking is that the former offers greater technical efficiency.

This is not a claim about the desirability of the selected goals—in fact, private rulemaking may offer a technically efficient way of achieving an undesirable goal. For example, the higher consumer prices that result from the agricultural marketing boards that allocate production quotas are probably not socially desirable. Yet conditioned on the decision to establish production quotas, marketing boards almost certainly offer greater technical efficiency than public rulemaking. Indeed, public rulemaking probably would not be feasible with plausibly available resources. In other areas, such as securities regulation, private rulemaking provides a way of expanding the feasible regulatory scope.

Private rulemaking is likely to be technically efficient when two conditions hold. First, *the major stakeholders making up the NGO must encompass the expertise needed for informed decision making.* One rationale for delegation to agencies or private rulemaking organizations is the need for rules to be informed by expertise. In the case of public rulemaking, in-house expertise is supplemented by advisory panels. In the case of private rulemaking, expertise must adhere within the organization itself. If rules are to be made by the participating stakeholders, it is important that those stakeholders collectively have sufficient expertise to produce technically well-informed rules. Turning things around, when the stakeholders do encompass needed expertise, private rulemaking offers the advantage of providing a closer connection between experts and decision makers than is typically possible in public rulemaking.

Second, *the policy area must involve changing circumstances that demand frequent adjustment of the rules.* To paraphrase Cheit's comparative assessment of standard setting, "private rulemaking is prospective and ongoing, while public rulemaking is usually corrective and singular" (1990, 202). Private rulemaking, because it involves prominent stakeholders and directly taps their expertise, can move more quickly than public rulemaking. Especially under majority-rule voting, decisions, perhaps limited by compromise to obtain majorities, can be made fairly quickly. The decisions are likely to be incremental changes that can be reversed by additional information. The possibility for providing rapid and flexible responses to new information is the primary source of the technical efficiency of private over public rulemaking.

Ideally, one would want to test these claims about technical efficiency by making comparisons of the sort Cheit makes between public and private standard setting. The purpose of detailing the complaints against agency rulemaking and reviewing Cheit's work on standard setting is to assert implicitly counterfactual cases to the cases of private rulemaking reviewed—or, in John Gerring's (2004, 347) words, "One knows what blue is without going in search of blue cases." Nonetheless, one sort of direct comparison is possible: The OPTN regularly makes incremental changes to its rules, which actually govern the details of cadaveric organ allocation, whereas the DHHS has yet to approve a single rule formally.

Blame Avoidance The cases suggest a political explanation for the choice of private rulemaking: *a desire by legislators or executives to remove the content of the rulemaking from the political agenda to the greatest extent possible.* Morris Fiorina (1982, 46–47) notes that "shift-the-responsibility" models recognize that legislators may wish to shift political as well as decision-making costs away from themselves. The desire is likely to be strong for issues involving allocation that will unavoidably result in clearly identified losers. Considerable evidence from cognitive psychology suggests that those who suffer loss are more likely to perceive it, feel aggrieved by it, and act on that feeling than those who obtain a comparable gain (Kahneman and Tversky 1984); therefore, politicians are likely to see the opportunity to claim credit as more than offset by the risks of accruing blame in situations of zero-sum allocation. In the political calculus of "credit claiming" and "blame avoidance," the latter is likely to dominate (Weaver 1986, 1988). Delegating authority to a regulatory agency tends to shift the locus of debate from the legislative arena to the agency and the courts. In cases involving the direct allocation of things of value, however, primary stakeholders who do not receive satisfactory allocations may lobby the legislature or the executive to change the rules, returning the issue to the political agenda. To avoid blame, politicians may seek to insulate themselves from future appeals by delegating rulemaking to NGOs with internal procedural rules for resolving stakeholder conflicts.

The effectiveness of this insulation is clearly demonstrated by the long history of marketing orders. Despite strong objections from many economists and policy analysts, they have persisted since the New Deal. Even if the Department of Agriculture could set effective cartel quotas through public rulemaking, it is likely that the disputes this rulemaking would have engendered among the primary stakeholders would have led to their abandonment long ago.

One can easily imagine the difficulty the DHHS would face in directly formulating allocation rules for organs. Transplant centers that expected to lose organs under the proposed rules would likely seek help from their political representatives; this happened in 1999 when Congress placed a one-year moratorium on the implementation of the DHHS rules, pushing the OPTN away from local and regional priorities in organ allocation (Weimer 2004). Proposed changes in allocation rules would create winners and losers among patients waiting for transfers, encouraging them to seek intervention from their representatives, just as they did prior to the establishment of the OPTN. As identifiable "victims" of the proposed rules, those who would be disadvantaged would make dramatic witnesses at congressional hearings and attract human interest media coverage, further raising the prospect that opportunities for credit would be far exceeded by the risks of blame.

Availability John Kingdon (1995) sees policy windows opening when there is a confluence of problem and policy streams. For a policy window for private rulemaking to exist, it must be possible for the primary stakeholders to be identified and their cooperation within an NGO envisioned. An *existing model of stakeholder cooperation* facilitates these tasks. In the case of marketing orders, the voluntary cartels and cooperatives suggested that producers in particular geographic regions might be organized into legally formal cartels. It was natural to see the stock exchanges themselves as SROs. Both agricultural marketing boards and the SROs were applications of a general model of delegation to stakeholders that was employed widely in the New Deal (Jaffe 1937). The existence of the Internet Assigned Numbers Authority, with experienced personnel, provided both a model for ICANN and an important component for its creation. In 1977, the South East Organ Procurement Foundation began listing patients at nonmember centers, and by 1983, about 130 of the approximately 150 kidney transplant centers were listing patients with the UNOS (Denny 1983, 26). Consequently, a private organization already existed to take on the responsibilities of the OPTN. Indeed, the 1984 act's requirement that the OPTN administrator "be a private nonprofit entity which is not engaged in any activity unrelated to organ procurement" (P.L. 98-507, sec. 372[b][1]A) and perform functions already being performed by the UNOS suggests anticipation that the UNOS would become the OPTN administrator.

For a policy window for private rulemaking to exist, it must be possible for the primary stakeholders to be identified and their cooperation within an NGO envisioned.

Beyond the existence of a model of stakeholder cooperation to enable politicians to envision the possibility of private rulemaking, *it must actually be possible to enlist all prominent stakeholders.* Prominent stakeholders are those with sufficiently strong interests to be willing to invest resources in lobbying and other political activity. They must acquiesce in the creation or designation of the NGO—in doing so, á la McCubbins, Noll, and Weingast (1989, 432), they increase the likelihood that the NGO will produce outcomes that are acceptable to its political creators. Once the NGO is established, its members gain a stake in its preservation because participation in its procedures provides an opportunity to influence, or at least anticipate, policies. Even persistent losers within the NGO may hesitate to seek a return to public regulation, which brings greater uncertainty and higher stakes because of the episodic nature of major public rulemakings. An analogy may be drawn to John Aldrich's (1995) explanation for the formation and stability of legislative parties: Facing unstable (and therefore uncertain) policy outcomes resulting from the formation of short-run coalitions around particular issues, legislators may organize parties as long-term coalitions to provide stability in some fundamentally important policy dimension. In the case of private rulemaking organizations, that dimension is collective stakeholder control over the details of the rules.

Stakeholder incentives within private rulemaking organizations differ from those faced in negotiated rulemaking. In negotiated rulemaking, a consensus is sought on the design of a particular rule (a short-term coalition) in the absence of stakeholder concerns about preserving a decision-making body (a long-term coalition). Withholding consensus may stalemate the negotiation, whereas initial acceptance may be negated through court challenges. Decision making by majority-rule voting rather than by consensus allows private rulemaking organizations to avoid stalemate. The desirability of preserving the organization's authority to make decisions and the desirability of continued participation in the exercise of that authority discourages stakeholders from seeking to overturn specific decisions by moving issues onto the political agenda. Of course, the anticipation of persistent losses on important issues may induce some stakeholders to challenge the long-term coalition.

Conclusion

Private rulemaking may be an attractive form of governance in circumstances involving rapidly changing conditions in which the most current expertise inheres in the stakeholders. If stakeholders can be identified and organized into an NGO, and the stakeholders provide broad value representation, then private rulemaking may be desirable. The actual choice, however, depends on the balance of blame and credit that

politicians anticipate from private versus public rulemaking. The tendency for the allocation of valuable goods—such as production quotas, Internet domain names, and transplant organs—to involve greater potential for blame than credit helps to explain the puzzle of the use of private rulemaking in these important applications.

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