Background on the Rulemaking Process

III. The Players in Rulemaking

Rules are developed by federal agencies often working with those being regulated, such as businesses and nonprofit organizations, individuals affected by the presence or absence of regulations (for example, transportation workers or miners), and those who care about certain issues like wildlife protections or food safety.

Oftentimes, rulemakings are made by the authority of the agency. However, in many cases, an agency is mandated to make a rule by Congress or a court order. Sometimes, a rule will be made in response to a petition filed by a corporation or a private citizen. Federal agencies are required to respond to all petitions for rulemakings within a specified time period.

A. Agencies' Role in Rulemaking

Public attention is generally focused on Congress and the President in the development of public policy, but most of the work of carrying out policy involves dozens of administrative agencies.

The scale of administrative government is enormous. In 2006, the executive branch employed over 2.6 million civilians and spent approximately $500 billion on non-defense, discretionary programs.

Each federal agency was created by Congress to ensure that specific laws are properly implemented. The President, as Chief Executive, supervises agencies' work through his appointed cabinet secretaries and department heads. The President can also propose to Congress the consolidation or creation of new agencies.

There are many different kinds of federal agencies. Some are primarily administrative-managing billions of dollars of federal grants, contracts, and other programs. Some are primarily regulatory-policing and enforcing laws that control activities from racial discrimination to environmental pollution.

Federal agencies are also distinguished from each other by their status in the federal government. Although they all are thought of as part of the executive branch, they have varying degrees of independence from presidential control.

There are 15 major executive branch departments, such as the Department of State, Department of Defense and Department of Health and Human Services. Each is headed by a secretary (agency head) who is appointed by the President and confirmed by the Senate. The secretary serves at the pleasure of the President (i.e., can be fired at will), and is a member of his cabinet.

Some important agencies are units within the major executive departments. For example, the Food and Drug Administration is in the Department of Health and Human Services and the Occupational Safety and Health Administration is in the Department of Labor. Still other agencies, while not ranked with the major executive departments, are considered to be executive branch agencies, such as the General Services Administration or Central Intelligence Agency.
Congress has also created independent regulatory commissions which are part the executive branch but are more independent of political control by the President than are other executive branch agencies. Examples of independent commissions are the Interstate Commerce Commission, the Federal Communications Commission, and the Consumer Product Safety Commission.

All the independent regulatory commissions are headed by boards or commissions, whose members serve set terms and generally can be removed only for misconduct, unfit service, or some such cause.

There are also agencies that combine elements of both types of agencies. For example, the Environmental Protection Agency is characterized as an independent agency, yet its administrator is appointed by the President with the advice and consent of the Senate and serves at the pleasure of the President.

Another kind of federal entity is the nonprofit government corporation such as the Pension Benefit Guaranty Corporation. These corporations operate under their own rules, free from many government agency restrictions.

Differentiating among these federal bodies can be difficult at times, but it is important to remember the distinctions between the independent regulatory agencies and the other executive branch agencies. They have different procedures and different relations with Congress and the President which affect their decision-making. For instance, the independent regulatory agencies are exempt from White House review of proposed and final regulations.

B. The White House's Role in Rulemaking

The White House plays a substantial role in rulemaking. Much of the White House's work on regulatory policy falls to the White House Office of Management and Budget (OMB). OMB is integral in constructing the president's budget and setting an administration's priorities. OMB's Office of Information and Regulatory Affairs (OIRA) plays the most important role in rulemaking by conducting reviews of agency regulatory policy.

1. Centralized Review

Within the current framework for White House regulatory review (Executive Order 12866 as amended in 2007), agencies must notify OIRA of all planned regulatory actions as well as a judgment as to whether those regulations are "significant" or "economically significant." The OIRA Administrator retains the final say on the determination of significance or economic significance. In doing so, OIRA and the agencies determine which proposed regulations will be subject to regulatory review.

Under E.O. 12866, agencies are to prepare a list of "all regulations under development or review." These lists are published collectively in the form of the Unified Regulatory Agenda which appears semiannually in the Federal Register. Agencies identify whether rules in the Agenda are "economically significant," "other significant" or not significant. For rules under development (the prerule stage), this designation reflects the agency's opinion as to whether the rule warrants OIRA review under E.O. 12866.

For rules the agency determined to be not significant, OIRA has ten working days to notify the agency as to whether OIRA would like to review those rules. If OIRA does not overrule the opinion of the agency in that time, the agency will not submit those rules to OIRA for review. If OIRA does overrule the opinion of the agency, those rules will be considered "significant."
In cases where an agency is developing a significant rule, the agency must submit all regulatory actions related to that rule to OIRA for review. Some of these regulatory actions are relatively inconsequential, such as an Advanced Notice of Proposed Rulemaking which solicits public opinion. In those cases, OIRA will waive review or notify the agency of its thinking.

For a significant rule, E.O. 12866 requires agencies to submit the following: the text of the draft rule; a written identification of the need for the rulemaking and an explanation of how the rulemaking will meet that need; and the potential costs and benefits of the rule.

A subset of significant rules is "economically significant" rules. Economically significant rules are those which the agency and/or OIRA anticipate will have an annual effect on the economy of $100 million or more. Economically significant rules are subject to the same submission requirements as significant rules with one additional requirement - a Regulatory Impact Analysis (RIA).

OIRA may also require the submission of an RIA for any rule which is "significant" but not "economically significant." Economically significant rules and significant rules for which OIRA requires an RIA are sometimes collectively known as "major rules" in order to distinguish them from rules which do not require an RIA.

For every major rule, an agency must complete an RIA that describes the costs and benefits of the proposed rule and alternative approaches, and justifies the approach chosen. This analysis is a far more rigorous and complex assessment than the simple identification of costs and benefits required for significant rules.

The RIA is a detailed assessment sometimes resulting in hundreds of pages. In preparing an RIA, agencies are required to explain how all aspects of the proposed rule would result in costs and benefits. Additionally, tangential benefits and costs of the rule should be identified. Agencies should then monetize all costs and benefits and, where monetization is not possible, identify other qualitative and quantitative costs and benefits.

Agencies must perform this assessment not just for the proposed rule, but for alternatives to the proposed rule. This is intended to give the agencies and OIRA an idea of comparable costs and benefits for other regulatory actions (including not regulating at all) relative to an identified baseline. Agencies must then provide their rationale for choosing the proposed regulatory action over the alternatives.

Upon receiving the submission of agency documents for significant rules, OIRA has 90 calendar days to review and notify agencies of its thinking. OIRA or the agency may extend one time the review period by up to 30 days.

OIRA reviews the agency submission and returns the rule to the agency in one of three ways: consistent without change, consistent with change, or returned. Consistent without change means OIRA did not alter the proposed rule. Consistent with change means OIRA generally agreed with the intent of the rule, but made some substantive changes. This is the most common type of action OIRA takes. Returned means OIRA had serious concerns with the agency's proposed rule and does not approve the publication of a Notice of Proposed Rulemaking. Returned rules are always accompanied by a return letter which is posted on OIRA's online docket. Return letters explain OIRA's concern and either instruct the agency to conduct further study of some aspect of the rule or abandon the rulemaking altogether. Agencies may also withdraw proposed or final regulations during the review process.
If a proposed or final regulation is subject to a statutory or court deadline, agencies may publish an NPRM before receiving OIRA approval.

Upon completion of OIRA review, the proposed rule is published in the Federal Register in the form of a Notice of Proposed Rulemaking (NPRM). The rule is opened to a public comment period generally lasting 60 days.

The OIRA administrator occasionally issues a "post-review" letter as a means of publicly conveying OIRA's concerns after returning a rule consistent with change. Post-review letters outline the nature of OIRA's concerns (often related to the RIA) and are posted on OIRA's online docket. These post-review letters may suggest further analysis or study which OIRA believes would strengthen the rule in question or future rulemakings.

After the public comment period, the agency makes any changes to the rule and resubmits it to OIRA for another round of review. Again, OIRA has a 90 day window in which to complete its review process. When OIRA completes its final review, the agency may set a date for promulgation of the rule and publish the final rule in the Federal Register.

Publication of a proposed rule in the Federal Register initiates the public notice-and-comment period of the rulemaking process.

In January 2007, President George Bush issued E.O. 13422 which amends President Clinton's E.O. 12866. The same day, OMB issued its Final Bulletin for Agency Good Guidance Practices. The Bulletin further clarifies the definitions of significant guidance documents contained in the executive order amendments. It also instructs agencies on "policies and procedures for the development, issuance, and use of significant guidance documents." Together, these two changes to the regulatory process require significant agency guidance documents to undergo a similar regulatory review process that includes many of the same steps OIRA uses for regulations.

2. Developing Rules
The White House often has a hand in developing rules. As with the process of centralized review, OIRA is the primary conduit through which the White House exerts its influence.

One way OIRA can influence the commencement or development of a rulemaking is through the use of "prompt letters." Prompt letters were introduced in 2001 by OIRA Administrator John D. Graham. Prompt letters do not comment on current rulemakings but rather encourage agencies to take up a rulemaking or to elevate an issue among the agency's regulatory priorities.

OIRA also influences the development of rules through the use of meetings. The administrator of OIRA and senior OIRA and OMB officials will frequently meet with appropriate members of stakeholder groups - federal agencies, industry, the public interest community - to discuss a rulemaking currently under development or an issue which may be subject to a future rulemaking.

3. Setting Priorities
The White House's regulatory power is not all centralized in OIRA, or even OMB. The president plays an important role in determining what types of rules agencies will promulgate during his administration and how they will do so.
One of the first ways presidents set regulatory priorities is through the selection of personnel. Agency heads, the Director of OMB, and the Administrator of OIRA (not to mention numerous senior agency officials) are presidentially-appointed officials. Presidents are likely to choose for these positions individuals who are ideologically attuned to his own regulatory priorities. Presidents may also dismiss any of these officials at any time for any reason.

Another method for setting regulatory priorities is through the presidential budget request. Each year, the president outlines and OMB prepares a request to Congress for appropriations reflective of the president's priorities. Requests for sharp increases or decreases in funding for a program or an agency are strong indications of a president's priorities.

OIRA also plays an important role in setting regulatory priorities. Under E.O. 12866, part of OIRA's review responsibility is to ensure agency rules are consistent with "the President's priorities, and the principles set forth in this Executive order."

Under the administration of President George W. Bush, OMB has made extensive use of directives and memoranda issued to agencies. These documents allow OMB to set informal administration policy. Directives have often intended to micromanage agency functions by focusing on standardized methods for various forms of agency analysis. For example, OMB issued Circular A-4, Regulatory Analysis in 2003. It directs agencies in precisely how to conduct their cost-benefit analysis and how to construct RIAs.

C. Congress's Role in Rulemaking
Congress laid out the basic framework under which rulemaking is conducted when it enacted the Administrative Procedure Act (APA) in 1946. It remains the basic legislative standard even though its processes have been affected by more recent statutes.

Of course, setting administrative procedure is not the only way Congress directs agency decision-making. In addition to substantive program legislation, Congress also monitors agency performance through its powers in the appropriations process, by approval of presidential appointees, and by conducting investigations and oversight.

1. Organic Laws
Congress influences the rulemaking process primarily through legislative action. Through legislation, Congress directs the agencies to carry out policies. Often legislation gives agencies only broad directives and leaves the details to the agency. In other cases, Congress will set out specific procedures and objectives. Congress not only uses legislation to create rules for specific policy issues, but it also uses legislation to shape the rulemaking process itself.

2. Appropriations Process
A completely separate process, that of appropriations, significantly impacts agencies. Each year, as Congress puts together the federal budget with the executive branch, agencies must explain and justify their activities. Since agencies can do nothing without money, they are sensitive to the interests of those members of Congress who sit on the appropriations subcommittees handling their budget requests.

Even the threat of a rider (i.e., an amendment to a bill) may cause an agency to abandon a proposal. On occasion, Congress uses riders on appropriations bills to prohibit an agency from using funds from its appropriation for an activity to which Congress objects.
3. Approval of Presidential Appointees

Confirmation hearings for Presidential nominees to high agency positions often are the occasion for debate about agency policies and programs. If a nominee is identified with a certain position or issue, Senators scrutinize the nominee on that issue or use the hearing as a means to express their own opinion. Senators also use confirmation hearings to be sure nominees understand the intentions of Congress regarding agency activities.

4. Oversight and Investigations

Oversight enables Congress to examine how agencies are implementing laws. This process is important because, as the late Chief Justice Charles Evan Hughes observed:

Legislators have little time to follow the trails of expert inquiry and so we turn the whole business over to a few with broad authority to make actual rules which control our conduct. The exigency is inescapable but the guardians of liberty will ever be watchful lest they are rushed from legislative incapacity into official caprice.

Oversight is conducted by committees and subcommittees organized expressly to monitor particular programs and agencies. An oversight agenda or investigation often results in a hearing or series of hearings in which agency personnel, issue experts, and affected parties testify in order to further inform Congress.

Much of the actual work is done by committee staff with research help from other offices of Congress such as the Government Accountability Office, the Congressional Budget Office, and the Congressional Research Service. Oversight and investigation work often involves research, interviews and requesting documents from agencies. Congress is privy to certain documents which may be unavailable to the public. Some committees have subpoena power as well that may be used to compel documents and testimony from government officials.

The outcome of an oversight agenda or investigation varies. If an agency has been lax in enforcing a statute, Congress may prod the agency into beginning or committing to begin a rulemaking. If an agency official is implicated in wrongdoing, Congress may uncover more details of the situation which may result in formal reprimand or dismissal. At the very least, oversight and investigation raises the visibility of a given issue by spurring media attention and public debate. Oversight by congressional committees is one of the most effective tools Congress has to hold the executive branch accountable.

D. The Courts' Role in Rulemaking

Courts review administrative decision-making under the requirements of the APA. These requirements are intended to ensure that an agency rule is neither "arbitrary" nor "capricious," and that it does not exceed statutory authority. Under other APA tests, courts can review a decision to see if an agency followed legally required procedures and did not delay its action unreasonably.

If a rule fails to satisfy these tests and other statutory requirements, courts may "vacate" (cancel) the rule and "remand" it back to the agency (send it back for further action).

Courts have set aside a rule if an agency failed to publish a Federal Register notice, failed to include mention of a significant subject covered in a final rule, or failed to contain in the published notice a reference to the legal authority under which the rule is proposed.
If an agency buries some important information in an NPRM by "incorporating by reference" (listing the source of material the agency used, but not printing the material itself), a court may decide that the agency failed to give adequate notice to interested parties—if the incorporated material is significant to the rule.

"Information that is material to the subject at hand should be disclosed as it becomes available," the courts have said.

**E. Your Role in Rulemaking**

American citizens have an important role in rulemaking as well. The APA's notice-and-comment requirements allow the public to participate in the rulemaking process by providing an opportunity to submit comments to agencies on most proposed rules. For more on how you can participate in the rulemaking process, please visit our Advocacy Center.

Available online: www.ombwatch.org/article/view/4011/1/494