Background on the Rulemaking Process

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I. Basic Outline

A. What is a federal regulation?

A regulation is a rule spelling out how a law will be implemented. When Congress passes a law, it often leaves details up to administrative agencies. This is because certain decisions require expertise that may exist in the administrative agency but not in Congress. Correctly made rules (that is, developed in compliance with the process set out in the Administrative Procedure Act) have the force of law for both those engaged in the regulated activity and the agencies which generated the rules.

B. What is regulatory policy?

Environmental protection, consumer safety, public health, civil rights: what all these important goals share is the two-step process of Congress enacting broad protective statutes followed by federal agencies developing regulations that implement and give meaning to those laws. Regulatory policy provides the frameworks used by agencies when developing rulemakings. It sets forth the guidelines for developing, promulgating, implementing, and enforcing this complex system of public protections. For example, regulatory policy gives guidance on how to prioritize rulemaking agendas, defines constraints to agencies' rulemaking ability, and determines the breadth and depth of information necessary for an agency to proceed with a rulemaking.

Regulatory policy guides agencies' rulemaking agendas. It has been used to create many of our most valued public protections, such as the removal of lead from gasoline, the ban on arsenic in drinking water, or the installation of airbags in cars.

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 federal agencies. There are many different kinds of 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.

The regulatory process is unfamiliar to the general public and these agencies are largely unknown. Regulatory issues tend to be technical, detailed, and complex-everything that makes them unappealing topics for the press and public. And yet we are governed by regulations everyday: the standards for drinking water, home cleaning products, cars and trucks (and their parts) and public transportation, the carpeting and flooring in our homes and offices, the safety of electricity usage, and for much more. The work of federal agencies is critically important.

C. Basic Theory of Administrative Government

The blurring of functions that takes place when an executive branch agency exercises quasi-legislative rulemaking authority is accepted as a necessity. However, it is rationalized on the grounds that the agency is acting within limits prescribed by Congress. This is the origin of the notion that agencies only exercise discretion delegated to them by Congress.

Unfortunately, the limits are not always easy to find. Congress has directed agencies simply to "promote the common defense and security," to "protect the public health," and to regulate in a "just" and "reasonable" manner "in the public interest." This kind of language has allowed federal agencies wide latitude to set policies and promulgate regulations.

In passing the Clean Air Act in 1970, for example, Congress authorized the administrator of the Environmental Protection Agency (EPA) to "prescribe such regulations as are necessary to carry out his functions under [the Act]."

But when agencies try to implement such broad mandates, they sometimes find themselves accused by members of Congress, the White House, or people outside the government of trying to set independent policy. If they proceed cautiously because they are not sure what Congress intended or are concerned about possible political ramifications, they face the charge that they are procrastinating or being obstructive.

As Senator Patrick J. Leahy (D-VT) once said: "We pass such fuzzy legislation. Then we pass it on to administrative agencies and say: 'You work it out.' Then members and the president go out and campaign against those 'crazy bureaucrats.'"

Occasionally, Congress turns in the other direction-over-prescription. Legislation may require an agency to follow particular procedures, make specific findings, and take final action with a certain time period. Sometimes Congress may even pass a bill that contains equally precise and vague provisions.

There is no clear rule or set pattern. Congress acts as the representative body it is, responding to people's concerns with varying degrees of forethought, debate, and agreement. Not surprisingly, this process is reflected in our laws and their delegations of authority to administrative agencies.

II. A Brief History of Administrative Government

A. The Early Years

Federal administrative agencies have been a critical part of our political process for over 100 years, but their role in our government has changed considerably over that period of time.

When the American republic was young, the executive branch of the government was small. The first agencies of the federal government were the Departments of War, State, Navy, and Treasury. There was also an Office of the Attorney General.

The growth of the country and the expansion of governmental responsibilities led to the creation of the Department of the Interior in 1849, the Department of Justice in 1870, and the Post Office Department in 1872.

Agencies began to adopt formal operating standards and publish rules in response to public criticism of abuses of power under the spoils system. In 1868, for instance, the Treasury Department began publishing its customs decisions, followed in 1869 by the Patent Office.

The period between 1865 and 1900 saw the birth of independent regulatory commissions. Congress created these agencies to set rates and bring order into industry competition. The first of these so-called economic regulatory agencies was the Interstate Commerce Commission. It was established in 1887 in response to charges that farmers and merchants were being forced to pay exorbitant railroad rates to ship their products to market.

Reformers believed independent regulatory commissions would bring greater, expertise, specialization and continuity to bear on economic problems than Congress could, and would operate in a dispassionate, nonpolitical environment.

However, many regulatory commissions had dual and sometimes contradictory objectives: To control and direct a specific industry and to promote those same industries. It was not long before many "independent" regulatory commissions were being accused of being "captives" of the industries they were supposed to regulate. In some cases industries themselves supported the creation of regulatory rate commissions as a way to help end competitive practices.

The economic concerns that led Congress to create independent regulatory commissions were soon joined by more social concerns such as public health and safety. For instance, in the early 1900's, the publication of Upton Sinclair's The Jungle brought nationwide attention to unsanitary practices in the meat industry. This followed news of rotten canned meat being served to American soldiers in the Spanish-American War and two decades of complaints about U.S. meat exports-for a time banned in Europe.

Congress tried unsuccessfully to solve the problem with a number of meat inspection laws. The solution was finally found in more comprehensive legislation and broadened authority for an administrative agency. The Food and Drug Act of 1906 mandates protection of the public from the health hazards of adulterated and mislabeled foods, drugs, cosmetics, and medical devices. The Bureau of Chemistry, which later became the Food and Drug Administration, was given expanded powers to implement the new law.

B. Bureaucratic Expansion

Governmental concern with social issues took an even greater leap during the Depression years. President Franklin D. Roosevelt's New Deal brought a vast expansion in federal government programs and agencies as the nation struggled toward economic recovery.

Another expansionary period took place in the 1960's and early 1970's as a result of the consumer, health and safety, and environmental movements. The Occupational Safety and Health Administration was created in 1971 and the Consumer Product Safety Commission in 1973. The Environmental Protection Agency was created by an executive reorganization plan in 1970 that pulled together 15 components from five departments and agencies.

With the creation of these regulatory agencies came an acceleration of regulatory activity. However, by the late 1970's this trend slowed. "Excessive" regulation began being blamed for everything from raising interest rates to forcing small business into bankruptcy and making U.S. businesses uncompetitive in world markets.

The regulatory process itself came under sharp attack. Complaints became commonplace about "interference in the marketplace," "red tape," "big government," and "faceless, nameless bureaucrats." The sheer volume of federal rules and regulations with their complexity, costs, and delays were leading to public and business-sector frustration and impatience with the federal government.

C. Influence of Congress and the White House

It was becoming increasingly clear that power in federal decision-making was shifting away from elected officials and toward government agencies. Subsequently, policy makers began to push back against what they perceived to be a swelling tide of regulatory bureaucracy. Congress passed a number of laws with the intention of exerting control over federal agencies. These laws include the Unfunded Mandates Reform Act and the Congressional Review Act which affords Congress an expedited process for nullifying federal regulations. The Paperwork Reduction Act, signed into law in 1980, created within the White House Office of Management and Budget (OMB) the Office of Information and Regulatory Affairs which serves as the regulatory review body for the president.

The White House led the charge in attempting to create a system in which agencies operate under the scrutiny and control of elected officials. Starting in 1971, presidents began issuing executive edicts as a means to achieve that end. The edicts often took the form of executive orders many of which focused on providing the White House some opportunity to review federal regulations during their development.

In 1971, through a memorandum from OMB, President Richard M. Nixon introduced the idea of a White House regulatory review process. The memo required agencies to submit summaries of proposed regulations as well as alternatives considered. In 1974, President Gerald Ford introduced cost-benefit analysis as a tool agency officials would be required to use in developing significant regulations. In 1978, President Jimmy Carter strengthened aspects of White House regulatory review and further defined certain issues germane to the process.

President Ronald Reagan went further in exerting White House control over the rulemaking process than any other president. In addition to tightening White House control and adding additional requirements of agencies, a 1981 executive order marked a shift in the White House's tone regarding federal regulations. Executive Order 12291, stating its intent "to reduce the burdens of existing and future regulations," reflected the administration's deregulatory viewpoint. In 1985, Reagan issued Executive Order 12498 requiring agencies to develop a detailed regulatory plan in order to assure OMB forthcoming regulations were consistent with White House priorities.

In 1993, President Bill Clinton issued Executive Order 12866 which combined and revised the two Reagan era orders to be consistent with the regulatory views of the Clinton administration. Much like the Reagan executive orders before it, E.O. 12866 became standard operating procedure for federal rulemaking. The Clinton order allowed the White House to continue to exert substantial control over agency proceedings.

In 2007, President George W. Bush made significant amendments to E.O. 12866 by issuing Executive Order 13422. The amendments allowed the White House to further manage the activities of federal agencies by including agency guidance documents (interpretive memos, guidelines, policy statements, etc.) into the regulatory review process and installing presidentially-appointed regulatory policy officers in the agencies themselves. The changes to the regulatory process, in effect as of late July 2007, continue the trend over several presidential administrations of exerting more control in the executive branch over agency rulemaking.

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 rule. For more on how you can participate in the rulemaking process, please visit our Advocacy Center.

IV. Rulemaking

To understand how the laws and executive orders that govern the regulatory process interact with agency activities, it is important to know how agencies develop regulations.

An agency's work does not consist solely of rulemaking, of course. Agencies recommend legislation to Congress and help draft bills. Some agencies adjudicate and settle cases, issue cease and desist orders or try civil penalty actions. And once programs are put into place and regulations published, agencies must ensure they are implemented.

Also, many other forces besides legislation may propel agencies to initiate rulemaking or take other actions: Public opinion, presidential politics, industry influence, natural disasters, and many others.

Thus, separating out the rulemaking process from all other agency activities can be somewhat misleading since agencies and their staffs have many responsibilities, only some of which have to do with drafting rules. And rulemaking itself is seldom a simple process.

A. Gathering Information

Gathering information is basic to agency work. Federal agencies cannot make decisions or regulate without information to guide them. Information comes from studies, surveys, and other kinds of data collection-sometimes conducted by the agency itself, collected from other agencies, private companies and public organizations, and sometimes data collection is contracted out to consultants.

When an agency proposes to collect information, it sends its research proposal and supporting documentation to the Office of Information and Regulatory Affairs (OIRA) at the White House Office of Management and Budget (OMB). At the same time, the agency sends a public notice to the *Federal Register* regarding the request that has been forwarded to OMB.

Within OIRA, agency proposals are reviewed by desk officers who have responsibility for specific agencies. These same desk officers review both paperwork and regulatory proposals.

The OIRA desk officer will review the proposal and will allow an agency to undertake an information collection activity, if he or she is satisfied the collection of information is:

- "the least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives";
- "not duplicative of information otherwise accessible to the agency"; and
- of "practical utility." (5 C.F.R. 1320.9)

If OIRA approves the agency proposal, the agency is given an "OMB control number," which must be displayed on every form and which is good for no more than three years. If the agency wants to keep collecting the information after the expiration of the OIRA approval, it must resubmit the information collection proposal for OIRA review. If OMB does not approve, the agency may not collect the information.

For basic information requests (i.e., non-regulatory paperwork), the Paperwork Reduction Act gives OIRA 90 days to review the request. If the review goes over 60 days, OIRA must notify the agency. If the review exceeds 90 days, the proposal is to be automatically approved for a year.

Once approved by OIRA, the agency can conduct its studies or surveys and accumulate the information necessary to make program or policy decisions.

B. Regulatory Planning Process

As agency personnel begin working on issues which may lead to regulations, they have to comply with the requirements of Executive Order 12866, Regulatory Planning and Review. Independent regulatory agencies are subject to planning requirements as well.

To comply with E.O. 12866, an agency must prepare semiannually an agenda of all its proposed regulations. The agendas of all agencies are published collectively as the Unified Agenda of Federal Regulatory and Deregulatory Actions (Unified Agenda). The Unified Agenda is typically published in April and October of each year.

The Unified Agenda is to include regulatory actions in the prerule, proposed rule, and final rule stages as well as long-term and completed actions. Due to the length of the rulemaking process, many regulations repeatedly appear in the Unified Agenda.

Rulemakings listed in the Unified Agenda are to include, among other things, a summary of the rule, the legal authority for the rulemaking, and any legal deadline for promulgation of the rule.

E.O. 12866 also requires each agency to prepare a Regulatory Plan of the "most significant regulatory actions" the agency anticipates pursuing. The Plan is included in the fall publication of the Unified Agenda.

The Plan is more focused than the Unified Agenda. Whereas the Unified Agenda is to include "all regulations under development or review," the Plan includes only "significant" regulations. Significant regulations, those expected to have "an annual effect on the economy of $100 million or more," require a more detailed submission of information to OIRA. Significant regulations are pared even further so that only the most important are included in the Plan. Additional requirements associated with each rule in the Plan include a statement of need and may include a summary of legal basis, alternatives to the proposed regulation, anticipated costs and benefits, and risks.

The anticipated costs and benefits section should provide a brief description of the impact the regulation is expected to have on agencies, industry, and the public. When possible, agencies often include dollar amounts to quantify these expectations, and often a quantified net impact on the economy.

Even as an agency is developing its regulatory plan, it is also in the midst of on-going activities. By the time the Regulatory Plan has been published, an agency may well want to begin work on issues not included in the Regulatory Plan. These, too, will have to be submitted to OIRA for review. The agency cannot act until the review is completed, unless there is an "unanticipated" emergency or statutory or judicial deadline.

C. Writing the Rule

The process of writing regulations varies considerably among federal agencies. Some have detailed procedures for rulemaking; others operate more informally. The time it takes from initial drafts of a regulation to publication as a final rule can range from a few months to several years. Most often, it takes a few years to complete a regulation because of the complexity of the issues, the collection of appropriate information, and the inherent delays built into the regulatory process. It usually involves considerable staff time and financial costs.

Often a program office within an agency is assigned the main responsibility for drafting a regulation. The program office is staffed by professionals who generally possess technical knowledge and experience with the subject of the regulation.

An alternative to the program office writing the rule is a team or working group assembled from different agency offices. These may include the office of the general counsel, regional and field personnel, policy planners and economists.

Specific laws sometimes dictate these procedures. For example, if a proposed rule would affect the environment significantly, agency personnel are required to send a copy of their proposal to agencies having environmental jurisdiction. Comments from those agencies will accompany the proposal through the agency review process.

Although many agency professionals have graduate degrees and specific technical expertise, they may still need the assistance of scientists or academics from outside the agency. These consultants may be hired to review agency proposals or to conduct studies for information lacking in the agency.

Not infrequently, agency personnel have discussions with representatives of the regulated industry or other interest groups. Industry representatives might be asked, for instance, to estimate the projected costs for a regulatory proposal. State officials may be asked about the mechanics of operating a program that they will have to administer.

On occasion agencies will attempt to formalize the process of consulting with interested parties by engaging in "negotiated rulemaking." Negotiated rulemaking attempts to move interested parties to compromise among themselves and help the agency develop a widely accepted regulatory proposal. The Negotiated Rulemaking Act of 1990 outlines the framework for the procedure, and Congress occasionally mandates its use when passing a law. However, due to the difficulty of incorporating the views of diverse groups of stakeholders, agencies do not often pursue negotiated rulemaking.

The internal agency steps involved in drafting a rule include gathering and evaluating data, participating in inter- and intra-agency meetings, drafting the proposed rule that will go into the *Federal Register*, and preparing background material and option papers for the agency decision-maker. An agency may also analyze public comments if any interested parties have submitted comments in the pre-rulemaking stage.

Agencies can sometimes skip some of these steps if there is an emergency (such as an immediate threat to public health and safety). The agency may also have to speed up the process due to a congressional or court order to issue a regulation by a specific deadline. In the interests of speed, an agency might publish an "interim" regulation, to be followed by a final regulation.

The drafting of a rule is a long process of inter- and intra-agency reviews and edits. Agency staff incorporates collected information, the views of other government bodies, the opinions of stakeholders and public comments where appropriate.

After a rule is drafted, it undergoes the centralized review process described in Section III. Once this process is complete, the rule is published in the *Federal Register* as a notice of proposed rulemaking (NPRM).

The NPRM will rarely describe the consultations between agency officials and their OIRA desk officer over the proposed rule. If an agency withdraws a proposed rule after OIRA review, there will of course be no NPRM published.

The public may request drafts of proposed rules sent to OIRA for review after they have been published in the *Federal Register*. Simple comparisons of a draft with a final rule will not reveal why any changes were made or who initiated them.

D. Publication in the *Federal Register*

After a proposed rule is reviewed by OIRA, it is published in the *Federal Register*. As required by the Administrative Procedure Act (APA), the NPRM must contain a description of the agency's rulemaking process, legal authority for the proposed rule, and the text or summary of the rule. The NPRM will announce what the agency intends to do and will also solicit comments on specific questions related to the rulemaking.

E. Notice-and-Comment Period

Generally, an agency will also announce a comment period, during which time interested parties can submit written comments either supporting or opposing the proposed regulation or offering ideas for changes. These comments can be simple or contain detailed arguments. Anyone can submit comments on a proposed rulemaking.

The publication in the *Federal Register* of an NPRM, or an advanced notice of proposed rulemaking (ANPRM), serves as an invitation for public participation in the rulemaking process.

The NPRM will likely be the first detailed presentation of the proposed rule. Agencies may already have published some description of the regulatory proposal in the Regulatory Plan or the Unified Agenda, but the NPRM is likely the first time the public is able to see the whole rule.

The APA only requires agencies to solicit written comments from the public. However, a number of agencies also hold hearings on proposed rules either because of the agency's desire to do so or because of a requirement in the statute the agency is enforcing.

The NPRM will describe how comments should be prepared and when they are due at the agency. The public is generally allowed access to the material and information the agency has collected in preparation for the filing, unless the Freedom of Information Act exempts a document.

Some rulemakings are exempt from the notice-and-comment period. Rules that are exempt from APA notice-and-comment period requirements are those dealing with military or foreign affairs and those "relating to agency management or personnel or to public property, loans, grants, benefits or contracts." Agencies may voluntarily waive an exemption if they so choose.

Comments received and the results of any hearing (when applicable) are put into a "rulemaking record," also known as the agency docket. The record should also include all the information collected in the course of agency research and investigation. The existence and organization of such a record is important if a court reviews the final agency decision and tries to determine the basis for the decision.

Searching through an agency's rulemaking record for information on how the agency reached its decision can be difficult since staff may have compiled hundreds (even thousands) of pages. While some agency rulemaking files are well organized, tabulated and indexed, searching through others may be, as one circuit court judge said, like "a safari through uncharted lands without benefit of a guide."

As part of e-rulemaking efforts, agency dockets are increasingly available online through the agency websites. However, much like the hard copy records, these online versions can often be difficult to navigate.

Not only does a poorly organized record make researching the rulemaking decision difficult, it may result in a court decision against the agency. Courts have invalidated rules when the record failed to demonstrate factual support for the rule or failed to show that the agency considered all relevant data.

To submit your own comments, please visit our Comment on a Rule page.

F. Review of Comments

Once the comment period ends, the agency reviews public comments received and may revise the rule.

The agency then goes through its final internal review process, which usually involves those same offices brought into the process earlier — the Secretary, the general counsel, program office, policy and planning staff, etc. They may be represented on a team or they may be asked only to sign off on the final proposal.

G. Publication of the Final Rule

When the agency makes its final rulemaking decision, it must again submit the final rule to OIRA for review. If it is a major rule it must also be accompanied by a final Regulatory Impact Analysis. OIRA will review the costs and benefits of the rule and determine if the rule fits the administration's regulatory priorities under E.O. 12866.

This final OIRA review may involve further negotiations with the agency, and the agency must again wait for the conclusion of OIRA review. For more on review of rules by OIRA, see Section III.

The final rulemaking notice will contain the text of the final rule as well as a statement of its basis and purpose. In a preamble, there will be a summary and analysis of the issues raised during the earlier stages in the process. If the rule is "major," the notice will also include an announcement of the availability of the final Regulatory Impact analysis and a legal memo on the agency's authority. Both the RIA and the memo must be placed in the rulemaking record.

Once the final rule has been published, an agency usually must wait at least 30 days before implementing it. While Congress or a court may occasionally give an agency a deadline for starting or completing rulemaking, most often agencies are free to set their own schedules. These are sometimes reflected in the timetables contained in the Regulatory Plan and the Unified Agenda.

For major rules the Congressional Review Act (CRA) grants Congress a 60-day window to review the rule. Congress may also review non-major rules, however those rules are not subject to further delay in the way major rules are. Congress is allowed to nullify the rule by simple majority. Since the enactment of the CRA in 1996, Congress has rarely considered the strategy and used it successfully only once.

V. Making Rules Work

Federal agency decision-making does not end with the publication of a final rule in the *Federal Register*. After all, once a regulation is issued an agency must administer or enforce it in order to fulfill the purposes of its statutory mission. A number of activities are critical to this process of implementation.

A. Guidance Documents

All regulations set forth policy and many of the details necessary for their implementation. However, they often do not provide all of the needed details. For example, they may not describe how an agency should coordinate the implementation of the new regulation with existing regulations, or who in the local or regional offices should approve exemption decisions.

As such questions arise, agencies often produce guidance documents to advise staff in national, regional, state, and local offices on regulatory implementation. These publications may not only become quite lengthy, but also are changed frequently to reflect regulatory revisions or new internal procedures.

Guidance documents are a broadly-defined class of information. They include any document which sets forth a policy, aids regulated bodies in complying with rules, or suggests action to the public or private sector on a matter the issuing agency feels it necessary to address. Guidance documents can take the form of memos, policy statements, brochures, and oral, written or visual communications.

Guidance documents do not have the force of law in the way regulations do. In some cases, agencies issue guidance documents to express a thought or opinion which may help the general health and welfare of the nation. Other times, agencies issue guidance to govern their own decision-making process. Regulated bodies may also ask for guidance in situations in which proper methods of compliance are unclear.

Beginning in July 2007, the Office of Information and Regulatory Affairs (OIRA) within the White House Office of Management and Budget (OMB) began reviewing guidance documents in the same way it does proposed regulations. (For more on OIRA's review process, see Sec. III.) OIRA subjects only "significant" guidance documents to its review process.

Significant guidance documents are those classified as affecting the economy by more than $100 million, affecting the actions of other agencies, affecting non-discretionary programs, or raising new policy issues.

Due to the expanded review process, the public has easier access to agency guidance documents. Significant guidance documents are published in the *Federal Register* and made available on agency websites. In some situations, agencies will give the public an opportunity to comment on a proposed guidance document in the same way as proposed rules. (For more on commenting on proposed rules, see Sec. IV.)

B. Inspections and Enforcement

Once a regulation takes effect and agency personnel have integrated it into their program operations, the agency must ensure regulatory compliance.

The agency may require those individuals, companies or institutions subject to regulation to report to the agency on compliance or keep records to prove compliance. The agency may conduct surveys or

scientific studies to determine if regulations are solving problems as intended. As discussed in Section IV, these information collection activities will require OMB clearance under the Paperwork Reduction Act.

Agencies also use inspectors to investigate how well laws and regulations are being followed. Inspectors for the Department of Labor's Occupational Safety and Health Administration check factories and work sites for proper equipment maintenance and worker safety measures and instruction. Nuclear Regulatory Commission inspectors monitor nuclear power plant operations. National Transportation Safety Board investigators sift through airplane wreckage to ascertain the cause of crashes. Securities and Exchange Commission officials monitor stock transactions to guard against insider trading. The Department of Agriculture Animal and Plant Health Inspection Service inspectors examine imported animals for disease.

Agency investigations can lead to adjudications or enforcement proceedings in which the agency may charge individuals with violating a regulation. Agency hearing examiners or administrative law judges may impose penalties ranging from further audits to suspension from federally-funded programs. In some situations, agencies will levy fines for failure to comply with a regulation.

If the matter is so serious as to suggest possible violations of criminal statutes, the case may be referred to the Department of Justice for criminal prosecution.

C. Program Management

For an agency to implement a regulation effectively it must be sure that its own operations are in order. This is a never ending task. Congress passes government improvement laws, agencies issue administrative regulations, and even the president, through OMB, instructs agencies on how to manage their programs, perform audits, distribute grant money, buy equipment, and investigate fraud, waste, and abuse.

Part of managing an agency is working to ensure that it is staffed with the needed experts and that the budget is sufficient to meet he mission the agency or program must carry out. Congress and the president, however, have the final say about the resources each agency receives. It isn't enough that Congress pass legislation authorizing regulatory policy; it needs to appropriate sufficient finding for an agency to implement the legislation.

Available online: www.ombwatch.org/article/archive/504