Chairman Cicilline, Ranking Member Buck, and members of the Subcommittee, I appreciate the opportunity to testify today. My name is Wendy Wagner. I am the Richard Dale Endowed Chair at the University of Texas School of Law and teach courses on regulatory process, law and science, and environmental protection. My publications focus primarily on administrative law and process as it intersects with the protection of public health and the environment. Included in my publication list are several large empirical studies of agency rulemakings that were funded by the National Science Foundation, including a study that was awarded the ABA’s Annual Scholarship Award. On issues related to the use of science in regulation, in addition to my published books and articles on the topic, I served as the consultant on the Administrative Conference of the US on science and regulation and was responsible for writing a detailed report and proposing recommendations. I have also served on several National Academies of Science committees, the Bipartisan Policy Center committee on science and regulation, and the National Conference of Scientists and Lawyers (a joint committee of AAAS and the ABA).

Agencies serve a vital function in US government, promulgating thousands of rules and policies needed to effectuate Congress’ laws. Yet because of their significant place in our separation of powers system, the legitimate scope of agency authority has been a continuing source of
controversy. In response, overlapping oversight mechanisms have been devised by Congress, the courts, and the Executive Branch to curb agency power. See Appendix 1 and 2.

Over the last few decades, however, it has become clear that the various legal checks on agencies are not working nearly as well as they should. Some of these oversight mechanisms tend to work at cross-purposes. Other legal checks impose requirements on agency action that are ineffective or can even backfire. Indeed, because there are so many “cooks” in the kitchen, the possibility of counter-productive process requirements emerging in administrative law is almost inevitable.

I am delighted that Congresswoman Jayapal and this Subcommittee are undertaking a more holistic and systematic examination of administrative process and the challenges that have arisen over the last few decades. In my testimony, I focus on two important goals of administrative law – ensuring agency expertise and accountability – and discuss how the existing body of oversight mechanisms emerging from Congress, the courts, and the Executive Branch are proving incomplete and sometimes even counterproductive in advancing these goals. I then trace how Congresswoman Jayapal’s bill is well positioned to improve both agency accountability and expertise and suggest ways that future legislation could go still farther in this regard.

I. AGENCY EXPERTISE

Agencies provide expertise to the nation on thousands of issues that range from modeling human responses to reactive chemicals to designing corporate disclosures for shareholders and investors. Agency staff who provide this expertise are generally regarded as professionals who produce high quality work. Yet several structural impediments – most of which originate in the Executive Branch – currently hinder the ability of agencies to consistently deliver excellent expert advice.

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A. The Politicization of Agency Science

Agency experts in most Executive Branch agencies serve as subordinates to political officials, and thus the work of these experts can be influenced and even controlled by appointees and other policymakers within the government.6 Despite the obvious risks of the resultant politicization of science within the agencies, the decision processes used in agencies rarely separate or insulate the foundational agency scientific analyses from subsequent policy (and often political) decisions about the best course of action.7 Political appointees thus retain the prerogative to alter underlying technical analyses in ends-oriented ways that compromise the integrity of the science.8 In some rules, politically-driven changes to the scientific record are also made by other Executive Branch agencies, particularly through or by the White House’s Office of Information and Regulatory Affairs (OIRA).9

The resulting potential for the manipulation of scientific analyses generated by agency experts is now well-documented.10 Political officials within the Executive Branch have censored scientific staff, directed politically-driven revisions to foundational technical analyses in nontransparent ways, and used other means to manipulate the scientific record to advance predetermined policy ends. Political officials have even “stacked” the composition of the members serving on science advisory panels to ensure their peer review is more favorable to a preferred political position.11

However, since these internal deliberations involving changes to the scientific record are considered “deliberative process,” the Executive Branch claims they are uniformly exempt from public disclosure under the Freedom of Information Act (FOIA). As a result, there is the ever-present potential for political meddling of foundational technical analyses, and this activity is

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7 See, e.g., WENDY WAGNER, SCIENCE IN REGULATION: A STUDY OF AGENCY DECISIONMAKING APPROACHES (2013), available at https://www.acus.gov/sites/default/files/documents/Science%20in%20Regulation_Final%20Report_2_18_13_0.pdf. One notable exception is EPA’s setting of National Ambient Air Quality Standards (NAAQS) under the Clean Air Act, which offers a possible best practices model for ensuring the integrity of agency expertise in decisionmaking. See id; see also Sidney Shapiro, et al., The Enlightenment of Administrative Law: Looking Inside the Agency for Legitimacy, 47 WAKE FOREST LAW REVIEW 463, 491-501 (2012).


9 See supra notes 6-8.


completely hidden from public view.\textsuperscript{12} Indeed, for many rules, the public has no way to access information about the scientific record prior to it being altered or influenced by political officials.

**Recommendations to Address the Politicization of Agency Science**

To ensure that national policies are informed by the very best available science, the agency scientific staff doing the initial review of the scientific literature as it informs specific policy questions must be insulated from all political influence.\textsuperscript{13} For major rules at least, the staff reports synthesizing the relevant literature should list the staff authors by name and be made public before policymaking commences.\textsuperscript{14} Agency processes should also provide assurances (through peer review or other mechanisms) that scientific scrutiny is rigorous and that staff scientific reviews can be trusted. Taking these steps will ensure that the public is aware of what our nation’s experts believe the relevant scientific information to be before this information and analysis is used to inform policymaking. Agency officials are free to ignore or correct the scientific analyses of staff, but these discussions will be on the record. In fact, this is the same model that the National Academy of Sciences recommended for agency decision-making in 1983 for many of the same reasons.\textsuperscript{15}

Congress could require agencies to follow this process by law or alternatively could offer agency incentives, such as directing reviewing courts to afford added deference to agency processes that meet these requirements, consistent with an affirmative defense discussed below at page 10.

Congresswoman Jayapal’s bill makes excellent progress in addressing this recommendation by requiring the agency to describe “how the agency considered scientific evidence, including any study or research.”\textsuperscript{16} However, more specific direction would help to ensure the agency understands that it must document in more detail agency processes for using science, including firewalling the initial staff review of the literature from political influence.

**B. The Use of Unreliable Scientific Information to Inform Public Regulatory Decisions**

Under existing legal procedures, agencies must promulgate rules, such as protective standards for public health and environment, based on the available scientific evidence, but the agencies lack the funding and time to conduct this research themselves. As a result, agencies are often dependent – sometimes by statutory design – on the work of regulated parties for the foundational research that informs their regulatory decisions.

\textsuperscript{12} See supra notes 6–8.
\textsuperscript{13} For fuller discussion, see McGarity & Wagner supra note 10; P. BAHARARA ET AL., supra note 5; Wagner, supra note 7.
\textsuperscript{14} As discussed supra note 7, the EPA’s NAAQS process provides a template for best practices on designing these more rigorous science-policy processes in agency decisionmaking.
\textsuperscript{16} Section 3 “Stop Corporate Capture Act.”
The conflict of interests inherent in a regulated party providing the scientific information used to develop regulations that govern its activities raise fundamental challenges to ensuring the integrity and reliability of this private research. Regulated parties provide the needed information, but they have an interest in the outcome that can affect how they design the studies, who they chose to conduct the research, and even which results they publish or share with agencies.\textsuperscript{17} See Appendix 3. Indeed, in the scientific literature there is a well-known “funding effect” that reveals a statistically significant correlation between an interested, private sponsor (e.g., drug manufacturer) and the findings in its published studies of its products (e.g., more favorable to the sponsor than publicly-funded research).\textsuperscript{18}

Agencies have endeavored to limit this funding effect in part by prescribing protocols for some tests in advance and by requiring “good laboratory practices”. Yet these efforts are grossly inadequate to ensure that private research is of sufficient quality to inform public regulation. And, while there have been a number of Congressional and Executive efforts to address information quality (e.g., Data Quality Act, bills on transparency, Executive Branch Orders, etc.), these projects generally apply only to public research and exempt private research from their reach, despite the fact that private research is most at risk of being compromised.\textsuperscript{19}

Adding to this challenge of ensuring the integrity of private research produced to inform regulation is the inaccessibility of much of this privately produced research once it is shared with the agencies. Because agencies sometimes only require industry to submit study summaries and not the studies themselves, public commentators are frequently unable to review the underlying research. In addition, overgenerous trade secret and related protections shield a large amount of this research from public view.\textsuperscript{20} Such restrictions are proving particularly disastrous in some areas, like the regulation of PFAS. In fact, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) actually prohibits the agency from openly sharing underlying health and safety studies with the public; interested members of the public instead must visit EPA headquarters to view studies on the toxicity of a pesticide and these visits can only take place after the EPA has finalized its decision on that pesticide.\textsuperscript{21}

\textsuperscript{17} See, e.g., DAVID MICHAELS, DOUBT IS THEIR PRODUCT: HOW INDUSTRY’S ASSAULT ON SCIENCE THREATENS YOUR HEALTH (2008); DAVID MICHAELS, THE TRiumPH OF DOUBT (2020); THOMAS McGARITY & WENDY WAGNER, BENDING SCIENCE (2007).


\textsuperscript{20} See, e.g., ENVTL. WORKING GROUP, OFF THE BOOKS II: MORE SECRET CHEMICALS (2016), available at https://www.ewg.org/research/books-ii-more-secret-chemicals; see also Wagner & Michaels, supra note 19.

\textsuperscript{21} 7 U.S.C § 136h(g)(1).
Recommendations to Address Unreliable Private Scientific Information

Legislation is needed to correct these well-documented problems with the integrity of private research by requiring conflict disclosures, as proposed by Congresswoman Jayapal’s bill. But legal reform should go further by also requiring the disclosure of contracts governing private research as well as requiring standard authorship forms, common for the scientific journals, that disclose the level of researcher control. In terms of the more challenging problem of limited public access to underlying private research, agencies that rely on private studies should be expected under normal conditions to request the full study from the submitter and to make those studies available to the public as a matter of course, with redactions of only limited information to reflect trade secret concerns. Finally, Congress should undertake a study of how agencies are currently implementing trade secret claims in health and environmental laws to determine whether this broad privilege – that often shields even the existence of claimed chemicals or products from public view (including the underlying health studies) – comports with Congress’ intent.

II. ACCOUNTABILITY OF AGENCIES TO THE PUBLIC

Agencies are credited with utilizing processes for major decisions – adjudications and rulemakings – that are among the most democratically deliberative in our government. To promulgate a regulatory rule, for example, the agency must solicit all public views on its proposal and “consider” and provide rigorous and often very specific explanations for its response to each and every comment. If the agency does not do this, any member of the public may sue the agency for a rule that the litigant demonstrates is arbitrary and capricious, outside the four corners of the law, or based on other enumerated grounds.

Adding to this required deliberative process supporting agency rules are a number of other procedural checks, some coming from Congress, some from the courts through common law-type of interpretation of the Administrative Procedure Act (APA), and some coming from the White House. The cumulative requirements on agencies now are quite extensive. See, e.g., Appendices 1 and 2.

While individually some of these requirements may seem sensible, their cumulative impact can produce agency incentives that actually work to undermine accountability goals, rather than

23 See supra note 20.
advance them. The literature yields a number of key problems. I identify a few of the more significant concerns below.

**A. Perverse Incentives for Overly Complex and Opaque Decisions**

Under the APA and various judicial doctrines, agencies may fully comply with every analytical requirement and transparency demand, and yet their explanations and rules may be effectively inscrutable except to those in the inner circle of a subset of stakeholders. As Professor Farina and colleagues describe, from the perspective of affected citizens, the agency’s rule and accompanying analysis is often “about as accessible as if the documents were written in hieroglyphics.” Requiring more transparency from agencies alone (e.g., supporting documents, additional cost-benefit analysis and other requirements, etc.) does not address the underlying reality that the explanations and agency proposals can be lengthy, unduly complicated, and effectively inaccessible, even to the most sophisticated stakeholders.

Existing administrative process, particularly in the wake of decades of court interpretations, deserve significant blame for the incomprehensibility of some agency rules. In the text of the APA, Congress did in fact require that agencies provide a “concise general statement” of their proposals and rules. But over the last sixty years of litigation, this well-meaning directive has been transformed by the courts’ unrelenting insistence on comprehensive records and elaborately supported rules. As administrative law expert, Richard Pierce, notes, “[t]he courts have replaced the statutory adjectives, ‘concise’ and ‘general’ with the judicial adjectives ‘detailed’ and ‘encyclopedic.’” For example, the courts’ hard-look doctrine, which is sometimes used to review agency rules, is notorious for exerting pressure on agencies to become obsessively detailed in their final rules, sometimes at the expense of maintaining a grasp of the big picture and communicating that big picture to stakeholders. And the courts’ logical outgrowth test encourages agencies to develop a proposed rule that is as complete as possible, which in turn encourages agencies to negotiate the rule proposals with high stakes, litigious stakeholders outside the sunshine of the APA.

More generally, the “robed roulette wheel” of judicial review, evidenced by inconsistent and sometimes ideologically-driven opinions, encourages agencies to adopt a litigious posture in rule

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26 5 U.S.C. § 553(c).
drafting to avoid the chance of vacatur and remand. In such a legal environment, agencies rationally assume the worst and write their rules more like litigation briefs than open-minded proposals soliciting public input on policy options. Regulatory law scholar Shep Melnick observes from his study of agency rulemakings: “Since agencies do not like losing big court cases, they reacted defensively [to the courts’ requirements], accumulating more and more information, responding to all comments, and covering their bets. The rulemaking record grew enormously, far beyond any judge’s ability to review it.”

And “[t]hus began a vicious cycle: the more effort agencies put into rulemaking, the more they feared losing, and the more defensive rulemaking became.”

B. Imbalanced Participation

At least on paper, U.S. administrative law places a premium on ensuring complete and meaningful participation in agency rulemakings. Participants are not only guaranteed the opportunity to comment on agency proposals, but agencies are legally required to consider participant comments. If an agency fails to comply with these requirements, it can find itself defending its rule in court.

What actually happens in practice, however, can be quite different. Even though legal requirements impress upon agencies the need to provide formal opportunities for participation, agencies are not required to ensure that the opportunities they do provide are meaningful or effective for affected publics. Administrative law also does not require that all significantly affected parties be actively represented in a rulemaking that affects their interests. Instead, in the APA model, the agency operates as a passive recipient of stakeholder input. Agencies therefore rarely, if ever, endeavor to ensure balanced stakeholder engagement (much less track the diversity of stakeholders), subsidize or actively solicit underrepresented groups, or otherwise ensure that the actual participants bear any resemblance to those who are actually affected by the agency’s action. If affected groups lack the resources to participate in a rulemaking that affects their interests, they are unrepresented and have no legal claims after the fact.

30 JERRY L. MASHAW, GREED, CHAOS, AND GOVERNANCE: USING PUBLIC CHOICE TO IMPROVE PUBLIC LAW 181 (Yale, 1999); Pierce, supra note 27, § 7.4 at p.449-50.
32 Id.
33 Wagner, supra note 25.
34 Congress, however, did create an office to advocate on behalf of small businesses. The Small Business Regulatory Enforcement Fairness Act, 5 U.S.C. § 611(a)(3), although as the Center for Progressive Reform has documented, this SBREFA process is dominated by large businesses and thus does little to advance genuine small business concerns. SIDNEY SHAPIRO & JAMES GOODWIN, DISTORTING THE INTERESTS OF SMALL BUSINESS: HOW THE SMALL BUSINESS ADMINISTRATION OFFICE OF ADVOCACY’S POLITICIZATION OF SMALL BUSINESS CONCERNS UNDERMINES PUBLIC HEALTH AND SAFETY (Ctr. for Progressive Reform White Paper 1302, 2013), available at https://cpr-assets.s3.amazonaws.com/documents/SBA_Office_of_Advocacy_1302.pdf.
Exacerbating this lack of legal attention to ensuring equitable and meaningful participation by affected groups under the APA are gaps in the formal notice and comment requirements themselves. Over time, eager participants and overburdened agencies have learned to exploit these gaps, creating various end-runs around the notice and comment process to gain an edge. As just one example, while agencies must carefully attend to those commenting during the public comment period, there are effectively no restrictions on the processes agencies use to develop the initial rule proposal. As a result, agencies can manage litigation risks by negotiating the rule proposal with the most litigious stakeholders in advance, outside the formal comment and recordkeeping requirements. Under existing administrative law, agencies are not required to even docket these communications, and we know from at least one agency (EPA) that does record its preNPRM communications that the pre-proposal stage of the rulemaking involves considerably more stakeholder interaction (albeit only with regulated parties) than the notice and comment process itself.\(^{35}\) See Appendix 4. In these rules, this negotiated rule published in the Federal Register operates more as a final working draft than a preliminary opening statement. Similar nontransparent discussions appear to be occurring after a final rule is promulgated, evidenced by a high rate of rule revisions for many rules.\(^{36}\)

As a result of these notice and comment work-arounds, there can be significant slippage between the democratic deliberative opportunities promised by the formal U.S. administrative process on paper and what happens in practice. A number of empirical studies in fact consistently find significant evidence of inequities in the ability of affected parties to participate in rulemakings in a meaningful way, with thinly financed groups often absent from the deliberative scene altogether. See Appendix 4. Only about half the rules that affect the public involve at least one public nonprofit or other commenter that is not a regulated entity. For the other half of the rules, only industry and the occasional state or local government provide comments.\(^{37}\) And in proceedings in which a public interest representative does file a comment, that entity is almost always outnumbered—at least twofold and in some studies tenfold—when compared to industry comments.\(^{38}\)


\(^{38}\) Yackee & Yackee, supra note 37; Wagner et al., Rulemaking in the Shade, supra note 36, at 128–29.
The resulting imbalances among active participants in agency rules are amplified – rather than checked – by the courts’ approach to judicial review; the threat of subsequent legal challenges as a matter of law come largely, if not exclusively, from those who submit comments. Under the courts’ interpretation of the APA, an agency cannot be sued unless the litigant’s concern was raised with specificity during the comment period. If a critical comment is not entered into the record, then the agency need not anticipate or second guess that concern. Groups who are absent from the notice-and-comment process are foreclosed from litigating an agency’s decision unless there is a representative comment already submitted into the record from another participant.

C. Executive Branch Overrides

Over the last few decades, the Executive Branch has become more unitary, exerting control over agency rulemakings through mandatory clearance processes at OIRA. Under the deliberative process privilege, as noted, these internal deliberations and clearance discussions are deemed exempt from FOIA. Even efforts under Executive Order 12866 to require agencies to at least publicly document the changes made by OIRA to agency proposed and final rules have often not been followed in some rules.

The end result is a growing concern that the APA deliberative process established by Congress may sometimes be rendered a charade because the policy (and technical) choices have already been made high up in government, outside the agency. In this way, White House control impedes an agency’s ability to truly “consider” in good faith the comments offered on a rule proposal as required by the APA.

D. Inaction

A final, well-established problem embedded in the cumulative APA, judicial review, and related process controls are the perverse incentives for agencies to opt for delay and inaction. Agencies face a daunting maze of legal requirements governing rulemakings, including the prospect that – after years of deliberations – a court may vacate and remand a rule, requiring the agency to start over.

By stark contrast, there are effectively no countervailing incentives for agency action, at least in statutes without deadlines. Under the APA and related case law, while interest groups can challenge agencies when they miss statutorily prescribed deadlines, a petitioner seeking to force an agency to develop a long-awaited rule carries a high burden if Congress has left the regulatory timing to the agency’s discretion, which is often the case.\(^43\)

As a result, there is evidence of pockets of “ossification” and inactivity in sets of rulemakings.\(^44\) OSHA, for example, has promulgated very few worker protection rules over the last thirty years, despite the fact there is an ever lengthening list of potentially harmful substances used in the workplace that should be regulated. Likewise, in the last 40 years, the EPA has managed to ban only a handful of chemicals under its chemical regulatory statute. The Consumer Product Safety Commission (CPSC) similarly has done very little to regulate latent harms in consumer products through proactive product standards or retroactively through product bans. In each of these cases, agency inactivity was precipitated by an adverse court decision that vacated an early agency effort to regulate.\(^45\)

This asymmetry in the legal forces that operate on agencies, effectively insulating agencies for inaction and delay, are difficult to correct legislatively. For example, too much judicial oversight of agency inaction might allow the courts to micromanage agency priorities, while also fueling abusive litigation. Yet the current balance of incentives – high burdens to promulgate rules with no legal consequences for inaction – are clearly out of sync.

**Recommendations**

Legislative solutions must address head-on the systemic legal disincentives that currently discourage agencies from employing rigorous, meaningful deliberative processes that advance the public interest. To that end, Congress should require agencies (for at least the most significant rules) to justify the decision processes underlying each of their rulemakings. Specifically, agencies should be required to document how they ensure meaningful participation by affected groups, how this public input influences the decision-making and is considered in good faith, and how the agency uses scientific information and analyses in ways that are insulated from political control. This documentation should also include an accounting of all communications with persons outside of the agency, including all inter-agency communications occurring within the Executive Branch.\(^46\)

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\(^46\) For more details on this proposal, see WAGNER, INCOMPREHENSIBLE!, *supra* note 25, at 192-203; Wagner, *Filter Failure*, *supra* note 25, at 1403-04; Wagner, *supra* note 6, at 2065-66.
Congresswoman Jayapal’s bill makes superb progress on these recommendations, particularly in creating the Public Advocate and calling for greater transparency of OIRA’s role in influencing agency rules. To go still further and ensure that the foundational cracks in agency processes are adequately addressed, however, agencies should also be required by law to document how they arrived at a decision, from beginning to end.

Rather than a direct requirement which could entail unintended consequences, Congress could provide statutory rewards that encourage agencies to voluntarily provide this explanation and documentation. For example, Congress could afford the agencies with an affirmative defense if the agency convinces the court that it hosted rigorous and meaningful public deliberations. Accordingly, if a court is satisfied that the agency’s deliberative processes underlying a rule is rigorous, it would be required to afford the agency’s policy and factual decisions “extra deference” unless there are clear errors in statutory interpretation.47

Beyond clear legislative directives that provide strong incentives for agencies to employ rigorous, equitable public deliberations on rulemakings and other decisions, Congress should consider other reforms as it renovates administrative law for the 21st century. There are two outstanding reports published by the American Constitutional Society that provide numerous important proposals that warrant the Subcommittee’s attention.48 There are also several other more specific proposals in the extant literature that deserve careful consideration.

- Rather than layering more and more prescriptive analytical requirements on agencies to support their decisions, Congress should take an inventory of how well the existing legal requirements (including requirements imposed by Executive Orders and court doctrines) are actually working in practice.49 Congress can then cull out the most costly and counter-productive requirements, including demands that are inconsistent with statutory purposes and/or that serve only to further drain agency time and attention, lead to still more unwieldy and complex rules, and provide marginal if no benefit to the integrity of the deliberative processes.50
- Interagency coordination is important and beneficial, but it should not be allowed to interfere with an agency’s faithful compliance with its statutory mandates or render the

47 See, e.g., WAGNER, INCOMPREHENSIBLE!, supra note 25, at 195-99.
50 For example, superfluous laws like the Data Quality Act that purport to advance the quality of science used by agencies but appear to have no track record of success could be repealed. Sidney A. Shapiro, The Information Quality Act and Environmental Protection: The Perils of Reform by Appropriations Rider, 28 WM. & MARY ENVTL. L. & POL’Y REV. 339 (2004).
APA notice and comment process a meaningless exercise. Greater legislative constraints on tracking these inter-agency communications are needed, as are potential limits on Executive Power if it intrudes on the rulemaking process.51

- Courts have imposed a number of common law requirements on agencies, such as the logical outgrowth test and the exhaustion requirements, that may be causing counter-productive agency behaviors. Some of these doctrines should be adjusted legislatively to offset their negative effects on agency processes.52
- The strong incentives embedded in existing legal process that favor agency inaction over carrying out statutory mandates should be addressed systematically, perhaps by adjusting rules governing agency responses to petitions, as Congresswoman Jayapal’s bill does, and/or by other types of reforms.53
- Agencies should be required to provide more balanced processes for drafting proposed rules. A good start is to at least require or encourage agencies to document all of the communications in and outside of government that inform the drafting of a proposed rule, as well as the nature of those communications. Ideally agencies should also explain how their proposed rulemaking process was conducted in a way that ensured the views of all major affected groups were considered.54

III. CONCLUSION

Seventy-five years of piecemeal administrative reforms imposed on agencies through courts, the Executive Branch and incremental legislation have taken their toll on the ability of agencies to serve the American public. Under existing process rules, agencies face legal impediments and disincentives to provide rigorous expertise, to engage with stakeholders in meaningful deliberations, and to promulgate timely rules to address controversial but important public problems. Under the circumstances, it is remarkable that agencies have been able to carry out their missions of protecting the public as well as they have. Congress is well-positioned to rehabilitate the rickety state of US administrative process by engaging in a systematic examination of the ways that the current oversight mechanisms fall short and devising procedural rules to address the shortfalls.

52 Markoff, supra note 40; WAGNER, INCOMPREHENSIBLE!, supra note 25, at 193-95.
53 Supra note 42.
54 Simon F. Haeder & Susan Webb Yackee, Out of the Public’s Eye? Lobbying the President’s Office of Information and Regulatory Affairs, 9 INTEREST GROUPS & ADVOCACY 410 (2020); STEINZOR ET AL. supra note 51.
### Specific Analyses for Steps Three and Seven

#### Regulatory Planning and Review (E.O. 12866)

- **Question**: Would the rule have a $100 million annual impact, raise novel issues, or have other significant impacts?
- **Yes/No**
- **Action**: Prepare economic impact analysis.

#### Regulatory Flexibility Act (5 U.S.C. 601-612)

- **Question**: Is a notice of proposed rulemaking required by law?
- **Yes/No**
- **Action**: Prepare regulatory flexibility analysis.

#### Paperwork Reduction Act (44 U.S.C. 3501-3520)

- **Question**: Does the rule contain a collection of information?
- **Yes/No**
- **Action**: Prepare information collection clearance package for OMB review and approval, and prepare request for public comments.


- **Question**: Does the rulemaking process include a proposed rule?
- **Yes/No**
- **Action**: Prepare unfunded mandates analysis unless an exclusion applies.

#### Indian Tribal Governments (E.O. 13175)

- **Question**: Is the rule a discretionary rule that has federalism implications and imposes substantial or unsolicited direct compliance costs on tribal governments?
- **Yes/No**
- **Action**: Prepare federalism summary impact statement.

#### National Environmental Policy Act (42 U.S.C. 4321-4347)

- **Question**: Does the rule contain provisions for which the use of voluntary standards is applicable?
- **Yes/No**
- **Action**: Adopt voluntary consensus standards or explain why not.

#### National Technology Transfer and Advancement Act (15 U.S.C. 272 note)

- **Question**: Does the rule regulate property private use for the protection of public health or safety?
- **Yes/No**
- **Action**: Prepare takings analysis.

#### Federal Register Publications

- **Question**: Does the rule contain the proposed rulemaking notice required by law?
- **Yes/No**
- **Action**: Prepare draft rule.

### Step Six: Comments

- **Under the Administrative Procedure Act provisions of 5 U.S.C. 553, an agency must provide the public the opportunity to submit written comments for consideration by the agency.

- **As required by Public Law No. 101-196, agencies must provide for submission of comments by electronic means and must make available online the comments and other materials included in the rulemaking docket under 5 U.S.C. 553.

- **Executive Order 12866 established 60 days as the standard for the comment period.

- **The holding of a public hearing is discretionary unless required by statute or agency policy.

### Appendix 2: Drafting Requirements for Rulemaking Documents

- **Regulatory Planning and Review (E.O. 12866)**
  - Rulemaking documents must comply with the specified regulatory philosophy and principles of regulation.

- **Civil Justice Reform (E.O. 12898)**
  - Rulemaking documents must be written in clear language designed to help reduce litigation.

- **Presidential Memorandum on Plain Language (63 FR 31885)**
  - Rulemaking documents must comply with plain language principles.

- **Federal Register Publications**
  - Rulemaking documents must comply with Federal Register regulations (1 CFR). Additional guidance and requirements are contained in the Federal Register’s Drafting Handbook.

### Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (E.O. 13211)

- **Proposition**: Does the rule regulate property private use for the protection of public health or safety?
- **Yes/No**
- **Action**: Prepare takings analysis.

- **Proposition**: Is the rulemaking a “covered regulatory action”?
- **Yes/No**
- **Action**: Prepare analysis of the environmental health or safety effects on children.

- **Proposition**: Does the rule contain provisions for which the use of voluntary standards is applicable?
- **Yes/No**
- **Action**: Adopt voluntary consensus standards or explain why not.

- **Proposition**: Is the rulemaking a “significant energy action”?
- **Yes/No**
- **Action**: Prepare statement of energy effects.

### Step Seven: Final Rule

- **Final Rule**
  - A final rule adds, changes, deletes, or affirms regulatory text.
  - OMB review only those rulemaking actions determined to be significant.
  - Independent agencies are exempt from OMB review.

- **Interim Final Rule**
  - An interim final rule adds, changes, or deletes regulatory text and contains a request for comments.
  - The subsequent final rule may make changes to the text of the interim final rule.

### Step Eight: OMB Review Under Executive Order 12866

- **OMB Review Under Executive Order 12866**
  - An OMB review is not required if the rulemaking action is determined to be insignificant.
  - Independent agencies are exempt from OMB review.

### Step Nine: Congressional Review Act

- **Congressional Review Act (5 U.S.C. 801-808)**
  - An agency must submit final rules, interim final rules, and direct final rules, along with supporting information, to both houses of Congress and the General Accounting Office before they can take effect.

- **Major rules are subject to a delayed effective date (with certain exceptions).**

- **Action by Congress and the President could have an impact on the rule.”

### Using The Reg Map

The Reg Map is based on general requirements. In some cases, more stringent or less stringent requirements are imposed by statutory provisions that are agency specific or subject matter specific. Also, in some cases more stringent requirements are imposed by agency policy.

In a typical case, a rulemaking action would proceed from step one through step nine with a proposed rule and a final rule. However, if a rulemaking action is exempt from the proposed rulemaking procedures under the Administrative Procedure Act provisions (explained under step three) or under other statutory authority, an agency may:

- Promulgate a final rule omitting steps three through six, or
- Promulgate an interim final rule omitting steps three through six, but providing a comment period and a final rule after step nine.

Also, if an agency determines that a rule likely would not generate adverse comment, the agency may promulgate a direct final rule, omitting steps three through six, but with a duty to withdraw the rule if the agency receives adverse comments within the period specified by the agency.

### OMB Prompt Letters

- **OMB Prompt Letters**
  - OMB Prompt Letters might be required if the agency is requested to publish in the Federal Register’s Unified Regulatory Agenda in the fall of each year.

### Administrative Procedure Act Provisions

- **The Administrative Procedure Act provisions that are included as part of the Freedom of Information Act at 5 U.S.C. 552, agencies are required to publish in the Federal Register.

- **Substantive rules of general applicability**
  - Interpretive rules
  - Statements of general policy
  - Rules of procedure
  - Information about forms
  - Information concerning agency organization and methods of operation

- **Executive Order 13132**
  - Constitutional Protection for Property Rights
  - Rulemaking documents must comply with the specified regulatory philosophy and principles of regulation.

- **Executive Order 12866**
  - Major rules are subject to a 60-day OMB review.

- **Executive Order 13045**
  - Protection of Children from Environmental Health Risks and Safety Risks

- **Executive Order 12630**
  - Rulemaking procedures must comply with the specified regulatory philosophy and principles of regulation.
APPENDIX 4

These figures are drawn from Wagner et al., Rulemaking in the Shade (2011). They record the participation occurring in EPA air toxic rules (N=90). Most of the rules were promulgated during the Clinton and George W. Bush Administrations.

![Figure 2: Interest Group Participation (Total Contacts) at Pre-NPRM and Notice-and-Comment Stages of Rulemaking](image)

(The solid bars represent the mean number of contacts; the thin lines represent the standard deviation on these means).

![Figure 4: Interest Group Participation During the Notice-and-Comment Process](image)

(M=Mean; SD=Standard Deviation; Max=maximum value within the 90 rules). An additional 7% of comments came from regulated governments and other/unknown groups.)
These figures were published in Wagner et al., Deliberative Rulemaking (2021). They summarize interest group participation in all of EPA’s TSCA Test rules promulgated from the late 1980’s through the early 2000s.