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Laws, Rulemaking, and Regulations: An Overview of the Federal Regulatory Process

Last updated June 21, 2022

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Introduction

Regulations are one of the most significant tools the federal government possesses to achieve public policy goals. Federal agencies issue and enforce regulations on topics as varied as public health and safety to consumer protection, business and banking practices, Internet privacy, and the environment.

How regulations are actually developed, implemented, and enforced varies greatly among agencies and often can mean the difference between success and failure. For example, will the Occupational Health and Safety Administration's (OSHA) forthcoming heat stress standard meaningfully protect workers from preventable illness and death, or will it rubberstamp the status quo?[1] With regulations, the answer is often as much the process as the substantive details. In the best circumstances, regulations are grounded in the best available science and are the product of extensive public outreach. However, the political influence, technical language, and extended time periods often associated with rulemakings can make them challenging to understand and limit public participation. This is especially true in low-income, rural, and minority communities that have much to gain from well-designed regulations but whose members have historically been excluded from the process of their development. Moreover, cost-benefit analysis of proposed regulations, which elevates economic efficiency above all other objectives, can make it exceedingly difficult for agencies to justify regulations protecting values like the climate, employee rights, and public health.

Federal Laws and Regulations

Regulations begin with an act of Congress. In order for a federal agency to issue a legally binding rule or regulation, it must derive that authority from an act of Congress — an agency cannot issue a substantive rule unless granted authority to do

[1] 86 FR 59309.

so by law.[2] When Congress passes laws, however, it often grants agencies broad "rulemaking authority" to implement statutory programs by issuing and enforcing regulations. These grants of authority make clear the goals and purposes of the program, but leave the agency significant discretion to design the program's details based on its subject matter expertise. These programmatic frameworks are also more adaptive and responsive since federal regulations can often be updated more quickly than federal statutes to account for new developments in science and technology or to address new and emerging threats that the statute was intended to address.

Agency regulations specify the details and requirements necessary to guide their implementation and adjudicate administrative litigation.[3] For example, in 1996 Congress passed the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[4] The act provided for the regulation of pesticide distribution, sale, and use to protect the country's food supply. It also required the Environmental Protection Agency (EPA) to license all pesticides distributed or sold domestically. EPA subsequently issued detailed regulation and, using the authority provided to it through the statute, now requires approval and reporting for more than 500 pesticides.[5] The implementation of this program provides clear rules of the road and certainty to the manufacturers and users of pesticides, supporting America's agricultural economy, and it also provides confidence to America's consumers that the food on our store shelves is safe to eat and feed to our children.

Regulations contain detailed definitions and examples designed along with "authority notes" that list the specific sections of a law passed by Congress authorizing its promulgation (e.g., 7 U.S.C. § 136). Once finalized, these regulations are printed in the Federal Register and codified in the Code of Federal Regulations (CFR).[6] [7] Upon enactment, they carry the force and effect of law.[8]

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[2] FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 151 (2000) ("It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress."); *See also* Bowen v. Georgetown Univ. Hosp., 488 U.S.204, 208 (1988). ("An administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress.").

[3] 5 U.S.C. § 551(4). The Administrative Procedures Act defines a rule as "the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy."

[4] 7 U.S.C. § 136 *et seq*.

[5] 40 C.F.R. § 152.

[6] The Code of Federal Regulations contains 50 subject matter titles updated yearly on a staggered basis: titles 1-16 are revised as of January 1; titles 17-27 are revised as of April 1; titles 28-41 are revised as of July 1; and, titles 42-50 are revised as of October 1.

[7] The Federal Register is the "legal newspaper" of the federal government. It is the official daily publication for rules, proposed rules, and notices of federal agencies and organizations, as well as executive orders and other presidential documents.

[8] National Latino Media Coalition v. Federal Communications Commission, 816 F.2d 785, 788 (D.C. Cir. 1987) ("A valid legislative rule is binding upon all persons, and on the courts, to the same extent as a congressional statute. When Congress delegates rulemaking authority to an

Rulemaking and the Administrative Procedures Act

When issuing regulations, agencies are required to follow a certain set of procedures prescribed by law and executive order. This "rulemaking" process is principally governed by the Administrative Procedure Act (APA).[9] Passed in 1946, the APA was born out of concern that the rapid expansion of federal agencies and regulations necessary to implement President Franklin D. Roosevelt's New Deal lacked transparency and accountability. The APA defines rulemaking as the "process for formulating, amending, or repealing a rule" and establishes a minimum degree of public participation a federal agency must undertake when developing new regulations.[10] Thus, the rulemaking process is effectively the intermediate process between the enactment of a law by Congress and the promulgation of achievement of a substantive rule.

Unless an authorizing statute provides for a different set of procedures, federal agencies usually promulgate rules using "informal" notice-and-comment rulemaking.[11] In informal rulemaking, a federal agency must first notify the public that it intends to promulgate a rule by publishing a Notice of Proposed Rulemaking (NPRM) in the Federal Register. This notice must include: (1) a statement of the time, place, and nature of public rulemaking proceedings; (2) reference to the legal authorities under which the rule is proposed; and, (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.[12] The NPRM also includes a deadline for comments, how and where to file comments, and relevant agency personnel to contact about the proposal. In novel, controversial, or especially significant cases, a federal agency may elect to issue an Advanced Notice of Proposed Rulemaking (ANPRM), which is intended to help it to refine relevant legal and policy questions that will later be addressed in the NPRM.[13]

Federal agencies must then provide an opportunity for the public to meaningfully comment on the content of the proposed rule. Typically, an agency will provide at least 30 days for public comment. Public comments as well as other supporting materials (e.g., hearing records) are placed in a rulemaking "docket" available for public inspection. The public docket for executive branch agency rulemakings can be found at Regulations.gov. This docket is also examined by the courts when

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agency, and the agency adopts legislative rules, the agency stands in the place of Congress and makes law.").

[9] *See generally*, 5 U.S.C. §§ 551–559.

[10] 5 U.S.C. § 551(5)-(7).

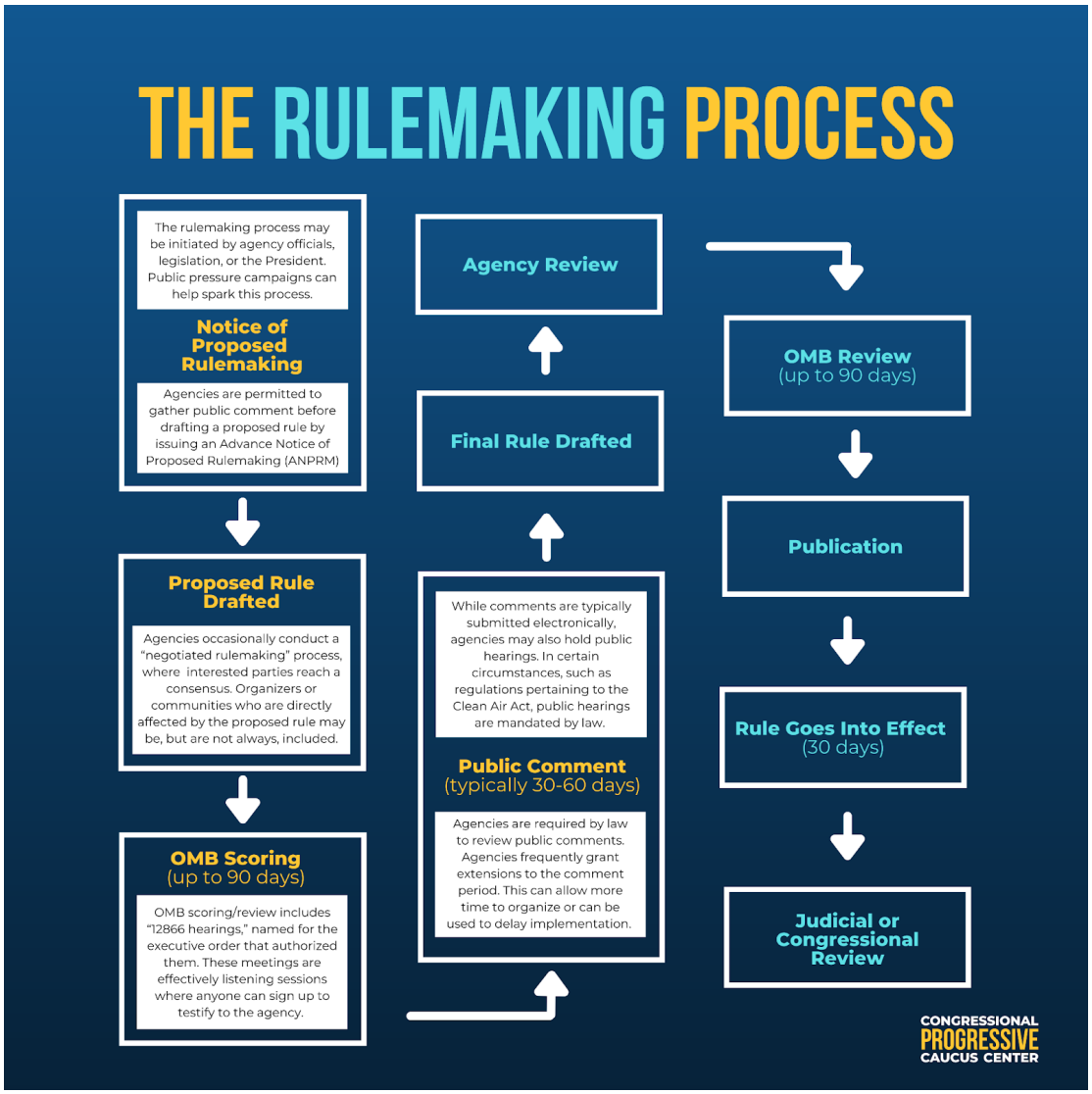
[11] § 553.

[12] § 553(b).

[13] *E.g.,* 86 FR 54667. Federal courts may not impose procedural requirements beyond what Congress has provided for in the APA. *See* Vermont Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519, 546 (1978) ("In short, all of this leaves little doubt that Congress intended that the discretion of the agencies and not that of the courts be exercised in determining when extra procedural devices should be employed.").

settling legal challenges to regulations – it provides the "record" on which courts will rely when resolving disputes over a regulation. Only after review and response to "significant" comments, which sometimes result in changes to the final proposal, may a federal agency publish a final rule in the Federal Register.[14] The rule may not go into effect until at least 30 days after it is published in the Federal Register, with certain exceptions.[15] These same procedures also apply when an agency chooses to repeal a rule (i.e. "deregulation" requires the same process as regulation) or to amend any aspect of a rule (e.g., even changing a rule's effective date must go through the APA rulemaking process).[16]

Figure 1



[14] *See* Perez v. Mortg. Bankers Ass'n, 575 U.S. __, 135 S. Ct. 1199, 1203 (2015) ("An agency must consider and respond to significant comments received during the period for public comment."); *See also* Am. Mining Cong. v. EPA, 965 F.2d 759, 771 (9th Cir. 1992) (The court described "significant comments" as "those which raise relevant points and which, if adopted, would require a change in the agency's proposed rule.").

[15] 5 U.S.C. § 553(d).

[16] *E.g.*, 86 Fed. Reg. 2744.

As noted above, there are several notable exceptions to APA's requirement for notice and comment. First, rulemakings may be exempted when a federal agency finds "good cause."[17] This exemption requires agencies to demonstrate that the use of the standard procedures would be "impracticable, unnecessary, or contrary to the public interest." One of the most common uses of the good cause exception is the issuance of interim final rules. To prevent abuse, courts have traditionally interpreted this exception narrowly.[18] Guidance documents, such as policy statements, memoranda, and other interpretive rules (discussed below), are also exempt from the APA's notice and comment rulemaking.[19]

Other Rulemaking Procedures

In addition to informal notice-and-comment rulemaking, federal agencies less frequently promulgate rules using the following procedures.

(1) Interim Final Rule (IFR): An Interim Final Rule is a rule issued by a federal agency that becomes effective immediately without first seeking public comment on the rules' substance.[20] Instead, federal agencies solicit public comment at the time of publication and then revise the rule after collecting feedback. Because of its immediacy, IFRs are generally intended for use only in emergency or otherwise unique situations. An example of an IFR is a rule jointly issued by the Department of the Treasury and the Small Business Administration (SBA) in 2020 to implement the Paycheck Protection Program.[21] Because language in the Coronavirus Aid, Relief, and Economic Security (CARES) Act required the agencies to operationalize the program within 30 days of passage, there was no time to issue a draft rule and solicit public comment. In this instance, Treasury and SBA used an IFR to establish the initial parameters by which small businesses would be eligible for the program, including requirements on lenders and borrowers.

(2) Direct Final Rule (DFR): Direct final rulemakings are a mechanism used to adopt non-controversial regulations on an expedited basis where an agency has determined that such an action is in the public interest and unlikely to result in adverse comment.[22] DFRs are a rarely used mechanism (on the order

[17] § 553(b)(A).
[18] *See* Am. Fed. of Gov't Emp. v. Block, 655 F.2d 1153, 1156 (D.C. Cir. 1981) (quoting N.J. v. EPA, 626 F.2d 1038, 1045 (D.C. Cir. 1980))
[19] § 553(b)(A).
[20] The legal justification for interim final and direct final rulemakings is rooted in § 553(b)(B) of the Administrative Procedures Act, which exempts rules from notice-and-comment obligations when the agency finds good cause that those procedures would be "unnecessary."
[21] 85 FR 20811 and EPA-HQ-OPPT-2017-0244.
[22] *See* Sierra Club v. EPA, 99 F.3d 1551, 1554, (10th Cir. 1996) ("A direct final rule becomes effective without further administrative action, unless adverse comments are received within

of 100-350 times per year). In a DFR, an agency publishes a final rule stating an effective date. If an adverse comment is filed within the specified comment period — generally 60 days after publication in the Federal Register — the agency must rescind the rule and undertake the standard rulemaking process. Otherwise, the rule goes into effect on the date stated in the DFR. Because DFRs offer agencies greater speed than the typical rulemaking process, it can lead to abuse of the APA's good-cause exception. The EPA's attempt to extend the compliance date for formaldehyde emission standards for composite wood products using a DFR is a recent example.[23]

(3) Negotiated Rulemaking: In a Negotiated Rulemaking ("reg neg"), a federal agency follows the usual rulemaking process, publishing the proposed rule in the Federal Register requesting public comment.[24] After this, an agency usually convenes a committee of key stakeholders to directly negotiate the terms of a proposed rule. This supplemental round negotiation is intended to help achieve consensus, thereby making the agency's final rule easier to implement and less likely to face litigation. Negotiated rulemakings, which are especially favored by the Department of Education, originated in the 1980s.[25] Importantly, a rule that is the product of negotiated rulemaking is still subject to judicial review and "shall not be accorded any greater deference by a court than a rule which is the product of other rulemaking procedures."[26] Negotiated rulemaking has become somewhat controversial in recent years, given concerns that it reinforces power disparities between targets of regulations (e.g., industry) and the beneficiaries of regulations.

(4) Formal Rulemaking: In rare circumstances, such rules pertaining to ratemaking or food additives, agencies may be required to use a more formal rulemaking process.[27] This "formal" rulemaking includes a quasi-judicial hearing where the agency must present their case and witnesses can be subject to lengthy cross-examination by other stakeholders. These proceedings are usually presided over by an administrative law judge or official who has the power to issue subpoenas and administer oaths. Historically, formal rulemaking procedures dragged on for years and generated voluminous written records, delaying agency action and wasting scarce public resources. Thanks to one particularly infamous episode involving an FDA rule that sought to determine whether peanut butter should contain at least 90 percent peanuts or only 87 percent, this process is now regarded as

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the time limit specified in the proposed rule. If adverse comments are received, the Agency withdraws its direct final rule and issues a final rule that addresses those comments.").

[23] 82 FR 23735.

[24] *See* 5 U.S.C. § 561 *et seq*.

[25] *E.g.*, 86 FR 54666.

[26] § 570.

[27] § 556 and 557. Ratemaking is the formal regulatory process by which public utilities set the prices ("rates") they will charge consumers.

highly controversial and strongly disfavored. Agencies are only required to submit to this formalized process of adjudication when authorizing legislation explicitly requires that the rulemaking process proceed "on the record."[28] The Dodd-Frank Act is an instructive example. Section 1044 authorized preemption of certain state consumer protection laws by the Office of Comptroller of the Currency (OCC), but only after on the record adjudication or rulemaking.[29]

(5) Hybrid Rulemaking: As the name suggests, hybrid rulemaking is a cross between informal and formal rulemaking procedures. Hybrid rulemaking occurs when Congress imposes specific procedural requirements beyond the APA's informal, notice-and-comment rulemaking (i.e, "substantial evidence" review), but such obligations fall short of on-the-record, formal rulemaking. Hybrid rulemaking statutes may require an agency to hold public hearings, allow interested persons to submit oral testimony, and grant participants opportunities for cross-examination or questioning. The Occupational Safety and Health Act, which requires public hearings, is an example of a statute necessitating hybrid rulemaking, and is often cited as one of the reasons why OSHA rulemakings take so long to complete compared to those of other agencies.

Additional Statutory Provisions

The rulemaking process is also governed by other laws including the Congressional Review Act, Regulatory Flexibility Act, and Information Quality Act. Other major statutory authorities are outlined below.

(1) Congressional Review Act: The Congressional Review Act (CRA) provides a set of parliamentary procedures that Congress can use to overturn certain federal agency actions.[30] Under the CRA, all final agency rules and guidance documents must be reported to Congress. Upon receipt, Congress then has 60 legislative working days to pass a joint resolution of disapproval (JROD) to overturn the rule. If the JROD passes both chambers of Congress with a simple majority and is signed into law by the President, the rule "shall be treated as though such rule had never taken effect." If the rule has not yet gone into effect by the time the resolution of disapproval is enacted, it will not take effect.

Importantly, once Congress passes a JROD an agency rule "may not be reissued in substantially the same form, and a new rule that is substantially

[28] § 706(2)(E) and United States v. Florida East Coast Ry. Co., 410 U.S. 224 (1973).
[29] Dodd-Frank Wall Street Reform and Consumer Protection Act, P.L. 111-203 § 1044, 124 Stat. 1376 (2010) (codified at 12 U.S.C. §§ 25b, 5551).
[30] Contract with America Advancement Act of 1996, P.L. 104-121, Title II, Subtitle E, 110 Stat. 847 (codified at 5 U.S.C. § 801 *et seq.*).

the same…may not be issued, unless the reissued or new rule is specifically authorized by a law enacted after the date of the joint resolution."[31] After a rule is disapproved under the CRA, an agency is barred from promulgating a rule that is "substantially the same in form" unless Congress authorizes it to proceed.[32] The CRA does not indicate what would constitute a substantially similar rule and federal courts have not yet heard a case on which they could make a determination. The uncertainty around the CRA's future prohibition clause thus warrants selective use by Congress.

CRA resolutions are most likely to be used against rules issued at the end of a presidential term. Consequently, this can discourage agencies from issuing any rules of consequence during these months.

(2) Regulatory Flexibility Act: The Regulatory Flexibility Act (RFA) requires federal agencies to prepare a "regulatory flexibility analysis" assessing the impacts of forthcoming regulations on "small entities" unless the agency certifies that the proposed rule will not "have a significant economic impact on a substantial number of small entities."[33] Executive Order 13272, signed on August 13, 2002, required agencies to establish procedures and policies to promote compliance with the RFA. The RFA also created the Small Business Administration's Office of Advocacy, which is charged with ensuring agency compliance with RFA analytical requirements. The Office of Advocacy is highly controversial, now seen as captured by large industry and trade associations to advocate on their behalf instead of on behalf of small businesses.

(3) Small Business Regulatory Enforcement Fairness Act (SBREFA): Under the Small Business Regulatory Enforcement Fairness Act (SBREFA), the EPA, OSHA, and Consumer Financial Protection Bureau (CFPB) are required to conduct a Small Business Advocacy Review (SBAR) panel before publishing a proposed rule with an Initial Regulatory Flexibility Analysis.[34] The SBAR panel process is highly controversial because it is seen as a source of major delays in the rulemaking process, often delaying rulemakings by years. The Small Business Administration's Office of Advocacy plays a role in setting up the SBAR panels, and often permits representatives of large trade associations to participate instead of representatives of small businesses. SBREFA also expanded the ability of small businesses to recover legal costs under the Equal Access To Justice Act (EAJA).

(4) The National Environmental Policy Act: The National Environmental Policy Act (NEPA) requires federal agencies to assess and disclose the

[31] § 801(b).
[32] § 801(b)(2).
[33] Regulatory Flexibility Act, P.L 96-354, 94 Stat. 1164 (codified at 5 U.S.C. § 601).
[34] Small Business Regulatory Enforcement Fairness Act of 1996, P.L. 104-121, 110 Stat. 857 (codified at 5 U.S.C. § 601 *et seq*.).

environmental, public health, and socio-economic effects of all major federal actions.[35]

(5) Federal Advisory Committee Act: The Federal Advisory Committee Act (FACA) governs the operation of federal advisory committees composed of regulatory experts and representatives of affected interest groups. With few exceptions, each advisory committee meeting is presumptively open to the public and membership of committees must be considered to ensure a balance of views on a given issue.

(6) Information Quality Act: The Information Quality Act (IQA) required the Office of Management and Budget (OMB) to provide guidance to federal agencies to ensure use of the best available scientific information.[36] The IQA is controversial because it permits regulated parties to slow down new health, safety, and environmental standards.

(7) Negotiated Rulemaking Act: The Negotiated Rulemaking Act (NRA) endorsed and formalized a procedural framework for negotiated rulemaking.[37] Importantly, the NRA clarified that negotiated rulemakings are principally designed to supplement, not replace, the standard notice and comment procedures under the APA.[38]

Procedures for Amending or Repealing Rules

To amend or repeal a regulation issued pursuant to agencies' discretionary authority generally requires compliance with the default notice-and-comment process outlined in § 553 of the APA, which defines "rulemaking" to be the "process for formulating, *amending*, or *repealing* a rule."[39] An agency may not repeal any regulation mandated by statute or court order. An agency may also choose to re-open or extend a public comment period when it is not satisfied it has received enough high quality comment or upon request from the public.[40] If granted, an agency must publish a supplemental notice in the Federal Register specifying the length of the extension and the revised comment deadline.

Although the APA requires that a rule may not take effect until 30 days after the date of publication of the final rule, rule repeals, which are generally deregulatory in nature, may be excused from the APA's delayed effective date if they are deemed to

[35] *See* 40 C.F.R. 1500-1508 and 42 U.S.C. §§ 4321 *et seq.*
[36] *See* Office of Management and Budget, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies" (February 22, 2002).
[37] Negotiated Rulemaking Act of 1990, P.L. 101-648, 104 Stat. 4,969, amended 1996, P.L. 104-320, 110 Stat. 3,870 (codified at 5 U.S.C. § 561 *et seq.*).
[38] 5 U.S.C. § 561.
[39] § 551(5).
[40] *E.g.*, 85 FR 22690.

"relieve a restriction."[41] As discussed in greater detail below, policy statements, interpretive rules, and other guidance documents that lack the independent force of law and were not subject to notice-and-comment during their initial promulgation may be altered immediately and without public participation.[42]

Executive Orders

A series of executive orders, bulletins, and memoranda — first issued by President Reagan — have also established general principles and non-statutory requirements that must be followed during the rulemaking process (though, compliance with these requirements must be ensured through presidential oversight and cannot be made judicially enforceable). The most consequential of these measures have been adopted via executive order (EO). Executive orders are exempt from the APA. Presidents cannot use executive orders to create new law, but instead can only use them to exercise authorities under existing laws and consistent with authorities granted under Article II of the Constitution.[43]

Since President Reagan issued EO 12291 in 1981 centralizing the regulatory review process, covered agencies have been required to perform a cost-benefit analysis for all "major" rules.[44] EO 12291 also required agencies to submit draft and final rules to the Office of Management and Budget (OMB) and Office of Information and Regulatory Affairs (OIRA) — the White House's gatekeeper for federal rulemaking — for approval prior to publication in the *Federal Register*.[45] EO 12291 is controversial because using cost-benefit analysis to guide regulatory decision-making is inconsistent with the vast majority of authorizing statutes and because OIRA was created to implement a specific law (the Paperwork Reduction Act), not to supervise agency rulemaking. In each of these ways, EO 12291 (and later related EOs) seems to stretch presidential authority to the breaking point, if not beyond it.

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[41] § 551(5).

[42] *See* Perez v. Mortg. Bankers Ass'n, 135 S. Ct. 1199, 1206 (2015) (Because an agency is not required to use notice-and-comment procedures to issue an initial interpretive rule, it is also not required to use those procedures when it amends or repeals that interpretive rule.); *See also* Vermont Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519, 524 (1978) ("[The APA] established the maximum procedural requirements which Congress was willing to have the courts impose upon agencies in conducting rulemaking procedures. Agencies are free to grant additional procedural rights in the exercise of their discretion, but reviewing courts are generally not free to impose them.").

[43] Franklin v. Massachusetts, 505 U.S. 788, 800–01 (1992). Although presidential actions are exempt from the APA, they are still subject to "nonstatutory review" to ascertain whether the action was unconstitutional or inconsistent with the governing statute; *See also* Chamber of Commerce v. Reich, 74 F.3d 1322, 1328 (D.C. Cir. 1996).

[44] Executive Order 12291, 46 FR 13193 (1981).

[45] Executive Order 12866, which superseded Executive Order 12291, exempts "independent regulatory agencies" (defined at 44 U.S.C. § 3502) from OMB review and the requirement to submit significant regulatory actions to OIRA for review.

EO 12866, issued by President Clinton in 1993 and still in effect today, superseded EO 12291 and further reinforced centralized regulatory review by the White House. As one of its "principles of regulation," EO 12866 directed agencies to show that the benefits merely "justify" their costs, rather than requiring that benefits "outweigh" costs.[46] Its most consequential reform, however, was to limit cost-benefit analysis to "economically significant" rules with an estimated annual economic impact greater than $100 million. According to the Congressional Research Service (CRS), this reform reduced the number of rules requiring OIRA review from between 2,000 and 3,000 per year to between 500 and 700 per year. In all other cases involving "significant" rules, agencies may submit a less detailed regulatory impact analysis to OIRA for review. EO 12866 defines "significant" rules as those that may:

(1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
(2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
(3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or,
(4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the executive order.[47]

EO 12866 also requires that OIRA generally complete its review of proposed and final rules within 90 calendar days, although there have been numerous examples over the years where the agency fails to meet this target. In cases where a rule is extremely large or there is a statutory deadline, OIRA will often conduct an "informal review" before official submission. Such informal reviews are controversial because they defeat the 90-day limits and because they are otherwise exempted from EO 12866's transparency provisions. Nevertheless, OIRA defends the practice as "useful for agencies since they have the opportunity to educate OIRA desk officers in a more patient way, before the formal 90-day review clock at OMB begins to tick. The practice is also useful for OIRA analysts because they have the opportunity to flag serious problems early enough to facilitate correction before the agency's position is irreversible."[48] At the end of the review, OIRA either returns the draft rule to the agency "for reconsideration" (rare) or approves the rule and codes it into its database as either "consistent without change" (also rare) or "consistent with change." The "consistent with change" outcome is by far the most common, and indicates that OIRA has required an agency to make some change to its draft rule during the review. Quite often, these changes can be significant, drastically changing how the

[46] Executive Order 12866 § 1(b)(6), 58 FR 51735 (1993).
[47] *Id*. § 6(a)(3)(B).
[48] Office of Management and Budget, "Making Sense of Regulation: 2001 Report to Congress on the Cost and Benefits of Regulations and Unfunded Mandates on State, Local and Tribal Entities" (December 2001).

rule will operate in practice. The nature of these changes and their basis are seldom disclosed. In some circumstances, an agency may also choose to withdraw its draft rule during OIRA's review.[49] After receiving OMB approval, an agency may then submit a proposed or final rule for publication in the *Federal Register*.

Since President Clinton issued EO 12866 in 1993, there have been few substantive changes to OIRA's review process. One significant change did occur in the early 2000s when OIRA began placing increased emphasis on cost-benefit analyses for proposed rules and publishing more "return letters" explaining to the public why a rule was returned to an agency for further review.[50]

Most recently, President Biden issued a Presidential Memorandum titled "Modernizing Regulatory Review."[51] The memorandum directed OMB to update guidance documents such as Circular A-4 and to establish mechanisms to ensure that the regulatory review process "fully accounts for regulatory benefits that are difficult or impossible to quantify, and does not have harmful anti-regulatory or deregulatory effects." President Biden's memorandum also included substantive and procedural components to promote the values of justice and equity. On the substantive side, it called on OMB to ensure that regulatory initiatives appropriately benefit and do not inappropriately burden disadvantaged, vulnerable, or marginalized communities." On the procedural side, the memorandum directed OMB to "consider ways that OIRA can play a more proactive role in partnering with agencies to explore, promote, and undertake regulatory initiatives that are likely to yield significant benefits." This command seeks to expand OIRA's role to proactively push other agencies to promulgate equity-focused regulations.[52]

In addition to those outlined above, there are many other ancillary executive orders applicable to the federal rulemaking process, the most important of which are outlined below.

> **(1) Executive Order 12898:** Issued by President Clinton in 1994, EO 12898 formally acknowledged the statistical fact that low-income, rural, and minority communities suffer are disproportionately impacted by environmental pollution and its associated health effects.[53] The executive order also directed federal agencies to make achieving environmental justice part of their mission by adopting and implementing an environmental justice strategy. Few federal

[49] *E.g.*, 84 FR 37821.
[50] *See* U.S. General Accounting Office, "Rulemaking: OMB's Role in Reviews of Agencies' Draft Rules and the Transparency of Those Reviews," GAO-03-929 (September 2003).
[51] 86 FR 7223.
[52] Richard Revesz, "A New Era for Regulatory Review," *The Regulatory Review* (February 16, 2021).
[53] Executive Order 12898, 60 FR 6381 (1995); *See also* Department of the Interior Policy on Consultation with Indian Tribes, Secretarial Order No. 3317 (2011).

agencies have fulfilled this mandate, however, which in part prompted President Biden's Justice40 Initiative.

(2) Executive Order 13175: Issued by President Clinton in 2000, EO 13175 directed federal agencies to establish procedures to consult and collaborate with tribal governments when new agency regulations have tribal implications. EO 13175 also reaffirmed the federal government's commitment to government-to-government consultation with Indian tribes and prohibits the promulgation of any regulation not required by law that imposes a substantial burden on tribes without consultation and a "tribal summary impact statement" describing those consultations.[54] Importantly, EO 13175 falls short of free, prior, informed consent, a principle that would empower tribes to give or withhold consent to projects that may affect them or their territories. Currently, the right to tribal consultation when non-reservation cultural resources may be affected has also yet to be codified by Congress.[55]

(3) Executive Order 13563: Issued by President Obama in 2011, EO 13563 sought to reduce duplicative regulations, increase public input, and required OIRA to better incorporate qualitative factors that can be hard to quantify in cost-benefit analyses, such as equity, human dignity and fairness.[56] It also required agencies to retrospectively analyze rules for compliance.

(4) Executive Order 13579: Issued by President Obama in 2011, EO 13579 requested (but did not require) that independent regulatory agencies follow the key principles of Executive Order 13563.[57] The prevailing view is that presidents lack the constitutional authority to impose requirements on independent agencies through executive orders.

Guidance Documents

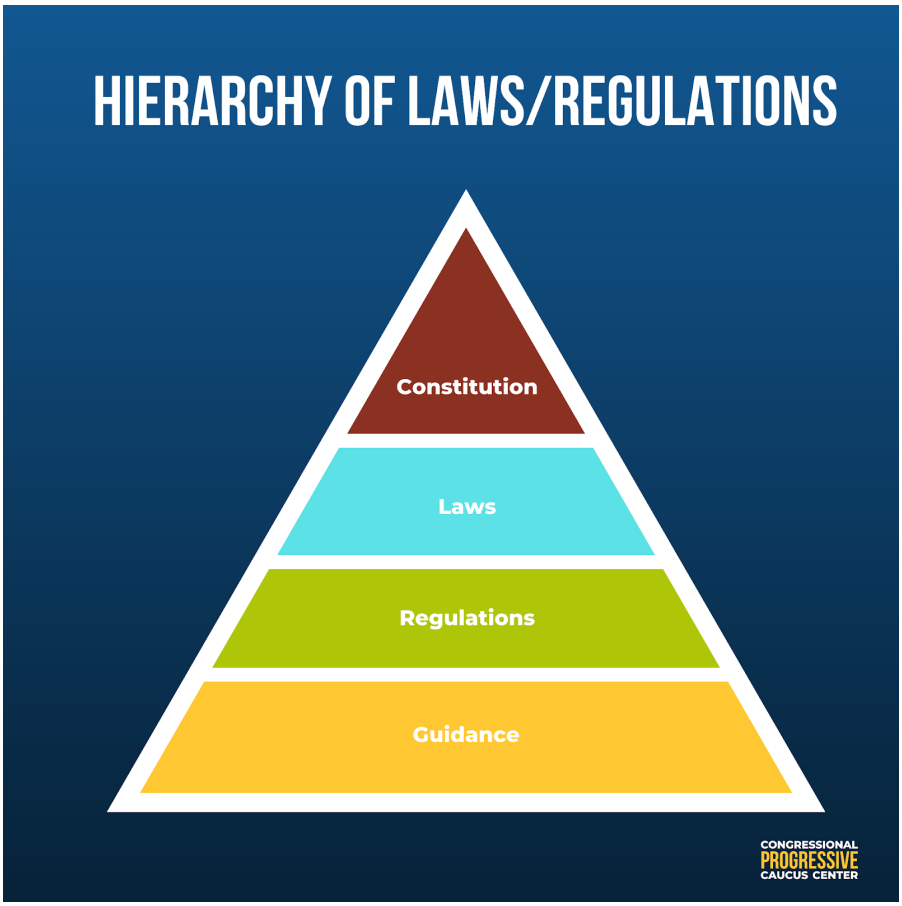
The President and federal agencies also publish numerous "guidance documents" further clarifying how to interpret and implement existing laws and regulations. Unlike substantive (or "legislative") rules and executive orders, "interpretive rules," agency procedural rules, and "general statements of policy" do not carry the independent force and effect of law.[58] Although they are exempt from the APA's notice and comment requirement, interpretive rules "only remind affected parties of existing duties" while general statements of policy only "advise the public

[54] Executive Order 13175, 65 FR 67249 (2000).
[55] *See* 254 U.S.C. § 300319, 36 CFR § 60.4, and 40 CFR § 1506.6. The right to off-reservation consultation is especially important in Alaska where, with one exception, Alaska Natives do not have reservations due to provisions in the Alaska National Interest Lands Conservation Act.
[56] Executive Order 13563 § 1(c), 76 FR 3821 (2011).
[57] Executive Order 13579, 76 FR 41585 (2011).
[58] 5 U.S.C. § 553(b) (The APA "does not apply…to interpretive rules, general statements of policy, or rules of an agency organization, procedure, or practice.").

prospectively of the manner in which the agency proposes to exercise a discretionary power."[59] [60] [61]

Federal agencies use these guidance documents — as they are collectively known — to interpret a law or regulation and provide suggested courses of action, making them invaluable for effective implementation of regulation. Regulated industries especially appreciate guidance documents as they provide essential certainty regarding their obligations for regulatory compliance. Guidance documents are only able to serve this function because they can be issued more quickly than a regulation. Of course, this added flexibility means that guidance can also be revoked more quickly by a subsequent administration. Guidance documents are issued by federal agencies in a variety of formats including policy statements, circulars, interpretive memos, bulletins, manuals, and advisories.

Figure 2



[59] Gen. Motors Corp. v. Ruckelshaus, 742 F.2d 1561, 1565 (D.C. Cir. 1984) and Pacific Gas and Elec. Co. v. Fed. Power Comm., 506 F.2d 33, 38 (D.C. Cir. 1974).
[60] Tom Clark, Attorney General, "Attorney General's Manual on the Administrative Procedure Act" (1947).
[61] Fertilizer Inst. v. EPA, 935 F.2d 1303, 1308 (D.C. Cir. 1991) ("An agency can declare its understanding of what a statute requires without providing notice-and-comment, but an agency cannot go beyond the text of a statute and exercise its delegated powers without first providing adequate notice and comment.").

OMB Circular A-4 and Cost-Benefit Analysis

The most important of these guidance documents is OMB's Circular A-4. Issued in 2003, Circular A-4 outlined "best practices" for agencies conducting analytical regulatory analysis under EO 12866. Specifically, it recommended that federal agencies include the following elements: (1) a statement of need for the regulatory action; (2) consideration of a "reasonable number" of alternative regulatory approaches; and, (3) a standardized estimate of the benefits and costs of the proposed action.[62] The circular also stated that agencies should use both cost-benefit analysis and cost-effectiveness analysis.

Although the Circular A-4 acknowledges the inherent difficulty of quantifying certain costs and benefits monetarily, stating that cost-benefit analysis can sometimes be "less useful" or even "misleading" (e.g., tons of pollution avoided or the number of children who will not suffer discrimination), it still instructs agencies to to attempt to quantity them as much as possible. It further states that a "distinctive feature of [benefit-cost analysis] is that both benefits and costs are expressed in monetary units."[63] According to Circular A-4, calculating "opportunity cost" is the most appropriate method for monetizing costs and benefits, and describes the principle of "willingness-to-pay" as capturing the notion of opportunity cost "by measuring what individuals are willing to forgo to enjoy a particular benefit."[64] The public's willingness-to-pay is usually measured using "revealed preference surveys" in which respondents are asked how much they would be willing to pay to avoid a particular risk or outcome.

In following this directive, agencies have frequently sought to quantify costs and benefits by estimating the number of "statistical lives" that a rule is expected to extend or save. For example, if the annual risk of death is reduced by one in a million for each of two million people, that is said to represent two "statistical lives" extended per year (i.e., 2 million people x 1/1,000,000 = 2). This number is then multiplied by the "value of a statistical life" (VSL) — estimated at "roughly $1 million to $10 million per statistical life" — to arrive at a final monetary number.[65] Although the current government-wide VSL average is $9.9 million, the precise number varies significantly between agencies.[66] In 2020 the Department of Transportation's (DOT) VSL was $11.6 million while the EPA chooses to utilize more than two dozen VSLs with a collective average of around $9.4 million.[67] According to an inter-agency memo subsequently

[62] Office of Management and Budget, Circular A-4, "Regulatory Analysis" (September 2003). OMB Circular A-4 does not apply to independent federal agencies (as defined in 44 U.S.C. § 3502(10).
[63] *Id*. at p. 10.
[64] *Id*. at p. 32.
[65] *Id*. at p. 30.
[66] *Id*. at p. 30. OMB Circular A-4 does not recommend a specific VSL value for agencies to calculate costs and benefits. Instead, it provides agencies with an upper and lower bound ($1 million and $10 million respectively) drawn from a survey of academic literature.
[67] Environmental Protection Agency, "Guidelines for Preparing Economic Analyses," May 2014.

confirmed by OSHA, the Department of Labor does not have a written policy on VSL calculation, instead preferring to follow the lead of the EPA.[68]

For particularly large rules with annual economic effects greater than $1 billion, agencies are also instructed to present a formal quantitative analysis of relevant uncertainties about benefits and costs. Finally, the circular provides analytical guidance explaining how to measure costs and benefits against a baseline, how to apply a "discount rate" when benefits and costs do not occur within the same time period (e.g., climate change).[69]

There are many other guidance documents that also provide federal agencies with instructions on how to best navigate the rulemaking process, the most important of which are briefly outlined below.

> **(1) OMB Circular A-94:** Titled "Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs," Circular A-94 provides a "checklist" to ensure agencies have properly dealt with all elements necessary for sound cost-benefit analysis.[70] The circular also specifies recommended "discount rates" for use in cost-benefit analyses where costs and benefits are distributed over time. Since it was issued in 1992, Circular A-94 has advised federal agencies to use two discount rates in policy analyses: 7 percent and 3 percent.
>
> **(2) OMB Final Bulletin for Agency Good Guidance Practices (GGP):** In 2007, OMB issued a Final Bulletin requiring federal agencies to establish procedures for issuing and using significant guidance documents.[71] The bulletin also required agencies to provide a means for public feedback on significant guidance documents and undertake notice and comment procedures before issuing economically significant guidance.

Cost-Benefit Analysis: A Flawed Methodology

The use of hyper-technical cost-benefit analyses that privilege economic efficiency as the primary objective of regulations is an inherently flawed methodology. This practice generates bias toward the status quo and makes it exceedingly difficult to justify regulations protecting the climate, public health, and other intrinsic values. Treating compliance costs incurred by a proposed air pollution regulation as ethically commensurate with the negative health outcomes and premature deaths that will be experienced by affected communities is clearly nonsensical. This same dogmatic

[68] *See* Memorandum to Secretarial Officers, Modal Administrators, from Tyler Duval, Assistant Secretary for Transportation Policy, and D.J. Gribbin, General Counsel, "Treatment of the Economic Value of a Statistical Life in Departmental Analyses" (February, 2008).
[69] Circular A-4, at pp. 31-36.
[70] Office of Management and Budget Circular A-94, "Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs" (November 2015).
[71] Office of Management and Budget "Final Bulletin for Agency Good Guidance Practices," 72 FR 3342 (2007).

commitment to ascribing monetary value to intrinsic goods also contributed to the cultural genocide of Native Americans and is a key factor driving both the ecoside of our planet and the structural racism that tens of of millions of Americans endure each day.[72]

Attaching monetary value to people's lives using the "value of statistical life" (VSL) also leads to arbitrary and racist conclusions. Low-income and minority communities experience more health problems and lower life expectancies, but the VSL metric can be used to imply that federal dollars spent on communities of younger or healthier people are more beneficial than dollars spent on communities with older or sicker people. In an egregious example, the Department of Justice (DOJ) even sought to put a monetary value on avoiding sexual assault in prisons. DOJ's cost-benefit analysis for the rule assigned monetary values to the prevention of 17 different categories of rape and sexual assault.

Although agencies use the VSL metric to analyze proposed regulations, they do not use the VSL to set penalty levels for regulatory violations leading to deaths. Enforcement practices at OSHA exemplify this bifurcation of agency practices. OSHA caps penalties for serious violations, defined as those “most likely to result in death or serious physical harm," at $14,502 per violation and $145,027 in cases of repeated violations.[73] These penalty levels are several orders of magnitude lower than the VSL metric used in cost-benefit analyses.

For reasons outlined above, more than 60 organizations wrote a letter to President Biden last November calling for fundamental reform of OIRA's system of regulatory review. The letter warned:

> "The antiquated and biased system of regulatory review, as currently implemented by OMB and OIRA, risks becoming a barrier to continued progress on the administration’s future regulatory priorities that are designed to protect the American public."

After a Louisiana District Court struck down the Biden Administration's social cost of carbon metric in February 2022 — on the grounds that the cost-benefit analysis was insufficient — a broad coalition of environmental and environmental justice organizations went even further. In a letter, they called on President Biden to revoke Executive Order 12866, Executive Order 13563, and OMB Circular A-4. Although the court's decision is a legal outlier, it still resulted in the delay of numerous rulemakings at the EPA and Department of the Interior addressing toxic pollution and fossil fuel extraction. The letter asserts that "we can no longer pretend that antiquated economic approaches to assessing costs and benefits of regulations will

[72] Kelli Mosteller, "For Native Americans, Land Is More Than Just the Ground Beneath Their Feet," *The Atlantic* (September 7, 2016).
[73] W. Kip Viscusi, "Pricing Lives: Guideposts for a Safer Society," 2-3, 226 (2018).

ever consider — let alone protect — those most harmed by the ravages of capitalism."

Recent polling conducted by Data for Progress and the Center for Progressive Reform found voters across the spectrum share these concerns. After explaining many of the common methodological techniques used in regulatory cost-benefit analysis, voters expressed disapproval by a wide margin. In another recent poll, Data for Progress and the Center for Progressive Reform also found that voters strongly support regulatory action on issues such as climate change even if it means giving up some economic growth — a result at odds with how cost-benefit analysis is currently used to evaluate regulations.

Democratizing Regulatory Analysis: A Progressive Roadmap

There are many steps that the Biden Administration can take to immediately improve regulatory review. No law or act of Congress authorizes or mandates Executive Orders 12866 and 13563 or OMB Circular A-4. As guidance documents, President Biden has considerable leeway to modify or withdraw them as the Administration thinks best. Although President Biden issued a memorandum titled "Modernizing Regulatory Review" on Inauguration Day in 2021, achieving lasting regulatory reform requires making its implementation a true priority.[74]

It would be helpful for the Biden administration to also require OIRA to publish an estimate of the total cost associated with its cost-benefit requirements and perform a cost-benefit analysis of its own mandates. To date, no such cost-estimates have been published. Ideally, this analysis would include: (1) direct costs such as agency staff time and their diversion from other projects); (2) the cost of delaying regulations that are ultimately approved resulting in environmental public health, and other harms; and, (3) the increased compliance costs and regulatory uncertainty associated with such delays.[75]

Improving regulatory analysis begins with acknowledging that Congress has already determined the proper approach for weighing the pros and cons of individual regulatory decisions.[76] They are the values and policy goals embedded in each agencies' authorizing and organic statutes. Except in the rare cases where they might be legally required, the worst aspects of cost-benefit analysis should be jettisoned, including monetization of non-market benefits and decision-making based on maximizing net benefits. Other useful aspects of the methodology, such as systematized comparisons of the impacts of regulatory alternatives could still be preserved as one of many tools that agencies use to analyze proposed regulations instead of the only one.

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[74] 86 FR 7223.
[75] James Goodwin, "Restoring Scientific Integrity to the Regulatory System Means Overhauling Cost-Benefit," *Center for Progressive Reform* (October 2020).
[76] *Id*.

When agencies do utilize cost-benefit analysis, they should ensure that regulatory reviews account for benefits that are difficult to quantify and refrain from assigning monetary values to regulatory impacts that are not already monetized in the marketplace. Similarly, agencies should be required to take into account both distributional effects and "co-benefits" — benefits that are secondary or unrelated to a rule's statutory purpose – when conducting cost-benefit analysis.[77] Such a requirement would make the benefits of many beneficial regulatory actions more apparent. For example, in analyzing the costs and benefits of reducing toxic mercury emissions from power plants in 2011, the Obama Administration also considered how the installation of pollution control technology would affect levels of fine particulate matter (i.e., soot). Accounting for both the co-costs and co-benefits, the EPA found that the proposed regulation would result in an annual benefit of $37-$90 billion, 99.9 percent of which stemmed from co-benefits.[78] However, in 2020 the Trump Administration redid its analysis of the rule to exclude co-benefits. Using this revised methodology, the EPA instead calculated that the quantifiable benefits of the Obama-era rule were between $4 and $6 million per year.[79] (Note that substantial direct benefits that could not be quantified were also ignored.) Given the rule's estimated costs of $7.4 billion to $9.6 billion, ignoring co-benefits severely weakened the justification for the rule.

Judicial Review

Judicial review of final agency actions is governed by the APA, plus any specific provisions in the agency's enabling or program statutes.[80] Unless otherwise specified by congressional statute, challenges to agency decisions are generally subject to a six-year statute of limitations.[81] Unfortunately, there has been a growing trend in Congress to shorten this window on a statute by statute basis. These shortened windows — often 30-120 days – serve as de facto 'no judicial review' provisions.

The APA limits judicial review in four circumstances: (1) where another statute specifically precludes review; (2) where agency action is committed to agency discretion by law; (3) where administrative remedies have not been exhausted; and,

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[77] Analysis of distributional effects entails examining how rules affect different people in society differently (e.g., race, class, and gender). Co-benefits are those benefits that are secondary or unrelated to the statutory purpose of the rulemaking.
[78] "Regulatory Impact Analysis for the Final Mercury and Air Toxics Standards," *Environmental Protection Agency* (2011).
[79] *See* 85 FR 31286, "National Emission Standards for Hazardous Air Pollutants: Coal- and Oil-Fired Electric Utility Steam Generating Units—Reconsideration of Supplemental Finding and Residual Risk and Technology Review," *Environmental Protection Agency* (2020).
[80] *See* 5 U.S.C. §§ 701-706 (The APA states that a person "suffering [a] legal wrong because of agency action," or "adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review.").
[81] *See, e.g.*, 42 U.S.C. § 4370m(6).

(4) when the action is taken by the President.[82] A lawsuit must also be presented to a court at the proper time for judicial review. There are four primary grounds for arguing that a final agency action is substantively unlawful.

(1) Violation of notice-and-comment procedures: Failure to comply with the rulemaking procedures of the APA or other relevant procedural statutes can render an agency rule invalid.

(2) Arbitrary and capricious agency action: The "arbitrary and capricious" standard is one of the most common forms of review. The contours of arbitrary and capricious review are narrow. Agencies must only demonstrate that they engaged in reasoned decision-making. The Supreme Court has further cautioned that "a court is not to substitute its judgment for that of the agency." A court may find a final rule to be arbitrary and capricious only "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise."[83]

(3) Agency lacks authority or agency action not in accordance with law: Final agency actions may also be invalidated when they are "not in accordance with law," "contrary to constitutional right, power, privilege, or immunity," or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right."[84] This occurs when a final agency action violates a federal statute or the Constitution. Under Chevron deference, discussed below, courts are supposed to defer to agency interpretations of relevant statutory provisions when considering this question.

(4) Unreasonable delay: When propagating regulations, the APA requires agencies to act within a reasonable timeframe.[85] In cases where evidence demonstrates an agency has "unlawfully withheld or unreasonably delayed" a rulemaking, courts may compel the agency "to take action upon a matter, without directing how it shall act."[86] Delays in rulemaking may also violate statutory directives when Congress has ordered an agency to regulate in a particular area. Courts grant agencies considerable leeway in considering this

[82] 5 U.S.C. § 701(a); Sackett v. EPA, 566 U.S. 120, 126-31 (2012); Franklin v. Massachusetts, 505 U.S. 788, 801 (1992). If a rule (not the presidential proclamation) has operational effect, then it is reviewable under the APA. *See* Chamber of Commerce v. Reich, 74 F.3d 1322, 1326-27 (D.C. Cir. 1996).
[83] Motor Vehicles Manufacturers. Association v. State Farm Insurance, 463 U.S. 29, 42-44 (1983).
[84] 5 U.S.C. § 706(2)(A)-(C).
[85] § 706(1).
[86] Norton v. S. Utah Wilderness Alliance, 542 U.S. 55, 63 (2004).

question, and absent a specific judicial deadline will rarely force an agency to undertake a regulatory action on the basis of unreasonable delay.

Although the APA provides a general “cause of action" entitling an individual to seek judicial relief, it does not give a court the authority to hear the case.[87] To establish subject matter jurisdiction, plaintiffs must rely on a separate statutory provision to establish subject matter jurisdiction in court. For example, 33 U.S.C. § 1369 authorizes individuals to seek judicial review of agency actions taken under the Clean Water Act.

Access to the courts provides a means to hold federal agencies and corporations accountable when they break the law, but it is also important to note a growing trend in Congress seeking to limit this judicial right. Supported predominantly by special interests, the most common of these provisions limiting access to the courts are outlined below.

(1) **No Judicial Review:** The most direct way to deny access to justice is to deny access to the courts. The most common of these provisions often state that an agency action is “not subject to judicial review" or that "no court shall have jurisdiction to review."

(2) **Forced Arbitration/Restrictions on Class Actions:** In forced arbitration, plaintiffs such as consumers, employees, and small businesses lose the right to go to court to settle disputes with businesses. Instead, they must go before a private arbiteur with the power to render final and binding decisions. These tribunals tend to be secretive, are often biased toward corporations, and do not provide a right to appeal. When forced arbitration clauses are combined with class-action bans, neither judges nor arbitrators can assess or remedy the full scope of wrongdoing that affect multiple victims.

(3) **Limiting Injunctions/Legal Remedies:** Prohibiting the use of preliminary injunctions limit the power of courts to redress injuries. Bans on preliminary injunctions eliminate the court's ability to stop irreparable harm (an action that cannot be undone) during pending legal actions — for example, the destruction of sacred Native sites by a proposed mining operation on federal lands.

(4) **Blocking Timely and Meaningful Case Settlements:** When a federal agency fails to take action required by law (e.g., adopt new safety requirements), the agency can be held accountable in court and forced to act by a judge. Similarly, when an agency enforces the law – by, for example, bringing an action against a company that has violated pollution standards – the agency

[87] Califano v. Sanders, 430 U.S. 99, 107 (1997). Note: the APA includes a waiver of sovereign immunity for lawsuits seeking non-monetary relief, other than money damages (5 U.S.C. § 702).

often settles the case. In such settlements, agencies like the Environmental Protection Agency (EPA) have often encouraged violators to direct some kinds of payments or other benefits to communities or businesses that were injured as a result of the company's non-compliance. The growing trend of legislative attacks that prevent agencies from being held accountable for missing statutory deadlines prevents the public from holding the government accountable when they fail to uphold the law.[88]

(5) **Equal Access to Justice:** Congress has recognized the importance of addressing the legal and financial hurdles individuals face in bringing public interest litigation, especially when attempting to hold the federal government and big corporations accountable. To facilitate this, many statutes allow what are called "citizen suits." These statutory provisions, including the Equal Access to Justice Act, give judges the discretion to award reasonable attorneys' fees to citizens who successfully prove a violation of federal law. Eliminating attorney's fees awards in cases against the government and other provisions, such as unreasonably high bond requirements, make litigation extremely risky and expensive for frontline communities.[89]

Judicial Deference

Agencies are entitled to varying levels of deference from courts when defending rules that have been challenged in the courts. This doctrine of judicial deference recognizes that agencies should take the lead in interpreting the statutes they administer and the regulations they implement, given congressional intent and the agency's subject matter expertise and experience. There are two main types of agency deference: *Chevron* deference and *Auer* deference.

Under *Chevron* deference, agencies are entitled to deference when interpreting a statute that Congress directed the agency to administer if it is both ambiguous and the agency's interpretation of the law is deemed reasonable.[90] In such cases, agency interpretation is considered controlling and binding.

In certain circumstances, federal agencies are also entitled to *Auer* deference. Under *Auer* deference, a federal agency may be accorded deference when interpreting its own ambiguous regulations. When it applies, *Auer* deference effectively gives an agency significant leeway to say what its own rules mean. Agencies are only entitled to *Auer* deference when the regulation at issue is deemed "genuinely ambiguous" and reflects a "fair and considered judgment on the matter in question."[91] In such

[88] Earthjustice, "Access to Justice: Defending Our Country and Our Courts" (2018).
[89] *Id*., at pp 14-15.
[90] *See* Chevron U.S.A. Inc. v. NRDC, 467 U.S. 837 (1984).
[91] Kisor v. Wilkie, No. 18-15, 588, U.S. ___, 2 (2019); *see also* Bowles v. Seminole Rock & Sand Co., 325 U.S. 410, 414 (1945).

cases, the agency's interpretation of the regulation "becomes controlling weight unless it is plainly erroneous or inconsistent with the regulation."[92]

Conclusion

Regulations play a critical role in our democratic system of government. They are one of the most common instruments of public policy, designed to protect the climate, employee rights, public health, and the financial well-being of the economy. However, regulatory analysis, as it is currently performed, often utilizes arbitrary methodologies that are inherently biased toward the status quo. To better address the challenges we face in the 21st century, the Biden Administration must prioritize regulatory reform. As mentioned in above, essential reforms include updating Executive Order 12866, rescinding OMB Circulars A-4 and A-94, and moving away from assigning monetary values to regulatory impacts that are not already monetized in the marketplace.

CPC Center thanks the Center for Economic and Policy Research, Center for Progressive Reform, and Earthjustice for their comments and insights.

[92] *Id*. at 16 (citing Bowles v. Seminole Rock & Sand Co., 325 US 410, 414 (1945)).

Appendix A: Additional Resources

- Federal Register
- Code of Federal Regulations
- Regulations.gov
- A Guide to the Rulemaking Process
- Delivering Results: An Overview of Federal Implementation Processes
- Executive Order 12866
- Executive Order I3563
- The Congressional Review Act (CRA): FAQ
- Presidential Memorandum: "Modernizing Regulatory Review"
- Government-Wide Information Quality Guidelines
- Information Quality Bulletin for Peer Review
- OMB Circular A-4
- OMB Circular A-94
- Bulletin for Agency Good Guidance Practices
- OMB/OSTP Updated Principles for Risk Analysis
- Economically Significant Rules by Agency
- What Should The Government Spend to Save A Life?
- To Democratize Regulation, Reform Regulatory Analysis
- The Role of Distributional Impacts in Cost-Benefit Analysis
- Beyond 12866: A Progressive Plan for Reforming the Regulatory System
- A Brief Overview of Rulemaking and Judicial Review
- Agency Delay: Congressional and Judicial Means to Expedite Agency Rulemaking