OSSIFICATION'S DEMISE? AN EMPIRICAL ANALYSIS OF EPA RULEMAKING FROM 2001–2005

BY

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For more than a decade, academics have suggested agencies are increasingly avoiding notice and comment rulemaking because the process has become "ossified" by procedures imposed by Congress, courts and the Executive Branch, and because the rules ultimately issued by agencies are frequently challenged. This article reviews the rules the United States Environmental Protection Agency (EPA) issued between 2001 and 2005 to determine the validity of those criticisms.

With regard to judicial challenges, 75% of EPA's most important ("economically significant") rules issued between 2001 and 2005 were challenged in court. This is consistent with the anecdotal claims of former EPA Administrators that 80% of their rules were challenged in court. With regard to the "ossification" of the notice and comment rulemaking process, while academics have claimed the "ossified" process often takes 3 to 5 years, the rules issued by EPA between 2001 and 2005 were generally finalized within 1.5 to 2 years. In addition, it did not take EPA much longer to finalize rules subject to the most stringent procedural requirements imposed by the Executive Branch and Congress than it took to finalize rules not subject to those procedures. This does not necessarily mean, however, that EPA's rulemaking process is "deossified." In fact, one might predict the time it would take EPA to finalize rules would decrease if the agency were avoiding notice and comment rulemaking for particularly contentious rules due to "ossification" or the potential for legal challenges. More study is, therefore, necessary to determine whether EPA's rulemaking process is truly becoming "deossified."

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I. INTRODUCTION

For more than a decade, academics and policymakers have suggested that agencies are increasingly avoiding notice and comment rulemaking because of the frequency of judicial challenges to rulemaking[1] and because procedures imposed by the courts, Congress, and the Executive Branch have "ossified" the rulemaking process.[2] To support the ossification claims, academics often cite studies from a decade ago that found the Occupational Safety and Health Administration (OSHA) and the Federal Trade Commission (FTC) generally took more than five years to promulgate rules[3] and most agencies took at least three years to finalize rules.[4] Regarding judicial challenges, commentators frequently reference

[1] For a discussion of the frequency of challenges to agency rulemaking, see Cary Coglianese, *Assessing Consensus: The Promise and Performance of Negotiated Rulemaking*, 46 DUKE L.J. 1255, 1296 (1997); PHILIP K. HOWARD, THE DEATH OF COMMON SENSE: HOW LAW IS SUFFOCATING AMERICA 87 (1994); JAMES Q. WILSON, BUREAUCRACY: WHAT GOVERNMENT AGENCIES DO AND WHY THEY DO IT 284 (1989).

[2] *See* Stephen M. Johnson, *Good Guidance, Good Grief!*, 72 MO. L. REV. 695, 700–01 (2007) [hereinafter Johnson, *Good Guidance*]; Stephen M. Johnson, *Ruminations on Dissemination: Limits on Administrative and Judicial Review under the Information Quality Act*, 55 CATH. U. L. REV. 59, 79 (2005) [hereinafter Johnson, *Ruminations*]; Stephen M. Johnson, *The Internet Changes Everything: Revolutionizing Public Participation and Access to Government Information Through the Internet*, 50 ADMIN. L. REV. 277, 282–84 (1998) [hereinafter Johnson, *Internet*]; Thomas O. McGarity, *The Courts and the Ossification of Rulemaking: A Response to Professor Seidenfeld*, 75 TEX. L. REV. 525, 528–36 (1997) [hereinafter McGarity, *Response*]; Mark Seidenfeld, *Demystifying Deossification: Rethinking Recent Proposals to Modify Judicial Review of Notice and Comment Rulemaking*, 75 TEX. L. REV. 483, 483–90 (1997); Richard J. Pierce, Jr., *Seven Ways to Deossify Agency Rulemaking*, 47 ADMIN. L. REV. 59, 60–62 (1995); Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1385–86 (1992) [hereinafter McGarity, *Some Thoughts*]; JERRY L. MASHAW & DAVID L. HARFST, THE STRUGGLE FOR AUTO SAFETY 9–25 (1990) (discussing ossification of National Highway Traffic Safety Administration (NHTSA) rulemaking). One relevant definition of "ossify" is "to make callous, rigid, or inactive." WEBSTER'S THIRD NEW INT'L DICTIONARY 1597 (1971).

[3] *See, e.g.*, McGarity, *Some Thoughts*, *supra* note 2, at 1387–90.

[4] *Id.; see also* Cornelius M. Kerwin & Scott R. Furlong, *Time and Rulemaking: An Empirical Test of Theory*, 2 J. PUB. ADMIN. RES. & THEORY 113, 134 (1992) (finding the average start-to-finish time for the EPA to promulgate a rule was 1,108 days).

an assertion by former United States Environmental Protection Agency (EPA) Administrator William Ruckleshaus that 80% of EPA's rules are challenged[5] and studies that have found agency rules are invalidated in 30%–50% of the cases in which they are challenged.[6]

Many factors are blamed for the "ossification" of notice and comment rulemaking, including judicial interpretation of the rulemaking provisions of the Administrative Procedure Act (APA)[7]; the procedural requirements imposed by the Regulatory Flexibility Act,[8] the Small Business Regulatory Enforcement Fairness Act[9] and similar laws,[10] and the review procedures imposed by the Executive Branch through Executive Order 12,866 (requiring Office of Management and Budget (OMB) review)[11]; and a variety of executive orders addressing takings,[12] federalism, and children's health protection, among other topics.[13]

In light of the "ossification" of rulemaking and the frequency of challenges to rules, academics have noted that agencies are reluctant to change existing rules or to issue rules that will need to be changed,[14] and that agencies are relying more frequently on adjudication and informal tools, such as guidance documents, policy statements, and interpretive rules, to make policy and interpret laws.[15] When agencies rely on those informal tools, it becomes more difficult for the regulated community to find and comply with the law and reduces opportunities for the public to participate in the development of agencies' policies or to challenge those policies.[16]

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5 *See* William D. Ruckelshaus, Environmental Negotiation: A New Way of Winning, Address to Conservation Foundation's Second National Conference on Environmental Dispute Resolution (Oct. 1, 1984), *cited in* Lawrence Susskind & Gerard McMahon, *The Theory and Practice of Negotiated Rulemaking*, 3 YALE J. ON REG. 133, 134 (1985) (stating that almost 80% of the agency's major rules were challenged while he was EPA Administrator).

6 *See* Pierce, *supra* note 2, at 84 (indicating courts uphold less than 50% of the legislative rules under the arbitrary and capricious standard).

7 5 U.S.C. §§ 551–559, 701–706, 1305, 3105, 3344, 4301, 5335, 5362, 7521 (2000); *see* McGarity, *Some Thoughts*, *supra* note 2, at 1385, 1436; Pierce, *supra* note 2, at 66; *see also infra* note 44 and accompanying text.

8 5 U.S.C. §§ 601–612 (2000).

9 Small Business Regulatory Enforcement Fairness Act of 1996, 15 U.S.C. § 657, 5 U.S.C. §§ 801–808 (2000).

10 *See infra* notes 51–54 and accompanying text (discussing the Information Quality Act, Paperwork Reduction Act, Unfunded Mandates Reform Act, and Congressional Review Act).

11 Exec. Order No. 12,866, 58 Fed. Reg. 51,735, 51,737 (Oct. 4, 1993).

12 Exec. Order No. 12,630, 53 Fed. Reg. 8859, 8859–61 (Mar. 18, 1988).

13 *See, e.g.*, Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 10, 1999) (concerning federalism); Exec. Order No. 13,045, 62 Fed. Reg. 19,885 (Apr. 23, 1997) (concerning children's health protection); *see also infra* Part II.B (exploring in detail the requirements of the Executive orders and other Executive Branch initiatives, including initiatives under the Information Quality Act).

14 *See, e.g.*, McGarity, *Some Thoughts*, *supra* note 2, at 1390–91 (discussing EPA's grudging re-examination of existing air quality standards and the reluctance of OSHA to modify Reagan era standards).

15 *See infra* note 82.

16 *See infra* notes 89–91 and accompanying text.

Since I have often cited articles that discuss the "ossification" of the rulemaking process and the frequency of challenges to rulemaking,[17] I decided to examine EPA's rulemaking from 2001 through 2005 to determine the extent to which specific legislative and Executive Branch procedures impacted the length of time it took the agency to finalize rules adopted through notice and comment rulemaking during that period.[18] I focused specifically on OMB review under Executive Order 12,866[19] and agency compliance with the Regulatory Flexibility Act and Executive Order 13,045,[20] the executive order protecting children from environmental health and safety risks. I also examined EPA's rulemaking during that time period to determine how frequently those rules were challenged.

I discovered that the rules finalized by EPA during that time period were finalized, on average, within 1.5 to 2 years after publication as proposed rules,[21] much faster than the 3 to 5 years cited in many articles as the post ossification standard. While OMB review impacts the content of EPA's rules and probably affects the amount of time the agency spends preparing rules for publication as proposed rules,[22] the OMB review process did not appear to impact the amount of time it took EPA to finalize rules after issuing them as proposed rules. For rules finalized between 2001 and 2005, EPA generally took about the same amount of time to finalize rules subject to OMB review as it took for the agency to finalize rules not subject to OMB review.[23] Surprisingly, when compared to other rules listed in the agency's semiannual regulatory agenda, it took *less* time for the agency to finalize the "economically significant" rules subject to the greatest amount of OMB review, than it took for the agency to finalize other rules not subject to OMB review.[24] It was also interesting to note that only a small number of EPA rules were subject to the OMB review requirements of Executive Order 12,866. Less than 4% of the rules finalized between 2001 and 2005 were "significant" rules triggering OMB review under the Order and less than 1% of the rules were "economically significant" rules triggering the most stringent form of OMB review under the Order.[25] In addition, almost none of the rules finalized by EPA triggered the requirements of the Regulatory Flexibility Act or Executive Order 13,045.[26]

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[17] *See* Johnson, *Good Guidance*, *supra* note 2; Johnson, *Ruminations*, *supra* note 2; Johnson, *Internet*, *supra* note 2.

[18] The empirical research design is outlined in Part III of this Article. The study focused on rules finalized between January 1, 2001 and December 31, 2005, regardless of whether they were proposed before January 1, 2001, and excluded rules *proposed* during that time period that were *finalized* after December 31, 2005.

[19] Exec. Order No. 12,866, 58 Fed. Reg. 51,735, 51,737 (Oct. 4, 1993).

[20] Exec. Order No. 13,045, 62 Fed. Reg. 19,885 (Apr. 23, 1997).

[21] *See infra* Part IV.A. (discussing findings of the study)

[22] *See infra* Part V.A (discussing limitations of the study).

[23] *See infra* notes 110–11 and accompanying text.

[24] *See infra* notes 111–12 and accompanying text.

[25] *See infra* notes 101–06 and accompanying text.

[26] *See infra* note 107 and accompanying text (only 0.2% of the rules required a regulatory flexibility analysis and 0.16% required compliance with Exec. Order No. 13,045).

While the regulations were finalized more quickly than might be expected based on the ossification literature, the major regulations issued by the agency were challenged as frequently as expected. Of the "economically significant" rules issued by EPA, 75% were challenged at some point after they were promulgated.[27] In light of this finding, it is easy to see why a litigation-averse agency would strive to avoid notice and comment rulemaking whenever possible.

The findings regarding ossification of EPA's rules are, however, more ambiguous. While my analysis suggests that OMB review and other procedural requirements may not significantly slow down EPA's rules *after* the agency issues proposed rules, my study did not examine whether those requirements increase the amount of time the agency spends preparing a rule *before* issuing it as a proposed rule.[28] My analysis also did not examine whether the OMB requirements and other procedural requirements encouraged EPA to avoid rulemaking,[29] or the manner in which OMB review and other procedures impacted the substantive content of the rules.[30] Those factors are probably much more significant than the impact of the procedures on the timing of promulgation.

Part II of this Article outlines the debate regarding the trend of agencies away from rulemaking due to ossification of notice and comment rulemaking and the frequency of challenges to agencies' rules. Part III of the Article examines the procedure I used to determine the impact of OMB review and the requirements of the Regulatory Flexibility Act and Executive Order 13,045 on the timing of rules finalized by EPA between 2001 and 2005, and the frequency of challenges to those rules. Part IV outlines the findings of that analysis and Part V attempts to critique and draw conclusions from those findings.

II. THE TREND AWAY FROM RULEMAKING

A. Challenges to Rulemaking

For years, scholars, journalists, and government officials have asserted that more than 80% of the rules EPA issues every year are challenged in

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[27] *See infra* notes 119–21 and accompanying text. More generally, more than 40% of the "significant" rules issued by EPA were challenged. *See infra* notes 116–18 and accompanying text.

[28] *See infra* notes 123–28 and accompanying text.

[29] *See infra* notes 129–39 and accompanying text. In fact, the short time frame for development of EPA rules could be caused precisely by the agency avoiding adoption of more contentious policies through rulemaking.

[30] A more detailed analysis of regulatory flexibility analyses prepared under the Regulatory Flexibility Act and the comments submitted by OMB as part of its formal review of agency rules under Executive Order 12,866 compared to the changes made by agencies to those rules would provide some insight into the impact of OMB review. However, this would paint an incomplete picture. OMB review and involvement in the development of EPA rules begins before OMB's formal review under Executive Order 12,866, and much of the communication that occurs before the formal review is not documented for public review. *See infra* notes 125–28 and accompanying text.

court.[31] As Professor Cary Coglianese has pointed out, these oft-repeated assertions are based primarily on anecdotes, rather than empirical study.[32] Statements by former EPA Administrator William Ruckleshaus are generally cited as the basis for the 80% figure.[33] Based on his own empirical study, Professor Coglianese maintains only 26% of EPA's rules or 35% of EPA's "significant"[34] rules are challenged each year.[35] While there is a substantial

[31] *See* Johnson, *Internet*, *supra* note 2, at 287; Coglianese, *supra* note 1, at 1296 (including, as an appendix, a bibliography of citations to the 80% figure).

[32] *See* Coglianese, *supra* note 1, at 1297. Professor Coglianese also points out that while the 80% figure is used, at some times, to refer to 80% of all rules or even all agency decisions, at other times it is used to refer simply to 80% of all "major" rules. *Id.*

[33] *See* Ruckleshaus, *supra* note 5; William D. Ruckelshaus, *Environmental Protection: A Brief History of the Environmental Movement in America and the Implications Abroad*, 15 ENVTL. L. 455, 463 (1985) ("Eighty percent of what the agency does is finally decided either in a negotiated or formal court decision."). Former EPA Administrators Lee Thomas and William Reilly have made similar claims. *See* Lee M. Thomas, *The Successful Use of Regulatory Negotiation by EPA*, 13 ADMIN. L. NEWS 1, 3 (1987) ("We found that over three-quarters of our regulations once promulgated were litigated . . . ."); ROSEMARY O'LEARY, ENVIRONMENTAL CHANGE: FEDERAL COURTS AND THE EPA 17 (1993) ("Reilly once estimated that 80 percent of his decisions were appealed to courts.").

[34] Throughout this article, "significant" rules refers to the category of rules identified as "significant" by Executive Order 12,866. Pursuant to the Order, a significant regulatory action includes:

> [A]ny regulatory action that is likely to result in a rule 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 this Executive order.

Exec. Order No. 12,866, 58 Fed. Reg. 51,735, 51,738 (Oct. 4, 1993).

[35] Coglianese, *supra* note 1, at 1298–1300. Professor Coglianese reviewed EPA's litigation docket, covering litigation filed against the agency in any federal court between 1987 and 1991, and the docket for the United States Court of Appeals for the District of Columbia Circuit for the same period. *Id.* at 1298. When he conducted a computer search of the Federal Register to determine the number of rules EPA issued during that time period and compared it to the litigation dockets, he concluded 26% of all of the rules issued by EPA during that time period were challenged. *Id.* In addition to evaluating the litigation rate for all rules, Coglianese attempted to determine the litigation rate for "significant" or "major" rules of the agency during that time period. In order to do that, Professor Coglianese reviewed the semiannual regulatory agenda EPA published in the Federal Register to identify significant rules issued by the agency under the Clean Air Act and the Resource Conservation and Recovery Act (RCRA) between 1980 and 1991. *Id.* at 1299–1300. Most of the significant rules issued by agencies are listed in the agencies' semiannual regulatory agenda. Coglianese then reviewed the docket of the Court of Appeals for the District of Columbia Circuit for that same time period and determined 35% of EPA's "significant" rules issued between 1980 and 1991 under those two statutes were challenged. *Id.* at 1300. Prior to Coglianese's study, James Hamilton and Christopher Schroeder conducted a study of EPA rules issued under RCRA and concluded that only 21.8% of the rules had been subject to a court remand or consent decree. *See* James T. Hamilton & Christopher H. Schroeder, *Strategic Regulators and the Choice of Rulemaking Procedures: The Selection of Formal vs. Informal Rules in Regulating Hazardous Waste*, 57 L. & CONTEMP. PROBS. 111, 153 (1994).

difference between Professor Coglianese's findings and the 80% figure, litigation-averse agencies may take little comfort in knowing they will have to defend one-quarter to one-third of all of their significant rules in court.

When agencies' rules are challenged in court, most empirical studies have found courts invalidate the rules in 30%–40% of the cases.[36] For instance, in a recent article, Professors Thomas Miles and Cass Sunstein analyzed 183 recent federal appellate cases where panels reviewed EPA's legal interpretations and found that the judges only deferred to the agency 64% of the time.[37] Similarly, when Professor Jason Czarnezki reviewed ninety-three environmental law cases decided between 2003 and 2005, he found that courts affirmed EPA's decisions in 69% of the cases.[38]

B. Ossification

While the frequency of litigation and judicial invalidation of rules can discourage agency rulemaking, the "ossification" phenomenon is often cited as a major impediment to rulemaking. In a landmark article in 1992, Professor Thomas O. McGarity noted that the analytical requirements imposed on informal rulemaking over the preceding decade by courts, Congress, and the Executive Branch had transformed rulemaking into a rigid and burdensome process.[39] He asserted that the "ossification"[40] of rulemaking was widely regarded as one of the most serious problems facing regulatory agencies at the time.[41] Professor McGarity argued that due to ossification, it took OSHA and FTC more than five years to issue rules the agencies previously issued within six months to two years.[42] For more than a decade and a half since then, academics and policymakers have explored the ramifications of ossification and suggested reforms to "de-ossify" the rulemaking process.[43]

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[36] *See, e.g.*, Pierce, *supra* note 2, at 84 (indicating courts uphold less than 50% of the legislative rules under the arbitrary and capricious standard).

[37] *See* Thomas J. Miles & Cass R. Sunstein, *Do Judges Make Regulatory Policy? An Empirical Investigation of* Chevron, 73 U. CHI. L. REV. 823, 825, 849 (2006).

[38] *See* Jason J. Czarnezki, *An Empirical Investigation of Judicial Decisionmaking, Statutory Interpretation & the* Chevron *Doctrine in Environmental Law*, 79 U. COLO. L. REV. (forthcoming 2008) (manuscript at 24, *available at* http://ssrn.com/abstract=996955).

[39] *See* McGarity, *Some Thoughts*, *supra* note 2, at 1385.

[40] Professor E. Donald Elliott, former General Counsel of EPA, is credited with labeling the transformation of the rulemaking process as "ossification." *Id.* at 1386.

[41] *Id.*

[42] *Id.* at 1387–90. In the same article, Professor McGarity described a joint EPA and OSHA rulemaking regarding 4,4 methylendianiline that took nine years to progress from an advanced notice of proposed rulemaking to publication of a final rule. *Id.* at 1388.

[43] *See supra* note 2; *see also* Stephen M. Johnson, *Junking the "Junk Science" Law: Reforming the Information Quality Act*, 58 ADMIN. L. REV. 37, 61–63 (2006) [hereinafter Johnson, *Junk Science*]. *But see* William S. Jordan, III, *Ossification Revisited: Does Arbitrary and Capricious Review Significantly Interfere with Agency Ability to Achieve Regulatory Goals Through Informal Rulemaking?*, 94 NW. U. L. REV. 393, 396 (2000) (disputing the ossification claim).

Courts have played a role in the ossification of rulemaking by interpreting the procedural requirements of the APA expansively.[44] Congress has also played a major role by passing several laws imposing analytical and procedural requirements on agencies for rules they issue through notice and comment rulemaking. Most of the requirements of the laws focus on "significant" rules.[45] The Regulatory Flexibility Act, for instance, requires agencies to prepare a "regulatory flexibility analysis" for all "significant" rules.[46] The analysis must describe the impact of proposed and final significant rules on small businesses, and must identify alternatives to the approaches adopted in the rules and describe the impacts of those alternatives.[47] The law also requires agencies to publish a "regulatory flexibility agenda" in the Federal Register during October and April of each year, listing rules the agencies expect to propose or finalize that are likely to have a significant economic impact on small businesses.[48] The law was amended by the Small Business Regulatory Enforcement Fairness Act of 1996, which requires agencies to provide Congress with cost benefit analyses, regulatory flexibility analyses, and other information that is prepared for major rules that impact small businesses[49] and delays the effective date of such rules to allow Congress to disapprove of the rules.[50]

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[44] *See* McGarity, *Some Thoughts*, *supra* note 2, at 1400. Courts have interpreted the requirement in the APA that agencies provide a "concise general statement of the basis and purpose" of their rules, under § 553(b) of the APA, broadly to require agencies to document, in detail, a rational response to public comments on rules and to explain, in detail, the reasonable basis for the rules. *See* United States v. N.S. Food Prods. Corp., 568 F.2d 240, 252–53 (2d Cir. 1977). Agency rules can be set aside if they are "arbitrary or capricious," represent an "abuse of discretion," or are "otherwise not in accordance with law." Administrative Procedure Act, 5 U.S.C. § 706(2)(A) (2000). Consequently, agencies spend significant time and resources to develop and articulate defensible responses to public comments when they issue rules. *See* Johnson, *Good Guidance*, *supra* note 2, at 701 n.23; McGarity, *Some Thoughts*, *supra* note 2, at 1412.

[45] *See supra* note 34 (defining "significant" rules).

[46] Regulatory Flexibility Act, 5 U.S.C. § 603(a) (2000). However, an agency does not have to prepare a regulatory flexibility analysis if it certifies that the rule will not "have a significant economic impact on a substantial number of small entities." *Id.* § 605(b).

[47] *Id.* § 603. The Act applies to "small entities," which primarily includes small businesses. *Id.* § 601.

[48] *Id.* § 602. The law does not, however, prohibit agencies from proposing or finalizing rules that affect small businesses that are not included in the agenda. *Id.* § 602(d).

[49] Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. §§ 602–604, 801 (2000).

[50] *Id.* § 802. Major rules cannot take effect until 60 days after Congress receives the analyses required by the law or the rule is published in the Federal Register, whichever is later. *Id.* § 801(a)(3). A "major rule" is

> any rule that the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget finds has resulted in or is likely to result in—(A) an annual effect on the economy of $100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign based enterprises in domestic and export markets.

Id. § 804(2).

The Information Quality Act,[51] Paperwork Reduction Act,[52] Unfunded Mandates Reform Act,[53] and Congressional Review Act[54] all impose additional analytical and procedural requirements on notice and comment rulemaking.

The Executive Branch has also imposed substantial analytical and procedural requirements on notice and comment rulemaking.[55] Compliance with those requirements is time consuming and can be expensive, even though an agency's failure to comply with an executive order is not generally subject to judicial review.[56]

Executive Order 12,866 imposes the primary Executive Branch limitation on agency rulemaking.[57] For "significant" rules,[58] the Executive Order requires agencies to prepare an assessment of the costs and benefits of the rules[59] and to adopt regulations only upon a "reasoned determination that the benefits of the intended regulation justify its costs."[60] More importantly, though, the Order requires agencies to submit "significant" rules, along with detailed descriptions of the need for the rules and the cost benefit analyses for the rules, to the Office of Information and Regulatory Affairs (OIRA), within OMB, for review.[61] Agencies must submit "significant"

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[51] 44 U.S.C. § 3516 (2000 & Supp. 2006) (requiring agencies to respond to challenges to the "quality" of information disclosed in, or relied upon in, rulemaking).

[52] Paperwork Reduction Act of 1995, 44 U.S.C. §§ 3501–1549 (2000). In particular, the Paperwork Reduction Act requires agencies to submit information collection requests to OMB for rules that require submission of information by 10 or more persons. *Id.* § 3502(3)(A)(i).

[53] Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1501–1571 (2000). Section 1532 specifically mandates thorough analysis of rules if they would cause expenditures of more than $100 million by state, local, or tribal governments.

[54] 5 U.S.C. §§ 801–808 (2000). In particular, the Congressional Review Act demands that federal agencies promulgating a rule with a significant impact on the economy submit it to Congress before it can take effect. *Id.* § 801.

[55] There is a long history of presidential controls over rulemaking, beginning with President Nixon's imposition of a "quality of life" review on EPA and OSHA regulations in the early 1970s. *See* McGarity, *Some Thoughts*, *supra* note 2, at 1405. Presidents Ford and Carter both imposed additional inflation impact analysis and regulatory analysis requirements on rulemaking. *Id.* The most dramatic expansion of procedural and analytical requirements for rulemaking, however, began during President Reagan's Administration, with the issuance of Executive Order 12,291, which required agencies to prepare regulatory impact analysis for all major rules. *See* Exec. Order No. 12,291, 46 Fed. Reg. 13,193, 13,194 (Feb. 19, 1981). Executive Order 12,291 explicitly required agencies to conduct a cost benefit analysis for major rules (rules having an annual impact of $100 million or more on the economy) and required agencies to refrain from issuing rules unless the benefits outweighed the costs. *Id.* at 13,193–94. In 1990, President George H.W. Bush created a Council on Competitiveness, chaired by Vice President Quayle, to oversee implementation of Executive Order 12,291 and provide additional oversight of rulemaking. McGarity, *Some Thoughts*, *supra* note 2, at 1429.

[56] *Id.* at 1406.

[57] Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Oct. 4, 1993).

[58] *See supra* note 34 (defining "significant" rules). Agencies determine which of their rules are "significant," but the Administrator of OIRA in OMB can determine that an agency's rule is "significant" even though the agency has not made that determination. *See* 58 Fed. Reg. at 51,740–41.

[59] *Id.*. at 51,741.

[60] *Id.* at 51,736.

[61] *Id.* at 51,741. OMB may waive review of "significant" rules. *Id.* Executive Order 12,291, the

rules to OMB for review before the rules are initially proposed and before the rules are published as final rules, and Executive Order 12,866 provides that OMB review should normally be completed within ninety days.[62]

At the end of its review, OMB can return the rule to the agency "for reconsideration," return the rule to the agency with a finding that the rule is consistent with the Executive Order without any changes, or return the rule to the agency with a finding that the rule is consistent with the Executive Order with changes made to the rule during the review period.[63] Agencies may also decide to withdraw proposed or final rules during OMB review.[64] Agencies normally cannot publish a significant rule in proposed or final form until OMB completes its review of the rule without asking the agency to reconsider the rule, or until the time for OMB review expires before OMB completes its review.[65] Executive Order 12,866 does not give OMB the authority to "approve" or "disapprove" of rules and agencies may publish rules without making changes suggested by OMB during its review, but agencies rarely publish rules without making those changes.[66]

"Significant" rules that will have an annual effect on the economy of $100 million or more or adversely affect the economy in a material way ("economically significant" rules) are subject to additional procedures.[67] In addition to complying with the requirements for "significant" rules outlined above, if the impact of a rule is "economically significant," agencies must prepare and provide a "regulatory impact assessment" for OMB review.[68] The assessment must compare the approach taken in the rule to alternative approaches, compare the costs and benefits of the preferred approach and the alternatives, and explain why the preferred approach is preferable to the alternatives.[69]

Executive Order 12,866 imposes additional planning requirements on agencies for rulemaking. The Order requires agencies to prepare a "regulatory plan" of "the most important significant regulatory actions that the agency expects to issue in proposed or final form" in the current fiscal

predecessor to Executive Order 12,866, did not limit OMB review of rules to "significant rules," so the number of rules reviewed by OMB each year dropped substantially after Executive Order 12,866 was adopted and superseded Executive Order 12,291. For instance, while OMB reviewed 2,167 rules in 1993, the agency only reviewed 831 rules in 1994. *See* Office of Management and Budget, Review Counts, http://www.reginfo.gov/public/do/eoCountsSearchInit?action=init (last visited July 20, 2008) [hereinafter OMB, Review Counts] (entered query "Number of Rules and Economically Significant Rules Reviewed and Average Review Times," between 01/01/1993 and 12/31/1993, and between 01/01/1994 and 12/31/1994).

62 58 Fed. Reg. at 51,742. The review process may be extended once by no more than 30 days by OMB or it may be extended at the request of the agency head (without a time limit). *Id.*

63 Curtis W. Copeland, *The Role of the Office of Information and Regulatory Affairs in Federal Rulemaking*, 33 FORDHAM URB. L.J. 1257, 1273–74 (2006).

64 *Id.* at 1273.

65 58 Fed. Reg. at 51,743–44.

66 Copeland, *supra* note 63, at 1278.

67 58 Fed. Reg. at 51,738.

68 *Id.* at 51,741.

69 *Id.*

year and beyond, and to submit the plan to OMB annually.[70] Further, the Order requires agencies to prepare a "unified regulatory agenda," which is an agenda of all regulations under development or review by the agency.[71] The agenda is published semiannually in the Federal Register and includes the "regulatory plan."[72] Like many agencies, EPA includes the agenda required by the Regulatory Flexibility Act in the agency's unified regulatory agenda.[73]

Several other executive orders require agencies to prepare analyses and follow additional procedures when issuing rules through notice and comment rulemaking. Executive Order 13,045, titled "Protection of Children from Environmental Health and Safety Risks," requires agencies to conduct additional analyses for rules that are "economically significant" under Executive Order 12,866 and concern environmental health or safety risks that may disproportionately affect children.[74] Specifically, the Order requires agencies to evaluate the environmental health and safety effects of those rules and to explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency.[75] Executive orders also require agencies to review the federalism impacts of rules[76] and to evaluate whether rules will effect a taking of property.[77] The White House also recently imposed additional limits on agency rulemaking through the OMB's Information Quality Act Guidelines[78] and Peer Review Bulletin.[79] Finally, John Graham, the former Administrator of OIRA, has predicted there will be increased collaboration between agencies in the United States and their counterparts in the European Union on regulatory reform efforts.[80] Such collaboration could lead to additional

70 *Id.* at 51,738.

71 *Id.*

72 *Id.*

73 *Id.*

74 Exec. Order No. 13,045, 62 Fed. Reg. 19,885 (Apr. 23, 1997).

75 *Id.* at 19,887.

76 *See* Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 10, 1999).

77 *See* Exec. Order No. 12,630, 53 Fed. Reg. 8859 (Mar. 18, 1988). Several other executive orders may impose additional limits on informal rulemaking. *See, e.g.*, Exec. Order No. 13,211, 66 Fed. Reg. 28,355 (May 22, 2001) (applicable to actions concerning regulations that significantly affect energy supply, distribution, or use); Exec. Order No. 13,175, 65 Fed. Reg. 67,249 (Nov. 9, 2000) (requiring consultation and coordination with Indian tribal governments); Exec. Order No. 12,898, 59 Fed. Reg. 7629 (Feb. 16, 1994) (addressing environmental justice in minority and low-income populations).

78 Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication, 67 Fed. Reg. 8452 (Feb. 22, 2002).

79 *See* Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664 (Jan. 14, 2005). For a critique of the Information Quality Act Guidelines and Peer Review Bulletin, *see* THOMAS O. MCGARITY ET AL., TRUTH AND SCIENCE BETRAYED: THE CASES AGAINST THE INFORMATION QUALITY ACT 10–12 (2005), *available at* http://www.progressiveregulation.org/articles/iqa.pdf; Thomas O. McGarity, *Our Science Is Sound Science and Their Science Is Junk Science: Science-Based Strategies for Avoiding Accountability and Responsibility for Risk-Producing Products and Activities*, 52 U. KAN. L. REV. 897, 935 (2004); 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, 364 (2004); Johnson, *Junk Science*, *supra* note 43, at 62–63.

80 *See* John D. Graham et al., *Managing the Regulatory State: The Experience of the Bush Administration*, 33 FORDHAM URB. L.J. 953, 1001–02 (2006).

analytical and procedural limitations on rulemaking by agencies in the United States. Although the Executive Branch, through the executive orders and guidelines outlined above, has greatly increased OMB's role in reviewing the policy development of agencies, the size of OMB's staff has decreased during the same time period.[81]

C. Trend Toward Informal Procedures

The "ossification" of rulemaking and the frequency of challenges to rulemaking are widely blamed for a shift away from rulemaking in agencies towards adjudication and informal tools, like interpretive rules, policy statements, and guidance documents.[82] In some agencies, interpretive rules and policy statements comprise more than 90% of the their "rules."[83] Agencies have an incentive to choose informal adjudication, interpretive rules, policy statements, and guidance documents over notice and comment rulemaking because there are very few procedures agencies must follow under the APA, or other laws, when using those tools.[84] Accordingly, the process is generally quicker and less costly than notice and comment rulemaking.[85] Agencies can also change policies more quickly and fine tune their policies with more flexibility when they adopt them informally, rather than through notice and comment rulemaking.[86] In addition, since the

[81] OIRA had a "full-time equivalent" (FTE) ceiling of 90 staff members when it was created in 1981. *See* Copeland, *supra* note 63, at 1293. The allocation was reduced to 47 by 1997, but increased somewhat, to 55, by 2003. *Id.* Critics often argue that OMB's staff is too small to carry out its responsibilities in a timely manner. *See* Graham et al., *supra* note 80, at 982. In addition to the responsibilities outlined above, OIRA is also significantly involved in developing the current Bush Administration's electronic rulemaking initiative. Copeland, *supra* note 63, at 1302.

[82] *See, e.g.*, Johnson, *Good Guidance*, *supra* note 2, at 700–701; Johnson, *Internet*, *supra* note 2, at 278, 283–84; McGarity, *Response*, *supra* note 2, at 528; Pierce, *supra* note 2, at 82; *see also* David Zaring, *Best Practices*, 81 N.Y.U. L. REV. 294 (2006) (discussing a trend in Congress to require agencies to establish "best practices" for regulated entities through informal means, rather than adopting standards through notice and comment rulemaking). In addition, Professor Cornelius Kerwin has noted that the number of final rules adopted by federal agencies declined from 6,329 in 1982 to 4,074 by 2004. Cornelius Kerwin, Professor, American University, Remarks at the Opening Session of the Conference on the State of Rulemaking in the Federal Government 6 (Mar. 16, 2005), *available at* http://www.american.edu/rulemaking/openingpanel05.pdf.

[83] Pierce, *supra* note 2, at 82; Johnson, *Internet*, *supra* note 2, at 284.

[84] Johnson, *Internet*, *supra* note 2, at 284, 287–89. The notice and comment procedures of the APA do not apply to interpretive rules, guidance documents, and policy statements. Administrative Procedure Act, 5 U.S.C. § 553(b)(3)(A) (2000). The APA merely requires agencies to publish "statements of general policy or interpretations of general applicability" in the Federal Register and to make adjudicative decisions and the remainder of the agencies' policy statements and interpretive rules "available for public inspection and copying." *Id.* § 552(a)(1)–(2).

[85] Johnson, *Good Guidance*, *supra* note 2, at 701; Johnson, *Internet*, *supra* note 2, at 284–85.

[86] Johnson, *Good Guidance*, *supra* note 2, at 701. When agencies adopt rules through notice and comment rulemaking, they can only change those rules through subsequent notice and comment rulemaking. Accordingly, when agencies adopt rules through notice and comment rulemaking, the ossified process creates an incentive to avoid making changes to the rules, frustrating the accomplishment of the goals of the statute. *See* McGarity, *Some Thoughts*, *supra* note 2, at 1390–1392. It also creates an incentive to avoid experimenting with flexible or temporary rules that will need to be amended. *Id.* at 1392.

policies adopted through interpretive rules, policy statements, and guidance documents are not generally legally binding requirements, it is much harder to challenge them in court.[87] Finally, agencies are subject to less congressional and executive control when they adopt policies through informal tools, rather than through notice and comment rulemaking.[88]

While the trend away from notice and comment rulemaking provides some benefits to agencies, it also creates many problems for the public, the regulated community, and the agencies themselves. When agencies adopt policies informally, regulated entities and the public have fewer opportunities to participate in their development.[89] Public participation in the development of agencies' policies is essential because

> (1) it provides oversight of agency action and prevents agencies from being captured . . . ; (2) it provides the agency with important information about the impacts of proposed decisions that enable the agency to . . . administer the law in a rational, defensible manner; and (3) it instills a sense of legitimacy [and fairness] in the public regarding the agency's decisions.[90]

When agencies adopt policies informally, it also makes it more difficult for the public to know what the law is and how to comply with it, and for agency employees to apply the law consistently.[91]

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[87] *See* Johnson, *Good Guidance*, *supra* note 2, at 701. While "final agency actions" are presumptively reviewable under § 704 of the APA, interpretive rules, policy statements, and guidance documents frequently are not "final agency actions." *See* 5 U.S.C. § 551(13) (2000) (defining "agency action" to include "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act"). However, the nonbinding nature of the informal tools also provides a *disincentive* to their use, as it is harder for the agency to enforce the policies adopted through those tools than it is to enforce policies adopted through notice and comment rulemaking. While policies adopted through notice and comment rulemaking generally have the force of law and are binding on courts and the public, policies adopted informally are not generally binding on courts or the public and must be independently justified when an agency enforces the policy in adjudication. *See* Johnson, *Internet*, *supra* note 2, at 285 nn.35–37.

[88] Johnson, *Good Guidance*, *supra* note 2, at 702. Until recently, most of the additional procedural requirements and review requirements imposed by executive orders did not apply to guidance documents, interpretive rules, and policy statements. However, President Bush recently issued Executive Order No. 13,422 which imposes additional review and procedural requirements on the issuance of guidance by agencies, which could slow down the process for issuing guidance. Exec. Order No. 13,422, 72 Fed. Reg. 2763, 2763–64 (Jan. 18, 2007).

[89] Johnson, *Good Guidance*, *supra* note 2, at 702–03; Johnson, *Internet*, *supra* note 2, at 289; McGarity, *Some Thoughts*, *supra* note 2, at 1393.

[90] Johnson, *Internet*, *supra* note 2, at 289; *see also* Johnson, *Good Guidance*, *supra* note 2, at 702–03.

[91] Johnson, *Good Guidance*, *supra* note 2, at 703; *see also* Johnson, *Internet*, *supra* note 2, at 288 ("The public suffers because most of the law that agencies make through these vehicles will be inaccessible to them, or will be very difficult to access. . . . The public cannot comply with a 'shadow law' if they cannot find it."). If agency employees, like the public, cannot find the policies, it will be difficult for the agency to apply the policies even-handedly, and it will be more likely that the agencies' actions will be struck down as arbitrary and capricious. Johnson, *Internet*, *supra* note 2, at 289. The trend toward informal tools also increases the risk that agencies will treat interpretive rules and policy statements in practice like binding legislative rules, thus evading the procedural requirements of the APA. *See* Johnson, *Good Guidance*,

III. EMPIRICAL RESEARCH DESIGN

In an attempt to determine whether the analyses and procedural requirements imposed on notice and comment rulemaking by Congress and the Executive Branch have substantially delayed the adoption of "significant" rules by EPA and to determine the extent to which those rules are challenged in court, this Article examined significant rules finalized by EPA between 2001 and 2005.[92]

Review of the regulatory agendas published by EPA in the Federal Register biannually between 2001 and 2006,[93] combined with a computerized search of the Federal Register,[94] identified ninety-four "significant" rules

supra note 2, at 703. "Even if agencies do not treat [them] as binding legislative rules, [they] may have a coercive effect, in that the regulated community may choose to 'comply' with the rules, rather than to challenge them or wait for the agency to enforce the rules against them." *Id.*

92 Thus, "significant" rules that were published in the Federal Register as proposed rules prior to January 1, 2001, but were published as final rules between January 1, 2001 and December 31, 2005, were included, while "significant" rules that were published before December 31, 2005, but were not published as final rules until after December 31, 2005, were not included in the study. The study focused on "significant" rules because most of the congressional and Executive Branch procedures blamed for the "ossification" of rulemaking are limited to "significant" rules.

93 EPA Spring 2006 Regulatory Agenda, 71 Fed. Reg. 23,226 (Apr. 24, 2006); EPA Fall 2005 Regulatory Agenda, 70 Fed. Reg. 65,206 (Oct. 31, 2005); EPA Spring 2005 Regulatory Agenda, 70 Fed. Reg. 27,510 (May 16, 2005); EPA Fall 2004 Regulatory Agenda, 69 Fed. Reg. 73,786 (Dec. 13, 2004); EPA Agenda of Regulatory and Deregulatory Actions, 69 Fed. Reg. 38,154 (June 28, 2004); EPA Fall 2003 Regulatory Agenda, 68 Fed. Reg. 73,540 (Dec. 22, 2003); EPA Spring 2003 Regulatory Agenda, 68 Fed. Reg. 30,942 (May 27, 2003); EPA Fall 2002 Regulatory Agenda, 67 Fed. Reg. 75,168 (Dec. 9, 2002); EPA Spring 2002 Regulatory Agenda, 67 Fed. Reg. 33,724 (May 13, 2002); EPA October 2001 Agenda of Regulatory and Deregulatory Actions, 66 Fed. Reg. 62,240 (Dec. 3, 2001); EPA Semiannual Regulatory Agenda, 66 Fed. Reg. 26,119 (May 14, 2001). As EPA notes on its website, the agency's regulatory plans, published in the semiannual agenda, describe "the most important regulatory and deregulatory actions that [the agency] expect[s] to issue in proposed or final form during the upcoming fiscal year." EPA, Regulatory Agendas and Regulatory Plans, http://www.epa.gov/lawsregs/search/regagenda.html#background (last visited July 20, 2008). Regulations and major policy documents are included in the semiannual agendas, but the agency stresses that "there is no legal significance to the omission of an item from the Agenda." *Id.* Only about 13% of the final rules issued by EPA between 2001 and 2005 were included in the semiannual regulatory agendas. *See infra* note 95 and accompanying text. Nevertheless, almost all of the agency's "significant" rules are included in the Agenda, as well as many rules that are not "significant," but are important agency actions. *See* EPA, Regulatory Agendas and Regulatory Plans, http://www.epa.gov/lawsregs/search/regagenda.html#background (last visited July 19, 2008) ("[T]hese are the regulatory actions that embody the core of our regulatory priorities . . . and we generally do not include minor amendments or actions . . . .").

94 The actual searches, in the Lexis FR (Federal Register) Database, were as follows: 1) action w/3 "final rule" & "environmental protection agency" and not "Action: Proposed Rule" and not "Action: Notice" and date(geq (01/01/2001) and leq (12/31/2001)); 2) action w/3 "final rule" & "environmental protection agency" and not "Action: Proposed Rule" and not "Action: Notice" and date(geq (01/01/2002) and leq (12/31/2002)); 3) action w/3 "final rule" & "environmental protection agency" and not "Action: Proposed Rule" and not "Action: Notice" and date(geq (01/01/2003) and leq (12/31/2003)); 4) action w/3 "final rule" & "environmental protection agency" and not "Action: Proposed Rule" and not "Action: Notice" and date(geq (01/01/2004) and leq (12/31/2004)); 5) action w/3 "final rule" & "environmental protection agency" and not "Action: Proposed Rule" and not "Action: Notice" and date(geq (01/01/2005) and leq (12/31/2005)). The results of each search were reviewed to eliminate actions that were

published by EPA as final rules between January 1, 2001 and December 31, 2005. Although approximately 2,500 final rules were published by EPA in the Federal Register during that time period, only 328 of those rules were included in the agency's semiannual regulatory agendas.[95]

To facilitate a comparison between the time required to finalize "significant" rules and the time required to finalize other rules, all of the final rules included in the semiannual regulatory agendas were included in a database, regardless of whether the rules were "significant" rules or not. The database included the date each rule was published as a final rule in the Federal Register, the date each rule was published as a proposed rule in the Federal Register, whether each rule was a "direct" final rule, the statutory authority for each rule, whether each rule was "significant" or "economically significant," whether OMB review was required for each rule under Executive Order 12,866, whether a regulatory flexibility analysis was required for each rule under the Regulatory Flexibility Act, and whether each rule triggered the analytical requirements of Executive Order 13,045, regarding children's health protection.[96]

Further data regarding the impact of Executive Order 12,866 on the timing of issuance of significant rules by EPA between 1996 and 2005 was obtained by querying an OMB database that includes information regarding the number of rules reviewed by OMB, the type of rules reviewed by OMB, and the length of time required for OMB review of the rules.[97]

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not the publication of final rules by EPA and to identify any "significant" rules that may not have been included in the agency's semiannual regulatory agenda. The searches only identified one "significant" rule published between January 1, 2001 and December 31, 2005 that was not identified in EPA's semiannual regulatory agendas.

95 Based on the Lexis searches outlined above, 2,521 final rules were published by EPA between January 1, 2001 and December 31, 2005. The number of final rules listed in the agency's semiannual regulatory agendas for the years 2001–2005 were: 1) 2001: 61 rules; 2) 2002: 64 rules; 3) 2003: 69 rules; 4) 2004: 60 rules; 5) 2005: 74 rules. *See* Stephen M. Johnson, Microsoft Access Database: 2001–2005 Final EPA Rulemakings–Significant Rules and Other Rules Listed in the Semi-Annual Regulatory Agenda, *available at* http://www.law.mercer.edu/elaw/epa/epa rules.zip (last visited July 20, 2008) [hereinafter Johnson, Database]. Supporting data also on file with author.

96 *Id.*

97 OMB maintains a database of information regarding its review of agency regulations pursuant to Executive Order 12,866. Office of Management and Budget, EO 12,866 Regulatory Review, http://www.reginfo.gov/public/do/eoPackageMain (last visited July 20, 2008) [hereinafter, OMB, EO 12,866 Regulatory Review]. A query from the "Review Counts" section of the database generated reports that detailed the number of rules and economically significant rules reviewed by OMB for each agency, as well as the average review times, for each year between 1996 and 2005. OMB, Review Counts, *supra* note 61. Another query from the same section of the database generated reports that detailed the number of rules reviewed at various stages of rulemaking (proposed rulemaking, final rulemaking, etc.) for each agency, for each year between 2001 and 2005. *Id.* A query from the "Historical Reports" section of the database generated detailed information regarding each EPA rule for which OMB completed a review under Executive Order 12,866 between 2001 and 2005. Office of Management and Budget, Historical Reports, http://www.reginfo.gov/public/do/eoHistoricReport (last visited July 20, 2008) [hereinafter OMB, Historical Reports].

Regarding judicial challenges to EPA's rules, a computerized search of reported opinions in federal courts from 2001 through 2007,[98] combined with a review of the "Table of Cases" listed weekly in the Bureau of National Affairs Environment Reporter from 2001 through 2007,[99] identified lawsuits involving challenges to thirty-nine of the "significant" rules published by EPA between January 1, 2001 and December 31, 2005.

While the study attempted to determine whether congressional and Executive Branch requirements substantially delayed the issuance of "significant" rules and attempted to determine the frequency of challenges to such rules, it did not attempt to determine whether the analytical and procedural requirements imposed by Congress and the Executive Branch created other incentives for agencies to avoid notice and comment rulemaking.[100]

IV. FINDINGS

A. Ossification

A review of the final rules published by EPA between January 1, 2001 and December 31, 2005, suggests that the analytical and procedural requirements imposed by Congress and the Executive Branch on notice and comment rulemaking may not delay the issuance of EPA's rules as substantially as has been suggested in the past.

1. Limited applicability of requirements

One of the first things that was clear upon review of the final rules issued by EPA between 2001 and 2005 was that very few of EPA's rules were subject to the analytical and procedural requirements of the Regulatory Flexibility Act, Executive Order 12,866, or Executive Order 13,045. Less than 4% of the rules EPA finalized during that time period were "significant" rules subject to OMB review and required preparation of analyses under Executive Order 12,866.[101] More than half of the "significant" rules subject to

[98] For each "significant" rule finalized by EPA between January 1, 2001 and December 31, 2005, a search was conducted in the Lexis "Federal Court Cases, Combined" database for the Federal Register cite of the final rule.

[99] Cases can be viewed by issue date on the BNA Environment Reporter website. Bureau of National Affairs, *ENVIRONMENT REPORTER*, http://pubs.bna.com/ip/BNA/ENR.NSF/CaseCiteIssue Date?OpenView (last visited July 27, 2008). The lists of cases were cross-referenced with the identified "significant" rules.

[100] For instance, the Executive Order 12,866 procedures and other Executive Branch requirements enable OMB and the President to exercise substantial control over the substantive content of regulations, and thus, could create an incentive for agencies to avoid adopting rules through notice and comment rulemaking, in order to maintain control over policymaking. This study did not examine whether the procedures had that effect.

[101] 94 of the 2,521 final rules EPA published in the Federal Register between 2001 and 2005 (3.73%) were "significant" rules. The number of significant rules published each year was as follows: 1) 2001: 20; 2) 2002: 12; 3) 2003: 14; 4) 2004: 22; 5) 2005: 26. *See* Johnson, Database, *supra* note 95. On average, therefore, EPA published 18.8 "significant" rules as final rules each

OMB review were issued under the Clean Air Act,[102] and another quarter of the rules were issued under the Clean Water Act[103] and the Resource Conservation and Recovery Act.[104]

Even fewer rules were "economically significant" rules, triggering the cost-benefit analysis requirements and the more stringent review requirements of Executive Order 12,866. Less than 1% of the EPA rules finalized between 2001 and 2005 were "economically significant" rules.[105] Of the "economically significant" rules, 75% were issued under the Clean Air Act.[106]

While the percentage of rules subject to review under Executive Order 12,866 was small, the percentage of rules subject to review under Executive Order 13,045 or the Regulatory Flexibility Act was infinitesimal. Only 6 of the 2,521 final rules published by EPA between 2001 and 2005 (0.2%) required preparation of a regulatory flexibility analysis and only 4 of the 2,521 final rules (0.16%) triggered the requirements of Executive Order 13,045.[107]

While there were very few rules that triggered the analytical and procedural requirements of the Regulatory Flexibility Act and Executive Orders 12,866 and 13,045, there were a surprising number of rules issued through a streamlined process as "direct final rules."[108] In 2005, 27% of the

year. John Graham, the former Administrator of OIRA, notes that each year, only 600 of the approximately 8,000 new rulemakings by *all* federal agencies are subject to the OMB review requirements for "significant" rules. *See* Graham et al., *supra* note 80, at 983. Under the prior executive order, Executive Order 12,291, agencies submitted *all* rules to OMB for review. *Id.* at 984.

102 Clean Air Act, 42 U.S.C. §§ 7401–7671q (2000).

103 Federal Water Pollution Control Act, 33 U.S.C. §§ 1251–1387 (2000).

104 Resource Conservation and Recovery Act of 1976, 42 U.S.C. §§ 6901–6992k (2000 amending Solid Waste Disposal Act, Pub. L. No. 89-272, 79 Stat. 992). Of the 94 "significant" rules, 53 were issued under the Clean Air Act, 13 were issued under RCRA, 12 were issued under the Clean Water Act, 3 were issued under the Safe Drinking Water Act, 2 were issued under the Emergency Planning and Community Right to Know Act, 2 were issued under the Toxic Substances Control Act, 1 was issued under the Federal Insecticide, Fungicide and Rodenticide Act, 1 was issued under CERCLA, 1 was issued under the Oil Pollution Act, and 5 were issued under "General" authority. *See* Johnson, Database, *supra* note 95.

105 Of the final rules EPA published between 2001 and 2005, 16 of the 2,521 final rules (0.59%) were "economically significant" rules. The number of "economically significant" rules published each year was as follows: 1) 2001: 4; 2) 2002: 1; 3) 2003: 2; 4) 200 : 6; 5) 2005: 3. *Id.* On average, therefore, EPA published 3.2 "economically significant" rules as final rules each year.

106 Of the 16 "economically significant" rules, 12 were issued under the Clean Air Act, 2 were issued under the Clean Water Act, 1 was issued under the Toxic Substances Control Act, and 1 was issued under the Safe Drinking Water Act. *Id.*

107 *Id.*

108 The Administrative Conference of the United States described this process as involving:

> [A]gency publication of a rule in the Federal Register with a statement that, unless an adverse comment is received on the rule within a specified time period, the rule will become effective as a final rule on a particular date. . . . However if an adverse comment is filed, the rule is withdrawn, and the agency may publish the proposed rule under normal notice-and-comment procedures.

Administrative Conference of the United States Adoption of Recommendations, 60 Fed. Reg.

final rules published by EPA in the Federal Register were issued as direct final rules.[109]

2. Timing of Review

Contrary to what might be expected, OMB review and the analytical and procedural requirements of Executive Order 12,866 did not appear to substantially delay the publication of rules by EPA. On average, between 2001 and 2005, EPA published "significant" rules as final rules approximately 651 days (1.75 years) after publishing the rules as proposed rules.[110] That was not substantially slower than the average 605 days that it took the agency to publish rules listed in the semiannual regulatory agenda that were not significant rules or direct final rules.[111] Even more surprising, EPA published "economically significant" rules *more* quickly than the rules listed in the semiannual regulatory agenda that were not "significant" rules. On average, EPA published "economically significant" rules as final rules approximately 566 days (1.5 years) after publishing the rules as proposed rules.[112] Those time frames are significantly shorter than the three year time frame frequently cited in "ossification" scholarship as the normal minimum time frame for finalizing rules.[113] OMB review accounted for only a small portion of the time between proposed and final rulemaking. Between 2001 and 2005, OMB generally completed its review of EPA's "economically significant" final rules (the ones subject to the most procedural and analytical requirements under Executive Order 12,866) within fifty-one days.[114]

43,108, 43,110 (Aug. 18, 1995). The process, which was invented by EPA, is used for routine and noncontroversial rules as an alternative to issuing the rule without any notice and comment procedures, pursuant to the "good cause" exception to the notice and comment process for rules where the agency finds notice and public procedure "impracticable, unnecessary, or contrary to the public interest." *See* Administrative Procedure Act, 5 U.S.C. § 553(b)(3)(B) (2000).

109 An earlier empirical study by another researcher determined that almost one-third of the rules published in the Federal Register during a six-month period dispensed with notice and comment procedures due to "good cause." Juan J. Lavilla, *The Good Cause Exemption to Notice and Comment Requirements Under the Administrative Procedure Act*, 3 ADMIN. L.J. 317, 339 (1989).

110 The average time to finalize "significant" rules published as final rules each year was as follows: 1) 2001: 577 days; 2) 2002: 970 days; 3) 2000: 540 days; 4) 2004: 547 days; 5) 2005: 709 days. *See* Johnson, Database, *supra* note 95.

111 However, the average time to finalize all rules in the semiannual regulatory agenda other than "significant" rules drops to 390.4 days when direct final rules (which take, in essence, no time to finalize) are included. *See id.*

112 The average time to finalize "economically significant" rules published as final rules each year was as follows: 1) 2001: 600 days; 2) 2002: 400 days; 3) 2003: 532 days; 4) 2004: 574 days; 5) 2005: 583 days. *See id.*

113 *See supra* note 4 and accompanying text.

114 During 2001, when President George W. Bush took office, he ordered a review or suspension of most significant agency rules. *See* Memorandum for the Heads and Acting Heads of Executive Departments and Agencies, 66 Fed. Reg. 7702 (Jan. 24, 2001) (including memorandum from Chief of Staff Andrew Card). Not surprisingly, due to the volume and significance of rules being reviewed, OMB review under Executive Order 12,866 was much

B. Judicial Review

While the findings regarding the effect of congressional and Executive Branch analytical and procedural requirements on agency rulemaking were somewhat surprising, the findings regarding judicial review of EPA's significant rules were not. In fact, the empirical data provides some support for the anecdotal claims of former EPA Administrators regarding the rate at which the agency's major rules are challenged in court, depending on which rules are examined.[115] More than 40% of the "significant" rules that EPA published as final rules between 2001 and 2005 were challenged in court.[116] Seventy percent of the significant rules that were challenged were issued under the Clean Air Act[117] and more than 80% of the challenges were brought in the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit).[118]

When the focus is narrowed to the "economically significant" rules, 75% of the final rules published by EPA between 2001 and 2005 were challenged in court.[119] Half of the challenged rules were issued under the Clean Air Act[120] and more than 90% of the challenges were brought in the D.C. Circuit.[121]

slower during that year. If that year is excluded from calculations, between 2002 and 2005 OMB generally completed its review of "economically significant" *final* rules in 41 days. *See* OMB, Historical Reports, *supra* note 97 (entered queries of "Economically Significant Reviews Completed" for EPA for 2001, 2002, 2003, 2004, and 2005). The average time for OMB review of "economically significant" final rules between 2001 and 2005 was as follows: 1) 2001: 81.6 days; 2) 2002: 48 days; 3) 2003: 26 days; 4) 2004: 26.6 days; 5) 2005: 59.3 days. *Id.*

115 While Professor Cary Coglianese disputed the validity of the claims regarding the rate at which EPA's rules were challenged, his empirical research focused simply on "significant" rules and did not focus more directly on "economically significant" rules. *See supra* note 35. When limited to "economically significant" rules, the statements of the EPA Administrators are more supportable. *See supra* note 33.

116 39 of the 94 "significant" rules issued as final rules between 2001 and 2005 (41.5%) were challenged in court at some point after promulgation of the rules. *See* Johnson, Database, *supra* note 95.

117 28 of the 39 rules challenged were issued under the Clean Air Act, 5 were issued under the Clean Water Act, 2 were issued under RCRA, and 1 each under the Oil Pollution Act, the Emergency Planning and Community Right to Know Act, the Toxic Substances Control Act, and the Safe Drinking Water Act. *Id.*

118 33 of the 39 rules challenged were challenged in the D.C. Circuit, 3 were challenged in the Second Circuit, 1 was challenged in the Ninth Circuit, and 3 were challenged in the federal district court for the District of Columbia. *Id.*

119 12 of the 16 "economically significant" rules issued as final rules between 2001 and 2005 were challenged in court at some point after promulgation of the rules. *Id.*

120 8 of the rules challenged were issued under the Clean Air Act, 2 were issued under the Clean Water Act, 1 was issued under the Toxic Substances Control Act, and 1 was issued under the Safe Drinking Water Act. *Id.*

121 11 of the 12 rules challenged were challenged in the D.C. Circuit and the last case was challenged in the Second Circuit. *Id.*

V. IMPLICATIONS OF THE FINDINGS

A. Limitations

What conclusion should be drawn from the finding that there was not much difference between the amount of time it took EPA to issue "significant" rules as final rules after publishing them as proposed rules, and the amount of time it took EPA to issue other rules as final rules after publishing them as proposed rules? On one hand, it could be argued that, contrary to conventional wisdom, the congressional and Executive Branch analytical and procedural requirements have not "ossified" EPA's rulemaking process. After all, if the congressional and Executive Branch requirements only apply to a very small number of rules issued by the agency each year, and if it does not take the agency considerably longer to issue a "significant" rule (which requires compliance with the analytical, procedural, and review requirements of Executive Order 12,866) than other rules (which do not require compliance with the Order), then the congressional and Executive Branch requirements should not be blamed for "ossifying" the agency's rulemaking process, should they?

Although it may be tempting to jump to the conclusion that the data contradicts the claims that congressional and Executive Branch requirements have "ossified" EPA rulemaking, it would be unwise to reach that conclusion. By focusing solely on the time required to issue a rule as a final rule after publishing the rule as a proposed rule, the study paints an incomplete picture of the rulemaking process. Before EPA or any agency publishes a rule as a proposed rule, the agency spends a substantial amount of time developing the proposed rule. For "significant" rules, including "economically significant" rules, EPA must prepare the analyses and reports required by Executive Orders 12,866 and 13,045, and by the Regulatory Flexibility Act, *before* the agency publishes the rules as proposed rules.[122] At a minimum, therefore, compliance with those planning and analytical requirements will require agencies to spend more time developing a rule, or at least materials to support the rule, before the rule is published as a proposed rule. The analysis of the timing of the issuance of EPA rules outlined above focused only on the length of time it took EPA to issue rules as final rules *after* publishing the rules as proposed rules. At a minimum, therefore, this study does not reflect any delay or ossification of the process caused by preparation of the analyses and reports required by executive orders and legislation. It would be difficult to determine how much additional time agencies must spend to prepare those documents for proposed rules requiring that analysis than for rules not subject to the requirements because data regarding the amount of time agencies spend preparing the documents is not readily available.

The study in this Article also paints an incomplete picture because it does not include the amount of time required for OMB's review of rules under

[122] *See supra* notes 58–69 and accompanying text.

Executive Order 12,866 *before* they are published as proposed rules. First, as noted above, the Order requires EPA to submit "significant" rules to OMB for formal review before they are published as final rules *or proposed rules*.[123] Pursuant to the Executive Order, OMB can take up to ninety days, and perhaps more in some cases, to review rules before they are published as proposed rules.[124] Rules not subject to the Executive Order obviously do not have to be delayed for that additional time prior to publication as proposed rules. While factoring in the additional time required for prepublication OMB review of significant rules may have slightly widened the gap between the amount of time that it takes EPA to issue "significant" rules and other rules, it would not have had a major effect, as OMB review is limited in most cases to ninety days.

However, in addition to the *formal* review of significant rules required by Executive Order 12,866, OMB increasingly engages in *informal* review of those rules before the agencies submit them for formal review.[125] The ninety day review limit of the Executive Order does not apply to the informal review period, and informal review of agency rules often takes substantially longer than the formal review of the rules.[126] A comparison of the amount of time that it takes EPA to finalize rules after publication of the rules as proposed rules is misleading, therefore, in that it does not account for the additional time that may be required for informal review of "significant" rules prior to publication of the rules as proposed rules.[127] The informal review process has been

123 Exec. Order No. 12,866, 58 Fed. Reg. 51,735, 51,740–41 (Oct. 4, 1993).

124 *Id.* at 51,742.

125 During the leadership of OIRA Administrator John Graham, OMB used several tools to expand their review of rules prior to publication of the rules as proposed rules. *See* Graham et al., *supra* note 80, at 972; Copeland, *supra* note 63, at 1280. Early involvement of OIRA prevents agencies from devoting significant time and resources to rulemaking proposals that will raise concerns for OIRA. Lisa Schultz Bressman & Michael P. Vandenbergh, *Inside the Administrative State: A Critical Look at the Practice of Presidential Control*, 105 MICH. L. REV. 47, 96 (2006); Copeland, *supra* note 63, at 1279 (describing a rule where informal review took four times as long as the formal review). At the same time, though, OIRA's informal review is not very transparent, because the disclosure requirements of Executive Order 12,866 do not apply to the informal review process. *See* Bressman & Vandenbergh, *supra*, at 96. During *formal review*, OIRA must publicly disclose "all substantive communication" between OIRA and outside parties "regarding a regulatory action under review." 58 Fed. Reg. at 51,743. The Executive Order requires OIRA to send copies of communications that it receives to relevant agencies, to keep a log of all of its interactions with outside parties, and to invite agency representatives to any meetings it holds with outside parties. *Id.* Those requirements of the Executive Order do not apply to the *informal review* process.

Furthermore, OIRA discourages agencies from disclosing changes made to their rules at OIRA's "suggestion" during informal review. Copeland, *supra* note 63, at 1311. Since informal review often results in significant substantive changes to agency rules, early involvement of OIRA in review of agency rulemaking raises concerns about accountability and the improper influence of outside parties on agency rulemaking. *See* Bressman & Vandenbergh, *supra*, at 96. In addition, since the APA does not apply to OIRA, its conduct during review of agency rules, including meeting with outside parties and influencing the content of the rules, is not subject to judicial review or the APA's procedural safeguards. Nicholas Bagley & Richard L. Revesz, *Centralized Oversight of the Regulatory State*, 106 COLUM. L. REV. 1260, 1281 (2006).

126 Copeland, *supra* note 63, at 1278–79.

127 *See* Bagley & Revesz, *supra* note 125, at 1281 (noting that OIRA's informal review is likely

frequently criticized as a process that lacks transparency,[128] and it is difficult to obtain data regarding when informal OMB review begins. Thus, it would be difficult to extend the analysis in this Article to compare the amount of time required to issue "significant" rules, including formal and informal OMB review before publication of a proposed rule, to the amount of time required to issue rules not subject to OMB review.

The findings of this study regarding delay in rulemaking caused by compliance with congressional and Executive Branch requirements may also be misleading because the study focused on rules that were issued as final rules between 2001 and 2005. During that time period, and especially during 2001,[129] OMB was very aggressive in its review of the regulations of EPA and other agencies.[130] At least during the first few years covered by the study, the number of rules returned to agencies by OMB and withdrawn by agencies during OMB review increased substantially.[131] Over the five years covered by the study, except for one rule finalized pursuant to a judicial deadline, *none* of EPA's "economically significant" rules completed OMB review without the agency making some change to the rule during the review or withdrawing the rule.[132] Many critics assert that OMB adopts a

to delay rulemaking during the initial negotiations even if it does not unduly hamper rulemaking during OIRA's formal review).

128 *See, e.g.*, Copeland, *supra* note 63, at 1267.

129 Shortly after President George W. Bush took office, Andrew Card, the President's Chief of Staff, issued a memorandum to cabinet departments and independent agencies which directed them:

> (1) not to send proposed or final rules to the Office of the *Federal Register*, (2) to withdraw from the Office rules that had not yet been published in the *Federal Register*, and (3) to postpone for sixty days the effective date of rules that had been published but had not yet taken effect.

Copeland, *supra* note 63, at 1275–76.

130 *See* Graham et al., *supra* note 80, at 969. Although OMB was criticized for lax oversight of agency rulemaking during the Clinton Administration, *see* Robert W. Hahn et al., *Assessing Regulatory Impact Analyses: The Failure of Agencies to Comply With Executive Order 12,866*, 23 HARV. J.L. & PUB. POL'Y 859, 861–68, 877 (2000), in most Administrations, OMB has taken on the role of regulatory "gatekeeper." Copeland, *supra* note 63, at 1286.

131 *See* Graham et al., *supra* note 80, at 969. Between July and December 2001, OMB issued more "return letters" to agencies suggesting that rulemaking proposals should be reconsidered than the agency issued during the entire eight years of the Clinton Administration. *Id.* John Graham referred to the letters as the agency's "ultimate weapon." *See* Copeland, *supra* note 63, at 1287. Between 2002 and 2005, however, the pace at which OMB issued return letters slowed considerably. *Id.* at 1288.

During the period covered by the study that is the subject of this Article, the number of rules withdrawn by EPA increased dramatically. While EPA voluntarily withdrew, on average, 2.9 rules per year for each year between 1990 and 2000, EPA withdrew 21 rules in 2001 alone. *See* OMB, Review Counts, *supra* note 61 (entered query "By OIRA Conclusion Action" between 01/01/1990 and 12/31/2000; and between 01/01/2001 and 12/31/2001). EPA withdrew more than three times as many rules (27) between 2001 and 2005 as it withdrew in the preceding five years (eight withdrawn between 1996 and 2000). *See id.* (entered query "By OIRA Conclusion Action" between 01/01/1996 and 12/31/2000; and between 01/01/2001 and 12/31/2005).

132 Based on data reported in OMB's RegInfo database, between 2001 and 2005, OMB reviewed 49 "economically significant" EPA rules, including 21 final rules. *See* OMB, Historical Reports, *supra* note 97 (entered query of "Economically Significant Reviews Completed" for

probusiness[133] and antiregulatory approach during its review of agency rules.[134] It is very likely, therefore, that many controversial rules, which

EPA for 2001–2005). 10 of the rules, including 4 final rules, were withdrawn. *Id.* The rest were coded as "consistent with change," except for the one rule that was coded as "Statutory or Judicial Deadline." *Id.* None of the rules were coded as "consistent without change." *Id.*

There are limits to the conclusions that can be drawn from a simple analysis of the data in the OMB database, however. For instance, when a rule is coded as "consistent with change," the coding means that the rule was changed *while* it was being formally reviewed by OMB, but not necessarily *because* it was being reviewed by OMB. Copeland, *supra* note 63, at 1275. Similarly, since the coding only focuses on changes during formal OMB review, it does not identify whether a rule was changed outside of OMB's formal review process, even if the rule was changed at the suggestion of OMB. *Id.*

Between 2001 and 2005, generally more than half of *all* rules reviewed by OMB for all agencies were coded as "consistent with change" in OMB's database. *See id.* This trend began before 2001, though. For instance, after reviewing the data in the OMB database, Professor Steven Croley observed that the ratio of rules changed during OMB review to those that were not changed increased dramatically between 1981 and 2000. Steven Croley, *White House Review of Agency Rulemaking: An Empirical Investigation*, 70 U. CHI. L. REV. 821, 849 (2003). Croley also found that between 1998 and 2000, EPA submitted 242 rules to OIRA for review, including 62 "economically significant" rules, and only 26 of the rules were unchanged during the review process. *Id.* at 868. Further, he noted that for the period of time he was reviewing, when OMB held meetings with outside parties regarding EPA rules as part of its review, EPA's rules were changed during the review process in 94% of the cases. *Id.*

In a separate study, the United States Government Accounting Office (GAO) examined proposed and final rules reviewed by OMB for all agencies between July 1, 2001 through June 30, 2002 to explore the impact of OMB review on agency rulemaking. *See* GAO, RULEMAKING: OMB'S ROLE IN REVIEWS OF AGENCIES' DRAFT RULES AND THE TRANSPARENCY OF THOSE REVIEWS (2003) [hereinafter GAO REPORT]. 61% percent of the rules reviewed during that time period were coded as "consistent with change," "withdrawn," or "returned." *Id.* at 70. GAO selected 85 of the rules that were coded as "consistent with change," "withdrawn," or "returned" and reviewed the documents accompanying the rules in order to determine, if possible, the reasons for the changes, withdrawal, or return of the rules. *Id.* at 70, 73. Upon review of the underlying documents, GAO concluded that "25 of the 85 rules from these agencies were significantly affected by OIRA's review." *Id.* at 72. More importantly, though, GAO determined that OIRA had a significant effect on 59% of the rules (13 out of 22) submitted by EPA's Office of Air and Radiation and Office of Water. *Id.* at 75. GAO's review still paints an incomplete picture, though, because it did not examine changes made to rules outside of the formal OMB review process.

133 The GAO, in its 2003 report, concluded that the outside parties who contacted OIRA during its review of agency rulemaking were "most commonly representatives of regulated entities." GAO REPORT, *supra* note 132, at 11. Similarly, Professor Steven Croley, in his analysis of OIRA review of rulemakings between 1993 and 2000, found that 56% of the meetings that OIRA held with outside parties only involved narrow interests, such as industry representatives, while only 10% of the meetings involved "broad interests," such as nonprofit public interest groups. Croley, *supra* note 132, at 858.

134 Graham et al., *supra* note 80, at 985–86; *see also* Bressman & Vandenbergh, *supra* note 125, at 74–75 (finding, based on interviews with EPA officials that served between 1989 and 2001, that OIRA's review of EPA rules focused almost exclusively on the cost side of cost-benefit analysis and that OIRA frequently sought to reduce regulatory burdens and only infrequently sought to strengthen environmental protections).

However, John Graham, Administrator of OIRA during the time period covered by the study that is the focus of this Article (2001–2005), maintains that OMB's "smart regulation" approach at the turn of this century was not "anti-regulation." Graham et al., *supra* note 80, at 965. Indeed, Graham notes that the agency began sending "prompt letters" to agencies during that time, suggesting that agencies should consider taking various actions through rulemaking. *Id.* at 973.

would have taken longer to finalize, were withdrawn.[135] OMB's aggressive review of regulations during this time period could, therefore, have prevented EPA from finalizing some "significant" rules which, if finalized, would have taken much longer to finalize than rules not subject to OMB and congressional review requirements.[136] Similarly, OMB's aggressive review

Like many other critics, Professors Nicholas Bagley and Richard Revesz are skeptical of Graham's claims. As Bagley and Revesz note, "[a]lthough centralized review is sometimes justified on the grounds that it could harmonize the uncoordinated sprawl of the federal bureaucracy, . . . OMB[] has never embraced that role. It has instead doggedly clung to its original cost-reduction mission . . . ." Bagley & Revesz, *supra* note 125, at 1260. Regarding "prompt" letters, Professors Bagley and Revesz note that prompt letters are simply mechanisms to bring issues to the attention of agencies and can pressure agencies to deregulate as effectively as they can pressure agencies to regulate. *Id.* at 1278.

135 Professors Bagley and Revesz assert that Executive Order 12,866 contains several structural and institutional biases against regulation because: 1) OIRA reviews regulations only to determine whether they are too stringent (the benefits outweigh the costs), but not to determine whether the regulations are too lax; 2) OIRA reviews agency decisions to deregulate with less vigor than agency decisions to regulate; and 3) OIRA does not review agency inaction (decisions not to regulate). Bagley & Revesz, *supra* note 125, at 1267–68. Bagley and Revesz also note that the delay caused by OMB review under Executive Order 12,866 can discourage agencies from adopting rules. *Id.* at 1280.

To support their claim that OIRA review overemphasizes consideration of costs in rulemaking, Professors Bagley and Revesz point out that in a 2003 report on OIRA, the GAO examined all of the 393 "significant" rules reviewed by OIRA during a single year and determined that of the EPA rules significantly changed during OIRA review, *none* were made *more* stringent to capture greater benefits. *Id.* at 1269–70. They also note that OMB has pursued a deregulatory agenda outside of its review of rules under Executive Order 12,866. Specifically, in May 2001, OIRA asked the public to identify agency rules that should be rescinded or modified in order to reduce regulatory burdens. *Id.* at 1279.

Bagley and Revesz astutely observe that:

> Aware that overregulation may lead to reversal while underregulation will go unchecked, rationally risk-averse agencies initiating significant regulatory actions will . . . have powerful incentives to make their regulations less stringent . . . if the expected benefits of a particular regulation are contingent, fairly contestable, or difficult to quantify—that is, nearly always . . . . This dynamic effect will also extend to agency decisions of what to regulate: Confronted with biased OIRA review, agencies will naturally devote scarce resources to rulemakings that are less vulnerable to the charge that they reflect a too-rosy assessment of regulatory benefits.

Id. at 1270. Professors Bagley and Revesz highlight that OMB's antiregulatory approach is short-sighted because "[a]gencies' decisions *not* to regulate can be every bit as costly to society as overly expensive regulations . . . . '[S]tudies show that adding some regulations, while removing or improving others, could save tens of thousands of lives and millions of dollars annually.'" *Id.* at 1274 (quoting Robert W. Hahn & Cass R. Sunstein, *A New Executive Order for Improving Federal Regulation? Deeper and Wider Cost-Benefit Analysis*, 150 U. PA. L. REV. 1489, 1521–22 (2002)).

136 Agencies rarely challenge OMB's returns or suggestions for changes to rules and likely refrain from submitting rules for OMB review if they believe that the rules will be opposed. *See* Copeland, *supra* note 63, at 1306.

Commentators have noted that White House officials other than OMB representatives also exert substantial pressure on agencies to change or withhold rulemakings. Professors Lisa Schultz Bressman and Michael Vandenbergh interviewed EPA officials that served between 1989 and 2001 to examine their perspectives regarding the impact of OMB and the White House on EPA rulemaking during their tenures. Bressman & Vandenbergh, *supra* note 125, at 49. Based

may have discouraged EPA from issuing "significant" rules as proposed rules during that time period.[137] If OMB's actions diverted some "significant" (and potentially time consuming) rules out of the rulemaking pipeline, it would not be surprising to find that the amount of time required to finalize the remaining "significant" rules which EPA issued was not substantially different from the amount of time required to finalize other rules.

Along the same lines, it is also possible that there was not a substantial difference between the amount of time required to finalize "significant" rules and other rules because the "ossification" of the rulemaking process had driven EPA to avoid engaging in the rulemaking process when the process

on their interviews, Professors Bressman and Vandenbergh concluded that "OIRA is not the primary source of influence on many major rulemakings" and that, "[a]lthough OIRA exerts influence on many day-to-day issues, other White House offices wield more influence on high-profile or high-stakes matters." *Id.* They also concluded the review conducted by OMB and White House officials was selective and unsystematic, often driven by the interests of particular officials. *Id.* at 50. Further, the EPA officials whom they interviewed expressed significant concerns regarding the lack of transparency of the review of rules by White House officials other than OMB. *Id.* at 50–51.

137 Between 2001 and 2005, OMB reviewed 49 "economically significant" EPA rules in proposed or final form, an average of 9.8 "economically significant" rules per year. *See* OMB, Review Counts, *supra* note 61 (entered query "Number of Rules and Economically Significant Rules Reviewed and Average Review Times" between 01/01/2001 and 12/31/2005). In the preceding decade, 1990–2000, OMB reviewed 228 "economically significant" rules, or an average of 20.7 "economically significant" rules per year. *See id.* (entered query "Number of Rules and Economically Significant Rules Reviewed and Average Review Times" between 01/01/1990 and 12/31/2000). Thus, between 2001 and 2005, OMB reviewed about half as many "economically significant" EPA rules each year as it reviewed during the preceding decade.

Similarly, while EPA sent an average of about 24 "economically significant" rules to OMB for review each year between 1994 and 2000, *see id.* (entered query "Number of Rules and Economically Significant Rules Reviewed and Average Review Times" between 01/01/1994 and 12/31/2000), the agency only sent an average of 10 "economically significant" rules to OMB for review each year between 2001 and 2005. *See id.* (entered query "Number of Rules and Economically Significant Rules Reviewed and Average Review Times" between 01/01/2001 and 12/31/2005). Prior to 1994, under Executive Order 12,291, OMB's review of agency rules was not limited to "significant" rules, and OMB reviewed substantially more rules each year. *See* Exec. Order No. 12,291, 46 Fed. Reg. 13,193 (Feb. 19, 1981). For example, OMB reviewed 179 EPA rules in 1993. *See* OMB, Review Counts, *supra* note 61 (entered query "Number of Rules and Economically Significant Rules Reviewed and Average Review Times" between 01/01/1993 and 12/31/1993).

The decrease in "economically significant" EPA rules is not solely attributable to aggressive OMB review between 2001 and 2005, though, as the decrease began before President George W. Bush took office in 2001. For instance, while OMB reviewed an average of almost 20 "economically significant" EPA rules each year between 1985 and 1995, OMB only reviewed an average of about 13 "economically significant" EPA rules each year between 1996 and 2005. *See id.* (entered query "Number of Rules and Economically Significant Rules Reviewed and Average Review Times" between 01/01/1985 and 12/31/1995; and between 01/01/1996 and 12/31/2005).

In analyzing the trend in "major" (economically significant) rulemaking since 1981, John Graham noted that the volume of "major" rules adopted during each Administration has not been uniform. *See* Graham et al., *supra* note 80, at 976. Specifically, he noted that the number of "major" rulemakings for each Administration was as follows: 1) President Reagan (first term): 18; 2) President Reagan (second term): 24; 3) President George H.W. Bush: 50; 4) President Clinton (first term): 39; 5) President Clinton (second term): 66; and 6) President George W. Bush (first term and beginning of second term): 37. *Id.*

might be time consuming.[138] Instead, agencies may be increasingly relying on adopting, through adjudication, interpretive rules, and other guidance documents, the policies that they would have adopted through notice and comment rulemaking.[139]

B. Conclusion

Despite all of those caveats regarding the limitations of the study that is the subject of this Article, it appears clear that 1) the analytical and procedural requirements of Congress and the Executive Branch did not significantly increase the amount of time it took EPA to issue "significant rules" in final form between 2001 and 2005 after the agency issued them as proposed rules; and 2) 75% of the "economically significant" rules and more than 40% of the "significant" rules issued by EPA as final rules between 2001 and 2005 were challenged in court. It is clear, thus, that the rate at which "significant" and "economically significant" EPA rules are challenged in court can provide a strong incentive to the agency to avoid rulemaking whenever possible, and to adopt policies through adjudication and other informal means. It is less clear from this study, though, that the analytical and procedural requirements imposed by Congress and the Executive Branch have "ossified" EPA rulemaking and provided incentives for the agency to avoid rulemaking. More research regarding the timing of the development of rules *before* they are published as proposed rules is necessary to clarify whether the congressional and Executive Branch requirements have "ossified" EPA's rulemaking. While that research may clearly demonstrate the "ossification" of the rulemaking process, this study does not.[140]

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[138] Since it predates the influence of OIRA Administrator Graham, the substantial decrease in the number of "economically significant" rules prepared by EPA for OMB review over the past decade might be caused by the "ossification" of the rulemaking process. As noted above, EPA sent half as many "economically significant" rules to OMB for review each year between 2001 and 2005 as it sent between 1990 and 2000. *See supra* note 137.

[139] However, on January 23, 2007, President George W. Bush issued an Executive Order that requires agencies to submit "significant" guidance documents to OMB for review before the agencies adopt the guidance. Exec. Order No. 13,422, 72 Fed. Reg. 2763 (Jan. 23, 2007). Two days later, OMB issued guidelines that impose significant limits on the development of interpretive rules, policy statements and other guidance documents, including the imposition of notice and comment procedures for certain guidance documents. Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432 (Jan. 25, 2007). These additional analytical and procedural requirements could ossify the development of guidance and discourage agencies from adopting policies through guidance. *See* Johnson, *Good Guidance*, *supra* note 2, at 696–97.

[140] As noted previously, this study does not attempt to determine whether OMB's ability to influence the content of rulemaking through its review, rather than any increased time required for OMB review, affects EPA's decision to adopt a policy through rulemaking as opposed to adjudication or informal procedures.