PRE-ENFORCEMENT REVIEW: AN EVALUATION FROM THE PERSPECTIVE OF RIPENESS

NOTE

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The ripeness doctrine prevents federal courts from deciding cases when the injury alleged is too speculative. However, in *Abbott Laboratories v. Gardner* the Supreme Court held that the ripeness doctrine did not preclude drug companies from mounting a pre-enforcement challenge to a Federal Drug Administration regulation, thereby establishing a presumption in favor of pre-enforcement review of agency regulations. Since then, courts and commentators have often viewed pre-enforcement review favorably, based on its ability to guarantee certainty for regulated parties, check the excesses of the executive branch, and ensure that parties are not subjected to harm at the hands of unlawful agency conduct.

This Note uses the policy values underlying the ripeness doctrine to challenge the efficacy of pre-enforcement review. First, because pre-enforcement review involves adjudication of abstract disputes without a concrete set of facts, courts are less likely to reach correct decisions. Second, due to regulatory complexity, courts tend to defer to agencies in pre-enforcement proceedings, giving them inherent advantages. Finally, there is significant evidence demonstrating that pre-enforcement decisions have a prejudicial effect on regulated parties in future enforcement proceedings. These factors combine to significantly damage private litigants' chances of successfully challenging agency rules at both the pre-enforcement *and* enforcement stage.

For these reasons, use of pre-enforcement review as a means of achieving just outcomes for stakeholders should be reconsidered. By limiting pre-enforcement review of complex agency rules, private parties would actually gain access to higher quality and more meaningful judicial review. Agencies and public interest stakeholders would likewise benefit from the increased efficiency and enforcement ability that would result from limiting judicial review in pre-enforcement settings.

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I. INTRODUCTION

The judiciary is empowered by the Constitution through judicial review and by Congress through the Administrative Procedure Act ("APA") to strike down unlawful agency action.[1] Since the Supreme Court's seminal decision in *Abbott Laboratories v. Gardner*,[2] it has become regular practice for courts to conduct pre-enforcement judicial review of "notice-and-comment" agency rules.[3] In support of the practice

[1] Nicholas Bagley, *The Puzzling Presumption of Reviewability*, 127 HARV. L. REV. 1285, 1287 (2014) ("The presumption in favor of judicial review of agency action is a cornerstone of administrative law.").

[2] 387 U.S. 136 (1967).

[3] Bagley, *supra* note 1, at 1337 ("Preenforcement review—which is to say, judicial review of an agency rule before the agency moves to enforce it in an adjudication—is today widely accepted

of pre-enforcement review, *Abbott* cited the APA's default right of judicial review as well as the principle that "judicial review of a final agency action by an aggrieved person will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress."[4] The availability of pre-enforcement review has been lauded for enhancing certainty for regulated parties, checking the excesses of the executive branch, and ensuring that parties are not subjected to harm at the hands of unlawful agency conduct.

In recent years, the Supreme Court has come down squarely in favor of continuing the presumption of pre-enforcement review. Nowhere is this more evident than in the environmental context, where the Court has cited the need for certainty and the threat of draconian consequences for landowners facing enforcement actions by the Environmental Protection Agency ("EPA") or Army Corps of Engineers as justification for pre-enforcement review. In *Sackett v. EPA*,[5] decided in 2012, the Court held unanimously that EPA compliance orders may be challenged in court before an enforcement proceeding is initiated. In a case decided just last year, the Court found—also in unanimous fashion—that an Army Corps jurisdictional determination that a wetland was covered by the Clean Water Act ("CWA") was likewise challengeable before the landowner applied for a permit or faced an enforcement action.[6]

This Note challenges the claim that pre-enforcement review of lengthy, complex agency rules is overall more beneficial for regulated parties. The complexity of agency rules both decreases the accuracy of pre-enforcement rulings and provides significant advantages to agencies over regulated parties in pre-enforcement challenges to regulations. This Note also provides substantial evidence that pre-enforcement rulings ultimately prejudice future challenges to agency rules in enforcement proceedings. Thus, pre-enforcement review of complex agency rules significantly damages private litigants' chances of successfully challenging agency rules at both the pre-enforcement and enforcement stage.

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as an essential feature of the administrative law landscape."). "Informal" or "notice-and-comment-rulemaking" is the most common form of agency rulemaking and is subject to minimum procedural requirements, including (1) publication in the Federal Register, (2) opportunity for interested parties to submit comments and data, (3) a statement of basis and purpose accompanying the rule where the agency must demonstrate a rational connection between its policy choices and the facts available, and (4) at least a thirty-day waiting period before publication of the final rule. *See* Administrative Procedure Act, 5 U.S.C. § 553(b) and (c). *See also* Motor Veh. Mfrs. Ass'n v. State Farm Ins. Co., 463 U.S. 29 (1983).

4 *Abbott*, 387 U.S. at 140.

5 566 U.S. 120, 131 (2012).

6 Hawkes Co., Inc. v. U.S. Army Corps of Eng'rs, 136 S.Ct. 1807 (2016).

Despite promoting the practice of pre-enforcement review, *Abbott* nevertheless required that such challenges be ripe for review, thus preventing cases from being litigated prematurely.[7] Since *Abbott*, the ripeness doctrine has been interpreted to represent a set of policy goals, including (1) increasing the likelihood of a correct case outcome, (2) ensuring access to justice for affected parties, and (3) maintaining a proper balance of powers between the branches in our constitutional system. This Note evaluates the efficacy of pre-enforcement review of highly complex agency rules using these normative underpinnings of the ripeness doctrine, primarily through the lens of the Clean Water Rule that was recently issued by the EPA and Army Corps of Engineers as well as the Supreme Court case that inspired it. By examining the Clean Water Rule in this way, this Note argues that pre-enforcement review of highly technical regulations is problematic and should be reconsidered.

Despite scholarly debate on the merits of pre-enforcement review in terms of its effects on the rulemaking process,[8] the institutional relationship between branches of government,[9] and reasoned judicial decision making,[10] little attention has been given to the effect of inaccurate decisions and agency advantage in pre-enforcement review on regulated parties' ability to vindicate their rights later in enforcement proceedings.

In his recent article *The Puzzling Presumption of Reviewability*, Professor Nicholas Bagley presents a forceful rebuke to *Abbott*'s presumption of reviewability, arguing that (at least in its current form) it is unsupported by "history, positive law, the Constitution, or sound policy considerations."[11] This Note takes aim at the presumption in favor of *pre-enforcement* review in particular, contending that courts should view the

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[7] For a brief history of the evolution of the ripeness doctrine, see Marla Mansfield, *Standing and Ripeness Revisited: The Supreme Court's "Hypothetical" Barriers*, 68 N.D. L. REV. 1 (1992).

[8] *See, e.g.*, JERRY L. MASHAW, GREED, CHAOS, AND GOVERNANCE 158–81 (1997); JOHN M. MENDELOFF, THE DILEMMA OF TOXIC SUBSTANCES REGULATION 7–16 (1988); Mark Seidenfeld, *Playing Games with the Timing of Judicial Review: An Evaluation of Proposals to Restrict Pre-Enforcement Review of Agency Rules*, 58 OHIO ST. L. J. 85 (1997); Peter L. Strauss, *Rules, Adjudications, and Other Sources of Law in an Executive Department: Reflections on the Interior Department's Administration of the Mining Law*, 74 COLUM. L. REV. 1231 (1974).

[9] *See, e.g.*, Frank B. Cross, *Shattering the Fragile Case for Judicial Review of Rulemaking*, 85 VA. L. REV. 1243 (1999) (arguing the theoretical illegitimacy of judicial review from a separation of powers standpoint); John F. Duffy, *Administrative Common Law in Judicial Review*, 77 TEX. L. REV. 113 (1995) (arguing in favor of increased judicial review in light of statutory authorization in the APA).

[10] *See, e.g.*, Richard J. Pierce, Jr., *Seven Ways to Deossify Agency Rulemaking*, 47 ADMIN. L. REV. 59, 70 (1995).

[11] Bagley, *supra* note 1, at 1287. Professor Bagley's piece also favors less frequent use of pre-enforcement review, but is aimed mostly at rebutting the presumption of reviewability more generally.

presumption with greater skepticism in the context of complex agency rulemaking.

This Note proposes a new way to conceive of the stakeholder-agency relationship. It argues that by limiting pre-enforcement review of complex agency rules, private parties actually gain access to higher quality judicial review that has a more meaningful impact. Simultaneously, agencies and public interest stakeholders benefit from the increased efficiency and enforcement ability that result from limiting judicial review in pre-enforcement settings. Accordingly, courts should employ the ripeness doctrine more often to limit pre-enforcement review in challenges to lengthy and highly technical regulations.

Part II of this Note provides an overview of the ripeness doctrine through an illustration of *Abbott* and its two companion cases. Part III explores how pre-enforcement review either furthers or hampers the various normative underpinnings of the ripeness doctrine, including accuracy of judicial decision (section III.A), access to justice and the prevention of substantial, imminent harm (section III.B), and balance of power objectives (section III.C). Part IV briefly examines how the normative values associated with ripeness can become a more prominent part of judicial decision making. The Note concludes in Part V with some recommendations for how courts may go about limiting the use of pre-enforcement review through the use of existing doctrines such as ripeness as well as through interpretation of statutory text.

II. AN OVERVIEW OF THE RIPENESS DOCTRINE

The test for ripeness in the context of agency enforcement actions was established in the 1967 Supreme Court case *Abbott Laboratories v. Gardner*.[12] In that case, the Court reviewed a Food and Drug Administration ("FDA") regulation requiring that pharmaceutical companies include the generic name along with the trade name on a drug label.[13] The drug companies affected by the regulation brought suit, claiming that the Secretary of Health and Human Services had acted outside the authority of the Federal Food, Drug, and Cosmetic Act ("FDCA").[14] The plaintiffs alleged that they suffered harm from the extra cost incurred by the requisite redesigning and remanufacturing of the drug labels. However, since the plaintiffs brought suit after the regulation was promulgated but before it was enforced, the question before the Court was whether the challenge was "ripe" for review, i.e., whether the

[12] 387 U.S. 136, 148–49 (1967).
[13] *Id.* at 137–38.
[14] *Id.* at 139.

Secretary must implement the regulation before the plaintiffs would be able to challenge it.

As described by the Court, the rationale for waiting until a challenge is ripe is "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties."[15] To determine whether a case is ripe for review, a court must evaluate (1) "the fitness of the issues for judicial decision" and (2) "the hardship to the parties of withholding court consideration."[16]

The first factor requires a showing that the issues for review are "purely legal" and that accurate resolution of these issues would not rely on a more concrete factual setting.[17] In *Abbott*, the controversy was confined strictly to an issue of statutory interpretation as to whether the Secretary was authorized to require the drug companies to list the generic name every time the proprietary name was listed on a bottle.[18] Furthermore, the Court determined that the legal issues would not vary sufficiently based on various factual settings.[19]

To satisfy the second factor, the Court required that the rule trigger an "immediate and significant change in the plaintiffs' conduct of their affairs with serious penalties attached to noncompliance."[20] In *Abbott*, the Court found the effects of the regulation on the petitioner to be sufficiently direct and immediate.[21] The Court described the harm to the plaintiffs as a "quandary," where the drug companies would either have to spend a substantial sum of money upfront to comply with the labeling requirements or choose to disobey the regulation and wait to challenge the rule at an enforcement proceeding, where they would risk steep fines and even criminal penalties. In sum, the potential "hardship" following enforcement was both predictable and significant.[22]

Likewise, in a companion case, *Gardner v. Toilet Goods Ass'n, Inc.* ("*Gardner*"),[23] the Court held that the challenge to an agency regulation was sufficiently ripe for pre-enforcement review.[24] The regulation at issue

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15 *Id.* at 148–49.
16 *Id.* at 149.
17 *Id.*
18 *Id.*
19 *Id.*
20 *Id.* at 153.
21 *Id.* at 152.
22 *Id.* at 154.
23 387 U.S. 167 (1967).
24 *Id.* at 170.

in that case broadened the meaning of "color additives," originally defined in the Color Additive Amendments to the FDCA, to include a wider range of ingredients subject to the agency's certification process.[25] Respondents, who manufactured cosmetics, challenged the regulation as outside the scope of the statutory mandate.[26] The Court held the challenge ripe because the contested issue was a straightforward question of statutory interpretation.[27] Therefore, the legal issue would not "necessarily be facilitated if [it] were raised in the context of a specific attempt to enforce the regulations."[28]

As to the second factor, the Court found the regulation to have an "immediate and impactful impact" upon the plaintiffs. As in *Abbott*, the plaintiffs would face an unenviable dilemma: either comply with the regulation upfront and suffer the accompanying financial cost or ignore the regulations and risk losing to the government at an enforcement proceeding, with the serious financial and reputational harms resulting from a finding that the companies were engaged in marketing of "adulterated" products.[29]

Conversely, in *Toilet Goods Ass'n, Inc. v. Gardner* ("*Toilet Goods*"),[30] making up the third of what is known as the "*Abbott Labs* Trilogy,"[31] the Court found a challenge to an FDA regulation unripe.[32] The regulation at issue forced companies to allow FDA officials to randomly inspect factory sites or lose agency certification for their products.[33] Although the plaintiffs alleged that the regulation was outside the scope of the agency's authority under the statute and therefore the challenge was "purely legal," the Court found that the legal issues would be better determined after they were specifically applied in an enforcement proceeding.[34]

The Court distinguished *Toilet Goods* from *Abbott* on the ground that the statutory authority for the regulation in *Toilet Goods* derived from a broad standard permitting promulgation of regulations "for efficient enforcement of the Act."[35] Thus, unlike *Abbott*, here the validity of the

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[25] *Id.* at 171.

[26] *Id.*

[27] *Id.* at 170 ("The issue as framed by the parties is a straightforward legal one: what general classifications of ingredients fall within the coverage of the Color Additive Amendments?").

[28] *Id.* at 171.

[29] *Id.* at 172.

[30] 387 U.S. 158, 161 (1967).

[31] For a detailed account of the history of these three cases, see Ronald M. Levin, *The Story of the* Abbott Labs *Trilogy: The Seeds of the Ripeness Doctrine*, *in* ADMINISTRATIVE LAW STORIES 431, 477 (Peter L. Strauss ed., 2006).

[32] *Toilet Goods*, 87 U.S. at 161.

[33] *Id.*

[34] *Id.* at 163–164.

[35] *Id.* at 163.

regulation turned not only upon textual analysis but also upon "an understanding of what types of enforcement problems are encountered by the FDA, the need for various sorts of supervision in order to effectuate the goals of the Act, and the safeguards devised to protect legitimate trade secrets."[36] The Court concluded that these factors were better considered when the regulation was specifically applied in an enforcement proceeding.[37]

On the issue of hardship to the parties, the Court drew a distinction between *Toilet Goods* and *Gardner* on the basis of the immediacy and certainty of harm resulting to the plaintiffs. In *Gardner*, the regulation required cosmetic companies to certify ingredients in cosmetics that were already being marketed.[38] As such, the regulation was "self-executing," in that unless the plaintiffs took affirmative steps to come into compliance, they would automatically be in violation of the regulation.[39] By contrast, the regulation in *Toilet Goods* was not self-executing, as the plaintiffs would not be in violation of the regulation until the Secretary acted to enforce it against a particular company.[40] The Court was, therefore, satisfied that a plaintiff would not be sufficiently harmed by waiting to challenge the regulations post-enforcement, as enforcement "would at most lead only to a suspension of certification services to the particular party, a determination that can then be promptly challenged through an administrative procedure, which in turn is reviewable by a court."[41]

Courts have continued to apply *Abbott*'s two independent requirements for ripeness.[42] Since then, however, the doctrine has been supplemented and combined with other justiciability doctrines such as

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[36] *Id.* at 163–64.

[37] *Id.* at 164.

[38] *Id.*

[39] *Gardner*, 387 U.S. at 171.

[40] *Toilet Goods*, 387 U.S. at 164 (observing that "[t]he regulation challenged here is not analogous to . . . those other color additive regulations with which we deal in *Gardner v. Toilet Goods Assn.* where the impact of the administrative action could be said to be felt immediately by those subject to it in conducting their day-to-day affairs") (internal citation omitted).

[41] *Id.* at 165.

[42] A. Raymond Randolph, *Administrative Law and the Legacy of Henry J. Friendly*, 74 N.Y.U. L. REV. 1, 11 (1999) ("What is clear is that the ripeness doctrine that Judge Friendly set forth more than thirty years ago has stood the test of time."). *See, e.g.*, Nat'l Ass'n of Homebuilders v. U.S. Army Corps of Eng'rs, 440 F.3d 459 (D.C. Cir. 2006) (applying the *Abbott* two-part test).

standing,[43] final agency action,[44] and exhaustion[45] of administrative remedies.[46] In *Ohio Forestry Ass'n v. Sierra Club*,[47] the court added a third factor to the *Abbott* test, considering (1) whether there would be sufficient hardship to the plaintiff, (2) whether the case would benefit from additional factual development, and (3) whether judicial determination would sufficiently interfere with agency administrative decisions.[48] Although ripeness remains a constraint on a court's ability to conduct pre-enforcement review,[49] *Abbott*'s strong presumption in its favor is now seen as biasing the courts toward such review.[50]

III. THE NORMATIVE UNDERPINNINGS OF RIPENESS

Since the formulation of the ripeness test in *Abbott*, courts have employed it in a variety of cases to advance certain policy objectives, including obtaining accurate judicial decisions, ensuring access to justice, and maintaining a proper balance of power between branches of government. This section will outline each of these three policies in turn, followed by an analysis of whether allowing or dismissing pre-enforcement challenges actually furthers these underlying policies.

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[43] Standing is both a constitutional and statutory requirement. Article III mandates that a "plaintiff must have suffered an 'injury in fact'" that is both "concrete and particularized" and "actual and imminent." Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992). The APA also codifies the requirement for relief on statutory grounds. *See* 5 U.S.C. § 702 (2012). Standing is also a prudential limitation. *See* Bennett v. Spear, 520 U.S. 154 (1997).

[44] The APA codifies the requirement of final agency action, which provides, "[a]gency action made reviewable by statute and final agency action for which there is no adequate remedy in a court are subject to judicial review." 5 U.S.C. § 704 (2012).

[45] "Exhaustion" requires a petitioner to adequately utilize all available administrative remedies before seeking judicial review. *See* MICHAEL E. HERZ, RICHARD MURPHY, & KATHRYN WATTS, A GUIDE TO JUDICIAL AND POLITICAL REVIEW OF FEDERAL AGENCIES § 1.052 (2d ed. 2015).

[46] Gene R. Nichol Jr., *Ripeness and the Constitution*, 54 U. CHI. L. REV. 153, 173 (1987) ("The 'natural' overlap between standing and ripeness analysis occurs in the measurement of the cognizability of contingent or threatened harms."); Erwin Chemerinsky, *A Unified Approach to Justiciability*, 22 CONN. L. REV. 677, 692 (1990) ("The current multiplicity of justiciability doctrines contains multiple overlapping tests that serve little independent purpose."). *See, e.g.*, Clean Air Implementation Project v. EPA, 150 F.3d 1200, 1204 (D.C. Cir. 1998) (the determination of ripeness depends in part on "whether the agency's action is sufficiently final"); Ticor Title Ins. Co. v. FTC, 814 F.2d 731 (D.C. Cir. 1987) (three judges used three different timing doctrines to reach the same outcome). For an explanation of the relationship between "ripeness" and "standing" analyses, see Wilderness Soc'y v. Alcock, 83 F.3d 386, 389–90 (11th Cir. 1996).

[47] 523 U.S. 726, 732 (1998).

[48] *Id.* The Court found that a challenge to the National Forest Service's "National Forest Plan" "was not yet ripe for judicial review." *Id.* at 728.

[49] *See, e.g.*, Atl. States Legal Found., Inc. v. EPA., 325 F.3d 281, 285 (D.C. Cir. 2003).

[50] Randolph, *supra* note 42, at 9 ("There is, I believe, a serious question whether, since 1967, the pendulum has swung too far in favor of permitting [pre-enforcement review].").

A. Obtaining Accurate Decisions

Part A of this section will argue that in the case of highly complex agency rules, allowing pre-enforcement review fails the first policy rationale—obtaining an accurate judicial decision—for two reasons. First, without a concrete factual setting, judges evaluating the legality of a complex regulation are forced to rely solely on the administrative record, which is often insufficient to render accurate decisions because of its length, complexity, and incompleteness. Second, judges are often ill equipped to process the administrative record because of their lack of subject matter expertise in many regulatory areas.

While judges are fully capable of applying legal standards to the facts of particularized disputes, they are much less competent when it comes to interpreting masses of scientific data to determine the legality of an entire rule. To illustrate the impact of courts' scientific deficit on the accuracy of judicial decision making, this Note will examine the EPA's Clean Water Rule, which defines "navigable waters" under the Clean Water Act, and *Rapanos v. United States*,[51] the case that struck down previous EPA regulations on the matter.

1. Obtaining Accurate Decisions as a Normative Underpinning of Ripeness

In the administrative law context, perhaps the most important objective of the ripeness doctrine is to ensure courts intervene only when they have a sufficiently high chance of correctly determining whether a given regulation is unlawful.[52] The Court's opinion in *Toilet Goods* indicates that even when confronted with "purely legal" issues, the Court may benefit from a more defined set of facts in order to come to the correct conclusion.[53] The Court in *Babbitt v. United Farm Workers National Union*[54] noted that because of an insufficient factual record, judicial review was not appropriate at the current time "[e]ven though a

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[51] 547 U.S. 715 (2006).

[52] *See* Nichol, *supra* note 46, at 162 (noting that "[i]n a series of decisions in which the *Abbott Laboratories* formula figures prominently, the Supreme Court has attempted to time the intervention of judicial power so as to ensure more accurate rulings by the courts . . .").

[53] *See* Toilet Goods Ass'n, Inc. v. Gardner, 387 U.S. 158, 166 (1967). *See also* Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871, 873 (1990) ("[A]gency action is not ordinarily considered 'ripe' for judicial review under the APA until the scope of the controversy has been reduced to manageable proportions, and its factual components fleshed out, by concrete action that harms or threatens to harm the complainant."); Ark. Power & Light Co. v. Interstate Commerce Comm'n, 725 F.2d 716, 725 (D.C. Cir. 1984) ("There can be no doubt that review would be most appropriate after the [agency] applies its Policy Statement to concrete fact situations, when the precise operation and impact of its procedures are settled.") (internal quotation marks omitted).

[54] 442 U.S. 289 (1979).

challenged statute is sure to work the injury alleged."[55] Thus, courts implicitly acknowledge that ripeness is a balancing test: even apparent harm to a plaintiff can be overridden by the chance that the court will come to an incorrect decision.[56] As Professor Nichol stated, "[t]he interest protected by the Court is its own. Litigation based upon hypothetical possibility rather than concrete fact is apt to be poor litigation. The demand for specificity, therefore, stems from a judicial desire for better lawmaking."[57]

2. Quality of the Record

One of the ways pre-enforcement review decreases the likelihood a court will reach the correct outcome is the absence of a concrete factual setting. In place of case-specific facts, courts use the administrative record,[58] which is a compilation of agency documentation of its decision-making process, including studies, internal memoranda, and policy debates in formulating the final rule.[59] It also includes outside input from the notice-and-comment period and agency responses to those comments.[60]

Before *Abbott*, formal standards were not in place to govern the accumulation of an agency's administrative record.[61] Since then, Congress has instituted process requirements for agency recordkeeping[62] and courts have employed higher standards of review for evaluating

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[55] *Id.* at 300. *See also* Nat'l Mining Ass'n v. Fowler, 324 F.3d 752, 756 (D.C. Cir. 2003) ("[I]f we have doubts about the fitness of the issue for judicial resolution, then we balance the institutional interests in postponing review against the hardship to the parties that will result from delay.") (internal quotation marks omitted).

[56] Nichol, *supra* note 46, at 177 (citing Andrade v. Lauer, 729 F.2d 1475, 1480 (D.C. Cir. 1984) (noting that ripeness required the court to "balance *its* interest in deciding the issue in a more concrete setting against the hardship to the parties caused by delaying review") (emphasis added)).

[57] *Id.*

[58] Edison Electric Institute v. Occupational Safety & Health Admin., 849 F.2d 611, 617–18 ("Ordinarily, judicial review of informal agency rule-making is confined to the administrative record; neither party is entitled to supplement that record with litigation affidavits or other evidentiary material that was not before the agency.").

[59] JEFFREY S. LUBBERS, A GUIDE TO FEDERAL AGENCY RULEMAKING 212 (3d ed. 1998).

[60] *Id.*

[61] *Id.* at 209.

[62] *See, e.g.*, Regulatory Flexibility Act, 5 U.S.C. § 609(b)(5) (2012) (requiring review panel reports "be made public as part of the rulemaking record"); National Environmental Policy Act, 42 U.S.C. §§ 4332(C) and (E) (2012) (requiring agencies to publish environmental impact statements and a discussion of alternatives); Paperwork Reduction Act, 44 U.S.C. § 3507(a) (2012) (requiring agencies first obtain approval of the Office of Management and Budget before "conduct[ing] or sponsor[ing] the collection of information"); Small Business Regulatory Enforcement Fairness Act, 5 U.S.C. §§ 801–808 (2012) (requiring agencies to submit rules to both houses of Congress before they can be published).

agency decision making.[63] In *United States v. Nova Scotia Food Products Corp.*,[64] for example, the court required agencies to include in the administrative record scientific studies and other data they relied on to formulate their final rules.[65]

Some have argued that the administrative record, with its large scope and detailed policy analysis is sufficient for courts to render accurate decisions on the lawfulness of a rule.[66] But this argument does not take into account the question of whether courts are able to comprehend the data well enough to apply it to the law.[67] It also overlooks the fact that judges tend to be much better at applying vague legal standards, such as "reasonableness" and "arbitrary and capricious," to concrete facts. As Professor O'Grady noted, "[i]ndividualized case facts and context are comfortable ground for judges, while pragmatic decisionmaking based on empirical data and what might be deemed legislative fact-finding is suspect."[68]

Furthermore, the breadth of a rule and sheer volume of information present in an administrative record can increase the scope of the proceeding beyond what is manageable for a court.[69] As one D.C. Circuit judge put it in *Sierra Club v. Costle*, "we reach our decision after interminable record search (and considerable soul searching). We have read the record with as hard a look as mortal judges can probably give its thousands of pages."[70]

In addition to the administrative record being too long, its contents may be incomplete,[71] unhelpful, misleading, or even unreliable, as they are not subject to the evidentiary limitations found in typical enforcement proceedings, including relevancy and hearsay.[72] Moreover, judges in pre-

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[63] *See* Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 415 (1971) (holding "agency action subject to a probing, in-depth review").

[64] 568 F.2d 240 (2d Cir. 1977).

[65] *Id.* at 252. *See also* Home Box Office, Inc. v. FCC, 567 F.2d 9, 54 (D.C. Cir. 1977) (requiring review of "documents, comments, transcripts, and statements in various forms declaring agency expertise or policy—with reference to which some judgment was exercised").

[66] *See* Levin, *supra* note 31, at 476.

[67] *Id. See infra* notes 85-86 and accompanying text.

[68] Catherine Gage O'Grady, *The Role of Speculation in Facial Challenges*, 53 ARIZ. L. REV. 867, 882 (2011).

[69] *See* LUBBERS, *supra* note 59, at 219 ("The burden on judges reviewing rulemaking has increased along with the increase in the volume, importance, and complexity of rulemaking.").

[70] 657 F.2d 298, 410 (1981).

[71] STEPHEN BREYER, MAKING OUR DEMOCRACY WORK 114 (2010) (stating that judges must "deal with a[n] [administrative] record that rarely reflects all that the agency or its staff had to consider").

[72] *See* Natural Resources Defense Council v. SEC, 606 F.2d 1031, 1052 (D.C. Cir. 1979) (characterizing the administrative record as "a sump in which the parties have deposited a sundry mass of materials that have neither passed through the filer of rules of evidence nor undergone the

enforcement review proceedings do not enjoy the benefit of a record that was put together in an adversarial setting, which often helps to narrow the set of issues under consideration and bring out the facts that apply to the relevant law.[73] In fact, some of the administrative record may never be exposed to the adversarial process in a pre-enforcement proceeding. The D.C. Circuit in *Ass'n of Data Processing Service Organizations v. Board of Governors* remarked that the "administrative record might well include crucial material that was neither shown to nor known by the private parties in the proceeding."[74] As the court went on to explain, while "in informal rulemaking, at least the most critical factual material that is used to support the agency's position on review must have been made public in the proceeding and exposed to refutation . . . . That requirement, however, does not extend to all data."[75]

Professor Richard Pierce contends that the adversarial system—such as it is in pre-enforcement proceedings—actually serves to distort the record, as litigants take advantage of the judge's time constraints and technical deficiencies to paint an inaccurate picture of the major issues.[76] Enforcement adjudication would likely avoid this problem because the proceedings would be confined to a smaller portion of the record and litigants would be limited to a discrete set of issues within the scope of the facts.

Certainly, there are advantages to pre-enforcement review versus an enforcement proceeding in which, for example, the threat of large fines[77] or a sympathetic defendant could detract from the court's sound evaluation of the agency's decision-making process. Courts may also benefit from the perspective gained from reviewing all aspects of the rule at one time. An even stronger argument for pre-enforcement review is that by reviewing agency rules for arbitrariness, courts are evaluating the *process* by which an agency came to its determinations. In fact, courts are arguably stronger at judging an agency's methods of arriving at its conclusions, rather than those conclusions themselves.[78] Lastly,

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refining fire of adversarial presentation"). *See also* LUBBERS, *supra* note 59, at 217 ("Even the 'facts' on which the agency relies are accumulated expertise and experience of the agency and others, which are difficult if not impossible to package in the record of the proceeding.").

73 *See Natural Resources Defense Council*, 606 F.2d at 1052.

74 745 F.2d 677, 684 (D.C. Cir. 1984).

75 *Id.*

76 Pierce, *supra* note 10, at 70 (1995).

77 *See* Sackett v. EPA, 566 U.S. 120, 131 (2012) (Alito, J., concurring) (noting that the regulatees faced the threat of $75,000 of fines per day for violations of the Clean Water Act).

78 BREYER, *supra* note 71, at 116–17.

procedural claims are almost always ripe and should be reviewed before a rule goes into effect.[79]

But practical realities undermine these arguments. There is simply not enough time to adequately review an agency record that often ranges from 10,000 to 250,000 pages when judges spend on average less than one day per case.[80] Although delaying judicial review until enforcement would mean having to wait longer to know the validity of a rule, it would allow courts to adjudicate the rule in more manageable pieces, greatly increasing the quality of judicial decision making.[81]

Finally, another plausible argument exists for pre-enforcement review as it relates to the administrative record: that the record will have become stale if judicial review is done later on at enforcement proceedings.[82] This concern is especially salient in regulatory areas where technology and scientific knowledge are constantly changing. However, pre-enforcement review does not foreclose as-applied challenges to the rule in enforcement proceedings.[83] Thus, regulatees will be able to challenge the scientific data justifying the rule throughout the life of the rule, which gives the agency an incentive to continually assess the relevancy of their regulations from a scientific perspective.[84]

3. The Courts' Scientific Deficit

The accuracy of a decision is further compromised when the validity of the regulation depends on the evaluation of highly complex scientific data.[85] The courts are at a severe comparative disadvantage to agencies in

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[79] Ronald M. Levin, *Statutory Time Limits on Judicial Review of Rules: Verkuil Revisited*, 32 CARDOZO L. REV. 2203, 2211 (2011).

[80] Pierce, *supra* note 10, at 70. The Clean Water Rule received over one million comments, all of which must be incorporated into the administrative record. Clean Water Rule, 80 Fed. Reg. 37,054, 37,057 (Jun. 29, 2015).

[81] *But cf.* Pierce, *supra* note 10, at 90 (stating that review of rules in enforcement proceedings with an evidentiary record rather than an agency rulemaking record would not likely deossify the rulemaking process).

[82] Administrative Conference of the United States ("ACUS") Recommendation 82-7, Judicial Review of Rules in Enforcement Proceedings, 47 Fed. Reg. 58,208 (Dec. 17, 1982).

[83] *See* Adamo Wrecking Co. v. United States, 434 U.S. 275 (1978) (construing a statutory judicial review provision quite narrowly so as to allow as-applied challenges in enforcement proceedings).

[84] *See* Richard L. Pierce, *Reconciling Chevron and Stare Decisis*, 85 GEO. L.J. 2225, 2240 (1997) ("The policymaking process should be dynamic. It should produce relatively frequent changes in decisional rules attributable both to changes in our understanding of fields such as economics, engineering, toxicology and medicine . . . .").

[85] *See* Thomas O. McGarity, *On the Prospect of "Daubertizing" Judicial Review of Risk Assessment*, 66 L. & CONTEMP. PROBS. 155, 156 (Autumn 2003) ("Judges' limited competence in areas involving scientific data and analysis, complex modeling exercises, and large uncertainties is well recognized in administrative law and has been effectively demonstrated by the courts themselves in post-*Daubert* toxic tort opinions."). *See also* Wendy E. Wagner, *The "Bad Science"*

expertise and experience in particular regulatory areas.[86] The Court in *Gardner v. Toilet Goods* made special note of the need for concrete facts when dealing with a highly technical issue.[87] That need was also illustrated by *Rapanos*, the Supreme Court case which established the legal test for determining the validity of the Clean Water Rule.

a. Rapanos v. United States*: The Precursor to the Clean Water Rule*

Rapanos v. United States[88] was the third in a set of Supreme Court rulings on the meaning of "navigable water"—defined in the Clean Water Act[89] as "waters of the United States" ("WOTUS")[90]—specifically as they relate to the regulation of wetlands under § 404 of the Act.[91] In the first case, *United States v. Riverside Bayview Homes, Inc.*,[92] the Court took a broad view of the term "navigable waters," making it clear that it extended to waters "not . . . deemed navigable under the classical understanding of that term."[93] The Court held that wetlands abutting traditionally navigable waters were included in the CWA's jurisdictional reach, as they were presumed to have a hydrological connection to those waters.[94] But the court declined to elaborate on whether WOTUS would extend to wetlands with a more attenuated connection to traditionally navigable waters, including wetlands with no hydrological connection.[95]

The Court considered the issue again sixteen years later in *Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers* ("*SWANCC*"),[96] which addressed whether an isolated, intrastate wetland, lacking a hydrological connection to traditionally navigable waters,

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Fiction: Reclaiming the Debate over the Role of Science in Public Health and Environmental Regulations, 66 L. & CONTEMP. PROBS. 63, 97 ("[I]f the courts' scientific competency is less than that of the party they are reviewing, it is unclear what the courts are contributing to the exercise.").

86 Courts' comparative disadvantage to agencies in technical expertise is well documented. *See, e.g.*, Pierce, *supra* note 84, at 2239 ("Judges typically have little knowledge of the complicated regulatory benefit programs that agencies administer.").

87 In a footnote, the Court stated, "[i]f in the course of further proceedings the District Court is persuaded that technical questions are raised that require a more concrete setting for proper adjudication, a different issue will be presented." Gardner v. Toilet Goods Ass'n, Inc., 387 U.S. 158, 161 n.1 (1967).

88 547 U.S. 715 (2006).

89 33 U.S.C. §§ 1251–1387 (2012).

90 33 U.S.C. § 1362(7) (2012) ("The term 'navigable waters' means the waters of the United States, including the territorial seas."); 33 C.F.R. § 328.3(a) (2015).

91 Section 404 of the Clean Water Act forbids discharge into navigable waters of dredge or fill material. The Army Corps of Engineers and EPA jointly administer this section of the Act. 33 U.S.C. § 1344 (2012).

92 474 U.S. 121 (1985).

93 *Id.* at 133 (internal quotation marks omitted).

94 *Id.* at 135.

95 *Id*.

96 531 U.S. 159 (2001).

constituted WOTUS.[97] The Court held that it did not.[98] In doing so, the Court asserted that what had informed its decision in *Riverside Bayview* was the "significant nexus" in the form of the hydrological connection between the wetland and the adjacent navigable water.[99] The Court remarked that to extend Army Corps jurisdiction to isolated intrastate wetlands without a significant nexus to traditionally navigable waters would be to give the word "navigable" "no effect whatsoever."[100]

Finally, in *Rapanos*, the Court took on the issue of whether the Army Corps' jurisdiction extended to wetlands adjacent to non-navigable tributaries, which then flow into navigable waterways.[101] *Rapanos* consisted of two consolidated cases. The first involved a developer, John Rapanos, who filled wetlands without a permit in order to build a shopping center. The wetlands connected to a manmade drain or ditch, which in turn drained into a creek, which drained into a navigable river.[102] The Army Corps brought criminal and civil enforcement orders against Rapanos, arguing that the wetlands were within its jurisdiction because the hydrological connection to the manmade drain constituted a "tributary" to a "navigable water." The second case involved two residential developers, Keith and June Carabell, who were appealing the Army Corps' decision to deny them a permit to fill in wetlands. These wetlands were adjacent to, but hydrologically separate from, a ditch, which connected to a drain, which emptied into a creek, which emptied into Lake St. Clair, a "navigable water."[103] The government argued that the wetlands' close proximity to the drain was sufficient under *Riverside Bayview* to constitute WOTUS.

The Justices split 4-1-4, with Justice Scalia authoring a plurality opinion and Justice Kennedy joining the judgment under different reasoning. The plurality's test for the statute's regulatory jurisdiction was narrow and required first that the body of water adjacent to the wetland be a "water of the United States" "in its own right," which in the plurality's view must be "relatively permanent," having permanent standing water or continuous flow for a period of "some months" out of the year.[104] Second, the plurality required a continuous surface connection

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97 *Id.* at 166 (describing the Migratory Bird Rule, which extended Army Corps jurisdiction to activity on waters that, in the aggregate, would harm habitat for migratory birds); 51 Fed. Reg. 41,250 (1986).

98 *SWANCC*, 531 U.S. at 174 (2001).

99 *Id.* at 167.

100 *Id.* at 172.

101 Rapanos v. United States, 547 U.S. 715, 729 (2006).

102 *Id.*

103 *Id.* at 730.

104 *Id.* at 731–33.

from the wetland to a "relatively permanent" body of water such that "it [is] difficult to determine where the 'water' ends and the 'wetland' begins."[105]

The concurrence rejected the plurality's test and chose instead to use the "significant nexus" test from *SWANCC*. According to Justice Kennedy, "the Corps' jurisdiction over wetlands depends upon the existence of a significant nexus between the wetlands in question and navigable waters in the traditional sense."[106] Justice Kennedy defined "navigable waters" as "waters that are or were navigable in fact, or that could reasonably be so made."[107] Thus, Justice Kennedy made clear that this definition of "navigable waters" was broader than that of the plurality's, and included additional waterways such as "impermanent streams."[108] Justice Kennedy's concurrence also departed from the plurality in two other ways. First, in Kennedy's view, a wetland that abutted traditionally navigable water did not require a continuous surface connection to that "navigable water." Rather, it was reasonable for the Corps to assume that a wetland's adjacency to a navigable water would constitute a "significant nexus."[109] Second, a "significant nexus" could be established in ways other than physical hydrological connection. To this point, Justice Kennedy stated: "[W]etlands possess the requisite nexus, and thus come within the statutory phrase 'navigable waters,' if the wetlands, either alone or in combination with similarly situated lands in the region, significantly affect the chemical, physical, and biological integrity of other covered waters more readily understood as 'navigable.'"[110] In sum, under Justice Kennedy's test, wetlands adjacent to "waters that are or were navigable in fact, or could reasonably be made so" are presumed jurisdictional;[111] however, wetlands adjacent to or connected to a non-navigable tributary would not be jurisdictional barring a showing of either substantial hydrological *or* ecological connection to a traditionally navigable water.

Rapanos is revealing because it demonstrates how a concrete set of facts informed the decision in the case. Although the plurality and the concurrence used different tests, the concurrence and the dissent are largely in agreement as to the legal standard to use in determining the

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105 *Id.* at 742.
106 *Id.* at 779 (Kennedy, J., concurring).
107 *Id.* at 759.
108 *Id.* at 769–70.
109 *Id.* at 772–74.
110 *Id.* at 780.
111 *Id.* at 759.

Corps' jurisdiction.[112] Where they differed was in their evaluation of the facts—specifically, whether the wetlands at issue constituted a "significant nexus." As Justice Kennedy noted, "when . . . wetlands' effects on water quality are speculative or insubstantial, they fall outside the zone fairly encompassed by the statutory term 'navigable waters.'"[113] For Justice Kennedy, the record, as it was presented before the court, did not contain evidence demonstrating a significant enough "hydrologic linkage to establish the required nexus with navigable waters as traditionally understood."[114] Conversely, the dissent found the facts on the record to be sufficient to constitute a significant nexus.[115] Specifically, the dissent deferred to the Corps' determination that the wetlands in this case had the ecological effects necessary to satisfy Justice Kennedy's "significant nexus test."[116]

The need for a concrete set of facts is also apparent when *Rapanos* is viewed from a *Chevron* perspective. *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*[117] was a landmark decision in administrative law establishing the concept of deference to administrative agencies in areas of policy development and regulatory expertise. The opinion sets out a two-step analysis for courts when reviewing agency interpretations of statutes. First, if the statutory provision is clear and not subject to multiple interpretations, "that is the end of the matter; for the court, as well as the agency must give effect to the unambiguously expressed intent of Congress."[118] *Chevron* step one is a purely legal determination, where courts use descriptive methods of statutory

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[112] *Id.* at 807 (Stevens, J., dissenting) ("I generally agree with parts I and II-A of JUSTICE KENNEDY's opinion . . . ."). *See* Stephen M. Johnson, *The Rulemaking Response to* Rapanos*: the Government's Best Hope for Retaining Broad Clean Water Act Jurisdiction*, *in* THE SUPREME COURT AND THE CLEAN WATER ACT: FIVE ESSAYS 22, 27 (L. Kinvin Wroth ed., 2007) ("While the [*Rapanos*] dissenters did not agree that jurisdiction over waters of the United States should be limited to waters and wetlands with a significant nexus to traditional navigable waters, they did not think that the nexus test would significantly diminish the scope of wetlands covered under the Act.").

[113] *Id.* at 780 (Kennedy, J., concurring).

[114] *Id.* at 784.

[115] *Id.* at 807 (Stevens, J., dissenting) ("To the extent that our passing use of this term [significant nexus] has become a statutory requirement, it is categorically satisfied as to wetlands adjacent to navigable waters or their tributaries.").

[116] *Id.* at 788 ("The Army Corps has determined that wetlands adjacent to tributaries of traditionally navigable waters preserve the quality of our Nation's waters by, among other things, providing habitat for aquatic animals, keeping excessive sediment and toxic pollutants out of adjacent waters, and reducing downstream flooding by absorbing water at times of high flow.").

[117] 467 U.S. 837, 843 (1984) ("[I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.").

[118] *Id.* at 842–43.

interpretation to establish whether Congress has spoken to the issue at hand.[119]

Chevron step two on the other hand, represents the resolution of a policy dispute left to the agency to resolve.[120] Professor Levin has gone as far as to say that the D.C. Circuit's interpretation of a regulation under "step two" analysis is tantamount to arbitrary and capricious review,[121] where the agency's "interpretation depended in part on the quality of the agency's reasoning and the strength of the evidence in the record."[122] He went on to say, "the court apparently assumed that an agency is 'interpreting' not only when it decides in the abstract what the statute means, but also when *it applies that interpretation to a particular set of facts,* or when it exercises its discretion within the boundaries allowed by the statute."[123]

There is considerable evidence that all nine justices decided *Rapanos* based on a "step two" analysis.[124] Under this analysis, the justices all agreed on the threshold legal issue that the statute's term "navigable waters" was ambiguous and that Congress had not spoken to the precise issue at hand—namely whether wetlands adjacent to non-navigable tributaries of navigable waters are WOTUS. Where the Court split was on the application of whether or not the agency's interpretation was reasonable under *Chevron* step two *in light of certain facts*. The dissent found the agency's interpretation reasonable, while the concurrence and plurality found the agency's interpretation unreasonable for different reasons. Under Levin's conception of the reasonableness inquiry, the presence of concrete facts in *Rapanos* was crucial to the determination of

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119 *See* Pierce, *supra* note 84, at 2229 ("[T]he process of determining whether a statute is sufficiently ambiguous to support an agency's construction of the statute raises an issue of law that is suitable for judicial resolution.").

120 *Id.* at 2228–29.

121 Ronald M. Levin, *The Anatomy of* Chevron*, Step Two Reconsidered*, 72 CHI.-KENT L. REV. 1253, 1264 (1997). The "arbitrary and capricious test" is the standard courts use to determine whether informal agency rules are lawful under the APA. It requires agencies to sufficiently support their factual findings during the rulemaking process and to demonstrate reasoned decision making. *See generally* LUBBERS, *supra* note 59, at 320–25.

122 *See* Levin, *supra* note 79, at 1268–69 (internal quotation marks omitted). *See also* David Zaring, *Reasonable Agencies*, 96 VA. L. REV. 2317, 2337 (2010) (arguing that the multiple standards of review in administrative law have been blended together to essentially form one "reasonableness" test).

123 Levin, *supra* note 79, at 1269 (emphasis added).

124 *See* Jonathan H. Adler, *Reckoning with* Rapanos*: Revisiting "Waters of the United States" and the Limits of Federal Wetland Regulation*, 14 MO. ENVTL. L. & POL'Y REV. 1, 21 (2006) ("In administrative law terms, Scalia's opinion rejects the Corps of Engineers' interpretation at step two rather than step one of the familiar *Chevron* analysis."). *But see* Johnson, *supra* note 112, at 23 (stating "there was no consensus on the *Rapanos* Court that the agencies' regulations were entitled to *Chevron* deference").

whether the agency made a reasonable policy choice, as it allowed the Court to examine the real life consequences of the agency's scientific determinations.[125] This is especially so given the presence of equally compelling but contradictory scientific data that often appears in the administrative record.[126]

b. The Clean Water Rule

Nine years after the Court's decision in *Rapanos*, the Army Corps and EPA issued the Clean Water Rule,[127] a joint regulation aimed specifically at satisfying Justice Kennedy's "significant nexus" test.[128] The Clean Water Rule separates regulatory jurisdiction into two groups: the first being a series of six categories of waters that are *per se* jurisdictional;[129] the second group includes two categories of waters for which the Corps can make jurisdictional determinations on a case by case basis depending on whether a "significant nexus" exists.[130]

Four out of the six categories of *per se* jurisdictional waters—traditional navigable waters, interstate waters, the territorial seas, and impoundments—are unchanged from previous Army Corps' regulations defining WOTUS.[131] The last two categories—"tributaries" and "adjacent waters"—are newly included as *per se* jurisdictional based on the Corps' presumption that they share a "significant nexus" to "waters of the United States."[132]

The first of the two categories of waters left to a case-by-case "significant nexus" determination is called "similarly situated" waters, which presumptively includes prairie potholes, Carolina and Delmarva bays, pocosins, western vernal pools, and Texas coastal prairie wetlands.[133] The second category includes waters (a) within the 100-year floodplain of a traditional navigable water, interstate water, or territorial sea, or (b) within 4000 feet of the high-tide line or ordinary high

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125 *See* Richard J. Pierce, Jr., *What Do the Studies of Judicial Review of Agency Actions Mean?*, 63 ADMIN. L. REV. 77, 93-94 (2011) (citing empirical data to posit that consequentialist arguments are far more persuasive to reviewing courts than are doctrinal ones).

126 *See id.* at 92 (observing that the administrative record "often includes multiple scientific studies with conflicting conclusions with respect to issues that are unfamiliar to the judges").

127 Clean Water Rule, 80 Fed. Reg. 37,054 (Jun. 29, 2015).

128 *See* Christopher D. Thomas, *Defining Waters of the United States: A Mean Spirited Guide*, 30 NAT. RESOURCES & ENV'T 1, 2 (Summer 2015) (finding the Clean Water Rule uses the phrase "significant nexus" 438 times. Justice Kennedy is mentioned twenty-seven times in the rule; Justice Scalia is mentioned just once.).

129 *See* Clean Water Rule, 80 Fed. Reg. at 37,057–37,058.

130 *Id.* at 37,059.

131 *Id.* at 37,058.

132 *Id.*

133 *Id.* at 37,059.

watermark of a traditional navigable water, interstate water, territorial sea, impoundment or tributary.[134]

The Corps definition of "significant nexus" mirrors the one in Justice Kennedy's concurrence in *Rapanos* and relies on the Corp's scientific determinations.[135] This portion of the regulation seems to be responding to the advice from Justice Kennedy in his concurrence in *Rapanos*, which stated:

> Through regulations or adjudication, the Corps may choose to identify categories of tributaries that, due to their volume of flow (either annually or on average), their proximity to navigable waters, or other relevant considerations, are significant enough that wetlands adjacent to them are likely, in majority of cases, to perform important functions for an aquatic system incorporating navigable waters.[136]

c. The Clean Water Rule in the Context of Pre-enforcement Review

The Clean Water Rule illustrates the basic assertion stated earlier that courts are at a disadvantage to agencies when confronted with a highly complex regulation. Specifically, their ability to determine whether the Clean Water Rule conforms to the text of the Clean Water Act, as well as binding Supreme Court precedent, is made nearly impossible in the context of pre-enforcement review. Unlike in cases that are ripe, where the "meaning, effect, and impact of the accused rule or decision . . . are clear, simple, and obvious,"[137] there is no indication that analysis of the administrative record would encompass the variety of individual applications of the Clean Water Rule that might appear in the enforcement context.[138] As detailed as the rule is, it cannot span the gamut of ecological variations on private property everywhere in the United States.[139]

In any given proceeding concerning the Clean Water Rule, the court must evaluate a body of water under the "significant nexus" test by determining whether the ecological effects of a wetland on a

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134 *Id.*

135 *See id.* at 37,085–37,097.

136 *Rapanos*, 547 U.S. at 780-81 (Kennedy, J., concurring).

137 Gardner v. Toilet Goods Ass'n, Inc., 387 U.S. 167, 193 (Fortas, J., dissenting).

138 *See* Randolph, *supra* note 42, at 9–10 ("Increasingly, our court is confronted with regulations of the most abstract nature, often dealing with complex technological subjects. The challenges present us with the duty of deciding although we have only the vaguest notion of the settings in which the rule will apply or of their practical consequences.").

139 *See* Pierce, *supra* note 84, at 2238–39 ("[I]t is extraordinarily difficult for a decisionmaker to anticipate all of the future situations to which a rule will apply and to predict with tolerable accuracy the consequences of each of these potential future applications of a decisional rule.").

"traditionally navigable water" are "speculative or insubstantial." As Justice Kennedy's quote above indicates, courts in a pre-enforcement proceeding will have to ascertain whether a regulatory category such as "tributary" has an ecological connection to a "traditionally navigable water" not just in one case, but in a majority of cases. Without a concrete set of facts, the court making this determination will have to rely on the administrative record, which contains conflicting claims as to the scientific merit of the Corps' ecological assumptions. This involves a complex scientific analysis—a task best left to agencies, not courts.[140] Moreover, this scientific determination must span at least four categories and seven subcategories of waters that the Corps asserts are jurisdictional, making the breadth of review enormous. In short, in the context of the Clean Water Rule, pre-enforcement review would require courts to apply an abstract and expansive set of scientific data to a legal test that is itself abstract and loosely defined.[141]

B. Access to Justice

So far, we have examined how allowing pre-enforcement review fails to fulfill the first policy goal of the ripeness doctrine—accuracy of judicial decision making—when it involves complex scientific regulations such as the Clean Water Rule. This next section will address how pre-enforcement review of agency rules also hampers the second policy rationale of the ripeness doctrine: access to justice for parties affected by government regulation. When compared to review of rules at the enforcement stage, pre-enforcement review lessens access to justice for private parties in two principal ways.

First, several factors unrelated to the merits of the case coalesce to make pre-enforcement challenges to agency rules less likely to succeed than at the enforcement stage. Therefore, pre-enforcement review decreases a regulatee's likelihood of attaining a just outcome when challenging a rule. Thus far, the literature on judicial review of agency rules has paid scant attention to the advantages agencies have in challenges to rules at the pre-enforcement stage.[142]

The consequences of agency advantage are also important when considering the second—and less obvious—way that pre-enforcement review hampers access to justice: by prejudicing future courts at enforcement proceedings in favor of the government. This prejudicial

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[140] *See supra* notes 85–87.

[141] *See* Johnson, *supra* note 112, at 29 (criticizing the confusing nature of the "significant nexus" test and how it has led to splintered opinions in the circuit courts).

[142] *See, e.g.*, Randolph, *supra* note 42, at 10 ("The abstract nature of judicial review [in pre-enforcement settings] heightens the chances of having the rules sustained . . . .").

effect can occur for a variety of reasons, including both the precedential value of pre-enforcement decisions and the effect of the judicial imprimatur that attaches to a pre-enforcement ruling. Consequently, pre-enforcement review decreases the likelihood of success for those challenging rules at the pre-enforcement *and* enforcement stages. Although there is literature discussing statutory bars to challenging a regulation in enforcement proceedings, there are no articles critiquing pre-enforcement review based on the prejudicial effects on enforcement proceedings.[143]

1. Access to Justice as a Normative Underpinning of Ripeness

The second underlying rationale behind the ripeness doctrine is preventing injustice to innocent parties. This is clearly displayed in the second step of the two-part test in *Abbott*, which requires "direct and immediate" hardship to the challenging party.[144] As Professor Nichol points out, however, the "direct and immediate" hardship requirement of the *Abbott* test is easily subsumed by the concept of standing, which requires a minimum level of *current* harm to satisfy the "case and controversy" requirement in Article III.[145] So, the ripeness requirement may incorporate additional prudential considerations beyond what is constitutionally required.[146] The doctrine, therefore, allows courts to also take into consideration the current effects of *future* harms to plaintiffs as a result of government action.[147] For example, the Court in *Abbott* took

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143 *See* Levin, *supra* note 79. There have been several empirical studies on trends in judicial review of agency regulations. However, they have tracked (among other things) the amount of deference to agencies based on the type and subject-matter of agency rules, but based on the timing of challenges. *See, e.g.*, William Eskridge & Lauren Baer, *The Continuum of Deference: Supreme Court Treatment of Agency Statutory Interpretations from* Chevron *to* Hamdan, 96 GEO. L.J. 1083 (2008).

144 *See* Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871, 891 (1990) (requiring the presence of a "substantive rule which as a practical matter requires the [appellants] to adjust [their] conduct immediately" in order to satisfy the Article III standing requirement); Los Angeles v. Lyons, 461 U.S. 95, 101–102 (1983); Babbitt v. United Farm Workers Nat'l Union, 442 U.S. 289, 298 (1979). *See also* Dames and Moore v. Regan, 453 U.S. 654, 690 (1981) (Stevens, J., concurring) (stating injury was too remote).

145 U.S. CONST. art. III § 2. *See* Clapper v. Amnesty Int'l USA, 568 U.S. 398, 401 (2013) (holding that "respondent's theory of *future* injury is too speculative to satisfy the well-established requirement that threatened injury must be 'certainly impending'") (emphasis in original). For a criticism of the Court's "constitutionalization" of ripeness as limiting the doctrine's flexibility, see Nichol, *supra* note 46, at 173.

146 *See* Nichol, *supra* note 46, at 175. One of these additional prudential considerations is whether the court would benefit from concrete facts in an enforcement proceeding to avoid conjecture or speculation as to the legal issues.

147 *See* Harris v. FAA, 353 F.3d 1006, 1012 (D.C. Cir. 2004) (noting that "the focus of the second prong of the ripeness inquiry . . . is not whether [the parties] have suffered any direct

into account in its ripeness determination the financial and reputational harm a private litigant might face in later enforcement proceedings.[148]

Since courts have construed the ripeness doctrine to take into account the current harm from costs of compliance with a regulation,[149] future harm to private parties in later enforcement actions, and potential harm to nonlitigants (such as the court as an institution),[150] it follows that a normative goal of ripeness would be to guarantee a certain level of access to justice for future regulated parties who may be harmed by agency rules but who—for any number of reasons—do not challenge a rule at the pre-enforcement stage.

Accordingly, this Note postulates that pre-enforcement review may actually harm a private party's chances at defending itself down the road. This is because pre-enforcement review by its nature delivers distinct advantages to the government, which in turn serves to prejudice future private parties in enforcement proceedings because of precedential effects of unfavorable rulings.

2. Agency Advantage in Pre-enforcement Review

According to one empirical study, courts uphold seventy-three percent of *all* notice-and-comment rulemaking.[151] Without knowing for sure, there are many reasons to theorize that agency "success rate" in litigation at the pre-enforcement stage is even higher. First, empirical data suggest that courts defer to agencies in inverse proportion to the court's technical knowledge and grasp of the facts.[152] Therefore, since enforcement challenges are generally narrower than pre-enforcement challenges, contain a concrete set of facts, and present the possibility that a party will suffer significant regulatory penalties, judges may be willing to apply an extra level of scrutiny to an enforcement proceeding as compared to a pre-enforcement case. As Judge Randolph noted, "the abstract nature of judicial review [in pre-enforcement settings] heightens the chances of

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hardship, but rather whether *postponing* judicial review would impose an undue burden on [private litigants] . . .") (internal quotation marks omitted).

148 Abbott Labs v. Gardner, 387 U.S. 136, 152-53 (1967).

149 *See Harris*, 353 F.3d at 1012.

150 *See* AT&T Corp. v. FCC, 349 F.3d 692, 699–700 (D.C. Cir. 2003) (considering as part of the *Abbott* ripeness analysis "whether *the court* or the agency would benefit from postponing review until the policy in question has sufficiently 'crystalized' by taking on a more definite form") (emphasis added).

151 Eskridge & Baer, *supra* note 143, at 1147.

152 *Id.* at 1144–47 (finding the Supreme Court to affirm agency decisions seventy-seven percent of the time in the area of business regulation while affirming only sixty-two percent of decisions involving criminal or labor law).

having the rules sustained . . . ."[153] Thus, regulations such as the Clean Water Rule are likely to get more deference at the pre-enforcement stage than they would during enforcement proceedings and more deference than a comparable regulation in a subject area more familiar to courts such as criminal justice.[154]

Second, challenges to rules at the pre-enforcement stage are usually facial challenges,[155] which are generally more difficult to win than as-applied challenges.[156] In *Reno v. Flores*, the Supreme Court set out a stringent test for both constitutional and statutory facial challenges to regulations, requiring that in order to prevail, "respondents must establish that no set of circumstances exists under which the regulation would be valid."[157]

Some scholars have downplayed the effect of the "no set of circumstances test" in *Reno* as it applies to administrative law because it creates a more lenient standard for judicial review of regulations than does the *Chevron* test.[158] Stuart Buck and Mark Isserles have devised a

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153 Randolph, *supra* note 42, at 10.

154 *See* Eskridge & Baer, *supra* note 143, at 1144.

155 Amfac Resorts, L.L.C. v. U.S. Dept. of Interior, 282 F.3d 818, 827 (D.C. Cir. 2002) ("Lacking a rulemaking record containing evidence relating to the rule's application to a particular entity, petitioners ordinarily mount only facial attacks, often on the ground that the agency's product conflicts with the statute."). *See also* Maya Manian, *Rights, Remedies and Facial Challenges*, 36 HASTINGS CONST. L.Q. 611, 612 (2009) ("[A]ll pre-enforcement challenges are in some sense 'facial' challenges since the statute has never been applied and, given the lack of facts regarding enforcement, the statute is measured solely on its face, i.e., by its text alone."). In general, a facial challenge is one in which a private litigant challenges a statute or regulation in all of its applications, not just to the facts of his or her case; conversely, in an as-applied challenge, the private litigant claims only that the statute or regulation is invalid as to the that litigant's particular factual situation. For an overview of the distinction between facial and as-applied challenges, see O'Grady, *supra* note 68, at 871–73.

156 *See* United States v. Salerno, 481 U.S. 739, 745 (1987) ("A facial challenge to a legislative act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid."). *But see* Richard H. Fallon, Jr., *Fact and Fiction About Facial Challenges*, 99 CALIF. L. REV. 915, 941 (2011) (finding empirical evidence indicating that facial challenges prevail in the Supreme Court forty-four percent of the time, while as-applied challenges succeed only thirty-eight percent of the time).

157 Reno v. Flores, 507 U.S. 292, 301 (1993) (internal quotation marks omitted); Hecht v. Ludwig, 82 F.3d 1085, 1101 (D.C. Cir. 1996) (citing the "no set of circumstances" test in constitutional challenges). *But see* INS. v. National Center for Immigrants' Rights, 502 U.S. 183, 188 (1991) (stating that a regulation may be valid on its face even when some of its applications are *ultra vires*); National Mining Ass'n v. Army Corps of Eng'rs 145 F.3d 1399, 1407 (D.C. Cir. 1998) (declining to adopt the *Reno* "no set of circumstances" test in a comparable case). Justice Stevens has been critical of the "no set of circumstances test" as being too stringent and recognizes in its place a "all or most cases" standard. *See* City of Chicago v. Morales, 527 U.S. 41, 55 n.22 (1999) (plurality opinion by Stevens, J.).

158 *See, e.g.*, Stuart Buck, Salerno vs. Chevron*: What to Do About Statutory Challenges*, 55 ADMIN. L. REV. 427, 438 (2003) ("*Salerno*, at least on its face, is a much more demanding test for a plaintiff to have to meet in order to get an administrative interpretation declared unlawful.").

reformulated application of the "no set of circumstances" test to comport with *Chevron*. They assert that when courts analyze a facial challenge under *Reno*, they are not searching for any hypothetically valid application which would uphold the regulation. Instead, courts analyze the regulation under *Chevron* step one to determine if it clearly or "facially" violates the terms of the statute.[159] If it does, then it is facially invalid. If it does not and passes to step two, then it follows that the regulation has at least some valid application.

While it is clear that Isserles' and Buck's reformulated "no set of circumstances" test makes facial challenges to regulations easier in theory, it is not clear that it actually reduces *Reno*'s scope in practice. There is considerable evidence that courts do not employ the "merged *Reno*-*Chevron*" logic in many cases and in fact view facial challenges as significantly more difficult to win than as-applied challenges.[160]

Even if the "no set of circumstances" test is not in fact as stringent as it sounds, it does not address other underlying prudential concerns regarding facial challenges that may motivate judges to reject them. As Professor O'Grady puts it, "[t]he primary justification for the ['no set of circumstances'] standard seems to rest with the requested remedy. It is sensible, one might argue, to impose *Salerno's* weighty burdens on the statute's challengers simply because the remedy they seek—total invalidation of the statute—is extreme."[161] Proponents of the "no set of circumstances test" on the Court would seem to support O'Grady's assessment. Justice Scalia used the extreme effect of striking down an entire statute to justify the high burden imposed on litigants who bring facial challenges.[162] Recently the Supreme Court has been especially hostile to facial challenges in constitutional law, citing the severe effects of invalidating a statute in a facial challenge.[163] Although the effect of invalidating a statute is not the same as invalidating a regulation in terms of constitutional balance of powers implications, it is easy to imagine

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159 *Id.* at 469–70.

160 *Amfac Resorts*, 282 F.3d at 827 ("Either formulation—the no-set-of-circumstances test adopted from *Salerno* in *Reno v. Flores*, or the less strict *NCIR* standard—may pose potential problems for judicial review of agency regulations."). Other examples exist of courts requiring private parties making facial challenges to prove that literally all applications of a statute or regulation are invalid. *See, e.g.*, Chem. Waste Mgmt., Inc. v. EPA, 56 F.3d 1434, 1437 (D.C. Cir. 1995) (rejecting a facial challenge to an agency rule because of the existence of a "hypothetical scenario" involving a valid application).

161 O'Grady, *supra* note 68, at 874.

162 City of Chicago v. Morales, 527 U.S. 41, 77–78 (1999) (Scalia, J., dissenting).

163 Manian, *supra* note 155, at 611. *See, e.g.*, Wash. State Grange v. Wash. State Republican Party, 552 U.S. 442, 450 (2008) ("Facial challenges are disfavored . . . ."); Crawford v. Marion County Election Board, 553 U.S. 181, 201–03 (2008) (upholding a state statute because evidence in the record did not meet the high standard imposed on litigants making facial challenges).

judges having similar prudential concerns when confronted with a facial challenge to an entire regulation, especially one which took multiple years to develop and which drew considerable public attention.

Finally, with regard to facial challenges, the Court has also expressed concern over avoiding conjecture in judicial decision making,[164] an issue that also underlies justiciability doctrines such as ripeness.[165] To this point, Professor O'Grady has detected a trend in the Court's decisions on facial challenges, in which "pure" facial challenges—those occurring before a statute is enforced—are more likely to fail when a determination as to the statute's constitutionality relies too heavily on speculation.[166] In dissent, Justice Scalia identified the issues of timing and actionability to justify the rejection of a facial challenge in *City of Chicago v. Morales*:

> It seems to me fundamentally incompatible with this system for the Court not to be content to find that a statute is unconstitutional as applied to the person before it, but to go further and pronounce that the statute is unconstitutional in *all* applications. Its reasoning may well suggest as much, but to pronounce a *holding* on that point seems to me no more than an advisory opinion—which a federal court should never issue at all.[167]

The Court's negative stance toward facial challenges suggests that pre-enforcement facial challenges to agency regulations will have limited success. Furthermore, the Court's reliance on justiciability doctrines to reject facial challenges seems equally likely to apply to pre-enforcement facial challenges to regulations, many of which have the same nonjusticiable characteristics as failed facial challenges.

3. Harmful Effects of Pre-enforcement Review on Future Private Litigants

One obvious consequence of substantial agency advantage at the pre-enforcement stage is that private parties will lose cases more often than

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164 David L. Franklin, *Facial Challenges, Legislative Purpose, and the Commerce Clause*, 92 IOWA L. REV. 41, 55–56 (2006) ("The Court has explained that the act of striking down a statute on its face stands in tension with several traditional components of the federal judicial role, including a preference for resolving concrete disputes rather than abstract or speculative questions.").

165 O'Grady, *supra* note 68, at 876–77.

166 *Id.* at 881–83 ("[T]he Roberts Court is uniquely hostile to speculation and may be embracing a renewed support for the importance of concrete facts in adjudication.").

167 527 U.S. at 77 (Scalia, J., dissenting) (emphasis in original). In Justice Scalia's view, a statute cannot be held facially unconstitutional as-applied to a particular party before it can be shown that it is unconstitutional in all of its applications. *Id. See* Nichol, *supra* note 46, at 170 ("Because the federal courts may not issue advisory opinions, the ripeness requirement demands that the party show that he actually has been hurt in immediate terms by the actions of the defendant.").

they would have if they had waited until the enforcement stage to sue. However, the effect of judicial blessing on a rule at the pre-enforcement stage also prejudices regulated parties later on when attempting to invalidate a rule or in defending themselves in an enforcement proceeding. This prejudicial effect is problematic for multiple reasons. First, it decreases access to justice for private litigants challenging a rule at the enforcement stage, who through no fault of their own did not participate in the pre-enforcement litigation. Second, it cements pre-enforcement rulings that may have been wrongly decided because of the informational and technical disadvantages judges face in pre-enforcement settings.[168]

The most straightforward way in which this prejudicial effect occurs comes from vertical *stare decisis*, a doctrine which mandates that a lower court is bound by relevant precedent of a higher court in the same geographic jurisdiction.[169] *Stare decisis* can also be horizontal, requiring appellate courts to follow their own previously announced precedents.[170] When a circuit court upholds a rule in pre-enforcement review, that holding has precedential effect on that same court later on as well as lower courts in the same jurisdiction. Therefore, to the extent that a defendant's challenge to the lawfulness of the rule cannot be distinguished from a precedent set in the pre-enforcement suit, and that that precedent controls the outcome of the case, the court will be forced to rule against the defendant on that issue.[171]

Courts sometimes have a difficult time in pre-enforcement review deciding how broad or narrow to make a precedent—or "decisional rule"—in a case. In part because of the comparative disadvantage courts have with agencies, they are ill-equipped to accurately predict the future consequences of the precedents they set.[172] The extent to which a pre-enforcement precedent conflicts with a post enforcement challenge depends on two factors: (1) the breadth of a court's precedent and (2) the breadth of the private litigant's statutory challenge.[173] A broad statutory challenge and a broad court precedent, for example, will optimize the chance that a judge will be forced by *stare decisis* to uphold the regulation. However, "[c]areful analysis and characterization of a precedent can often avoid the need to choose between overruling a

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168 *See supra* Part II.A.

169 Jeffrey C. Dobbins, *Structure and Precedent*, 108 MICH. L. REV. 1453, 1460 (2010).

170 *Id.* at 1461–62.

171 Pierce, *supra* note 84, at 2237.

172 *Id.* at 2238–39.

173 *See* Levin, *supra* note 79, at 2233 n.142.

precedent and reaching an appropriate result in a case."[174] However, the prejudicial effect of pre-enforcement review on future enforcement proceedings may not always be a result of *stare decisis* alone.

In addition to the impact of *stare decisis*, future private parties may also be prejudiced by the norms of decision making resulting from the judicial imprimatur that attaches to a regulation approved in pre-enforcement review. Many statutes require pre-enforcement review occur in the D.C. Circuit,[175] which is viewed as the preeminent court for issues of administrative law.[176] There is also evidence that regulations get the most scrutiny in the D.C. Circuit compared to other circuit courts.[177] Therefore, when the D.C. Circuit approves a rule at the pre-enforcement stage, this may have a conscious or subconscious effect on future courts when reviewing challenges to the rule in enforcement proceedings.[178]

Judicial decisions at the pre-enforcement stage may also become entrenched through the phenomenon known as "path dependence" or the "lock-in" effect.[179] The "lock-in" concept is rooted in the theory that law is fundamentally shaped by history and is thus slow to change and heavily influenced by earlier legal outcomes.[180] The doctrine of *stare decisis* and the normative benefits associated with it, such as reliance and predictability, work to constrain the judiciary and discourage courts from diverging from existing judicial trends.[181] Courts are also sensitive to perceptions of their institutional legitimacy and thus tend to refrain from decisions that would significantly affect reliance interests.[182] Professor Kevin Lynch contends that courts are sensitive to outside criticisms of arbitrariness.[183] As a result, they tend to feel a need to justify their past

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174 Pierce, *supra* note 84, at 2237.

175 *See, e.g.*, Clean Air Act, 42 U.S.C. § 7607(b)(1) (2012).

176 The D.C. Circuit reviews over a quarter of all administrative law cases that go to appellate courts. Pierce, *supra* note 125, at 87.

177 The D.C. circuit upholds regulations twelve percent less frequently than other appellate courts. *Id*. at 88.

178 *See* Dobbins, *supra* note 169, at 1462–63 (describing the impact of "persuasive precedent" from a well-respected court on courts that are not otherwise bound).

179 Oona A. Hathaway, *Path Dependence in the Law: the Course and Pattern of Legal Change in a Common Law System*, 86 IOWA L. REV. 601, 604 (2003) (describing "path dependence" as "an outcome or decision is shaped in specific and systematic ways by the historical path leading to it. It entails, in other words, a causal relationship between stages in a temporal sequence, with each stage strongly influencing the direction of the following stage.").

180 *Id.* at 603–04.

181 *Id.* at 626–27.

182 *See* Pierce, *supra* note 84, at 2244. *See also* Franklin, *supra* note 164, at 55–56 (describing courts' hesitancy to uphold facial challenges because of the dramatic effect of invalidating an entire statute).

183 Kevin J. Lynch, *The Lock-In Effect of Preliminary Injunctions*, 66 FLA. L. REV. 779, 781 (2013).

decisions—both on account of the correctness of the reasoning and the judicial resources used to decide them—by ruling similarly in future decisions. This lock-in effect is particularly relevant to contentious agency rules, such as the Clean Water Rule, where a court is often asked to grant a preliminary injunction or stay. Because enjoining a rule requires a court to find an initial threshold chance of success on the merits, a court is less likely to, down the road, rule in favor of the challenging party because of both cognitive bias as well as a need to justify its previous decision.

Finally, substantial reliance interests at stake with regard to an informal agency rule may make judges hesitant to invalidate a rule at the enforcement stage that was incorrectly upheld during pre-enforcement review. These rules are often the culmination of a long process of development, negotiation, and implementation and present significant costs to the agency if overturned. In addition, they have the potential to both substantially change the behavior of regulated parties and significantly harm reliance interests if they are overturned later in enforcement proceedings. Consequently, regulated parties who suffer the effects of a wrong decision in pre-enforcement review face strong headwinds in trying to challenge the rule going forward.

4. Counterarguments

Before concluding this section on access to justice, it is necessary to address some of the counterarguments, many of which justify pre-enforcement review on the grounds that it increases access to justice and alleviates due process concerns related to unlawful agency action.[184] One contention is that in the absence of pre-enforcement review of agency rules, regulated entities would in effect be precluded from challenging a rule because the risk of incurring large penalties in an enforcement proceeding outweighs the costs of complying with the rule. Allowing parties to sue upfront alleviates this problem by helping to prevent unlawful rules from going into effect.

This is certainly a forceful argument and it has convinced courts for decades to expand access to pre-enforcement review for numerous agency rules.[185] However, this argument carries with it a number of assumptions: (1) that entities have the means to challenge a rule at the

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[184] *See* ACUS Recommendation 82-7, 47 Fed. Reg. 58,208; William Funk, *A Primer on Nonlegislative Rules*, 53 ADMIN. L. REV. 1321, 1340 (2001); Pierce, *supra* note 10, at 90.

[185] *See, e.g.*, Abbott Labs. v. Gardner, 387 U.S. 136, 152 (1967) ("Either [petitioners] must comply with the every time requirement and incur the costs of changing over their promotional material and labeling or they must follow their present course and risk prosecution.").

pre-enforcement stage, which can also be extremely costly;[186] (2) that parties will overcome the difficulty of winning cases at the pre-enforcement stage;[187] and (3) that the benefits to parties challenging a rule upfront outweigh the potential costs associated with losing a pre-enforcement challenge.[188]

Moreover, at least with regard to the Clean Water Act, concerns that a rule will go unchallenged at the enforcement stage because parties will not be willing to risk the costs of noncompliance penalties seem to be unfounded. For example, there were several as-applied challenges in enforcement proceedings to the Army Corps' so called "Migratory Bird Rule," a regulation asserting jurisdiction over remote waters as long as they served as habitat for migratory birds.[189] These challenges culminated in *SWANCC*, which invalidated the rule and established the "significant nexus" test used by the concurrence in *Rapanos*.[190]

Arguments in favor of pre-enforcement review of informal agency rules also overlook other options available to regulated parties who seek review of agency actions after the rulemaking period but before enforcement. In the Clean Water Act context, the Court recently allowed for pre-enforcement review of agency compliance orders against alleged violators.[191] Just last year, the court allowed pre-enforcement review of an Army Corps jurisdictional determination specifying that a property contained WOTUS.[192] Therefore, even without access to the courts before a rule goes into effect, regulatees are not entirely without recourse before they are accused of being noncompliant.

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186 Pre-enforcement review makes challenging a rule costly because (1) it requires hundreds of hours to review the entire administrative record, which can span hundreds of thousands of pages and (2) challenging parties must pay for scientific studies that contradict agency findings. *See* Pierce, *supra* note 10, at 70.

187 *See supra* notes 151–167 and accompanying text.

188 *See supra* Part III.A.3.

189 Leslie Salt Co. v. United States, 55 F.3d 1388 (9th Cir. 1995); Hoffman Homes, Inc. v. Administrator, U.S. EPA, 999 F.2d 256 (7th Cir. 1993); United States v. Hallmark Const. Co., 14 F. Supp. 2d 1069 (N.D. Ill. 1998). The rule was held invalid at the circuit level in United States v. Wilson, 133 F.3d 251 (4th Cir. 1997).

190 531 U.S. 159 (2001).

191 *See* Sackett v. EPA, 566 U.S. 120, 131 (2012).

192 Hawkes Co., Inc. v. U.S. Army Corps of Eng'rs, 136 S.Ct. 1807 (2016) (determining that private landowner seeking to mine peat would not have to complete the permit process or face an enforcement action before challenging the agency's jurisdictional determination that its property contained WOTUS). In affirming the Eighth Circuit decision, the Court resolved a circuit split. *Compare* Hawkes Co., Inc. v. U.S. Army Corps of Eng'rs, 782 F.3d 994 (8th Cir. 2015) (holding individual jurisdictional determinations subject to pre-enforcement review) *with* Belle Co. L.L.C. v. U.S. Army Corps of Eng'rs, 761 F.3d 383 (5th Cir. 2014) (individual jurisdictional determinations are not "final agency action" and thus not subject to pre-enforcement challenge).

Another common argument in favor of pre-enforcement review is that it increases certainty for regulated parties as well as agencies. The first strand of this argument can be summarized as follows: "[t]he uncertainty caused by the potential for conflicting court decisions and by the possibility that a rule may be overturned several years after its promulgation can be extremely disruptive of the regulatory scheme."[193] Regulatory certainty is obviously important. Judicial interference in a regulatory regime can cause immense financial harm.[194] Professor Pierce notes that agency rules create substantial reliance interests after being in place for as little as two years.[195] Yet, despite the fact that a pre-enforcement judicial decision upholding a rule will make it harder to challenge the rule during enforcement proceedings,[196] such a ruling does not actually guarantee the continued validity of a rule that has been upheld. The abovementioned Migratory Bird Rule was overturned fifteen years after it was adopted[197] and had been validated in several jurisdictions in the intervening period.[198]

The second strand of the reliance argument is that pre-enforcement review increases certainty by reducing the likelihood of diverging judicial opinions in multiple jurisdictions. The Administrative Conference of the U.S. cited "[t]he uncertainty caused by the potential for conflicting court decisions"[199] to recommend in favor of pre-enforcement review and claimed that "[d]irect review in the court of appeals is more likely to afford [prompt and dispositive] resolution [of disputed issues] than later enforcement review in one or more district courts."[200]

Yet, uncertainty still exists after a pre-enforcement ruling in a reviewing court. There remains a significant chance for conflicting rulings in multiple jurisdictions, which stems from the variety and unorthodox nature of appellate processes in place for reviewing agency rules.[201] Currently, many statutes require pre-enforcement claims to be

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193 ACUS recommendation 82-7, 47 Fed. Reg. 58,208. *See also* Levin, *supra* note 79, at 2204–05 ("[R]ules adopted in these regulatory areas can entail enormous up-front investments of money, effort, and advance planning. Both the agency and the private sector have interests in getting the legality of these rules settled one way or the other relatively quickly.").

194 *See* Pierce, *supra* note 84 at 2246 (documenting the harm to reliance interests from reversing regulatory precedent).

195 *Id.* at 2246 n.90.

196 *See supra* notes 151–167 and accompanying text.

197 *SWANCC*, 531 U.S. 159 (2001).

198 Leslie Salt Co. v. United States, 55 F.3d 1388 (9th Cir. 1995); Hoffman Homes, Inc. v. Administrator, U.S. EPA, 999 F.2d 256 (7th Cir. 1993); United States v. Hallmark Const. Co., 14 F. Supp. 2d 1069 (N.D. Ill. 1998). The rule was held invalid at the circuit level in United States v. Wilson, 133 F.3d 251 (4th Cir. 1997).

199 ACUS Recommendation 82-7, 47 Fed. Reg. 58,208.

200 *Id.*

201 Dobbins, *supra* note 169, at 1468.

brought within a certain time period in a primary reviewing court—often the D.C. Circuit,[202] but sometimes in any circuit court[203] or in federal district court.[204] These statutes may expressly foreclose review of the rule later in enforcement proceedings, though courts have repeatedly made end-runs around these provisions to allow these challenges.[205] Still other statutes provide for direct review in a particular court both at the pre-enforcement and enforcement stage.[206] Finally, many statutes are simply silent about where and when review of agency rules will take place.[207]

Further adding to the uncertainty, multiple petitions challenging a rule under statutes that do not vest exclusive jurisdiction in a particular reviewing court will be consolidated and randomly assigned to a federal circuit court.[208] The heart of the problem is that the law is unsettled as to whether rulings in these randomly assigned circuits are binding on all other appellate courts.[209] In addition, it remains an open question whether rulings in courts granted exclusive jurisdiction by statute to hear pre-enforcement claims are binding on courts in other jurisdictions.[210] Thus, depending on the statute governing a particular agency rule, conflicting court rulings could occur as a result of subsequent challenges by regulatees—pre or post enforcement—in courts of different jurisdictions.[211] Even if a particular pre-enforcement ruling were binding on regulatees in other jurisdictions, it would not be binding on federal

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202 *See, e.g.*, Clean Air Act, 42 U.S.C. § 7607(b) (2012). For a summary of statutory judicial review provisions, see Frederick Davis, *Judicial Review of Rulemaking: New Patterns and New Problems*, 1981 DUKE L.J. 279 (1981).

203 *See, e.g.*, Clean Water Act, 33 U.S.C. § 1369(b) (2012).

204 *See, e.g.*, Department of Energy Organization Act, 42 U.S.C. § 7192(b) (2012).

205 *See, e.g.*, United States v. S. Union Co., 630 F.3d l7 (1st Cir. 2010); Eagle-Picher Indus., Inc. v. EPA, 759 F.2d 905, 919 (D.C. Cir. 1985). Courts have raised concerns that preclusion provisions in enforcement proceedings may be a violation of due process. *See* U.S. CONST. amend. V; Adamo Wrecking Co. v. United States, 434 U.S. 275, 289–90 (1978) (Powell, J., concurring); Levin, *supra* note 79, at 2226 ("By and large, avoidance has indeed been the primary strategy by which courts have extricated themselves from this acutely uncomfortable dilemma."). Statutes that provide for direct review within a prescribed time period but do not expressly preclude review at the enforcement stage include the Hobbs Act, 28 U.S.C. § 2344 (2012).

206 *See, e.g.*, Toxic Substances Control Act, 15 U.S.C. § 2618 (2012).

207 *See, e.g.*, National Credit Union Central Liquidity Facility Act, 42 U.S.C. § 1302 (2012).

208 All petitions filed within ten days of an agency action will be consolidated by the Judicial Panel on Multidistrict Litigation and assigned to be reviewed by a particular circuit court. *See* 28 U.S.C. § 2112 (2012).

209 Dobbins, *supra* note 169, at 1470.

210 Thomas O. McGarity, *Multi-Party Forum Shopping for Appellate Review of Administrative Action*, 129 U. PA. L. REV. 302, 358 (1980) ("[V]esting exclusive venue in a single court for preenforcement review of major regulations would leave unanswered the question whether district courts and other appellate courts could reconsider the validity of the regulation at the enforcement stage.").

211 Dobbins, *supra* note 169, at 1468.

agencies.[212] Therefore, agencies could continue to apply a rule held invalid in one jurisdiction to parties in another.[213] In sum, the possibility of uncertainty as a consequence of non-uniform regulatory regimes across the country does not disappear with the availability of pre-enforcement review.

Finally, proponents of pre-enforcement review often cite its benefits for beneficiaries of regulatory regimes, i.e., the public, because of the ability of public interest groups to mount challenges to agency rules that may be too friendly to industry. Without pre-enforcement review, the argument goes, these groups may never have a chance to challenge a rule because the agency may never bring an enforcement action and, even if it did, public interest groups may not be able to participate.[214] Precluding public interest groups from challenging rules may be particularly damaging because they represent a counterweight to industry groups who have strong incentives to oppose agency regulatory initiatives that often have large but dispersed public benefit.[215]

Despite legitimate concerns relating to agency "capture" by industry, as well as the negative effect on agency rulemaking behavior that may flow from an agency's fear of industry lawsuits, it is hard to quantify the impact pre-enforcement public interest suits have on agency rulemaking. Limited empirical data indicate that public interest group challenges may not have much practical effect because of agency nonacquiescence and the limited percentage of rules public interest organizations are able to challenge due to resource constraints.[216] Thus, the benefits of citizen group participation in pre-enforcement review must be weighed against

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[212] *Id.* (noting that federal agencies are not subject to offensive nonmutual collateral estoppel).

[213] This is known as "intercircuit nonacquiescence." *Id.* at 1469.

[214] Levin, *supra* note 31, at 476. *See, e.g.*, Simpson v. Young, 854 F.2d 1429 (D.C. Cir. 1988); Mellwain v. Hayes, 690 F.2d 1041 (D.C. Cir. 1982). *But see* Envtl. Def. v. Duke Energy Corp., 549 U.S. 561 (2007) (leaving the door open for possible challenges to EPA regulations in the citizen suit enforcement context). For a criticism of the use of justiciability doctrines to block beneficiaries' access to the courts, see Eacata Desirée Gregory, Note, *No Time is the Right Time: The Supreme Court's Use of Ripeness to Block Judicial Review of Forest Plans for Environmental Plaintiffs in* Ohio Forestry Ass'n v. Sierra Club, 75 CHI.-KENT L. REV. 613 (2000).

[215] *See* Cass R. Sunstein, *Interest Groups in American Public Law*, 38 STAN L. REV. 29, 63 (1985) (favoring judicial review as a way to combat agency capture). *But see* Richard Murphy, *Enhancing the Role of Public Interest Organizations in Rulemaking Via Pre-Notice Transparency*, 47 WAKE FOREST L. REV. 681, 689–90 (2012) (contending that the increased participation of regulatory beneficiaries in the rulemaking process has "not eliminate[d] some of the root causes of industry influence over agencies" because of the pervasive contact between the bureaucracy and industry groups during the process of formulating and implementing regulations).

[216] Wendy Wagner, *Revisiting the Impact of Judicial Review on Agency Rulemakings: An Empirical Investigation*, 53 WM. & MARY L. REV. 1717, 1745–46 (2012) (finding in a case study that public interest groups were only able to challenge eight percent of air toxic rules, partly because of lack of resources).

the opportunity costs of devoting the same resources to bringing violators to justice and holding agencies accountable through alterative avenues such as citizen suit provisions.[217]

More importantly, benefits from public involvement through pre-enforcement review must be weighed against the negative consequences to agency efficiency and enforcement capabilities resulting from pre-enforcement review. These consequences have been termed generally as the "ossification" of the rulemaking process and have been thoroughly documented.[218] In brief, industry groups face strong incentives to challenge a rule before enforcement, as the deterrent effect of potential fines is absent. In turn, these pre-enforcement private litigants will attempt to flood the agency with comments during the notice-and-comment period in order to prepare the record for a pre-enforcement challenge.[219] This not only increases time and money spent by the agency to respond to the comments, but also incentivizes "defensive rulemaking" in order to combat the threat of pre-enforcement suits, which puts constraints on agencies' ability to enforce their rules and produces rules of poorer quality.[220]

Making pre-enforcement review unavailable also greatly increases compliance with a rule, as the risk of steep penalties will change the calculus for many regulated entities; rather than disrupt the rulemaking process, the industries must first comply.[221] Therefore, to the extent that robust agency enforcement, agency efficiency, and quality rulemaking benefit the taxpayer, it is possible that pre-enforcement review may actually harm the public interest more than it helps.

In conclusion, while the proposition that more judicial review earlier will always increase access to justice is intuitively appealing, the evidence does not bear this out. Regulated parties have trouble prevailing in pre-enforcement review and, to the extent they do not, they face an even steeper disadvantage later on when defending

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[217] *See, e.g.*, Clean Water Act, 33 U.S.C. § 1365 (2012); Daniel Selmi, *Jurisdiction to Review Agency Inaction*, 72 IND. L.J. 65, 77 (1996) ("[T]he 1972 Amendments to the [Clean Water Act] authorize citizen suits in the United States district courts to compel nondiscretionary actions without regard to the amount in controversy or citizenship of the parties.").

[218] *See, e.g.*, MASHAW, *supra* note 8, 158–81 (1997) (detailing, among other things, how the incentive effects of pre-enforcement review encourage litigation rather than regulatory compliance); Bagley, *supra* note 1, at 1338.

[219] Wagner, *supra* note 216, at 1721–22.

[220] Cross, *supra* note 9, at 1280–81 ("Judicial review may also hinder the ability of agencies to set a sensible regulatory agenda, may ignore political and practical constraints on agency action, and may systematically produce rules of poorer quality.").

[221] MASHAW, *supra* note 8, at 179. In the aftermath of *Toilet Goods v. Gardner*, where pre-enforcement review was disallowed, the rule was never subsequently challenged. Levin, *supra* note 31, at 474.

themselves in enforcement proceedings. Nor do private parties benefit from an increase in regulatory certainty as a result of pre-enforcement review. As disadvantaged as private parties are in pre-enforcement review, beneficiary groups face an even more uphill battle in vindicating public rights at the pre-enforcement stage. While agencies have a distinct advantage in pre-enforcement review, they are also harmed by the ossification of the rulemaking process and loss of resources that could otherwise be put towards effective rulemaking and enforcement.

C. Maintaining a Proper Balance of Powers

Maintaining the judiciary's proper role in our democratic and constitutional system is another key policy rationale behind the ripeness doctrine. The doctrine furthers this purpose in two ways. First, by demanding adjudication only occur with a sufficiently developed set of facts, it prevents courts from rendering judgments that would amount to mere conjecture. In turn, this helps maintain the judiciary's reputation and credibility as a legitimate branch of government that will use its power wisely.[222] Second, the ripeness requirement helps to prevent judges from interfering with the proper functioning of other branches of government.[223] For example, in several instances, courts have used ripeness as a way to prevent judicial interference with the prerogatives of the executive branch.[224] In *Abbott*, the Court addressed the possibility of encroachment on the executive branch in its ripeness analysis, stating, "[w]e fully recognize the important public interest served by assuring prompt and unimpeded administration of the Pure Food, Drug, and Cosmetic Act . . . ."[225]

Whether pre-enforcement review furthers this normative goal of ripeness is debatable. On the one hand, pre-enforcement review can act as a check on administrative agencies, the unelected "fourth branch" of government whose actions often have the force of law and impose

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[222] Nichol, *supra* note 46, at 176 (stating that "[r]ipeness analysis has been used, for example, as a tool by the Court to help ensure precision in judicial decision making and to prevent judicial intrusions on proper and efficient allocation of governmental powers").

[223] *Id.* at 178 (stating that employing the ripeness doctrine to allow other governmental decision makers "an opportunity to function . . . to accommodate special problems" obviously entails use of the doctrine to further interests in the separation of powers and federalism) (quoting Toilet Goods Ass'n, Inc. v. Gardner, 387 U.S. 158, 200 (1967) (Fortas, J., concurring in part)).

[224] *See, e.g.*, Goldwater v. Carter, 444 U.S. 996, 997–98 (1979) (Powell, J., concurring) (holding that the ripeness doctrine prevented the court from rendering judgment on a challenge that the President abrogated a treaty).

[225] Abbott Labs v. Gardner, 387 U.S. 136, 154 (1967).

significant burdens and obligations on private parties.[226] By increasing scrutiny on agency action, courts can increase agency accountability, improve the quality of agency decision making, and legitimize agency behavior.[227] On the other hand, the judiciary is also unelected and arguably has even less democratic legitimacy than bureaucracies, who are accountable to the President, who in turn is accountable to the electorate.[228] In addition, the judicial branch risks sacrificing its credibility when it adjudicates pre-enforcement challenges at the cost of precision and accuracy in case outcomes.

As empirical data have demonstrated, there is substantial evidence that judges uphold rules based on ideological preference.[229] This has concerning implications for both legitimacy as well as separation of powers. It is possible that pre-enforcement review either causes or accentuates this phenomenon, as it gives the judiciary broad discretion in how to decide cases due to the vastness of the administrative record, lack of applied facts, and vagueness of the standards of review.[230] Moreover, informal agency rules can be politically charged and divisive. By reviewing the rule all at once and thus increasing the stakes of litigation, pre-enforcement review may give judges unchecked authority over prominent issues of national policy, which could further politicize the judiciary as well as the overall rulemaking process.

Finally, the contention that pre-enforcement review increases agency accountability[231] overlooks the potential incentives created by foreclosing pre-enforcement review. Agencies benefit from pre-enforcement review by knowing in advance whether or not their rule will be invalidated before

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226 Sidney A. Shapiro & Richard E. Levy, *Heightened Scrutiny of the Fourth Branch: Separation of Powers and the Requirement of Adequate Reasons for Agency Decisions*, 1987 DUKE L.J. 387, 395 (1987) ("In this country, judicial review and the legitimacy of administrative government are inextricably intertwined.").

227 *See* Peter L. Strauss, *Legislation that Isn't — Attending to Rulemaking's "Democracy Deficit"*, 98 CAL L. REV. 1351, 1357 (2010) ("The legitimacy of delegated discretionary authority, that is, is tied directly to the possibility of judicial review for the rationality of its exercise."). *See also* Bagley, *supra* note 1, at 1319.

228 Cross, *supra* note 9, at 1290 ("Agencies are regularly held accountable by the President and the Congress, who are, in turn, accountable to voters.").

229 Pierce, *supra* note 125, at 88–89 (summarizing empirical data demonstrating a clear correlation between a judge's political ideology and the outcome of a challenge to a rule).

230 *See* Peter H. Schuck & E. Donald Elliott, *To the* Chevron *Station: An Empirical Study of Federal Administrative Law*, 1990 DUKE L. J. 984, 1027 (1990) ("The standards and scope of judicial review often are broad and unconstraining. The records in administrative cases often are so extensive that reviewing courts can extract from them plausible grounds for either an affirmance or a remand"). *See also* Pierce, *supra* note 10, at 69 ("It is impossible for any agency to identify and to discuss explicitly and comprehensively each of the myriad issues, alternatives, and data disputes relevant to a major rulemaking. After the fact, any competent lawyer with access to sufficient resources can identify issues that an agency arguably discussed inadequately.").

231 *See* Pierce, *supra* note 10, at 91.

spending resources to implement it.[232] Consequently, without the security of having a rule validated upfront, it is possible that the agency will respond by enforcing the regulation conservatively so as to lower the likelihood that the rule will be struck down later on in an enforcement proceeding or even challenged at all. Thus, the absence of pre-enforcement review may even increase agency accountability as well as the lawfulness of agency behavior.[233]

IV. METHODS OF PRECLUDING PRE-ENFORCEMENT REVIEW

As has been described above, there are multiple disadvantages to pre-enforcement review of complex agency rules. Since pre-enforcement review cannot be justified on the basis of maintaining balance of power, benefitting reliance interests, or decreasing agency "capture," it is worthwhile to consider how to reduce the prevalence of pre-enforcement review, particularly in situations where it is least efficacious.

A. Reinvigorating Ripeness Doctrine

Abbott established the presumption of reviewability for agency rules, opening the door for much greater use of pre-enforcement review. But, importantly, it also established the test for ripeness. As the companion case *Toilet Goods* demonstrates, ripeness is a viable method of foreclosing review of agency rules when appropriate.[234] As has been recognized, the prudential ripeness doctrine as it is formulated under *Abbott* is flexible enough to allow courts to employ it in a wider variety of pre-enforcement cases.[235] *Abbott*'s two-part test—inquiring into the (1) "fitness of the issues for judicial decision" and (2) "the hardship to the parties of withholding court consideration"[236]—could easily be construed

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232 *See* Randolph, *supra* note 42, at 10 ("For their part, I suspect the agencies are not too unhappy about putting an entire rulemaking to the judicial test in one fell swoop.").

233 In his dissenting opinion in *Toilet Goods v. Gardner*, Justice Fortas alluded to the discretion agencies have in how they implement regulations and the effects of subsequent agency enforcement decisions as a factor to consider in the ripeness inquiry, stating, "[n]one of [the challenged regulations are] . . . subject to the give-and-take of the administrative process as it works, for example, in the realities of the complex world of food, drug, and cosmetic regulation. None of them is subject to exception upon application. None of them depends upon the independent judgment of the Attorney General for enforcement." Toilet Goods Ass'n v. Gardner, 387 U.S. 167, 193 (1967) (Fortas, J., dissenting).

234 *But see* Duffy, *supra* note 9, at 140, 179 (1998) (arguing that courts should reign in ripeness review, as it conflicts with the right to judicial review codified in the APA).

235 *See* Levin, *supra* note 31, at 474 (claiming the Court in *Abbott* adopted "a formula that was relatively simple, yet flexible enough to be used in a wide range of situations"). *See also* Bagley, *supra* note 1, at 1339 (arguing that "courts should be open to the possibility of dismissing a greater number of preenforcement challenges as unripe").

236 Abbott Labs v. Gardner, 387 U.S. 136, 148 (1967).

to preclude pre-enforcement review for a larger number of cases once courts take into account the panoply of negative consequences pre-enforcement review has on a certain class of cases.[237] For example, as compared to *Abbott*, the Clean Water Rule and the *Rapanos* "significant nexus" test reveal a stark difference in the level of abstraction, uncertainty, and technical detail necessary to correctly determine the validity of the rule.

B. Mechanisms in Addition to Ripeness to Foreclose Pre-enforcement Review

Aside from the ripeness doctrine,[238] courts may still be able to rely on statutory and constitutional principles such as final agency action[239] and standing[240] to postpone review if a case would otherwise fail a proper ripeness analysis.[241] All three justiciability doctrines have been recognized as having overlapping functions[242] and have even been viewed as interchangeable.[243] Courts have read the Clean Water Act's judicial review provision allowing for pre-enforcement review of agency "action" to require "final agency action." Thus, in determining whether the Clean Water Rule is ripe for review, the "action" language in the Act's judicial review provision provides a textual hook for judges to preclude pre-enforcement review in order to further the values underlying the ripeness doctrine.[244]

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237 *See supra* Part III.

238 The United States as amicus has in at least one instance suggested that the Clean Water Act waives the prudential ripeness requirements in its pre-enforcement review provision. *See* Brief for United States Responding to the Court's Questions as Amicus Curiae at 56 n.2, Nw. Envtl. Def. Ctr. v. Brown, 640 F.3d 1063 (9th Cir. 2011) (stating that § 509 of the CWA "supersedes ordinary rules of prudential ripeness that might otherwise bar prompt review of promulgated regulations").

239 *See* 5 U.S.C. § 704 ("Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review.").

240 *See* U.S. CONST. art. III, § 2.

241 *See, e.g.*, David M. Moore, Comment, *Pre-enforcement Review of Administrative Orders to Abate Environmental Hazards*, 9 PACE ENVTL. L. REV. 675, 685 (1992) ("EPA has successfully prevented pre-enforcement review by arguing that its administrative actions are not final.").

242 *See* Sackett v. EPA, 566 U.S. 120 (2012) (Court used hardship to the party as a means of measuring whether there has been final agency action under the APA); Ticor Title Ins. Co. v. FTC, 814 F.2d 731 (1987) (three judges used three different timing doctrines to reach the same outcome). *See also* Dow Chemical v. EPA, 832 F.2d 319, 324 n.30 (5th Cir. 1987) ("Because finality is only one of the four ripeness factors outlined in *Abbott Laboratories*, an agency action may be final without being ripe.").

243 Sierra Club v. Gorsuch, 715 F.2d 653, 657 (D.C. Cir. 1983) ("The requirement of finality is in essence a question of ripeness, focusing on the appropriateness of the issues presented for judicial review. Courts have approached this determination in a pragmatic way, considering 'the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.'").

244 *See* 33 U.S.C. § 1369(b) (2012) ("Review of Administrator's Actions").

There are other good statutory arguments for why pre-enforcement review should be denied more often. While the presumption of pre-enforcement review created by *Abbott* has appeared insurmountable at times,[245] the Court has also identified cases in which the presumption can be overcome by sufficiently clear intention from Congress.[246] Furthermore, in *Shalala v. Illinois Council on Long Term Care, Inc.*,[247] the Court articulated a view of the presumption that provides an opening for courts to limit pre-enforcement review of informal agency rules more often. In that case, the statute provided for a "channeling" of all pre-enforcement claims to an administrative hearing and precluded all claims until after enforcement.[248] The Court cited *Thunder Basin Coal Co. v. Reich* to hold that the presumption of reviewability is much weaker—or even nonexistent—when the statute merely postponed review, rather than precluded it entirely.[249] Writing separately in dissent, Justice Scalia echoed the majority's view that there should be a weaker presumption in favor of pre-enforcement review when judicial review would be available later on.[250] He even went so far as to say that as applied to pre-enforcement review, *Abbott*'s "presumption" was merely a background rule.[251] Thus, the potential weakening of the presumption in the case of pre-enforcement review could provide ammunition to courts that choose to use statutory preclusion provisions to postpone such review going forward.[252]

V. CONCLUSION

Pre-enforcement review has advantages for regulated parties, agencies, and beneficiaries. But the advantages of pre-enforcement review are lessened dramatically in the context of complex agency rulemaking. Here, the likelihood of a precise and accurate case outcome is greatly

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245 *See, e.g.*, Reno v. Catholic Soc. Servs., Inc., 509 U.S. 43, 63–64 (1993) (finding that a statute explicitly disallowing district court review of person's immigration status did not preclude pre-enforcement review of agency regulations). *See also* Bagley, *supra* note 1, at 1294 (pointing out that the Supreme Court in *Sackett v. EPA*, 566 U.S. 120 (2012) found pre-enforcement review of compliance orders available under the Clean Water Act despite the fact that lower courts had been unanimous in concluding that the Act precluded such review).

246 Thunder Basin Coal Co. v. Reich, 510 U.S. 200 (1994) (denying pre-enforcement review on statutory grounds).

247 529 U.S. 1, 19 (2000).

248 *Id.* at 13.

249 *Id.* at 19.

250 *Id.* at 32 (Scalia, J., dissenting).

251 *Id.*

252 *See, e.g.*, Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), 42 U.S.C. § 9613(h)(2) (2012) (providing that "[n]o Federal court shall have jurisdiction . . . to review any order issued . . . until" EPA brings an enforcement action).

reduced, which in turn has a detrimental impact on stakeholders for years to come. When applying the *Abbott* ripeness test, courts too often fail to take into account the less obvious shortcomings of pre-enforcement review and the subsequent long-term impact on the private sector, the judiciary's institutional integrity, and overall efficiency of the rulemaking process. A more complete recognition of how pre-enforcement review furthers or hampers the normative values associated with ripeness will help courts to make the proper decision on whether to hear challenges to agency rules in pre-enforcement proceedings.