

OUT FROM UNDER THE GUISE OF JUDICIAL REVIEW

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Loper Bright—and the end of the Chevron era—seemingly outlaws the intermixing of agency policymaking review “under the guise” of judicial review of statutory interpretation. But, paradoxically, we argue that it presents an unanticipated opportunity for reform of judicial oversight of agency actions.

We propose that courts deploy a sliding scale of respect for an agency’s policy-based interpretation: the more the interpretation departs from the ordinary meaning, the more evidence would be needed to support that interpretation. Our proposed expanded arbitrary and capricious review under a reinvigorated State Farm “hard look” standard accommodates greater judicial deference when an expert agency has engaged in truly reasoned decisionmaking, while triggering greater scrutiny when the agency’s action has weaker justification or the agency lacks a track record of high-quality rulemaking.

Our proposal is consistent with Loper Bright’s insistence that judges retain their statutory interpretation role. But it resists the case’s premise (carried forward from Chevron) that issues of law and fact map onto separate regimes of statutory interpretation and policymaking. Instead, judges should extricate policymaking considerations “out from under the guise of judicial review” and treat them as an essential component of such judicial review. Under our approach, courts start with the agency’s explanation rather than exclusive reliance upon traditional lawyers’ tools. If the agency’s explanation is high quality per State Farm, a court may infer that the underlying question is one of policy and defer to the agency’s answer. Such judicial review would place greater emphasis on meaningful scrutiny of the agency’s policy-based reasons for its rules.

Finally, our proposed framework sets up strong regulatory incentives for courts, agencies, and Congress, which must face a new era for administrative law.

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INTRODUCTION

“Administrative law is highly complex.”¹ And so-called “[m]ixed questions of law and policy pose a puzzle for judicial review of agency interpretations.”² A recent U.S. Supreme Court case illustrates both points: In *Seven County Infrastructure Coalition v. Eagle County*,³ the Court unanimously chided the D.C. Circuit for failing to afford the U.S. Surface Transportation Board the substantial judicial deference required in National Environmental Policy Act (NEPA) cases.⁴ According to the Court, a “course correction” was needed “to bring judicial review under NEPA back in line with the statutory

1. OFF. OF MGMT. & BUDGET, OFF. OF INFO. AND REGUL. AFFS., M-25-36, STREAMLINING THE REVIEW OF DEREGULATORY ACTIONS, 2 (2025) [hereinafter 2025 OIRA MEMORANDUM].

2. Lisa Schultz Bressman, *The Ordinary Questions Doctrine*, 92 GEO. WASH. L. REV. 985, 995 (2024) [hereinafter Bressman, *Ordinary Questions*]; see *id.* at 1011 (offering “guidance to courts for navigating the problem of ordinary questions in the new administrative law era”).

3. 145 S. Ct. 1497 (2025).

4. *Id.* at 1508.

text and common sense.”⁵ The Court insisted that policy disagreements have no place in statutory interpretation.⁶ Indeed, the Court steeled itself against consideration of such policy issues “under the guise of judicial review.”⁷

The case at hand, the Court declared, presents a clear instance of statutorily granted discretion, meaning the scope of judicial review is limited and consideration of policy objectives is foreclosed. But what if—as we shall contend not only was the case in *Seven County*, but is typically the case—questions of law and policy (or fact) often cannot be cleanly separated and inherently bleed into each other?

Several justices raised this concern during the oral arguments for *Loper Bright Enterprises v. Raimondo*.⁸ Justice Kagan, for example, asked: “Is a new product designed to promote healthy cholesterol levels a dietary supplement or a drug?”⁹ The answer to Justice Kagan’s question has significant public health implications; only if the new product is deemed a drug will it be subject to the stringent regulation by the federal Food and Drug Administration (FDA), a highly expert scientific agency, internationally renowned for providing the “gold standard” for safety and efficacy of prescription drugs and medical devices.¹⁰ Nor, it turns out, was this question simply hypothetical.

Indeed, close on the heels of *Loper Bright*, a high-profile case raised the question whether “laboratory developed tests” (LDTs)—such as those that purport to screen for cancer and prenatal abnormalities—should be deemed “devices” subject to FDA regulation.¹¹ The LDT case portends salient risks to public health

5. *Id.* at 1514.

6. Plaintiffs’ policy objections to this 88-mile Utah railroad may or may not be persuasive. But neither “the language nor the history of [the National Environmental Policy Act (NEPA)] suggests that it was intended to give citizens a general opportunity to air their policy objections to proposed federal actions. The political process, and not NEPA, provides the appropriate forum in which to air policy disagreements.”

Id. at 1518 (quoting *Metro. Edison Co. v. People Against Nuclear Energy*, 460 U.S. 766, 777 (1983)).

7. *Id.* (“Citizens may not enlist the federal courts, ‘under the guise of judicial review’ of agency compliance with NEPA, to delay or block agency projects based on the environmental effects of other projects separate from the project at hand.”) (quoting *Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 558 (1978)).

8. 144 S. Ct. 2244 (2024); Transcript of Oral Argument at 7–12, *Relentless v. U.S. Dep’t of Com.*, No. 22-1219 (2024) (companion case of *Loper Bright*).

9. Transcript of Oral Argument at 11, *Relentless v. U.S. Dep’t of Com.*, No. 22-1219 (2024).

10. See 21 U.S.C. §§ 321(g)–(h), 331(a); Catherine M. Sharkey & Daniel J. Kenny, *FDA Leads, States Must Follow*, 102 WASH. U. L. REV. 155, 220 n.338 (2024) [hereinafter Sharkey & Kenny, *FDA Leads*].

11. *Am. Clinical Lab’y Ass’n v. FDA*, 776 F. Supp. 3d 554, 559–60 (E.D. Tex. 2025); see also Complaint at 59, *Ass’n for Molecular Pathology v. FDA*, No. 3:24-cv-00241 (S.D. Tex. Aug 19, 2024). The cases were subsequently consolidated under the *ACLA* name and case number.

and safety, which hang in the balance of the more abstract-seeming debates over the fact/law distinction and the extent to which judicial review can and should address policymaking considerations as part of statutory interpretation.¹²

The LDT case motivates our argument that judges should extricate policymaking considerations out from “under the guise of judicial review” and recognize them as an essential component of such judicial review. It is illustrative of a broader category of cases in which courts make essentially policy-based decisions, while nonetheless insisting they are instead grounded in statutory text. And, in so doing, courts—like that in the LDT case—forego examining whether the record of scientific evidence would support their policy decisions.¹³ Instead, an expert agency (the FDA) was forced into a position of fighting over dictionary definitions and canons of interpretation, while the decision itself remained silent about the scientific basis for regulating a new form of tests that pose health risks.

The LDT case offers some key lessons about the current state of judicial review of agency action, and about the future. First and foremost, it shows that statutory interpretation and reasoned decisionmaking analysis are not fully separable—*Loper Bright*’s insistence to the contrary notwithstanding. While the question “what is a device?” purports to be narrow, it is actually part of a larger discussion of which medical products are regulated, by whom, and why. To meaningfully participate in that debate, however, would require sustained engagement with the risks and benefits of regulating LDTs, an invitation the court declined to take up.

We propose a way forward, consistent with the thrust of *Loper Bright* and based on sound governance principles and policy rationales, that likewise withstands the extremes of ideologically charged, political flip-flopping: courts should decide cases like the LDT challenge by recognizing the interplay between reasoned decisionmaking and statutory interpretation.

12. Several features make the LDT case especially striking. First, parties regulated by the FDA rarely challenge the agency. See Nicholas R. Parrillo, *Administrative Law as a Choice of Business Strategy: Comparing the Industries Who Have Routinely Sued Their Regulators with the Industries Who Rarely Have*, 93 GEO. WASH. L. REV. 1031, 1073 (2025). Second, in cases where the FDA is challenged, courts tend to defer to the FDA’s scientific expertise. See Sharkey & Kenny, *FDA Leads*, *supra* note 10, at 162; cf. Erika Lietzan, *FDA Resilience After Loper Bright*, 79 SMU L. REV. 289, 303, 341 (2026) (arguing that FDA never relied strongly on *Chevron*, so *Loper Bright* may have a surprisingly minimal impact on the agency). Third, the FDA claimed that it already possessed the power to enforce the regulatory requirements against LDTs, thus rendering superfluous the entire process of notice-and-comment rulemaking that it carried out. See *ACLA*, 776 F. Supp. 3d at 570. The LDT case, with this combination of unprecedented occurrences, illustrates a state of administrative law in flux, with the regulator, regulated parties, and the court all breaking from past practices.

13. *ACLA*, 776 F. Supp. 3d at 571, 577.

While many scholars have called for courts to clarify or refine the relationship between the two issues,¹⁴ we advocate an embrace of this overlap in the form of a new administrative law framework that highlights the place of policymaking within statutory interpretation.¹⁵ In so doing, we also resist the emergent neo-textual movement in administrative law scholarship that characterizes textualists as “agents of the people” who “approach language from the perspective of an ordinary English speaker.”¹⁶

Agencies must often choose between equally plausible interpretations of a statute—where, in the words of DC Circuit Judge Wilkins, “the plain text of the statute does not get us home”—so policy concerns become the deciding factor.¹⁷ Under our proposed framework, judicial deference depends on the quality of the agency’s policy decision: the agency does not deserve deference for its resolution of ambiguities unless it can articulate a policy basis for that resolution that can meet the reinvigorated form of the standard announced in *Motor Vehicle Manufacturers Ass’n v. State Farm Mutual Automobile Insurance Co.*¹⁸

14. See *infra* note 156 and accompanying text.

15. Here, we agree with Professor Matthew Stephenson that an appropriate allocation of responsibility between courts and agencies:

[E]nabl[es] the judicial branch to exercise independent judgment on those questions for which the Court’s preferred textualist tools of statutory interpretation could plausibly supply a resolution, while allowing agencies to exercise discretion on those questions that textual analysis—even when considered together with statutory structure and semantic content—simply cannot answer.

Matthew C. Stephenson, *The Gray Area: Finding Implicit Delegation to Agencies After Loper Bright*, 78 ADMIN. L. REV. 99, 181 (2026). But we part ways with his insistence that this is only the case when agencies make policy-based line-drawing decisions inherent in the implementation of statutory terms. See *id.* at 196–99. In our view, the “gray” area is wider still, arising between legal and policy-based interpretations. At the core, we would cede much less ground to the domain of “pure or abstract questions of law,” which forms the baseline for Professor Stephenson’s approach. *Id.* at 136.

16. Kevin Tobia, Brian G. Slocum & Victoria Nourse, *Progressive Textualism*, 110 GEO. L.J. 1437, 1440 (quoting Amy Coney Barrett, Essay, *Congressional Insiders and Outsiders*, 84 U. CHI. L. REV. 2193, 2194–95 (2017)).

17. *Am. Gas Ass’n v. U.S. Dep’t of Energy*, 157 F.4th 476, 488 (D.C. Cir. 2025) (reviewing a challenge to a Department of Energy (DOE) rule increasing energy efficiency standards for home furnaces). In dissent, Judge Rao calls this “*Loper Bright* avoidance,” whereby the majority takes ambiguity in the statutory language as “a license to defer to the Department.” *Id.* at 506 (Rao, J., dissenting).

In *Loper Bright*, the Court equated a “permissible” interpretation with the “best” one—namely “the reading that the court would have reached’ if no agency was involved.” *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2266 (2024) (quoting *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984)). We explain below how neither *Loper Bright* nor its progeny stand in the way of our proposed framework. *Infra* Part II.B.

18. 463 U.S. 29, 43 (1983).

The stakes are colossal. To begin, the increasingly politically polarized conceptions of the administrative state lead to agency flip-flops on key regulatory actions, based on ideological commitment rather than empirical evidence. Thus, the Trump Administration “has prioritized, through many bold Executive Orders and presidential memoranda, the timely and efficient execution of his deregulatory agenda.”¹⁹ This state of affairs, particularly as concerns judicial oversight of the FDA, poses an acute risk to health and safety. Our proposed framework for judicial oversight can tame administrative law in this state of flux.

Part I presents the LDT case—significant in its own right given that it struck down the FDA’s authority to regulate LDTs, which the FDA claims pose serious health and safety risks to the public—as illustrative of the inextricable reasoned decisionmaking dimension of many statutory interpretation questions. While the statutory question appears narrow, it is part of a policy decision concerning the appropriate level and apportionment of regulatory power over medical devices. The court, however, even while wading into the policy debate, failed to partake in such examination of the evidence as would be warranted to establish reasoned decisionmaking under *State Farm*.²⁰

Part II takes up this “road not traveled”—a regime that combines statutory interpretation with reinvigorated *State Farm* review, wherein agencies face heightened scrutiny for the reasonableness of their decisions and the level of deference turns on the result of that inquiry. As a descriptive matter, the combination was reality for much of common law history; and as a normative matter, it is more attuned to the comparative expertise of courts and agencies and helps ensure that only well-justified policies become law. Nor, in our view, does *Loper Bright* (and its progeny) stand in the way. The conventional take on *Loper Bright* is two-fold: first, the general rule is that courts determine the “best reading” of the statute, perhaps aided by *Skidmore v. Swift & Co.*,²¹ which gives “power to persuade” or “respect” to the agency’s position.²² Second, there is an exception, which might turn out to be broad or narrow, where the best reading of the statute is that Congress has (impliedly) delegated interpretive authority to the agency.²³ Our framework—whereby an invigorated *State Farm*

19. 2025 OIRA MEMORANDUM, *supra* note 1, at 1.

20. *State Farm*, 463 U.S. at 43.

21. 323 U.S. 134 (1944).

22. *Loper Bright*, 144 S. Ct. at 2266–67 (requiring courts to independently determine statutory meaning); *Skidmore*, 323 U.S. at 140 (explaining that agency interpretations may inform judicial judgment depending on how persuasive they are).

23. See *Loper Bright*, 144 S. Ct. at 2263 (“In a case involving an agency, of course, the statute’s meaning may well be that the agency is authorized to exercise a degree of discretion.”); see also Stephenson, *supra* note 15, at 101 (“[T]he Court expressly acknowledged that sometimes vague or open-ended statutory language should be treated as an implicit delegation to the agency.”).

standard scrutinizes the policy-based reasoning under the *Skidmore* standard, or as part of implied delegation to the agency—provides a unified framework that essentially reaches the same conclusion under each of these prongs.

Part III moves us toward a vision of the future of administrative law. We argue that our proposed expanded arbitrary and capricious review under a reinvigorated *State Farm* standard aligns and improves the relevant incentives of key players in the administrative state—courts, agencies, and Congress—leading to expected improvements in the functionality of the administrative state. Our vision for the way forward is especially compelling in light of the Trump Administration’s recent acknowledgement that it is “committed to deregulating at an unprecedented scale,” while conceding that “deregulation will involve the development of a record, including reasoned decision making.”²⁴

I. THE LDT CASE: A SNAPSHOT OF ADMINISTRATIVE LAW IN FLUX

The high-profile court battle over LDTs is a tale of two very different stories about the FDA’s authority to regulate LDTs. With these dueling narratives in mind, we consider the specific claims of the Administrative Procedure Act (APA) challenge—statutory authority and arbitrary and capricious—before considering what this legal challenge reveals about the post-*Loper Bright* state of administrative law and where it can and should go from here. It also sets the stage for our proposed approach, which applies to any interpretive question that involves both policymaking and statutory interpretation, even those questions that might be characterized as jurisdictional.

But first, a bit of background. Almost immediately after the FDA issued the final LDT rule in May 2024, the American Clinical Laboratory Association challenged it on behalf of several labs.²⁵ As is the case with many challenges to agency action, it was brought in the “agency skeptical” Eastern District of Texas, where it was assigned to Judge Sean Jordan, known previously for striking down the Biden-era overtime pay rule.²⁶ Several months later, the Association for Molecular Pathology brought a similar challenge in the Southern District of Texas,²⁷ which was then consolidated in the Eastern District before Judge Jordan.²⁸

24. 2025 OIRA MEMORANDUM, *supra* note 1, at 1, 4.

25. Complaint, Am. Clinical Lab’y Ass’n v. FDA, 776 F. Supp. 3d 554 (E.D. Tex. 2025) (No. 4:24-CV-479) [hereinafter *ACLA* Complaint]. For the final rule, see Medical Devices; Laboratory Developed Tests, 89 Fed. Reg. 37,286 (May 6, 2024) (to be codified at 21 C.F.R. pt. 809.3).

26. Daniel Wiessner, *Another Judge Blocks Biden Rule Expanding Overtime Pay*, REUTERS (Dec. 30, 2024, at 16:35 ET), <https://www.reuters.com/legal/litigation/another-judge-blocks-biden-rule-expanding-overtime-pay-2024-12-30/> [<https://perma.cc/XV3J-8UBQ>].

27. Complaint, Ass’n for Molecular Pathology v. FDA, No. 3:24-cv-00241 (S.D. Tex. Aug. 19, 2024) [hereinafter *AMP* Complaint].

28. See *ACLA*, 776 F. Supp. 3d at 559–60.

A. *Dueling Narratives on FDA Regulatory Authority*

1. *The FDA's Position*

In the FDA's telling, the agency's authority to regulate LDTs, which are used to diagnose medical conditions in order to treat or cure them, has been longstanding. In 1972, the FDA promulgated a rule that interpreted the Federal Food, Drug, and Cosmetic Act (FDCA) to include "in vitro diagnostic products," known as IVDs, under the Act's definition of "device."²⁹ IVDs are "reagents, instruments, and systems" used to diagnose medical conditions,³⁰ meaning they refer to physical objects and chemicals used in testing. The FDA uses the term IVD to refer to the broader category of tests.³¹ LDTs are a sub-category of IVDs that are created by a lab and used within that same lab.³²

In 1976, Congress passed the Medical Device Amendments (MDA), which amended the FDCA to give more guidance on medical devices.³³ Soon after, the FDA promulgated a rule clarifying that the MDA covered all IVD test systems.³⁴ None of these regulations, as the FDA emphasized in court, contained exemptions for IVDs created by laboratories.³⁵ In 2000, the FDA issued a final rule explaining that laboratories that create such IVD tests are acting as "device" manufacturers for purposes of the FDCA³⁶—a

29. In Vitro Diagnostic Products for Human Use, 37 Fed. Reg. 819, 819 (Jan. 19, 1972); In Vitro Diagnostic Products for Human Use, 37 Fed. Reg. 16,613, 16,614 (Aug. 14, 1972) (to be codified at 21 C.F.R. pt. 809).

30. Medical Devices; Laboratory Developed Tests, 88 Fed. Reg. 68,006, 68,009 (proposed Oct. 3, 2023) (to be codified at 21 C.F.R. pt. 809).

31. In Vitro Diagnostic Products for Human Use, 37 Fed. Reg. 16,613, 16,614 (Aug. 14, 1972) (to be codified at 21 C.F.R. pt. 809).

32. Melissa M. Budelier & Jacqueline A. Hubbard, *The Regulatory Landscape of Laboratory Developed Tests: Past, Present, and a Perspective on the Future*, 28 J. OF MASS SPECTROMETRY & ADVANCES IN THE CLINICAL LAB 67, 68 (2023) ("CLIA defines an LDT as (1) any IVD test that is developed, manufactured, and used within a single laboratory, or (2) an FDA-approved assay that has been modified.").

33. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539, 539 (codified at 21 U.S.C. § 301).

34. Regulations Establishing Good Manufacturing Practices for the Manufacture, Packing, Storage, and Installation of Medical Devices, 43 Fed. Reg. 31,508, 31,513 (July 21, 1978) (to be codified at 21 C.F.R. pt. 820).

35. Defendants' Cross-Motion for Summary Judgment, Opposition to Plaintiffs' Motions for Summary Judgment, and Combined Memorandum of Points and Authorities at 22, Am. Clinical Lab'y Ass'n v. FDA, 776 F. Supp. 3d 554 (E.D. Tex. 2025) (No. 4:24-CV-479) [hereinafter FDA Brief].

36. Medical Devices; Laboratory Developed Tests, 88 Fed. Reg. 68,006, 68,015 (Oct. 3, 2023) (to be codified at 21 C.F.R. pt. 809) (citing 62 Fed. Reg. 62,243, 62,249 (Nov. 21, 1997)).

position the FDA has reasserted in several public documents in the decades since.³⁷

Notwithstanding its claimed legal authority to regulate LDTs, the FDA has generally chosen to exercise enforcement discretion and not apply pre-market reporting and other requirements to tests developed and used in the same laboratory.³⁸ The agency reasoned that LDTs tended to be used on a small scale, were composed of otherwise regulated components, and were administered by trained professionals.³⁹

Since the 1970s, two major changes pushed the FDA to reconsider its enforcement discretion. First, LDTs have become far more complex, increasingly software-based, and mass produced.⁴⁰ Second, many LDTs are used outside the labs that created them, transforming them into what the FDA describes as IVDs “offered as LDTs.”⁴¹ As a result of these changes, the FDA voiced safety concerns about the existing regulatory landscape.⁴² The FDA pointed to an especially high-profile scandal involving medical diagnostics company Theranos, which claimed that its LDT blood test could diagnose a multitude of diseases with a single drop of blood, as evidence of the danger of unapproved LDTs and the need for effective regulation.⁴³ Some scholars (including one of us) have expressed similar concerns regarding how the changing commercial environment impacts the regulatory calculus.⁴⁴ Accordingly, in 2023, the FDA started the rulemaking process to clarify that IVDs count as devices, even when the manufacturer is a laboratory, as is the case for LDTs.⁴⁵ The rulemaking was completed in 2024 and was promptly challenged by several industry groups.

The FDA took the unusual (and surprising) position that it did not need to go through notice-and-comment rulemaking in 2023–24, given that it

37. *Id.*

38. FDA Brief, *supra* note 35, at 6–7.

39. *Id.*

40. *Id.* at 1; Medical Devices; Laboratory Developed Tests, 88 Fed. Reg. at 68,009.

41. FDA Brief, *supra* note 35, at 1.

42. *Id.* at 1–2.

43. See Medical Devices; Laboratory Developed Tests, 89 Fed. Reg. 37,286, 37,317 (May 6, 2024) (to be codified at 21 C.F.R. pt. 809.3) (discussing the FDA’s role in addressing the problematic LDTs offered by Theranos).

44. Catherine M. Sharkey, *Direct-to-Consumer Genetic Testing: The FDA’s Dual Role as Safety and Health Information Regulator*, 68 DEPAUL L. REV. 343, 347–48 (2019) (finding regulatory challenges in the rise of direct-to-consumer testing); see also Catherine M. Sharkey, Xiaohan Wu, Michael F. Walsh & Kenneth Offit, *Regulatory and Medical Aspects of DTC Genetic Testing*, in CONSUMER GENETIC TECHNOLOGIES: ETHICAL AND LEGAL CONSIDERATIONS 277, 281 (I. Glenn Cohen et al. eds., 2021) [hereinafter Sharkey et al., *DTC Genetic Testing*].

45. Medical Devices; Laboratory Developed Tests, 88 Fed. Reg. at 68,006.

already had the authority to regulate LDTs as devices but had hitherto simply chosen not to enforce against them. The agency's official position is that the 2024 Rule was simply a change in enforcement protocol, not a change in statutory interpretation:

The phaseout policy described in the [notice of proposed rulemaking], and this preamble, is a general statement of policy and therefore, it is exempt from the rulemaking procedures of the APA. Moreover, the phaseout policy is an enforcement policy, and the FD&C Act's enforcement provisions commit broad discretion to FDA to decide how and when they should be exercised.⁴⁶

We are aware of no other instance where the agency claimed existing authority that it had chosen not to exercise but still engaged in "optional" notice-and-comment rulemaking when starting (or attempting to start) enforcement. The full significance of this novel move lies beyond the scope of this Article, but we call attention to it as a suggestion that this may be a feature of the post-*Loper Bright* world, in which longstanding and consistent interpretations receive greater weight.⁴⁷

2. *The Challengers' Position*

The challenging parties tell a strikingly different story. Their core contention is that the FDA never had authority to regulate LDTs, because if it did, the FDA would have taken enforcement action against them.⁴⁸ Specifically, the FDA made no attempt to regulate LDTs from the 1976 passage of the MDA until 1992, leading regulated parties to understand that LDTs were exempt from the Act.⁴⁹

In 1992, the agency tried to promulgate a rule specifically covering LDTs, but, according to the challengers, "when that suggestion drew immediate and strenuous objections, FDA essentially backed down and announced a 'policy' of not exercising jurisdiction."⁵⁰ After that, the FDA released several instances of "[s]poradic" and "non-binding" guidance purporting to include

46. Medical Devices; Laboratory Developed Tests, 89 Fed. Reg. at 37,366 (citations omitted).

47. See *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2259 (2024). The FDA never cites *Chevron* in the Rule and argues that since the statute confers clear authority, the agency does not need deference. Medical Devices; Laboratory Developed Tests, 89 Fed. Reg. at 37,330. This decision follows the trend of most agencies, which had stopped relying on *Chevron* in the years before it was officially overturned. Daniel Deacon, *Loper Bright's Impact: Evidence from Interviews with Agency Rule Drafters*, YALE J. ON REG. NOTICE & COMMENT (Mar. 23, 2026), <https://www.yalejreg.com/nc/loper-brights-impact-evidence-from-interviews-with-agency-rule-drafters/> [<https://perma.cc/4EKU-6XKJ>].

48. See *ACLA Complaint*, *supra* note 25, at 27.

49. *Id.*

50. *Id.* at 28.

LDTs as devices yet declining to bring regulatory action against any LDT makers.⁵¹ For the challengers, “the agency’s consistent policy of *not* treating laboratory-developed tests as devices made these occasional claims nothing but empty posturing.”⁵²

Finally, in response to the FDA’s novel claim of longstanding but dormant enforcement power, the challengers contend that such power is oxymoronic; there is no statutory power without enforcement.⁵³

B. *The Legal Challenge*

All of the relevant players—the challengers, the FDA, and the district court judge—treated the LDT case as a straightforward matter of statutory interpretation, turning on the definition of the word “device.” In their complaints, both challenging parties brought dual claims, arguing first that the rule exceeded the FDA’s statutory authority and second, that it was arbitrary and capricious.⁵⁴ But the space dedicated to the former statutory issue far eclipsed that devoted to the latter policy-based one.

This case stands out to us as one with a limited record—maybe enough to justify the rule, maybe not—but that record never receives meaningful scrutiny from the challenging parties or the court, since all attention is focused on statutory interpretation.⁵⁵ Although the rule has been struck down for now, the public is no closer to knowing whether there is a strong empirical foundation for the FDA’s decision to regulate LDTs.⁵⁶ Statutory issues aside, the case avoids ever questioning whether the FDA’s proposed regulations are sound and necessary policy in light of the risks to public health posed by LDTs.

1. *Statutory Authority*

The statutory authority challenge was a textbook example, invoking a dictionary definition, other provisions of the same statute, other statutes, historical interpretation, and—for good measure—the major questions doctrine.⁵⁷

51. *Id.* at 30–31.

52. *Id.* at 31.

53. *See id.* at 3.

54. *Id.* at 54, 57; AMP Complaint, *supra* note 27, at 59, 75.

55. *See infra* Part II.

56. The government did not appeal the decision vacating the rule. *FDA Declines to Appeal LDT Court Ruling*, AABB (June 4, 2025), <https://www.aabb.org/news-resources/news/article/2025/06/04/fda-declines-to-appeal-ldt-court-ruling> [<https://perma.cc/ZBP2-ZSZU>].

57. *See ACLA Complaint*, *supra* note 25. As part of its “deregulatory agenda,” the Trump Administration has urged agencies to “bolster, streamline, and speed . . . the deregulation of facially unlawful prior government regulations.” 2025 OIRA MEMORANDUM, *supra* note 1, at 1.

The regulated parties argued first and foremost that LDTs are not “devices” as defined by the FDCA, thus the FDA has no authority to regulate them as such.⁵⁸ Instead, they characterized LDTs as complex “services” performed by health professionals inside labs, more akin to a surgery than a simple blood test.⁵⁹ They also pointed to the structure of the Act, which requires “device[s]” to be “held for sale.”⁶⁰ Next, they argued that the Clinical Laboratory Improvement Amendments Act (CLIA) gives another agency—the Centers for Medicare and Medicaid Services (CMS)—jurisdiction to regulate LDTs, making it unlikely that Congress intended for the FDA to engage in duplicative work.⁶¹ Finally, the regulated parties contended that, if the statutory argument is not air tight, this is precisely the type of case that warrants application of the major questions doctrine—namely, an instance in which an agency discovers in a “long-extant statute” the apparent power to regulate large swaths of the economy.⁶²

The FDA—and ultimately, the judge—shared the regulated parties’ focus on statutory authority. In the FDA’s motion for summary judgment, the statutory issue has pride of place as the first point raised, followed by CLIA displacement, major question/rule of lenity, and finally (last and perhaps least), arbitrary and capricious.⁶³ In its memorandum (reaching fifty-one pages), the FDA dedicates a mere two-and-a-half pages to arbitrary and capricious, as a kind of afterthought to the body addressing the statutory question.⁶⁴ Tracking this allocation, in oral arguments, the agency spent only several minutes of a two-hour-plus hearing on arbitrary and capricious review.⁶⁵ The plaintiffs likewise devote little written space or oral argument

One part of this strategy implicates the major questions doctrine:

Another example of a facially unlawful regulation is where a rule violates the major questions doctrine explicated in *West Virginia v. EPA*. The major questions doctrine requires especially clear statutory text delegating authority to an agency the power to issue a rule in an area of vast economic and political significance before an agency can plausibly claim such authority. Hence, an agency concluding that it has current regulations on its books rooted in statutory ambiguity but which resolve questions of that high a level of significance can act to immediately repeal such regulations because they flunk the major questions doctrine.

Id. at 6 (citations omitted).

58. *ACLA Complaint*, *supra* note 25, at 54–55.

59. *Id.* at 12.

60. *Id.* at 18.

61. *Id.* at 21–23.

62. *Id.* at 56 (quoting *West Virginia v. EPA*, 597 U.S. 697, 724 (2022)).

63. *FDA Brief*, *supra* note 35, at 2–4.

64. *See id.* at 48–50 (the only section covering arbitrary and capricious review).

65. Transcript of Hearing, *Am. Clinical Lab’y Ass’n v. FDA*, 776 F. Supp. 3d 554 (E.D. Tex. 2025) (No. 4:24-CV-479).

time on the issue, clearly dwarfed by the statutory issue. The weight the parties gave to the issues also aligned with the judge's view, as he asked no questions on the arbitrary and capricious segments of oral arguments, while being quite engaged during the statutory interpretation part.⁶⁶

It is thus unsurprising that the court treated the case as raising a purely statutory interpretation question. The court granted the plaintiffs' motion for summary judgment, holding that LDTs are not devices under the FDCA.⁶⁷ After deciding the statutory issue, the court declined to pass judgment on the arbitrary and capricious claim.⁶⁸

Setting the standard of review, the court cites *Loper Bright* for the proposition that courts "must exercise their independent judgment in deciding whether an agency has acted within its statutory authority" and that doing so requires the use of the tools of statutory interpretation to arrive at the best reading of a statute.⁶⁹ "And when there is an ambiguity 'about the scope of an agency's own power,'" the court continues, "abdication in favor of the agency is *least* appropriate."⁷⁰

To arrive at its independently derived "best reading," the court carries out a textbook illustration of modern textual analysis. First, with the help of a dictionary, the court finds that the ordinary meaning of "device" contemplates only physical objects.⁷¹ Second, the court applies several canons of statutory interpretation.⁷² The FDCA definition of "devices" includes six examples ("instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent")⁷³ and a catch-all term, which the court decides, based on *ejusdem generis*, must only include physical things, rejecting the FDA's argument that LDTs are apparatuses.⁷⁴ Third, the court turns to other provisions within the FDCA, noting that several "are triggered only when a device is shipped or received in interstate commerce, commercially distributed, or held for sale—actions that, in ordinary parlance, can be performed on a manufactured product but not on a professional service."⁷⁵ Fourth, the court agrees with the plaintiffs' view that, by enacting CLIA, Congress delegated to CMS, not the FDA, the authority to regulate LDTs, as part of its role in

66. *Id.*

67. *ACLA*, 776 F. Supp. 3d at 554.

68. *Id.*

69. *Id.* at 573 (citing *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2273 (2024)).

70. *Id.* at 574 (citing *Loper Bright*, 144 S. Ct. at 2266).

71. *Id.* at 575.

72. *See id.* at 576 (analyzing both the dictionary definition of "device" and the common industry understanding of the word).

73. 21 U.S.C. § 321(h).

74. *ACLA*, 776 F. Supp. 3d at 577–78 (applying the *ejusdem generis* and *noscitur a sociis* canons).

75. *Id.* at 580.

certifying clinical laboratories.⁷⁶ Fifth and finally, the court notes that Congress has tried but failed to regulate this area.⁷⁷ The proposed VALID Act and Vital Act, both of 2020, failed to garner sufficient support.⁷⁸

Finally, in a mere footnote, the court rejects the FDA's claim that IVDs were considered devices as far back as 1973.⁷⁹ Under *Loper Bright* and *Skidmore*, such longstanding interpretation should afford the agency "respect." However, the court never cites *Skidmore* and, in any event, refuses to accept that the FDA even made such an interpretation in 1973.⁸⁰

2. *Arbitrary and Capricious*

Throughout the rulemaking process, the FDA maintained that, even if the evidence regarding LDTs was not the most robust, it was sufficient to warrant the rule. Recall, as outlined above, that the FDA's main rationale for the rule and the argument underlying its defensive strategy was that circumstances have changed in the medical testing world, such that it no longer makes sense to exercise enforcement discretion exempting LDTs, which pose risks to public health.

According to the FDA, there are enough different types of evidence pointing in the same direction to create an "overall picture" that suggests that LDTs need FDA oversight.⁸¹ Given that the judge declined to rule on the arbitrary and capricious challenge, we have no indication of how such an "agency-skeptical" judge would have viewed the evidentiary record.⁸² Below, we take on this review ourselves, assessing the agency's reasoned decisionmaking—or lack thereof—to see whether it would pass muster under *State Farm* "hard look" review.⁸³ Here, we unearth the FDA's justifications presented in the challenged rule before the court.

In both its Proposed and Final Rules, the FDA pointed to five main sources of evidence that LDTs imperil public health and thus need to be regulated: (1) scientific literature; (2) FDA experience; (3) complaints to the FDA; (4) news reports; and (5) lawsuits. The core of the FDA's evidence was a

76. *Id.* at 581.

77. *Id.* at 582.

78. *Id.* at 567–68.

79. *Id.* at 564–65 nn.3 & 5.

80. *See id.*

81. FDA Brief, *supra* note 35, at 8–9.

82. *ACLA*, 776 F. Supp. 3d at 554.

83. *See infra* Part II.C.

group of six peer-reviewed scientific articles.⁸⁴ The FDA identified four studies from the three years preceding the Proposed Rule (October 2023) that show high variability in LDTs.⁸⁵ These studies show varying results from different labs offering IVDs as LDTs and observe high rates of false positives.⁸⁶ The Proposed Rule also mentioned a 2016 article from the *New England Journal of Medicine*, which finds false positives in LDTs for certain heart conditions when used for Black patients.⁸⁷ Finally, an article from 2023 recounted an oncologist's experience with incorrect results from a multi-cancer, blood-based LDT.⁸⁸ Based on these studies, the FDA concluded that there was enough variability in the results from LDTs regarding health conditions to justify subjecting them to FDA oversight.⁸⁹

The FDA had previously released a 2015 report of twenty case studies (including the infamous Therasys blood test) involving unsafe or inaccurate LDTs and has issued several communications about specific types of tests, such as pharmacogenetic, non-invasive prenatal screening, and ovarian cancer screening.⁹⁰ The FDA also referenced its own experience with LDTs on the basis of some premarket approval requests submitted on a voluntary basis.⁹¹ The agency observed that “many laboratories fail to perform appropriate or adequate validation studies, have data demonstrating their test does not work as intended but offer the test anyway, or use instruments and other components that are not adequately controlled for clinical use.”⁹² The FDA conceded that this evidence is inherently limited since the prior enforcement regime did not mandate comprehensive validation of LDTs.⁹³ The emergency testing landscape provided further evidence, as enforcement discretion has not applied to IVDs under Emergency Use Authorization (EUA).⁹⁴ In

84. Medical Devices; Laboratory Developed Tests, 88 Fed. Reg. 68,006, 68,010–11 (Oct. 3, 2023) (to be codified at 21 C.F.R. pt. 809); *see* Medical Devices; Laboratory Developed Tests, 89 Fed. Reg. 37,286 (May 6, 2024) (to be codified at 21 C.F.R. pt. 809).

85. Medical Devices; Laboratory Developed Tests, 88 Fed. Reg. at 68,010–11.

86. *Id.* One of the cited articles is Sharkey et al., *DTC Genetic Testing*, *supra* note 44.

87. Medical Devices; Laboratory Developed Tests, 88 Fed. Reg. at 68,011 (citing Arjun K. Manrai, Birgit H. Funke, Heidi L. Rehm, Morten S. Olesen, Bradley A. Maron, Peter Szolovits, et al., *Genetic Misdiagnoses and the Potential for Health Disparities*, 375 *NEW ENG. J. MED.* 655 (2016)).

88. *Id.* (citing Donavyn Coffey, *Blood Test Positive for Cancer, but Is There Really a Tumor?*, *MEDSCAPE* (Feb. 23, 2023), <https://www.medscape.com/viewarticle/988431> [<https://perma.cc/7VMZ-A674>]).

89. *Id.* at 68,011–12.

90. *Id.* at 68,012.

91. *Id.* at 68,011.

92. *Id.*

93. *See id.*

94. *Id.*

the first round of COVID-19 requests for EUA, out of 125 tests, 82 had design or validation problems.⁹⁵

The FDA has received many complaints about problems with LDTs, especially those purporting to screen for cancer and prenatal screening tests.⁹⁶ The agency has not confirmed the veracity of all of these.⁹⁷ The FDA argued that “collectively, this information, though anecdotal, points to potential problems among IVDs offered as LDTs, the scope and scale of which FDA cannot fully assess or address without phasing out the general enforcement discretion.”⁹⁸

The agency also cited seven news articles and concerns from the general public about LDTs.⁹⁹ The *New York Times* published an article stating that prenatal screening tests were wrong 85% of the time.¹⁰⁰ As the agency conceded, these are screening tests, which should be confirmed by additional testing.¹⁰¹ However, the article mentioned that providers had been making decisions based on the screening test alone.¹⁰² The agency also noted the cost of further testing due to erroneous initial results.¹⁰³ Finally, the FDA pointed to several lawsuits filed against labs that offer LDTs, alleging misleading claims of efficacy of pharmacogenetic tests, which are used to determine drug selection.¹⁰⁴

The Final Regulatory Impact Analysis (RIA) provided estimates of the rule’s costs and benefits.¹⁰⁵ The analysis estimated the total number of labs

95. *Id.*

96. *Id.* at 68,011–12.

97. *Id.* at 68,011 n.10.

98. *Id.* at 68,012.

99. *Id.*

100. Sarah Kliff & Aatish Bhatia, *When They Warn of Rare Disorders, These Prenatal Tests Are Usually Wrong*, N.Y. TIMES (Jan. 1, 2022), <https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html> [<https://perma.cc/B3X3-3CGW>].

101. Medical Devices; Laboratory Developed Tests, 88 Fed. Reg. at 68,012.

102. Kliff & Bhatia, *supra* note 100.

103. Medical Devices; Laboratory Developed Tests, 88 Fed. Reg. at 68,012.

104. *Id.*

105. FDA, DOCKET NO. FDA-2023-N-2177 LABORATORY DEVELOPED TESTS FINAL RULE: FINAL REGULATORY IMPACT ANALYSIS (2024) [hereinafter RIA]. As for the need for the rule, the RIA mentions the same studies and articles from the Proposed Rule, without adding more. *See id.* at 40–45. It also makes a “cheapest-cost-avoider” argument in justifying the rule, noting that while patients and doctors could, in theory, figure out which LDTs are problematic, that would not only be time-consuming, but also difficult given their lack of information. *See id.* at 43–44. Patients, it continues, should not have to internalize the risk, because they may be unable to distinguish between FDA-approved IVDs and IVDs offered as LDTs. *See id.* at 43–45. The FDA is much better positioned to regulate and monitor the tests. *See id.* at 43. Additionally, the RIA argues that the current different treatment of IVDs and LDTs creates market distortion and social costs, further justifying the rule to make enforcement consistent. *Id.* at 45.

(11,808), the percentage of labs offering IVDs as LDTs (10%), the average number of LDTs per lab (67), and the percentage of LDTs that are problematic (47%).¹⁰⁶ The estimate assumes that only 50% of LDTs will need pre-market review, based on the various enforcement discretion categories.¹⁰⁷

In the Proposed Rule, costs are \$5.87 billion and benefits are \$31.41 billion,¹⁰⁸ while in the Final Rule, costs are \$1.29 billion and benefits are \$3.51 billion.¹⁰⁹ The quantified health benefits are avoidance of harm from diagnostic errors and future use of problematic LDTs during public health emergencies (like COVID-19).¹¹⁰ Due to data limitations, the FDA only quantifies health benefits from misdiagnosis of cancer, heart disease, and infections but expects that adding others would increase the total benefits of the rule.¹¹¹

106. *Id.* at 10–15.

107. *Id.* at 21.

108. Medical Devices; Laboratory Developed Tests, 88 Fed. Reg. at 68,008.

109. Medical Devices; Laboratory Developed Tests, 89 Fed. Reg. 37,286, 37,287 (May 6, 2024) (to be codified at 21 C.F.R. pt. 809). The costs are significantly lower in the final RIA due to enforcement discretion. *See* RIA, *supra* note 105, at 7. The one-time compliance costs show the largest difference because of the decision not to enforce against currently marketed tests. *See id.* at 23. In the preliminary RIA, the primary estimate of one-time costs is \$35.54 billion, while in the final RIA, it is \$32.57 million, over 100 times lower. *See id.* at 97; FDA, DOCKET NO. FDA-2023-N-2177 LABORATORY DEVELOPED TESTS PROPOSED RULE: PRELIMINARY REGULATORY IMPACT ANALYSIS 85 (2023) [hereinafter PRELIMINARY RIA]. The AMP points this out in their summary judgment motion, calling the enforcement discretion “illusory” and suggesting it is a ploy to make costs appear smaller on paper. Ass’n for Molecular Pathology Motion for Summary Judgment at 20, *Am. Clinical Lab’y Ass’n v. FDA*, 776 F. Supp. 3d 554 (2025) (No. 4:24-CV-479). Even though the FDA could still technically enforce against the exempted LDTs under the rule, AMP gives no reason to believe the FDA would do so. *See id.* After all, enforcement discretion was the only thing keeping the FDA from enforcing against LDTs before the rule. *See id.*

The reason benefits decrease disproportionately is that the final RIA considers both the new enforcement discretion and an adjustment in response to comments, changing the estimated percentage of IVDs offered as LDTs from 50% to 10%. RIA, *supra* note 105, at 13–14. As the RIA notes, this “reduces estimated benefits by a factor of five.” *Id.* The enforcement discretion reduces benefits by a factor of around two, resulting in a combined reduction by a factor of approximately 10 (\$31 billion to \$3.5 billion). *Id.* at 90; PRELIMINARY RIA, *supra* note 109, at 97. The costs are only changed by the newly added enforcement discretion categories, which account for the entire four-fold decrease. *See* RIA, *supra* note 105, at 7–8, 37–38, 91–92. Note that without the adjustment in percentage of IVDs offered as LDTs, the costs fall proportionately more than the benefits as a result of the enforcement discretion (factor of four vs. factor of two, respectively).

110. *See* RIA, *supra* note 105, at 88; Medical Devices; Laboratory Developed Tests, 89 Fed. Reg. at 37,287.

111. *See* RIA, *supra* note 105, at 57.

In the Final Rule, the FDA responded to several comments about the sufficiency of the data presented in the Proposed Rule. One comment claimed that phasing out a general enforcement discretion approach, like the FDA proposed, requires that the data “cross a predetermined threshold for action.”¹¹² The FDA responded that no such requirement exists in the law.¹¹³ Some comments noted that the FDA left out of the Proposed Rule several examples of high-quality genetic LDTs.¹¹⁴ The comments provided seven peer-reviewed publications that reviewed accurate results in LDTs.¹¹⁵ The FDA responded that the presence of accurate LDTs does not negate the existence of problematic ones.¹¹⁶ Additionally, these studies used proficiency testing which, according to the FDA, does not establish clinical or analytical validity.¹¹⁷ Here, the FDA engaged deeply with the methodology of the cited studies, pointing to several flaws and questioning their results.¹¹⁸

Finally, several comments urged that the FDA needed more evidence, calling the existing evidence anecdotal.¹¹⁹ One comment requested “evidence of multiple, conclusive, high-quality studies that show . . . that errors in laboratory testing are a pervasive and particularly dangerous problem.”¹²⁰ In response, the FDA reiterated that it “does not take the position that all IVDs offered as LDTs are problematic, but the collective evidence, including anecdotal evidence, regarding certain IVDs offered as LDTs is of significant concern, especially given there is no consistent reporting of adverse events.”¹²¹ The data covers a wide enough range that the FDA considered it to be representative.¹²² The agency also disagreed with the notion that it must have “multiple, conclusive, high-quality studies,” citing *FCC v. Prometheus*¹²³ for the proposition that the APA creates no duty for agencies to conduct their own empirical studies.¹²⁴ In sum, the FDA argued that it had “made a reasonable predictive judgment based on the evidence it ha[d].”¹²⁵

112. Medical Devices; Laboratory Developed Tests, 89 Fed. Reg. at 37,365.

113. *Id.*

114. *Id.* at 37,322.

115. *Id.*

116. *Id.*

117. *Id.* at 37,319.

118. *Id.* at 37,322–24.

119. *Id.* at 37,321.

120. *Id.*

121. *Id.* at 37,322.

122. *Id.* at 37,321.

123. 141 S. Ct. 1150 (2021).

124. Medical Devices; Laboratory Developed Tests, 89 Fed. Reg. at 37,322.

125. *Id.* (quoting *Prometheus*, 141 S. Ct. at 1160).

C. *What the Case Tells Us*

The LDT case offers a few lessons about the current—and future—state of judicial review of agency action.

First and foremost, it shows that statutory interpretation and reasoned decisionmaking analysis are not fully separable. In an opinion claiming to be purely statutory, the court considers the comparative advantages of different agencies, the costs of the rule, and its effects on reliance interests—all hallmarks of *State Farm* analysis.¹²⁶

Second, the case presents a statutory interpretation question with no “single, best meaning” per *Loper Bright*.¹²⁷ Both the FDA and the laboratory plaintiffs offer plausible definitions of the statutory meaning of “device.” Under the prior *Chevron* regime, a court facing two plausible interpretations would have deferred to the agency.¹²⁸ But now, the court is free to come to its own interpretation and reject the agency’s view. That is exactly what the judge does here, using dictionaries, canons, and other statutory provisions to decide whether an LDT—something the court necessarily understands far less well than the parties¹²⁹—is a device.¹³⁰ While the court engages in surface-level policy considerations, under the guise of congressional intent, what is missing from its determination is any meaningful engagement with the evidentiary record, consideration of the cost-benefit analysis, or understanding of the FDA’s role as an expert agency tasked with regulating a highly complex and technical industry.¹³¹ Rather, the court upholds an attack on the FDA’s authority to regulate tests that have demonstrated problems, implicating risks to public health.¹³²

126. See *supra* Parts I.B.1 & I.B.2.

127. *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2266 (2024).

128. *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–45 (1984).

129. Tellingly, the judge began the hearing by asking both sides to explain what an LDT is. Transcript of Hearing at 37–39, *Am. Clinical Lab’y Ass’n v. FDA*, 776 F. Supp. 3d 554 (E.D. Tex. 2025) (No. 4:24-CV-479).

130. While *Loper Bright* certainly enables this result—especially given its language of “independent judgment,” which the reviewing court emphasizes several times—it does not mandate it. Indeed, the *ACLA* court construes *Loper Bright* as a stronger anti-agency opinion than it truly is. For example, where the *Loper Bright* court speculates (in dicta) that instances of statutory ambiguity as to the agency’s own power are “*perhaps* the occasion on which abdication in favor of the agency is *least* appropriate,” *Loper Bright*, 144 S. Ct. at 2266 (first emphasis added), the *ACLA* court reformulates the language as a definitive standard, notably omitting the key word “perhaps.” See *supra* note 70 and accompanying text.

131. Sharkey & Kenny, *FDA Leads*, *supra* note 10, at 162 (noting that courts have tended to defer to the FDA’s scientific expertise).

132. *ACLA*, 776 F. Supp. 3d at 554.

The first lesson regarding the inextricable link between statutory interpretation and reasoned decisionmaking may at first seem paradoxical. Indeed, one of the notable features of the LDT case is that it looks enough like a straightforward statutory interpretation case that the court is willing—or perhaps more accurately, tempted—to treat it like one. As the district court judge framed the issue, the question was simply whether LDTs fit within the statutory definition of “device,” as considered by a judge, not the expert agency.¹³³ This is the prototypical case that the Supreme Court had in mind when it decided *Chevron* and again when it overruled *Chevron* in *Loper Bright*.¹³⁴

Does the LDT case validate the Supreme Court’s understanding of laws as containing simple terms amenable to interpretation by judges? This seems to be the position of the parties and the judge who focus their attention on the statutory issue. It was easy enough for the court to use a dictionary, some canons, and other statutory considerations to arrive at a seemingly text-based interpretation. But, upon closer inspection, that is not the full picture of how the case was decided. To the contrary, the decision reads like the final proclamation in a policy debate, considering costs and reliance interests in a decision that nonetheless purports to eschew the arbitrary and capricious question.¹³⁵ In other words, while the question “what is a device?” might at first appear to be narrow, it is actually part of a larger discussion of which medical products (and/or services) are regulated, by whom, and why. That debate, however, would require sustained engagement with the evidence, something the court declined to do.

Within the core statutory interpretation question resides a *policy* question about which agency is best suited to regulate LDTs. The FDA repeatedly argued that while CMS checks for analytical validity—“the accuracy and reliability with which the test system detects or measures the *analyte* that it is supposed to detect or measure”—only the FDA considers clinical validity—“the accuracy and reliability with which it identifies, measures, or predicts the presence or absence of a *clinical condition or predisposition* in a patient.”¹³⁶ Put more simply, analytical validity is satisfied when a test detects the

133. *See id.* at 574.

134. Edward L. Rubin, *Chevron Was Not, and Cannot Be, Overruled: The Dullness of Loper Bright*, 20 DUKE J. CONST. L. & PUB. POL’Y 31, 97–98 (2025).

135. Cost-benefit analysis and consideration of reliance interests are two typical hallmarks of reasoned decisionmaking. *See* Cass R. Sunstein, *Cost-Benefit Analysis and Arbitrariness Review*, 41 HARV. ENV’T L. REV. 1, 4 (2017) (noting that an agency’s failure to consider costs and benefits goes to the issue of whether the agency has acted arbitrarily); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515–16 (2009) (asserting that consideration of reliance interests is a component of arbitrary and capricious review).

136. FDA Brief, *supra* note 35, at 36–37 (emphasis added).

substance, but clinical validity considers whether that substance is worth testing for and whether it accurately predicts a medical condition. This distinction is significant, as scholars have pointed to evidence indicating increased marketing of tests that are analytically valid but not reliably associated with any medical condition.¹³⁷ In oral arguments, there were several exchanges about the analytical/clinical distinction, but the issue does not appear in the decision.¹³⁸ What does appear is a strong assertion that the “division of labor” between the FDA and CMS, wherein the former regulates medical devices and the latter regulates laboratories, has worked well for many decades and ought to continue.¹³⁹

The court also faults the FDA for failing to properly consider the “countless business decisions affecting the landscape of the U.S. health care system” [that] have been made in reliance on the prior regulatory regime.”¹⁴⁰ For the court, the magnitude of reliance interests is significant: “the new requirements will initially affect about 79,114 existing tests offered by 1,181 existing laboratories.”¹⁴¹ And the total costs over the next two decades could be as high as \$79 billion.¹⁴²

This entire line of inquiry would make sense if the question were whether the FDA *should* regulate LDTs. However, the decision is confined to the question of whether the FDA has the statutory authority to regulate LDTs. The district court judge squares this circle by framing the entire CMS question as one of congressional intent: Congress does not grant duplicative authority, so LDTs must be outside the FDA’s statutory authority.¹⁴³ This pseudo-policy analysis, however, lacks the depth and rigor one would expect in a decision grounded explicitly in arbitrary and capricious review.

The court also notes that the FDA’s longstanding authority argument, which the court describes as “far-fetched,”¹⁴⁴ would mean that labs have been breaking the law for decades, saved only by the grace of FDA enforcement discretion.¹⁴⁵ Making much of the fact that the FDCA carries criminal as well as civil penalties, the court describes as “implausible” the position that

137. Sharkey et al., *DTC Genetic Testing*, *supra* note 44, at 280.

138. Transcript of Hearing at 53–55, 92–94, *Am. Clinical Lab’y Ass’n v. FDA*, 776 F. Supp. 3d 554 (E.D. Tex. 2025) (No. 4:24-CV-479). This absence is a reminder that the decision eschewed policy grounds, as any policy-based decision would surely have to wrestle with this distinction.

139. *See ACLA*, 776 F. Supp. 3d at 574.

140. *Id.* at 570 (quoting Comment of *ACLA*, FDA2177-6369 at 71).

141. *Id.*

142. *Id.* at 570–71.

143. *Id.* at 562–63.

144. *Id.* at 565 n.5.

145. *Id.* at 583.

only agency discretion has stood between thousands of medical professionals and criminal sanction.¹⁴⁶ Again, to us, this sounds like a policy argument about reliance interests and the danger of leaning too heavily on enforcement discretion, but the district court judge insists that such an irrational result speaks only to congressional intent and against the FDA's reading of the statute. The implausibility argument, however, is "extra icing on a cake already frosted," according to the district court judge,¹⁴⁷ lest anyone accuse him of grounding the decision in something beyond the text.

In sum, what the decision striking down the rule demonstrates to us, then, is that even a committed textualist judge cannot help himself from venturing into the policy realm.¹⁴⁸

Our core position—elaborated in the Parts that follow—is that courts, in deciding cases like the LDT challenge, should pay heed to the interplay between an agency's reasoned decisionmaking and the court's statutory interpretation. The domain of "pure or abstract questions of law,"¹⁴⁹ divorced entirely from policy considerations, comprises a narrow subset of statutory interpretation questions. Where a statutory term is susceptible to multiple plausible interpretations (i.e., there is no "single, best meaning"), it is preferable as a matter of good governance that the court should come to its decision on the fate of the agency's action based on scientific evidence, not a

146. *Id.*

147. *Id.* (quoting *Yates v. United States*, 574 U.S. 528, 557 (2015) (Kagan, J., dissenting)).

148. As Professor Edward Rubin has pointed out, modern statutes tend to give instructions rather than normative declarations. Rubin, *supra* note 134, at 32. For example, in *Loper Bright*, the issue was whether the National Marine Fisheries Service (NMFS) could make fishing boats pay for on-board monitors, a question for which the statute likely yields a "best interpretation." See *id.* at 52–53. But what about the NMFS's decision to create eight regional fishery councils, rather than six or ten? No court can come to its own "interpretation" of the authorizing law, at least not without delving into policy-heavy considerations. According to Rubin, this latter form of instruction dominates modern administrative statutes, making the Supreme Court's entire premise—whether favoring judicial deference or not—a flawed conception of how agencies interpret laws. *Id.*

Professor Stephenson likewise agrees that rigid adherence to the view that "the usual tools in the textualist toolkit—language, structure, semantic context, and the like—really can and do produce determinate answers . . . will simply not be true." Stephenson, *supra* note 15, at 179. Moreover, such an approach "invites judges to smuggle in policy arguments or purposive considerations disguised as textual analysis." *Id.* We heartily agree; that is exactly what happened in the LDT case. But we are not persuaded by Stephenson's position that limits this concern to "factbound line-drawing questions that the *Gray* doctrine would leave to agencies." *Id.* We see no reason why the same concern would not apply, for example, to the court's determination of whether LDTs constitute "devices."

149. *Id.* at 136.

dictionary. Within our proposed framework, a version of *State Farm* analysis—namely policy considerations—can and should be the deciding factor when a term is textually ambiguous. Moreover, in many cases (including the LDT one), a court’s engagement in *State Farm* review of the evidence, rationale, and response to comments presents a viable alternative to negating the agency’s ability to regulate at all.

II. THE ROAD NOT TAKEN: REINVIGORATED “HARD LOOK” REVIEW

The LDT case highlights many of the contradictions and ambiguities that characterize the current state of administrative law. The court made an essentially policy-based decision, while insisting it was instead grounded in statutory text. At the same time, the court declined to examine the scientific record evidence that would undergird the reasonableness of its policy decision. An expert agency was forced into a position of fighting over dictionary definitions and canons of interpretation, while the decision revealed nothing about the scientific basis for regulating a new form of tests that pose medical health risks. This unsatisfactory outcome foreshadows two viable options as administrative law moves forward: a “brave new world” of vigorous challenges to agencies—who are accorded less deference by reviewing courts—rote dictionary analysis, and judicial forays into policy under the guise of congressional intent *or* a regime that allows agencies to double down on policymaking rationales and lets courts engage with the evidentiary basis for those rationales.

This Part considers the road not (yet) taken: a regime of reinvigorated *State Farm* review, wherein agencies face heightened scrutiny of the reasonableness of their policy-based decision and the level of deference turns on the result of that inquiry.¹⁵⁰ The court’s move in the LDT case—to consider questions of cost, reasonableness, and comparative agency expertise but couch its inquiry in statutory terms under the guise of congressional intent—shows the futility of forced separation of statutory interpretation and policymaking.¹⁵¹ The

150. Cf. Catherine M. Sharkey, *State Farm “with Teeth”: Heightened Judicial Review in the Absence of Executive Oversight*, 89 N.Y.U. L. REV. 1589, 1606 (2014) [hereinafter Sharkey, *State Farm*] (proposing a reinvigorated *State Farm* standard under which the stringency of hard look review of fact-based agency actions would turn on whether those determinations had been subject to cost-benefit review by the Office of Information and Regulatory Affairs within Office of Management and Budget).

151. Indeed, Justice Scalia made a similar move in *Riegel v. Medtronic*, where he considered whether exempting common law duties from statutory preemption made sense. 552 U.S. 312 (2008). After carrying out what looks like a policy-based comparison of jury-determined tort liability and regulation by agency, he concludes that agency regulation is preferable due to its ability to consider costs and benefits in the aggregate. *See id.* at 325. The greater sensibility of agency regulation, he insists, speaks merely to congressional intent. *See id.*

sleight of hand is fooling no one. If courts necessarily consider policy matters when interpreting statutes, they should do so openly, albeit with a higher bar for meeting the judicial standard of review.

We propose a sliding scale of respect for the agency's interpretation: the more the interpretation departs from the ordinary meaning, the more evidence would be needed to support that interpretation. We encourage courts to lean into their seemingly natural inclination to consider policy rationales and use that policy dimension to decide between potential interpretations, ensuring that the rules that survive challenge are sound policy ideas.

A regime of combined (heightened) reasonableness review and statutory interpretation is preferable on both descriptive and normative grounds. As a descriptive matter, this combination was reality for much of common law history. Recent caselaw suggests that the merger never really collapsed. Instead, judges jumped through hoops to confine their decision to one side of the separation, even while necessarily considering both. As a normative matter, a combined regime is more attuned to the comparative expertise of courts and agencies and helps ensure that only well-justified policies become law.

We argue that *Loper Bright* enables this regime of sliding-scale respect for the agency's interpretation by moving beyond *Chevron*'s fixed level of deference and allowing the court to consider how persuasive the agency's view is under *Skidmore*. Our framework, moreover, incorporates *State Farm* review into the court's analysis at each of *Loper Bright*'s two prongs: If the court comes to the "best reading" of the statute with the aid of *Skidmore*, the *State Farm* analysis becomes one of the "power to persuade" factors under *Skidmore*.¹⁵² Alternatively, if the court decides that the statute delegates discretionary interpretive authority to the agency, the court would review for reasoned decisionmaking under a heightened *State Farm* standard.

A. A Reinigorated *State Farm* "Hard Look" Review

In 2018, one of us advocated for the incorporation of *State Farm* "hard look" review into Step Two of *Chevron*.¹⁵³ The article noted that traditionally,

152. Contrary to the Court's assertion in *Loper Bright* that the issue is purely statutory, we contend that the question of the "best" interpretation of a statute is often infused with policy-based determinations. As exemplified by the district court decision in the LDT case, *see supra* text accompanying notes 65–75, 117–120, courts sometimes make such policy-based determinations *sub rosa* (under the guise of congressional intent). Our proposal instead seeks to bring such determinations into the open, where relevant policy-based input from the underlying regulatory agency is considered and subject to judicial review, enabling courts, agencies, and the public to know whether an agency rule constitutes sound policy.

153. Catherine M. Sharkey, *Cutting in on the Chevron Two-Step*, 86 FORDHAM L. REV. 2359, 2367 (2018) [hereinafter Sharkey, *Cutting in on Chevron*].

there has been an “acoustic separation” between *Chevron* and *State Farm* that pervades legal academia and practice.¹⁵⁴ Courts nonetheless observed the analytical similarities between arbitrary and capricious review and Step Two of *Chevron* and, at times, blended the two in practice.¹⁵⁵ While many scholars have called for courts to clarify or refine the relationship between the two issues,¹⁵⁶ we advocate an embrace of the overlap in the form of a new administrative law framework that places greater emphasis on policy matters. Agencies must often choose between equally plausible interpretations of a statute, so policy considerations become the deciding factor. Under our proposed framework, judicial deference depends on the quality of the policy decision: an agency does not deserve deference for its resolution of ambiguities unless it can articulate a *policy* basis for that resolution that can meet the standards of *State Farm*. This does not mean the ordinary *State Farm* standards, which have often come to mean a reflexive deference to the agency; rather, the framework includes a stronger reinvigorated *State Farm* standard that looks meaningfully into the agency’s rationale for the decision.¹⁵⁷

We offer two main justifications for our approach. First, under the rationale of comparative institutional competency—one of the original motivations of the *Chevron* decision—the reason to defer to agencies is that filling in statutory gaps requires policymaking expertise.¹⁵⁸ However, if the agency has not provided empirical backing for its policy-based rationale for an interpretive position, there is no reason to defer to the agency’s interpretation. An agency must effectively utilize its comparative expertise to merit the deference based on such expertise.

Second, by incorporating hard look *State Farm* review into the statutory interpretation analysis, courts ensure that agencies engage in reasoned

154. *Id.* at 2377–79. See *infra* notes 166–170 and accompanying text for a historical account.

155. Sharkey, *Cutting in on Chevron*, *supra* note 153, at 2390–91 (first citing *Judulang v. Holder*, 565 U.S. 42, 52 (2011); and then citing *Pharm. Rsch. & Mfrs. of Am. v. FTC*, 790 F.3d 198, 204 (D.C. Cir. 2015)); Leo Rassieur, *Characterizing Agency Determinations After Loper Bright*, 18 NYU J.L. & LIBERTY 273, 313 (2025) (finding empirically that lower courts tend to apply both standards but fail to explain the difference).

156. Among the most prominent are Ronald Levin and Mark Seidenfeld. See Ronald M. Levin, *The Anatomy of Chevron: Step Two Reconsidered*, 72 CHI.-KENT L. REV. 1253, 1254 (1997) (observing that the DC Circuit has recognized an “overlap” between *Chevron* Step Two and the arbitrary and capricious standard but has struggled to define their respective domains, and proposing that the two tests be treated as identical); Mark Seidenfeld, *A Syncopated Chevron: Emphasizing Reasoned Decisionmaking in Reviewing Agency Interpretations of Statutes*, 73 TEX. L. REV. 83, 127 (1994).

157. See Sharkey, *Cutting in on Chevron*, *supra* note 153, at 2407.

158. *Id.* at 2363–64.

decisionmaking.¹⁵⁹ This provides a bulwark against outcomes like that in *Catskill Mountains Chapter of Trout Unlimited, Inc. v. EPA*,¹⁶⁰ a Second Circuit decision decided under the *Chevron* regime. For several decades, EPA had held its controversial “unitary waters” reading of the Clean Water Act, which meant that water transfers did not count as discharges and were not subject to certain permitting requirements.¹⁶¹ After facing several successful challenges to this interpretation—including two instances of the Second Circuit ruling against EPA—the agency decided to formalize its interpretation via notice-and-comment rulemaking.¹⁶² Thereafter, the Second Circuit applied *Chevron* deference and upheld the interpretation, despite having struck down the same interpretation previously.¹⁶³ So what explains the judicial turnabout? Informal notice-and-comment rulemaking entitled EPA to deference whereas its prior internal interpretation guidance had not, so the agency was able to squeak by on a slim evidentiary record.¹⁶⁴ By contrast, our framework is designed to produce sounder policy decisions and ensure that judicial review moves agencies in that direction by leveraging their comparative expertise.

From a historical perspective, any modern attempt to cleanly separate statutory authority from reasoned decisionmaking—or law from fact—appears misguided. Arbitrary and capricious review has always been part of review of statutory authority, or *ultra vires*.¹⁶⁵ Professor Alexander Mechanick argues that the distinction modern lawyers and scholars draw between arbitrary and capricious and contrary-to-statute is unfounded historically.¹⁶⁶ As Mechanick shows, arbitrary and capricious review is not a creation of modern administrative law.¹⁶⁷ He traces the origins of such review back to common law courts in England, where agents of governments—such as sewer commissioners—were granted statutory authority to carry out tasks on behalf of the government.¹⁶⁸ The grant

159. *Id.*

160. 846 F.3d 492 (2d Cir. 2017).

161. *Id.* at 503–05.

162. *Id.* at 504.

163. *Id.* at 501.

164. Catherine M. Sharkey, *Catskill Mountains: A Spotlight on the Problem of Judicial Acquiescence to Agency Statutory Interpretations, and the Chevron–State Farm Solution*, HARV. L. REV. BLOG (Dec. 4, 2017) [hereinafter Sharkey, *Catskill Mountains*], <https://harvardlawreview.org/blog/2017/12/catskill-mountains-a-spotlight-on-the-problem-of-judicial-acquiescence-to-agency-statutory-interpretations-and-the-chevron-state-farm-solution/> [https://perma.cc/Y4NC-CXZ4].

165. See Alexander Mechanick, *The Interpretive Foundations of Arbitrary or Capricious Review*, 111 KY. L.J. 477, 528 (2023).

166. See *id.* at 481–82.

167. See *id.* at 484–87.

168. *Id.* at 485.

of authority was conditioned upon the agents being subject to arbitrary and capricious review.¹⁶⁹ Older common law courts viewed that “[i]mplicit in vesting an agent with limited power . . . was barring the use of that power in an arbitrary or capricious fashion.”¹⁷⁰ Making an unreasonable decision was deemed tantamount to exceeding the bounds of the statute, since the statutory delegation carried an assumption of reasonableness. This understanding, Mechanick notes, existed “from its origins in English law through the years preceding the enactment of the APA.”¹⁷¹ Only after the APA did the acoustic separation arise, a separation made all the more salient by the *Chevron* decision’s failure to even mention the APA standard of arbitrary and capricious review.

Within our new framework, the reinvigorated *State Farm* standard builds on earlier work that proposes such a standard in “fact-based agency decisions.”¹⁷² Starting from the premise that agency cost-benefit analysis should be based on empirical evidence, courts ought to take a more aggressive role in scrutinizing this evidence to determine if it supports the agency’s decision.¹⁷³ This scrutiny is important because at its best, judicial review serves as an information-forcing procedure for agencies.¹⁷⁴ If an agency knows that it must justify its rule to a generalist judge, the agency will be more likely to produce high-quality information and to deliberate throughout the decisionmaking process.

Conversely, the information-forcing role of administrative challenges is lost if the agency faces no meaningful review of its evidence. First, courts applying *State Farm* may use a lenient standard that only strikes down outlandish or completely unjustified agency actions.¹⁷⁵ Second, the availability of *Chevron* deference has allowed courts and agencies to frame issues as statutory rather than policy-based and approve actions even when the costs outweighed the benefits.¹⁷⁶ *Loper Bright* significantly narrowed the latter route, making all the more important our renewed proposal for a reinvigorated *State Farm* standard to address the former.

As to what such a standard looks like, one need not search any further than the namesake case itself. The *State Farm* opinion famously gives an unclear signal as to the stringency of review that the Court endorses. The Court

169. *See id.*

170. *Id.* at 528.

171. *Id.*

172. *See Sharkey, State Farm, supra* note 150, at 1604.

173. *Id.* at 1603–04.

174. *See id.* at 1605.

175. *Id.* at 1607 & n.67.

176. *See Jonathan S. Masur & Eric A. Posner, Chevronizing Around Cost-Benefit Analysis*, 70 DUKE L.J. 1109, 1139 (2021).

says that “[t]he scope of review under the ‘arbitrary and capricious’ standard is narrow and a court is not to substitute its judgment for that of the agency.”¹⁷⁷ But what the Court *does* is “mine[] the agency record on its own,” determining that the agency’s interpretation of the data is incorrect.¹⁷⁸ Specifically, the Court disagrees with the Department of Transportation’s conclusion from empirical evidence that requiring automatic seatbelts would not increase seatbelt usage.¹⁷⁹ The Court takes a remarkably deep dive into the agency’s evidence; the issue was not that the agency failed to conduct a cost-benefit analysis, or that the costs outweighed the benefits. Instead, the Court probed the methodology and underlying data to see if they supported the agency’s final decision.¹⁸⁰ Understood this way, a reinvigorated *State Farm* standard means a “do as I *do* not as I say” reading of *State Farm*: courts should look into the empirical or factual basis of the action and determine if the decision was based on the evidence. Even generalist judges are capable of this, and they will be assisted by the arguments of the challenging parties, who have (or can readily muster) expertise in the subject matter.¹⁸¹

After conducting a rigorous review of the agency’s justification, the court would decide how much deference to give the agency’s interpretation, based on whether it finds support in the evidentiary record. When an agency has decided between equally plausible readings from a statutory perspective, the court will determine if the evidence supports the one chosen. In cases where the agency’s interpretation strays further from the dictionary (or conventional) definition, courts can still recognize that interpreting technical terms requires specific expertise and may accept an interpretation that diverges from the most likely textual answer, but only if the agency has a good scientific or factual reason for that interpretation.

B. Consistency with Current Doctrine

We have argued that a judicial review regime combining statutory interpretation and reasoned decisionmaking with heightened *State Farm* review is normatively desirable. But is it doctrinally feasible? Recent Supreme Court cases have upended decades of administrative law doctrine. This Section considers the impact of *Loper Bright* and its recent progeny on judicial review

177. *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

178. Sharkey, *State Farm*, *supra* note 150, at 1611 (citing *State Farm*, 463 U.S. at 51–57).

179. *State Farm*, 463 U.S. at 51.

180. *See id.* at 53–57.

181. While we recognize that *State Farm* has increasingly been used to strike down agency actions for minor errors, on the whole, we believe that a heightened standard will result in higher quality agency policymaking. *See* Jack D. Malich, *The Judiciary’s Arbitrary and Capricious Problem*, 128 W. VA. L. REV. 499, 503 (2026).

of agency action. We ultimately conclude that our proposal is not only doctrinally feasible, but also that it would move unstable existing doctrine in a positive direction.

1. *Loper Bright: Obstacle or Opportunity?*

Loper Bright has thrown administrative law into flux, with some predicting the downfall of the administrative state as we know it¹⁸² and others downplaying its import¹⁸³ or even forecasting changes that might solve some of *Chevron*'s problems.¹⁸⁴ To be sure, courts have lost the comfort and guidance that *Chevron*'s two-step framework provided. At the same time, courts now have more power to come to their own "best" interpretation of a statute, listening to the agency as much or as little as desired.

While the bold holding of *Loper Bright*—"Chevron is overruled"¹⁸⁵—captivated attention, the Court's firm embrace of *Skidmore* was more understated. But this return to *Skidmore* is consistent with the longstanding history of judicial deference. Before *Chevron*, agencies could only receive judicial "respect" for their interpretations, based on the agency's consistency, validity, thoroughness, and any other "factors which give it power to persuade, if lacking power to control."¹⁸⁶ *Chevron* created a more emphatic level of deference for certain kinds of agency interpretations—namely those announced through notice-and-comment rulemaking—but the lower *Skidmore* standard remained for less formal interpretations.¹⁸⁷ Accordingly, when *Chevron*'s higher level of deference disappeared, *Skidmore* resurfaced and is now the standard for all statutory interpretation.¹⁸⁸

Because *Loper Bright* left *Skidmore* "respect" intact, courts remain free to be "persuaded" by agency interpretations, based on *Skidmore*'s enumerated

182. Steve Vladeck, *Destabilizing the Administrative State*, ONE FIRST (July 8, 2024), <https://www.stevevladeck.com/p/89-destabilizing-the-administrative> [<https://perma.cc/ZGU5-SG35>].

183. Jonathan H. Adler, *From "Deference" to "Respect"—The Real Import of Loper Bright*, REASON: VOLOKH CONSPIRACY (July 3, 2024, at 13:36 ET), <https://reason.com/volokh/2024/07/03/from-deference-to-respect-the-real-import-of-loper-bright/#> [<https://perma.cc/MFC2-6YBN>].

184. Mila Sohoni, *Chevron's Legacy*, 138 HARV. L. REV. F. 66, 67 (2025); Rubin, *supra* note 134, at 91.

185. *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2273. (2024).

186. *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944).

187. *See United States v. Mead Corp.*, 533 U.S. 218, 231–32 (2001) (explaining that, unlike notice-and-comment rulemaking, Congress did not intend classification rulings to receive deference).

188. At least for now, *Auer* deference remains for agency interpretations of their own regulations. *See Kisor v. Wilkie*, 139 S. Ct. 2400, 2408 (2019) ("This Court has often deferred to agencies' reasonable readings of genuinely ambiguous regulations. We call that practice *Auer* deference . . .").

factors, plus any others. Some, like Justice Kagan, are skeptical that *Skidmore* offers anything more than the opportunity for agencies to try to convince the court of their view—an opportunity afforded to all litigants in an adversarial system.¹⁸⁹ However, on the whole, *Skidmore* means that agencies gain some level of judicial respect, depending on how convincing their interpretation is. The thoroughness and validity of an agency's interpretation, in turn, depends on the quality of underlying evidence and analysis.¹⁹⁰ If an agency can show that a certain interpretation is supported by scientific studies, a cost-benefit analysis, and other factors, a court should find that an agency has successfully exercised its power to persuade.

What is notable about *Skidmore* is that it offers an inherently flexible and adjustable level of deference.¹⁹¹ *Chevron* required the court to defer to reasonable interpretations, no matter the quality of the policy-based evidence. And there was only one level of deference: if Congress had not spoken clearly on the issue and the agency's interpretation was reasonable, then the court was obliged to defer. As we noted above, a core rationale of judicial deference to agencies is that agencies hold specialized expertise in their respective fields and are therefore better suited than judges to make choices between equally plausible interpretations on policy grounds.¹⁹² Under *Chevron*, this rationale could break down when agencies had not exercised reasoned decisionmaking and were instead relying on the doctrinally mandated deference to usher their questionable interpretations past lax judicial review.¹⁹³ But under

189. Transcript of Oral Argument at 32, *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244 (2024) (“*Skidmore* means, if we think you’re right, we’ll tell you you’re right . . . *Skidmore* has always meant nothing.”).

190. See Michael Asimow, *Structuring Skidmore After Loper Bright* 26 (May 11, 2026) (unpublished manuscript) <https://ssrn.com/abstract=6198618> [<https://perma.cc/NG4L-JVNK>] (arguing that attention to an agency's policy considerations can help a court arrive at the best interpretation of the statute).

191. Professor Stephenson denigrates the *Skidmore* review approach:

True, in cases where textualist interpretive tools fail to provide an answer to the question at issue, a reviewing court could decide the case by giving substantial weight or respect to the agency's view. This would be a way for courts to pretend to resolve the issue independently while actually deferring to the agency. The results would mostly be the same as they would under the *Gray* doctrine, but it is unclear what is gained by this ruse.

Stephenson, *supra* note 15, at 179–80. What would be gained is that the approach would apply more widely to situations where the agency's policymaking factors overlap with statutory interpretation questions, not just to what seems (to us) like an artificial subset.

192. Sharkey, *Cutting in on Chevron*, *supra* note 153, at 2363–64.

193. See Masur & Posner, *supra* note 176, at 1150; see also Sharkey, *Cutting in on Chevron*, *supra* note 153, at 2369–73 (discussing Catskill Mountains Chapter of Trout Unlimited, Inc. v. EPA, 846 F.3d 492 (2d Cir. 2017)).

Skidmore or *Loper Bright*, the court can choose to give less weight to an interpretation unsupported by reasoned decisionmaking.¹⁹⁴

While the core method of determining the bounds of agency authority after *Loper Bright* is for courts to come to their own “best reading” of the statute, aided by *Skidmore*, the Court offers a second route for determining agency authority. The Court writes: “In a case involving an agency, of course, the statute’s meaning may well be that the agency is authorized to exercise a degree of discretion.”¹⁹⁵ When discretionary interpretive authority is the “best reading,” the court carries out its duty by “by recognizing constitutional delegations, ‘fix[ing] the boundaries of [the] delegated authority’ and ensuring the agency has engaged in ‘reasoned decisionmaking’ within those boundaries.”¹⁹⁶

As well as serving as a sobering reminder that Congress often does intend to delegate discretion to an administrative agency, this passage hints at a possible reintegration of statutory authority and reasonableness reviews. In noting that review for reasoned decisionmaking is part of the judicial duty to effectuate and police congressional delegation, the Court echoes how English common law courts saw reasonableness as part of *ultra vires* review.¹⁹⁷

Fundamentally, however, the Court still sees review of statutory interpretation and reasoned decisionmaking as distinct inquiries, even if closely related. As the passage states, in so many words, agencies that survive *Loper Bright* on the statutory side still must undergo *State Farm* review on the policy side.¹⁹⁸ What this passage offers is a relatively easy way for courts to make a certain instance of judicial review openly about policy: they may simply declare that the best reading of the statute is that Congress delegated discretion. This route may be especially attractive to agency-friendly courts who do not wish to second-guess the work of expert agencies.¹⁹⁹

194. See Kristin E. Hickman, *Anticipating a New Modern Skidmore Standard*, 74 DUKE L.J. ONLINE 111, 118–19 (2025) (noting that courts have traditionally treated *Skidmore* review as a sliding scale, where the weight given to an agency’s view depends on the persuasive factors).

195. *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2263 (2024).

196. *Id.* (quoting Henry Monaghan, *Marbury and the Administrative State*, 83 COLUM. L. REV. 1, 27 (1983)) (“For example, some statutes ‘expressly delegate[]’ to an agency the authority to give meaning to a particular statutory term. Others empower an agency to prescribe rules to ‘fill up the details’ of a statutory scheme, or to regulate subject to the limits imposed by a term or phrase that ‘leaves agencies with flexibility,’ such as ‘appropriate’ or ‘reasonable.’” (citations omitted) (first quoting *Batterton v. Francis*, 432 U.S. 416, 425 (1977); then quoting *Wayman v. Southard*, 10 Wheat. 1, 43 (1825); and then quoting *Michigan v. EPA*, 576 U.S. 743, 752 (2015))).

197. See *supra* text accompanying notes 166–171.

198. See *Loper Bright*, 144 S. Ct. at 2263–64.

199. See *infra* Section III.A.

This leads Professors Kristin Hickman and Amy Wildermuth to emphasize that *congressional delegation* is the dividing line between statutory interpretation and agency policymaking.²⁰⁰ Referring to the two key paragraphs of *Loper Bright* quoted above, they observe that the court's finding (or not) of explicit delegation will determine if the court reviews the case as a statutory or policy decision. The authors note that when delegation puts the action in the "reasoned decisionmaking" box, the agency will have more authority, a reference to the (generally) more deferential standard of *State Farm*.²⁰¹

Significantly, *Loper Bright* does not stand for the proposition that courts *cannot* defer to agencies; it simply says that they no longer *have to* defer to agencies. If a court decides that the interpretation of a statutory term is a task requiring specialized expertise, the court is free to defer to the agency's interpretation.²⁰² The Supreme Court points out that this option has existed all along:

The APA, in short, incorporates the traditional understanding of the judicial function, under which courts must exercise independent judgment in determining the meaning of statutory provisions. In exercising such judgment, though, courts may—as they have from the start—seek aid from the interpretations of those responsible for implementing particular statutes.²⁰³

The only difference for a court that finds the agency's interpretation convincing is that, after *Loper Bright*, the decision must be framed as a process of

200. Kristin E. Hickman & Amy J. Wildermuth, *Harmonizing Delegation and Deference After Loper Bright*, 100 N.Y.U. L. REV. 1924, 1929 (2025).

201. *Id.* at 1931. Hickman and Wildermuth lay out three types of statutory authority: specific, general, and hybrid. *Id.* at 1934. Specific authority allows the agency to fill in small statutory gaps or determine which things fit within a defined category. For example, the Endangered Species Act defines endangered and then gives the agency the power to determine when a species is endangered. *Id.* at 1936–37; 17 U.S.C. § 1532(2). General (or "housekeeping") authority is the broad power to adopt any rules "necessary" or "efficient" to carry out the statutory scheme. Hickman & Wildermuth, *supra* note 200, at 1938. Hybrid authority has general language, but is "embedded" in specific statutory situations. *Id.* at 1941. They predict that when a statute provides specific or hybrid authority, it falls within reasoned decisionmaking and the court will review a rule only under *State Farm*. *Id.* at 1972. Hickman and Wildermuth highlight that the seemingly never-discussed choice of the type of review may be the dispositive factor in a challenge. *Id.* at 1948.

202. *See, e.g.,* Am. Gas Ass'n v. U.S. Dep't of Energy, 157 F.4th 476, 487 (D.C. Cir. 2025) ("We note that DOE's interpretation of [the relevant statute] does not bind us, but 'it may be especially informative "to the extent it rests on factual premises within . . . [DOE's] expertise."'" (quoting *Loper Bright*, 144 S. Ct. at 2267 (2024)); *id.* at 492–93 ("We have no reason to second-guess DOE's view, 'especially since it "rests on the agency's evaluations of scientific data within its area of expertise."'" (quoting *Actavis Elizabeth LLC v. FDA*, 625 F.3d 760, 766 (D.C. Cir. 2010)).

203. *Loper Bright*, 144 S. Ct. at 2262.

coming to the best interpretation, rather than merely a reasonable or permissible one.²⁰⁴

Loper Bright further allows a shift toward an embrace of policymaking review by freeing courts from what Professor Edward Rubin calls the unhelpful and misplaced language of “ambiguity” in *Chevron*.²⁰⁵ As he notes, “ambiguity” implies that there was an error by Congress and neither the agencies nor the courts can tell what the intended meaning is.²⁰⁶ In reality, modern statutes contain what is better termed “open-ended language” that leaves the agency discretion to determine the means, manner, and extent of regulation or action to carry out a statutory objective.²⁰⁷ By moving away from a system wherein ambiguity formed the dividing line between judicial review centered upon statutory interpretation (judicial supremacy) versus policymaking review (agency discretion),²⁰⁸ *Loper Bright* allows courts to acknowledge that a statute is purposely open-ended and yields multiple interpretations, varying based upon policy, not textual considerations.²⁰⁹

204. See *id.* at 2266 (“In the business of statutory interpretation, if it is not the best, it is not permissible.”).

205. Rubin, *supra* note 134, at 97.

206. *Id.* at 97–98.

207. *Id.* at 98.

208. Although less commonly used to decide cases, Step One of *Chevron* allowed a court to find that a statute was not ambiguous and that interpretation fell to the court. *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984) (“If the intent of Congress is clear, that is the end of the matter . . .”); see Kent Barnett & Christopher J. Walker, *Chevron in the Circuit Courts*, 116 MICH. L. REV. 1, 6 (2017) (finding that when circuit courts used *Chevron*, they decided the case at step two 70% of the time).

209. Here, we agree with Professor Lisa Schultz Bressman:

Loper Bright ushers in a new era, directing courts to decide all questions of law, regardless of whether a statute is ambiguous. But it does not change the nature of ordinary questions: they often involve statutory language that gains meaning through the scientific, technological, economic, and policy judgments that agencies routinely make.

Bressman, *Ordinary Questions*, *supra* note 2, at 1048. Bressman, however, differs in proposing a framework for courts to evaluate such “ordinary questions”—namely to “pick a lane” (either *de novo* legal review or *State Farm* arbitrary and capricious review) for purposes of judicial review. *Id.* at 1012. Bressman makes the case that courts know there are well-recognized categories of agency policy decisions for which they should not substitute their judgment for that of the agency. *Id.* at 1018–19. If an agency decision, by its nature, as revealed in the agency record, falls into one of these categories, then courts should review it as a policy decision under the arbitrary and capricious test, even if the decision also involves the interpretation of statutory text. See *id.* at 1017–19. Our approach instead urges courts to address and scrutinize the policymaking considerations as part and parcel of their statutory interpretation exercise; it would not give courts the option of “picking” the *de novo* statutory interpretation route. The LDT case illustrates the danger of offering such an off-ramp to courts.

We propose, however, that courts not simply defer to agencies when the decision is technical, but instead engage in a “hard look” review of the agency’s evidence to ensure that deference is warranted. While this regime is not mandatory under *Loper Bright*, the consideration of *Skidmore* factors allows a level of deference tailored to the agency’s persuasiveness and expertise.²¹⁰ By making all forms of agency action subject to *Skidmore* review, *Loper Bright* greatly expands the reach of flexible review and importantly applies it to notice-and-comment rulemaking, which tends to involve more significant changes and a more robust evidentiary record.

Our proposal applies to both *Loper Bright* routes—the court’s own best reading (with *Skidmore*) and delegated agency authority—in contrast with other scholars who have focused exclusively on the latter.²¹¹ While the option of finding delegated discretion to agencies will certainly be an appealing option for courts, such discretion is not always present, and, taken to an extreme, this approach risks recreating the worst aspects of *Chevron*, namely agencies skating through cursory judicial review with poor policy decisions. Our approach allows a more flexible application of the first route, allowing courts to be persuaded by the agency when the evidentiary record justifies it. Significantly, we also propose applying a stricter *State Farm* review, applicable to both routes, ensuring that only sound policy survives judicial review, regardless of the statutory interpretation method deployed.

2. *Loper Bright’s Progeny*

Since *Loper Bright*, the Court has addressed challenges to agency action in two prominent cases: *FDA v. Wages and White Lion Investments*²¹² and *Seven County*.²¹³ In each case, the Court sided with the agency, in ways that show the limits of *Loper Bright* but also the doctrinal uncertainty that remains after (and in part because of) *Loper Bright*.

Taken together, *White Lion* and *Seven County* show that even a broadly agency-skeptical Court will defer at times, perhaps due to judicial overstepping by lower courts or the agency simply being correct. Since *Loper Bright* eliminated the main way for courts to defer, they now must seek other methods. This pair of cases is remarkable for showing the lengths to which the Court is willing to go to ensure deference to agencies when it seems appropriate to do so.

210. *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944).

211. See Ellen P. Aprill, *Unpacking the Most Important Paragraph in Loper Bright*, YALE J. ON REG. NOTICE & COMMENT (Jan. 15, 2025), <https://www.yalejreg.com/nc/unpacking-the-most-important-paragraph-in-loper-bright-by-ellen-p-aprill/> [https://perma.cc/4EKU-6XKJ]; Hickman & Wildermuth, *supra* note 200, at 1926–27.

212. 145 S. Ct. 898 (2025).

213. *Seven Cnty. Infrastructure Coal. v. Eagle Cnty.*, 145 S. Ct. 1497 (2025).

White Lion presents a bit of a paradox. It is a post-*Loper Bright* decision that does not mention *Loper Bright*—correctly so, since there was no rulemaking involved. We consider its import here, given that it shows marked and *unanimous* deference to the agency in the post-*Loper Bright* world of judicial review. Moreover, politically, the decision represents the overturning of an error-ridden,²¹⁴ unapologetically anti-agency crusade from the conservative Fifth Circuit.²¹⁵

In *White Lion*, electronic cigarette manufacturers challenged the FDA’s denial of premarket approval for flavored e-cigarette liquids.²¹⁶ All the justices who had voted to overturn *Chevron* were perfectly willing to uphold the FDA’s discretion to specify the type of evidence needed for e-cigarette approval. Justice Alito, writing for the Court, devoted several pages to background, establishing that the FDA was on incontrovertible statutory footing thanks to the Tobacco Control Act of 2009 and has clear authority to regulate flavored e-cigarettes, which the Court agreed pose a serious health risk to young people.²¹⁷

The FDA determined that the manufacturers had failed to provide sufficiently robust and reliable data supporting the claim that the product’s benefits to adults who wish to quit smoking traditional cigarettes outweigh its potential harm to minors who might be enticed by the fruit or candy-flavored e-liquids.²¹⁸ The manufacturers challenged this decision, arguing that the FDA was demanding different and more specific types of evidence than it had indicated it would require in various guidance documents.²¹⁹

The Court framed its inquiry as whether the FDA violated the newly coined “change-in-position doctrine,” a two-step test that asks first, whether the agency in fact changed its position and second, whether the agency recognized the change and provided good reasons for doing so.²²⁰ The standard of judicial review at the second step is deferential and the scope of review “is

214. The appellate decision, by Judge Andrew Oldham, contained such egregious errors that the e-cigarette manufacturers—the *prevailing* parties—filed a motion correcting several errors in the opinion. The court refused to do so. See Petitioners’ Unopposed Motion for Modification, Amendment, or Clarification of Opinion at 5, *Wages & White Lion Invs., LLC v. FDA*, 90 F.4th 357 (5th Cir. 2024) (Nos. 21-60766 & 21-60800) (requesting the court to modify, amend, or clarify its majority opinion to reflect that the FDA has “not approved menthol-flavored electronic nicotine delivery systems through the premarket tobacco application process”); *White Lion*, 90 F.4th at 362–63.

215. *White Lion*, 90 F.4th at 362–63.

216. *White Lion*, 145 S. Ct. at 913–14.

217. *Id.* at 907–10.

218. *Id.* at 914.

219. *Id.* at 919.

220. *Id.* at 917–18.

narrow.”²²¹ In the case before it, the Court determined that the FDA’s denial of the e-liquids was “sufficiently consistent with its predecisional guidance,” meaning it did not constitute a change of position.²²² Accordingly, the Court found it unnecessary to decide the reasonableness of its position.²²³

The Court’s “change-in-position doctrine” is a repackaging and relabeling of existing strains in prior case law.²²⁴ Drawing upon the established requirements that agencies changing position offer an awareness of and reasoned explanation for the change,²²⁵ Justice Alito creates (yet another) two-step test with the newly articulated first step being whether there has been a bona fide change in agency position. It is at this first stage—which is itself logically unnecessary given that the existing requirements inherently require that change had indeed occurred—that the Court lets the FDA escape review of its reasoning, evincing a willingness to be markedly deferential within the realm of unambiguously delegated authority.

Seven County, on the other hand, is more conventionally classified as one of *Loper Bright*’s progenies and likewise provides a target against which to measure our proposed framework. In *Seven County*, several environmental organizations challenged the Surface Transportation Board’s decision allowing a railroad line in Utah to connect an oil-producing region with the main rail network.²²⁶ Following the NEPA, the Board had collected comments and prepared a lengthy environmental impact statement (EIS).²²⁷ The challengers argued (and the D.C. Circuit agreed) that the Board failed to consider downstream

221. *Id.* at 917 (quoting *Motor Vehicle Mfrs. Ass’n. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

222. *Id.* at 919.

223. *Id.*

224. See Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 501 n.252 (2008) (“The Court has emphasized the need for agencies to provide adequate explanations of changes in position.”); Sharkey, *Cutting in on Chevron*, *supra* note 153, at 2435 (discussing reasoned decisionmaking in the “agency change-of-position scenario”); see also William W. Buzbee, *The Tethered President: Consistency and Contingency in Administrative Law*, 98 B.U. L. REV. 1357, 1396–401 (2018) (noting the Court’s use of the then-unnamed change-in-position doctrine).

225. See *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 503 (2009) (“[The agency] need not demonstrate to a court’s satisfaction that the reasons for the new policy are *better* than the reasons for the old one. It suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better, which the conscious change adequately indicates.”); *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016) (“Agencies are free to change their existing policies as long as they provide a reasoned explanation for the change.”).

226. *Seven Cnty. Infrastructure Coal. v. Eagle Cnty.*, 145 S. Ct. 1497, 1507–08 (2025).

227. *Id.*

environmental impacts of the rail line.²²⁸ The Court reversed and upheld the Board's decision.²²⁹ The Court emphasized that NEPA is "purely procedural" and affords substantial deference for the relevant agency to decide the scope and contents of the EIS.²³⁰ NEPA does not require consideration of upstream or downstream environment impacts that are distinct from the project at issue.²³¹ Here, the task of the Board was to consider the environmental impact of the rail line itself, not related drilling or refining projects.²³²

In articulating the applicable standard, the Court emphasizes the dichotomy between *de novo* judicial review of statutory interpretation under *Loper Bright* and deferential arbitrary and capricious review under *State Farm*.²³³ The instant case, the Court declares, is a clear instance of statutorily granted discretion, meaning the scope of review is limited.²³⁴ The decision of what to include in the EIS is a question of fact, one the agency is "better equipped" to make.²³⁵

Here, however, the Court gets muddled in its attempt to neatly separate questions of law and of fact:

NEPA says that the EIS should be "detailed." Of course, the meaning of "detailed" is a question of law to be decided by a court. But what details need to be included in any given EIS? For the most part, that question does not turn on the meaning of "detailed"—instead, it "involves primarily issues of fact."²³⁶

The Court does not even attempt to explain how the meaning of "detailed" can be a *legal* question while the relevant details remain a question of *fact*.²³⁷

228. *Id.* at 1509.

229. *Id.* at 1508.

230. *Id.* at 1510.

231. *Id.* at 1511.

232. *Id.* at 1510.

233. *Id.* at 1511.

As a general matter, when an agency interprets a statute, judicial review of the agency's interpretation is *de novo*. But when an agency exercises discretion granted by a statute, judicial review is typically conducted under the Administrative Procedure Act's deferential arbitrary-and-capricious standard. Under that standard, a court asks not whether it agrees with the agency decision, but rather only whether the agency action was reasonable and reasonably explained.

Id. (citations omitted).

234. *Id.*

235. *Id.* at 1512.

236. *Id.* (citations omitted) (quoting *Marsh v. Or. Nat. Res. Council*, 490 U.S. 360, 377 (1989)).

237. Nor are we persuaded by Professor Stephenson's attempt to fit this specific example into his "Gray zone." According to Stephenson:

The relevant legal question is not what the contents of the EIS *are*, but whether those contents—their length, specificity, and so forth—meet the *statutory requirement* that the

This conundrum reveals a key limitation of the Court's current administrative law doctrine: questions of law and fact cannot be cleanly separated and often inherently bleed into each other. The reasoning of *Loper Bright* and the separate doctrinal regimes of statutory interpretation and policymaking depend on the mistaken premise that fact and law are always separate, or at least separable.²³⁸ Several justices raised this concern during the *Loper Bright* oral arguments,²³⁹ but it went unaddressed in the final decision.

In sum, these post-*Loper Bright* decisions find the Court conjuring up a new doctrinal test and implicitly embracing questionable reasoning about the law/fact distinction, all to avoid second-guessing two sound agency decisions. Having created more and more barriers to judicial deference, the Court must jump through its own hoops when it wishes to defer. This is far from a well-designed framework. Our proposal offers a better option. In reviewing the agency's basis for decisionmaking, the court can find itself persuaded by the thoroughness of reasoning (*à la Skidmore*) and decide that the agency's determination was valid.

EIS be "detailed." That question—whether the level of detail in this particular EIS meets the statutory requirement—is not a pure question of fact On this sort of question, which calls for assessing whether a given item (here, the EIS) scores high enough on a particular dimension (here, the quantity and specificity of the information presented) to fall within some statutory category (here, "detailed" reports), it is most plausible to assume that Congress implicitly delegated to the agency the authority to make reasonable judgments about how much is enough.

Stephenson, *supra* note 15, at 167–68. It is not clear to us how "detailed" reports comprise a specific statutory category, within which the agency conducts a fact bound line-drawing exercise to situate the EIS before it as within the poles of said category.

238. Judge Rao's dissent in *American Gas Ass'n v. U.S. Department of Energy*, 157 F.4th 476, 505 (D.C. Cir. 2025) (discussed in *supra* notes 17, 202), illustrates the folly of trying to cleanly separate law from fact after *Loper Bright*. She chides the majority for having "largely duck[ed]" the legal question of what constitutes a "performance characteristic" of furnaces under the statute by instead "declaring that [the statute] is ambiguous as to the meaning of 'performance characteristic'" and deferring to the DOE on the factual record. *Am. Gas Ass'n*, 157 F.4th at 506. Judge Rao instead insists that the evidentiary burden imposed on the rule's challenger "applies only to the *factual* question of whether a standard will cause a protected product to become unavailable, not to the *legal* question of what qualifies as a protected 'performance characteristic.'" *Id.* Such rigid formalism, centered on an attempt to separate cleanly the issues of law and fact regarding a clearly policy-laden statutory phrase, is our prime target.

239. See Transcript of Oral Argument at 7, *Relentless v. U.S. Dep't of Com.*, No. 22-1219 (U.S. Jan. 17, 2024) (Chief Justice Roberts: "[L]et's suppose the statute says the Department of Transportation will set length limits for trucks that are reasonable Is that a legal question for the court, or is that a policy question for the agency?"); *id.* at 11, 14 (Justice Kagan: "Is a new product designed to promote healthy cholesterol levels a dietary supplement or a drug? . . . Does the term 'power production capacity' refer to AC power that is sent out to the electric grid or DC power that's produced by a solar panel?").

C. Revisiting the LDT Case

As cases like the LDT challenge show, in practice, agency action can be and is challenged under statutory authority *and* reasoned decisionmaking, and the agency must survive both to win. The parties, moreover, never explicitly addressed whether the court should review for statutory authority or reasoned decisionmaking. And we are aware of no authority commanding reviewing courts to prioritize one over the other. The district court was free to make the case rest solely on the statutory issue and ignore—at least formally—the policy side.

With regard to the LDT case, the decision of what constitutes a device is a technical decision. One might understand Congress as implicitly delegating this power to the FDA, rather than writing an exhaustive list itself, with the understanding that an expert agency is better equipped to make those categorizations, especially as technology and industries change. In specifying that the statutory gaps should be filled in by specialist experts—not generalist judges or lawyers—Congress is declaring that the issue is one of policy and that the agency should decide based on the policy factors that it has the comparative institutional advantage in evaluating. When the statute grants specific authority, courts “effectuate the will of Congress”—as *Loper Bright* instructs them to do—precisely by deferring to the agency’s interpretation, provided that it is supported by evidence and a process of reasoned decisionmaking.²⁴⁰ We argue courts should use a reinvigorated *State Farm* standard, carefully review the evidence, and determine if the benefits outweigh the costs.

There are two readings of the body of the evidence on which the FDA bases its rule. On the one hand, the FDA concedes that it has limited evidence, but insists that it is “enough.” The agency, however, has no articulated threshold for what amount of data constitutes “enough” but simply announces that the data on LDTs is sufficient for purposes of this rule. The core of the data is only four scientific studies, which are all limited to certain types of LDTs.²⁴¹

On the other hand, the lack of published evidence on a relatively new development is understandable and beyond the agency’s control. For the evidence that does exist, the agency engages with it, for example, providing a methodologically sophisticated critique of the seven pro-LDT studies over several pages in the Final Rule.²⁴² The FDA makes the most of what is available and demonstrates that it has engaged deeply with the entire universe of LDT-related evidence that exists.

240. *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2263 (2024).

241. Medical Devices; Laboratory Developed Tests, 88 Fed. Reg. 68,006, 68,010–11 (Oct. 3, 2023) (to be codified at 21 C.F.R. pt. 809).

242. See *supra* notes 115–118 and accompanying text.

It may be due to the thinness of evidence that the FDA is reticent to emphasize the reasoned decisionmaking side of the equation and instead accepts that the battle will occur on the statutory front. To the extent it does address reasoned decisionmaking, the FDA works to *lower* the evidentiary bar via its framing of the relevant legal standards. The agency characterizes the standards of APA § 706(2)(A) as “highly deferential,” citing *State Farm, Citizens to Preserve Overton Park v. Volpe*,²⁴³ and *FCC v. Prometheus*.²⁴⁴ The agency repeatedly argues that it only needs to demonstrate that some LDTs are problematic in order to justify the rule.²⁴⁵ Seen through the FDA’s lens, all examples of problems make its case, while counter-examples of high-quality LDTs do not necessarily detract from it. The agency also frames the issue as bringing the treatment of LDTs into line with that of IVDs, meaning the burden is only to disprove that the two tests should be treated differently.²⁴⁶ Since FDA approval is already required and accepted by the industry for IVDs, the agency only needs to show that there no longer exists any reason to exempt LDTs from the default regulatory regime. For example, some labs that have been rejected from approval for IVDs have then offered them as LDTs, skirting the registration requirements but offering the same problematic tests.²⁴⁷

In the litigation, the FDA concedes that while it did not have all the data about LDTs, it was enough.²⁴⁸ In response to the Association for Molecular Pathology (AMP) claiming that the FDA must use “empirical or statistical studies” to show that the benefits justify the costs, the FDA argues: “AMP’s argument imposes an evidentiary burden that does not exist, and the Final Rule is amply justified by FDA’s ‘reasonable predictive judgment based on the evidence it had.’”²⁴⁹ Similarly, with regard to the cost-benefit analysis, the FDA notes that it is relying partially on unquantifiable benefits, like more reliable tests and the “intangible fairness benefit of regulating similar products in the same way.”²⁵⁰

While we cannot say precisely how the LDT case would have come out under our proposed judicial review regime, we can say that the result would have been preferable regardless of the outcome. In applying a stringent *State Farm* standard, the court would have delved into the evidentiary record that

243. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402 (1971).

244. FDA Brief, *supra* note 35, at 17.

245. *See id.*

246. Medical Devices; Laboratory Developed Tests, 88 Fed. Reg. at 68,012.

247. *Id.*

248. FDA Brief, *supra* note 35.

249. Defendants’ Combined Summary Judgment Reply at 34, *Am. Clinical Lab’y Ass’n v. FDA*, 776 F. Supp. 3d 554 (E.D. Tex. 2025) (No. 4:24-CV-479) (quoting *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1160 (2021)).

250. *Id.*

the FDA had assembled and relied upon in making the decision. The record in this case is far from robust, and there exist many complexities and contradictions. For example, the court would have looked at the core scientific justification—the six peer-reviewed scientific articles on LDTs—and compared those with the articles mentioned in comments, which presented a different view of LDTs' accuracy.²⁵¹ Our proposed judicial review framework would require the court's reckoning with these conflicting reports. The court might also note that in the Final Regulatory Impact Analysis, both costs and benefits are lower than in the preliminary analysis, but benefits are reduced by a greater factor.²⁵²

Only after conducting this scrupulous review would the court decide whether to accept the FDA's bid to make LDTs count as devices under the FDCA. The court could find the evidence convincing, perhaps noting that there was not a lot, but that given the relatively recent nature of LDTs, it was enough. Under this route, the court would have allowed the rule to stand on policy grounds, recognizing the policy-based nature of the decision. Alternatively, the court might have found that the evidence was insufficient. After all, the FDA never sets any benchmark for itself as to how many reports of problematic LDTs necessitate regulatory involvement, instead declaring that the existing evidence was simply enough. The court could find that the decision to count LDTs as devices did not constitute reasoned decisionmaking, and that therefore, the court would set the rule aside (or remand back to the agency for reconsideration).

On the surface, the latter outcome may look exactly like what happened, but there are key differences. First, a finding on policy grounds does not impact the authority of the FDA in the future. Finding that the rule was not adequately supported by evidence is a much narrower decision than declaring that the FDA fundamentally lacks the statutory authority to regulate LDTs. A *State Farm* loss allows the agency to pursue another action in the future when it has better evidence or a more complete understanding of the industry.

Second, review for reasoned decisionmaking ensures that judicial review always plays the important information-forcing role mentioned above.²⁵³ Even if the court sets aside the rule, the meaningful review of evidence lets the agency, regulated parties, and the public know whether the rule was sound policy and cost justified in the first place. And the prospect of such review makes agencies confine their future actions to those supported by evidence.

251. See *supra* notes 115–118 and accompanying text.

252. See *supra* note 109 and accompanying text.

253. See *supra* note 174 and accompanying text.

III. SHAPING REGULATORY INCENTIVES FOR A NEW ADMINISTRATIVE ERA

In this Part, we show how our proposed expanded arbitrary and capricious review under a reinvigorated *State Farm* standard aligns and improves the relevant incentives of key players in the administrative state—courts, agencies, and Congress—leading to expected improvements in the functionality of the administrative state. As the three actors have divergent, sometimes even conflicting interests, it is an imperative (albeit sometimes overlooked) prerequisite for any administrative law proposal to consider the relationship between these actors and how different standards of judicial review might impact their respective incentives.

A. Courts

We begin our discussion of incentives with the courts, who are ultimately the arbiters of these administrative challenges and determine what level of review to apply to agency actions. In a federal judiciary that shows increasing signs of polarization, it is important to consider the roles and positions of archetypal judges that we might term “agency-friendly” and “agency-skeptical,” understanding that the reality is far more complex.

Under the old regime, Professor Lisa Bressman notes that courts tended to default to—and perhaps overuse—*Chevron*, and agencies leaned more heavily on it because of the “easier path to deference.”²⁵⁴ Without *Chevron*, she predicts that judges who want to avoid second-guessing agencies may use *State Farm* in place of *Chevron* to provide that deference.²⁵⁵ For agency-friendly judges, *State Farm* now represents the path of greater deference, since judges do not have to come to their own readings of statutes and are instructed specifically *not* to substitute their own judgment on policy matters. As Bressman observes, courts could easily choose to understand agency actions as policy decisions rather than interpretive issues.²⁵⁶ Under *Loper Bright*, a court need only declare that the “best reading of a statute is that it delegates discretionary authority to an agency” and then it may review the action for reasoned decisionmaking under a more deferential standard.²⁵⁷

On the flip side, agency-skeptical judges may seek to categorize cases as statutory interpretation, so that they can come to their own reading of the statute. In the LDT case, the challengers certainly worked hard to frame the

254. Lisa Schultz Bressman, *Lower Courts After Loper Bright*, 31 GEO. MASON L. REV. 499, 509 (2024) [hereinafter Bressman, *Lower Courts*].

255. *Id.*

256. *Id.*

257. *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2263 (2024).

case as a statutory issue, and the judge was willing to follow that conception—perhaps unsurprising from a judge previously known for striking down the Department of Labor’s overtime rule.²⁵⁸ With *Loper Bright* offering judges the last word, the court seemed uninterested in even discussing the policy side of the decision or engaging with the FDA’s evidence.²⁵⁹

Neither of these routes, however, is optimal from the perspective of encouraging beneficial and well-reasoned policy decisions. If agency-friendly judges simply switch to deferring to agencies under a presumed lax *State Farm* standard,²⁶⁰ then poorly justified rules may survive challenge. In contrast with the *Chevron* regime—as typified by *Catskill Mountains*²⁶¹—under *Loper Bright*, an agency would have to provide at least *some* evidence of reasoned decisionmaking, but this is not tantamount to ensuring meaningful judicial review. We contend that courts should only approve rulemaking that is sound policy—with cost-benefit analysis as a good benchmark²⁶²—not merely using their newfound interpretive power to proclaim “delegated authority”²⁶³ and then apply a highly deferential standard of review.

On the other side, the agency-skeptical judge remains overly skeptical in the wrong realm, putting agencies through the linguistic ringer with scant—or zero—focus on policymaking issues. These judges attack the basis of agency authority but fail to grapple with the question whether the policy is sound.

Our proposal—expansive use of arbitrary and capricious review, under a heightened *State Farm* standard—would be a better accommodation for *both* types of judges. For agency-friendly judges, the move ensures that agencies are still making beneficial policy that is the result of rigorous empirical study, consideration of reliance interests, and estimation of costs and benefits. For agency skeptics, our proposal might induce a more lenient view of delegated discretion on the statutory side, since the court can still scrutinize the agency closely on the policymaking side by using a stringent *State Farm* review standard. As the LDT opinion demonstrates, policy concerns can creep into even a committedly textualist opinion. Our solution is to embrace that tendency and turn it

258. Wiessner, *supra* note 26.

259. *Am. Clinical Lab’y Ass’n v. FDA*, 776 F. Supp. 3d 554, 571 (E.D. Tex. 2025) (“The Court agrees [that the rule exceeds the FDA’s statutory authority], and therefore need not address the Laboratory Plaintiffs’ additional claim that the final rule is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”).

260. As we discuss above, the presumed laxity of the standard may be called into question, as the Court articulated a more deferential level of review than it carried out in the instant case. See *supra* notes 177–181 and accompanying text.

261. See *supra* notes 160–163 and accompanying text.

262. Sunstein, *supra* note 135, at 4.

263. *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2263 (2024) (citation omitted).

into meaningful review of the evidentiary record, so that courts, agencies, and the public can know whether an agency rule constitutes sound policy.

While our proposal might be seen as pro-regulatory because it allows courts to apply a more flexible combination of statutory and policy review, we believe it would be attractive to judges across the spectrum of views toward agencies. What most concerns us are overly agency-friendly judges who are willing to let questionable policy proceed and overly agency-skeptical judges who block beneficial policy on the basis of text. By proposing a more stringent *State Farm* standard, we expect the setting aside of rules that would otherwise be upheld under a more lax standard. Rather than increase ideological differences, we expect that this proposal would encourage judges to engage with the evidence and decide how reasoned the agency decision is.

To be sure, there may be extremely agency-skeptical judges who strike down almost every agency action that comes their way. *Loper Bright* has made their work easier and judicial forum shopping has increased their influence. We hope to convince the judges who are more measured in their skepticism and remain willing to defer in certain instances (like Justice Kavanaugh, author of the unanimous *Seven County* opinion). Our proposal gives them a way to defer when the evidence is convincing and decline to defer when the evidence is lacking. Either way, there is the benefit of information-forcing and a more cohesive doctrinal regime. We also recognize that our proposal might be seen as more work for judges, as they would have to look into the evidentiary records of challenged actions. However, this is a small price to pay for a preferable system of administrative law and, ultimately, sounder government policy.

A regime of vigorous *State Farm* review could also create a hierarchy of deference to different agencies, depending on their level of expertise. Under *Chevron*, the level of deference to agencies was fixed, but in a system of foregrounded *State Farm* review, the court must decide how much to inquire into the agency's evidentiary basis. One basis for that determination might be an agency's expertise, which Professor Emily Hammond defines as the ability of agencies to convince courts that their actions are reasonable based on field-specific proficiency, as opposed to courts' generalist legal knowledge.²⁶⁴ Hammond predicts that, post-*Chevron*, courts will have to "grapple with agency expertise" as they decide how much to listen to the agency's specialized knowledge.²⁶⁵ Courts may develop informal—albeit likely undisclosed—hierarchies about the relative expertise of agencies, with scientific regulators like the FDA being toward the top. Even while carrying out rein-vigorated *State Farm* review, courts may choose to spare these agencies from

264. See Emily Hammond, *Finding A Place for Expertise After Loper Bright*, 31 GEO. MASON L. REV. 559, 561, 567 (2024).

265. *Id.* at 569.

the most exacting examinations, knowing that they generally employ experts in the field and produce high-quality data.

For Hammond, the end of *Chevron* allows for a system of judicial review wherein courts decide questions of law but respect agency expertise on questions of fact, a system that “respect[s] comparative institutional competence while reinforcing accountability and maintaining fidelity to statute.”²⁶⁶ *Loper Bright* undoubtedly mandates the first part—courts deciding questions of law²⁶⁷—and as this Article argues, it also opens the door for the second part—courts considering the expertise of agencies.

Loper Bright may further enable the shift toward an expertise-based order by eviscerating the democratic justifications of *Chevron*. As Professor Richard Murphy points out, the *Chevron* decision was grounded in democratic legitimacy, namely the idea of shifting authority from unelected courts to agencies ostensibly under the power of a democratically elected president.²⁶⁸ That reasoning, he argues, led to the one-size-fits-all style of deference, which in turn caused the separation of powers concerns that proved to be *Chevron*’s downfall.²⁶⁹ At the same time, in cases like *West Virginia v. EPA*,²⁷⁰ the Court cites democracy as a reason to *reject* the agency’s claim of expansive power because it belonged more appropriately with the democratic Congress.²⁷¹

For Murphy, this area of administrative law would be clearer and cleaner without democracy entering the picture as a justification.²⁷² We agree; courts should listen to—but not necessarily defer or acquiesce to—agencies, not because they are better representatives of the *demos* but because they are experts in certain scientific areas—or at least some are. As Murphy suggests, under the return to *Skidmore* “respect” that the Court endorsed in *Loper Bright*, “the weight of an agency explanation should be a function of how hard it is for a reviewing court to improve upon it.”²⁷³ And in turn, the greater the agency’s expertise, “the greater the burden on a court to engage this expertise and demonstrate that it has found a better statutory interpretation.”²⁷⁴

266. *Id.* at 572.

267. *Loper Bright*, 144 S. Ct. at 2265.

268. Richard W. Murphy, *Democracy, Chevron Deference, and Major Questions Anti-Deference*, 58 GA. L. REV. 987, 998 (2024).

269. *Id.* at 991.

270. 142 S. Ct. 2587 (2022).

271. Murphy, *supra* note 268, at 990.

272. *See id.* at 991 (“It seems plausible that legal doctrine would have evolved along better lines had the justices skipped the democracy talk supporting deference in *Chevron* and anti-deference in *West Virginia*.”).

273. *Id.* at 1012.

274. *Id.*

B. Agencies

We posit that one of an agency's goals (or its objective function) is to withstand challenges to rules—or adjudications, or rescissions of rules—so that it can carry out its mission.

In the rulemaking process, and in any subsequent challenges, we would expect the agency to act in a way that gives it the best chance of prevailing such that it can implement desired policies. Agency rulemakings face two types of legal challenges: (1) that they exceed the agency's statutory authority and (2) that they are arbitrary and capricious.²⁷⁵ A challenger may prevail on either claim to stop a rule from going into effect; whereas the agency must survive both attacks for a rule to survive.²⁷⁶

Under the prior administrative regime, *State Farm* and *Chevron* took on talismanic significance as rival standards of judicial review. Although the Court in *State Farm* declared officially that a court should not “substitute its judgment for that of the agency,”²⁷⁷ in practice, the case came to stand for “hard look” review, wherein the court would scrutinize the data and evidence upon which the agency had relied in making its putatively “reasoned” decisions.²⁷⁸ *Chevron*, on the other hand, stood famously for strong-form deference.²⁷⁹ As long as the agency's interpretation was within the range of reasonable meanings, the court would defer to the agency, regardless of whether the court would have come to that specific reading on its own accord.²⁸⁰ Agencies and challengers understood *Chevron* to be a thumb on the scale in favor of agencies, while *State Farm* offered courts a chance to scrutinize an agency's decision more closely.

Professors Jonathan Masur and Eric Posner have observed that the first Trump Administration strategically used the disparity in deference between these standards of review to defend agency decisions in court.²⁸¹ Specifically, the administration “*Chevronized*” around cost-benefit analyses (CBAs)—which have

275. DANIEL T. SHEDD & JARED P. COLE, CONG. RSCH. SERV., R44699, INTRODUCTION TO JUDICIAL REVIEW OF FEDERAL AGENCY ACTION 16 (2025).

276. *See id.*

277. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

278. Patrick M. Garry, *Judicial Review and the “Hard Look” Doctrine*, 7 NEV. L.J. 151, 152 & n.8 (2006).

279. *See United States v. Mead Corp.*, 533 U.S. 218, 227–28 (2001) (noting that *Chevron* deference is stronger than *Skidmore* “respect”).

280. *See* Matthew C. Stephenson & Adrian Vermeule, *Chevron Has Only One Step*, 95 VA. L. REV. 597, 601 (2009) (referring to the “zone of ambiguity”).

281. Masur & Posner, *supra* note 176, at 1113–14.

become a key part of *State Farm* review²⁸²—by framing issues as statutory interpretations rather than as policy decisions.²⁸³ This move sought to accord agencies *Chevron* deference and avoid their having to conduct a CBA or to get around the fact that costs exceeded benefits, making the decision notably *unreasoned*.²⁸⁴ The authors note the tension between judicial deference under *Chevron* and “the rise of cost-benefit analysis[, which] suggests that courts should push back against the executive branch when its regulatory decisions violate a cost-benefit test, even if the relevant statutory language is broad and ambiguous.”²⁸⁵

Masur and Posner were correct that one side of the tension would “have to give,”²⁸⁶ as the Supreme Court has ended judicial deference to agencies on the statutory front. Under this new regime, some scholars predict that agencies will try to reframe statutory interpretation as policymaking, to gain the greater deference that *State Farm* provides.²⁸⁷ Using gun regulations as a case study, Professor William Araiza predicts that the impact of *Loper Bright* on agencies will depend on the specific statutory scheme and the extent to which they can claim to be doing policymaking rather than statutory interpretation.²⁸⁸ Agencies seeking to win challenges will want to label rules as the results of policymaking whenever possible, but they remain subject to the specific nature of the rule and the authorizing statute. If the level of deference depends on how the agency’s rule is characterized, then this characterization is very important. Araiza sets out a spectrum from straightforward “linguistic parsing” to clear policymaking, with much in between.²⁸⁹ Here, he notes that agencies are often at the mercy of their enabling statute. As an example of simple statutory interpretation, he points to *Garland v. Cargill*,²⁹⁰ which the Supreme Court decided right before *Loper Bright*.²⁹¹ There, the issue was whether a semi-automatic weapon with a “bump stock” was a

282. See Sunstein, *supra* note 135, at 4 (suggesting that the need for adequate cost-benefit analysis (CBA) will depend in part on how intense the standard of judicial review is, with more deferential review likely not necessitating substantive CBA).

283. Masur & Posner, *supra* note 176, at 1113–14.

284. *Id.* at 1138.

285. *Id.* at 1148–49.

286. See *id.* at 1150.

287. William D. Araiza, *Gun Regulation After Loper Bright: The Statutory Interpretation/ Policymaking Continuum*, 73 BUFF. L. REV. 711, 739 (2025); Rassieur, *supra* note 155, at 314; cf. Bressman, *Lower Courts*, *supra* note 254, at 505 (noting that, without *Chevron*, judges may begin asking whether they should rely on *State Farm* in their review).

288. Araiza, *supra* note 287, at 739.

289. See *id.* at 722–31.

290. 144 S. Ct. 1613 (2024).

291. Araiza, *supra* note 287, at 722, 730.

“machinegun” as defined by the statute.²⁹² The Court disagreed with the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) in its view that such weapons were machineguns.²⁹³

The LDT case provides an example of this changing regime. Contrary to Araiza and others’ predictions, the FDA accepted that the LDT case was a question of statutory interpretation and did not attempt to double down on reasoned decisionmaking review.²⁹⁴ The LDT case differs from other examples for several important reasons. While it may be tempting to label the question of what is a “device” as “linguistic parsing”—and indeed the court took that view—this is a far different case from the gun stocks. First, the FDA is an expert, scientific agency in charge of regulating medical devices, whereas there is no equivalent authority on guns (ATF being a law enforcement agency). Second, the definition of a term like “device” is in fact a technical decision, requiring scientific expertise. Justice Kagan provides another strong example: defining the term “protein” might deceptively appear like a task suited for a judge with a dictionary but in fact may require determining when an “alpha amino acid polymer” qualifies a protein, something for which judges are poorly equipped but the FDA is highly competent.²⁹⁵ Accordingly, courts may be willing to change their level of respect for the agency’s interpretation based on regulatory expertise and credibility.²⁹⁶ To the extent that concerns about the administrative state focus on health and environmental regulations, a model that looks at the incentives and actions

292. *Cargill*, 144 S. Ct. at 1617.

293. *Id.* at 1618, 1623–27.

294. *See* Am. Clinical Lab’y Ass’n v. FDA, 776 F. Supp. 3d 554, 560 (E.D. Tex. 2025) (“FDA maintains that the final rule is well within its authority under the FDCA and does not otherwise violate the APA.”).

295. *See* Sharkey & Kenny, *FDA Leads*, *supra* note 10, at 163 n.27 (quoting *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2296 (2024) (Kagan, J., dissenting)). Here, Professor Stephenson’s attempt to fit the protein example within his “Gray zone” framework is unpersuasive. *See* Stephenson, *supra* note 15, at 181–86. Indeed, we find incredulous Stephenson’s assertion that “the question whether having a ‘specific, defined sequence’ of amino acids is a defining feature of a ‘protein,’ . . . is a ‘pure’ legal question: Does ‘protein,’ . . . include a ‘specific, defined sequence’ requirement or not?” *See id.* at 182–83 (emphasis added). We find it strains reality (or at least institutional comparative competence) to suggest that “[u]nder *Loper Bright/Gray*, . . . the court would need to decide which interpretation of ‘protein’ is better.” *Id.* at 183 (emphasis omitted). Nor (as discussed in *supra* note 191) does Stephenson place enough faith in *Skidmore*, when he concedes that “[t]he court might give considerable weight to the FDA’s view on the question, especially in light of the FDA’s extensive consultation with the scientific community in formulating its definition, but ultimately the court would need to use its independent judgment to resolve the issue.” *Id.* at 183.

296. *See supra* Part III.A.

of scientific agencies—and the reception to those actions—will be more useful than one centered on an agency like ATF.

The FDA could have tried to frame the LDT rule as an example of policy-making, arguing that the question of what constitutes a device is a scientific, not linguistic, decision. Seeking *State Farm* review, however, would have meant the court taking a hard look at the agency's evidentiary corpus, which, as detailed above, was thin. Thus, the FDA's acquiescence to a legal battle waged on statutory grounds may reflect a strategic decision based on the limited amount of evidence supporting the rule. The agency may have simply made a calculation that its best chance was to defend the rule on statutory grounds.

There is also the specific—and possibly unique—context of the FDA's claiming that it already had this authority. Following the agency's narrative, the original act of statutory interpretation occurred decades ago and has remained undisturbed by courts.²⁹⁷ If the court had accepted the agency's view of longstanding jurisdiction, then the statutory issue would have been a clear victory for the FDA. The FDA's unusual position raises the question why the agency would go through notice-and-comment rulemaking in the first place when it allegedly already had the authority to enforce against LDTs if it so chose.

Under the venerable *Chevron* regime, one reason agencies pursued notice-and-comment rulemaking was to secure judicial deference, which was not accorded to more informal agency actions such as enforcement guidelines and policy statements.²⁹⁸ After *Loper Bright*, all agencies receive *Skidmore* "respect" regardless of whether they have gone through the informal rulemaking process.²⁹⁹ Although the LDT rulemaking began before *Loper Bright*, the FDA clearly saw the writing on the wall, given that it asserted in the Final Rule that its interpretation was the best one and that it did not depend on judicial deference.³⁰⁰

Another reason we might expect an agency to use notice-and-comment rulemaking (as opposed to changing enforcement guidelines or internal policy) is to create an administrative record of evidence and consideration of comments, in anticipation of potential *State Farm* review. In this case, however, the empirical evidence provided by the FDA in the rulemaking record is far from robust (as we detail above).³⁰¹

297. Agencies will always be the first interpreters of statutes. *Chevron* recognized this truth not as doctrine but as fact. See Rubin, *supra* note 134, at 37–38.

298. See *United States v. Mead Corp.*, 533 U.S. 218, 234 (2001). In dissent, Justice Scalia predicted that such distinction would "artificially induce[]" an increase in notice-and-comment rulemaking by agencies seeking to fall under *Chevron*. *Id.* at 246 (Scalia, J., dissenting).

299. See *Loper Bright*, 144 S. Ct. at 2267.

300. Medical Devices; Laboratory Developed Tests, 89 Fed. Reg. 37,286, 37,330 (May 6, 2024) (to be codified at 21 C.F.R. pt. 809) (response to comment 50).

301. See *supra* Part II.C.

Perhaps the best explanation for the FDA's move is that, at the time of rule-making, Congress had recently declined opportunities to legislate this issue,³⁰² and the FDA wanted to do something big and "law-like" rather than simply start to enforce against LDT makers under the existing-jurisdiction theory.

Regardless of the FDA's reasoning, we must ask if this longstanding authority move is viable in a post-*Loper Bright* world. In upholding the traditional factors of *Skidmore* "respect," the *Loper Bright* court gives special weight to "interpretations issued contemporaneously with the statute at issue, and which have remained consistent over time."³⁰³ Indeed, the FDA cites this language in its brief and argues that its interpretation of "device" fits this category.³⁰⁴

Here, it is useful to contrast the LDT case with *Catskill Mountains*, discussed above.³⁰⁵ It is a striking case because we know that the court would not have come to the same interpretation on its own but was essentially forced to accept the EPA's reading.³⁰⁶ For skeptics of administrative delegation, this case could represent everything wrong with *Chevron* deference. But the case also highlights problems with judicial review for those, like us, who advocate empirically sound policymaking. The problem in *Catskill Mountains* was that *Chevron's* focus on statutory authority allowed the EPA to justify the rule solely with legal and statutory arguments, rather than providing evidence for what was ultimately a policy decision to not regulate water transfers.³⁰⁷ The case is also a reminder that judicial deference is not inherently pro-regulation (and non-deference is not necessarily anti-regulation), since the EPA was advancing—without scientific backing—an interpretation that allowed many potentially polluting activities to go unregulated.

Catskill Mountains serves as a useful counter-example to the LDT case; both cases turned on statutory interpretation, with limited examination of the evidentiary record. The difference is that under *Loper Bright*, the court could assert its own reading of the statute and owed no deference to the agency,

302. See *supra* note 78 and accompanying text.

303. *Loper Bright*, 144 S. Ct. at 2262.

304. FDA Brief, *supra* note 35, at 21.

305. See *supra* notes 158–163 and accompanying text.

306. Not only do the prior cases confirm that the Court did not agree with the EPA's interpretation, but in the final case, the Court said that it would have still interpreted the statute differently than did the EPA. *Catskill Mountains Chapter of Trout Unlimited, Inc. v. EPA*, 846 F.3d 492, 501 (2d Cir. 2017) ("While we might prefer an interpretation more consistent with what appear to us to be the most prominent goals of the Clean Water Act, *Chevron* tells us that so long as the agency's statutory interpretation is reasonable, what we might prefer is irrelevant.").

307. Sharkey, *Catskill Mountains*, *supra* note 164 ("[T]he EPA did not engage in any kind of scientific analysis of water transfers in order to consider the competing policy considerations, namely the potential environmental, health, and economic harms caused by some inter-basin transfers.").

reversing the outcome. While the anti-delegation critic may be satisfied by this outcome, the concerns about evidentiary soundness remain, since the LDT case still did not engage with the data. Even though *Loper Bright* may have changed the outcome in certain cases, it has not necessarily changed the focus of cases; agency actions still rise and fall at the mercy of a judge looking to a dictionary to discern the “best” reading of a statutory term.

Our proposal solves the problems that persist in the post-*Loper Bright* world and creates positive incentives for agencies. Under a regime of heightened *State Farm* scrutiny, agencies would know that they will face scrutiny of the evidentiary record, so they would have incentives to build a robust empirical showing and—ideally—only undertake those actions that satisfy cost-benefit analysis. Just as *Catskill Mountains* showed that judicial acquiescence goes both ways, a robust and integrated *State Farm* review would apply to both introduction and rescission of applications, the latter being especially relevant at the present moment as the Trump Administration has started rule-making to roll back many existing environmental, health, and labor regulations.³⁰⁸ For an Administration that faced an already low win rate in its first iteration,³⁰⁹ the end of *Chevron* means the prospect of greater judicial scrutiny and the foreclosed possibility of “*Chevronizing*” around rules that are not cost-justified. Recent guidance from the Trump Administration apparently recognizes that “deregulation will involve the development of a record, including reasoned decision making”—which is at the heart of our proposal.³¹⁰

C. Congress

Turning to Congress, the main question is what sort of authority or power the legislative branch grants to the agencies tasked with carrying out its

308. See, e.g., Memorandum from President Donald J. Trump to the Heads of Executive Departments and Agencies (Apr. 9, 2025), <https://www.govinfo.gov/app/details/DCPD-202500466> (ordering agencies to aggressively and quickly withdraw regulations that are facially unlawful); 2025 OIRA MEMORANDUM, *supra* note 1, at 1 (urging agencies to “redouble their efforts” to repeal unlawful regulations).

309. Bethany A. Davis Noll, “*Tired of Winning*”: *Judicial Review of Regulatory Policy in the Trump Era*, 73 ADMIN. L. REV. 353, 357 (2021) (noting that the first Trump Administration won only 23% of legal challenges to agency actions).

310. 2025 OIRA MEMORANDUM, *supra* note 1, at 1, 4 (noting that “development of a strong regulatory record [among other efforts] are examples of actions that will lead to long-lasting and successful deregulation of the economy”). At the same time, we note that the Administration still adheres to the conventional strict dichotomy of law versus fact-based reasons to overrule regulations. *Id.* at 6 (“It is true that once the agency has identified a regulation that is unlawful as a matter of law, there might be additional policy or fact-bound arguments one could advance as to why a rule should be repealed.”).

mandates. There is often no doubt that Congress has delegated decisionmaking authority to an agency, but it may be less certain what type of authority Congress envisions. Professors Hickman and Wildermuth divide statutory authorizations into specific, general, and hybrid authority, with specific authority being the case where Congress defines a term and then gives the agency authority to decide what things fall within that term.³¹¹ There remains, however, the issue of *how* the agency makes the decision whether something fits within the defined term. Should the agency use a dictionary or its field-specific expertise? Here, layering on Professor Rubin's distinction between traditional statutes that give normative declarations and modern statutes that give instruction to the agency provides further clarification within the category of specific authority.³¹² Normative declarations—"X shall be subject to regulation"—lend themselves to linguistic determination of whether something is X, while intransitive instructions—"the agency shall decide what X is"—are more likely to produce policymaking decisions.

We argue that an expansion of reasoned decisionmaking review would be salutary in all categories and might even change how Congress writes statutes. Agencies will create beneficial rules when they are thinking like policymakers instead of like interpreters of statutory text.

Using the LDT example, we can see how a slightly different statutory mandate would change the rulemaking process and the type of judicial review. Now, the FDCA defines "device" as any "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article," and then gives the FDA authority to decide what is a device.³¹³ But as Rubin's formulation reveals, this provision of the FDCA is not the modern "intransitive" statute but rather the older type that invites discrete interpretive issues.³¹⁴ Congress is giving the FDA the power to decide what is a "device," but only within the bounds of the definition that Congress has provided. It was ultimately on the basis of this list—and the court's interpretation that it contemplated only physical things—that the FDA lost the LDT challenge.³¹⁵

Under a different regime, however, Congress might recognize that the FDA's expertise lies not in interpreting ambiguous lists of terms, but in using its scientific knowledge and public health data to determine which products should be regulated, based on the risks presented.³¹⁶ If Congress knows that any rule will be reviewed under a stringent *State Farm* standard, it might be

311. Hickman & Wildermuth, *supra* note 200, at 1932, 1934.

312. Rubin, *supra* note 134, at 45–48.

313. 21 U.S.C. § 321(h).

314. Rubin, *supra* note 134, at 47.

315. *Am. Clinical Lab'y Ass'n v. FDA*, 776 F. Supp. 3d 554, 585 (E.D. Tex. 2025).

316. Sharkey & Kenny, *FDA Leads*, *supra* note 10, at 207–08.

willing to replace linguistic restraint with process-based controls. Congress could have written an alternative version of the FDCA that aligns with what Rubin calls the modern, instruction-based statutes. The relevant part could read: “The FDA shall determine what constitutes a device, based on a thorough review of all available data and after deciding whether the costs and benefits to public health justify regulation.” This would entirely remove the statutory question and mean that any rule promulgated under this provision would be reviewed for compliance with the statutory process (which could be made more detailed if desired). In a case like this where Congress has clearly delegated discretion, *Loper Bright*—in the key two paragraphs discussed above—instructs the court to effectuate congressional will by reviewing the action for reasoned decisionmaking.³¹⁷

It is difficult to know if Congress intended to include LDTs within the scope of regulation under the Medical Device Amendments; LDTs were not a significant part of the field in 1976 and did not present the risks to public health they do today.³¹⁸ We do know that Congress chose to give the FDA authority on the matter, limited statutorily by the list of terms defining “device.” But if the goal of agency delegation in the first place is to let a more knowledgeable body fill in the details, Congress should get out of the definition game in certain instances. And if Congress knows that agency action will be reviewed closely by the court, it might be more willing to expand the statutory grant.

In the LDT example, however, we must acknowledge that Congress had two opportunities to pass legislation explicitly giving the FDA authority over LDTs and declined—or failed—to do so both times.³¹⁹ This failure may reflect congressional ambivalence to the FDA’s explicit authority to enforce against makers of LDTs. We cannot say for certain how a reinvigorated *State Farm* standard would change the calculus, but it has a strong likelihood of curtailing such ambivalence.

CONCLUSION

The LDT case highlights many of the contradictions and ambiguities that characterize the current state of administrative law in flux. The court made an essentially policy-based decision, while insisting it was instead grounded

317. *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2263 (2024); see *supra* text accompanying notes 183–187.

318. See Lars Mouritsen, *Navigating the FDA’s Final Rule for Laboratory-Developed Tests (LDTs)*, MASTERCONTROL (Oct. 23, 2024), <https://www.mastercontrol.com/gxp-lifeline/navigating-fda-laboratory-developed-tests-ldt/> [https://perma.cc/4ARV-6CXY] (“Initially, [LDTs] were small-scale tests performed manually by pathologists and technical experts, utilizing components already marketed for clinical use.”).

319. See *supra* note 78 and accompanying text.

in statutory text. At the same time, the court declined to examine the scientific record evidence that would undergird the reasonableness of its policy decision. An expert agency was forced into a position of fighting over dictionary definitions and canons of interpretation, while the decision revealed nothing about the scientific basis for regulating a new form of diagnostic tests that pose medical health risks. This unsatisfactory outcome foreshadows the two viable options as administrative law moves forward: a “brave new world” of vigorous challenges to agencies, who are accorded less deference by reviewing courts, or a regime that allows agencies to double down on policymaking rationales and lets courts engage with the evidentiary basis for those rationales.

Taking up the latter “road not traveled,” with expansive use of arbitrary and capricious review, under a heightened *State Farm* standard, we propose a regime of judicial oversight that holds appeal across our increasingly polarized, ideologically charged administrative state. For agency-friendly judges, the move ensures that agencies are still making beneficial policy that is the result of rigorous empirical study, consideration of reliance interests, and estimation of costs and benefits. For agency skeptics, our proposal might induce a more lenient view of delegated discretion on the statutory side since the court can still scrutinize the agency closely on the policymaking side by using a stringent *State Farm* review standard. A regime of vigorous *State Farm* review could also create a hierarchy of deference to different agencies, depending on their level of expertise.

Our proposal also solves the problems that persist in the post-*Loper Bright* world and creates beneficial incentives for agencies. Under a regime of heightened *State Farm* scrutiny, agencies would know that they will face scrutiny of the evidentiary record, so they would have incentives to build a robust empirical showing and—ideally—only undertake those actions that satisfy cost-benefit analysis. A robust and integrated *State Farm* review would apply to both introduction and rescission of rules, with the rescission side being particularly important as the current Trump Administration touts its commitment to “deregulating at an unprecedented scale.”³²⁰

320. 2025 OIRA MEMORANDUM, *supra* note 1, at 4.