SUPER DEFERENCE AND HEIGHTENED SCRUTINY

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Abstract

Judicial review of federal agency action is systematically deferential. Such deference is arguably at its peak where agencies address scientific and highly technical matters within their area of expertise. This is what some call "super deference." While there may be strong arguments for deferential review of agency scientific determinations as a general matter, there are reasons to question such deference when agency action implicates constitutional concerns. In particular, where agency actions trigger heightened scrutiny, such as occurs when agency actions intrude upon expressly enumerated or otherwise recognized fundamental rights or adopt constitutionally suspect classifications, courts should not apply traditional levels of deference. This Article explains why the application of so-called "super deference" is inappropriate where federal agency action triggers heightened scrutiny and considers some of the potential implications of such a rule.

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INTRODUCTION

Regulations and other measures adopted in response to the COVID-19 pandemic have highlighted the potential conflict between science-based regulatory measures and constitutionally protected liberties.[1] Throughout 2020, government agencies adopted policies to control the spread of novel coronavirus, often with a necessarily incomplete understanding of the emergent threat.[2] At times, these measures constrained the exercise of constitutionally protected rights, such as the free exercise of religion[3] or a woman's right to terminate a pregnancy.[4] In some such cases, courts were forced to choose between deference to

1. *See* Lindsay F. Wiley & Stephen I. Vladeck, *Coronavirus, Civil Liberties, and the Courts: The Case Against "Suspending" Judicial Review*, 133 HARV. L. REV. F. 179, 179 (2020).

2. *See, e.g.*, Ewen Callaway, Heidi Ledford, Giuliana Viglione, Traci Watson & Alexandra Witz, *COVID and 2020: An Extraordinary Year for Science*, NATURE (Dec. 14, 2020), https://www.nature.com/immersive/d41586-020-03437-4/index.html [https://perma.cc/F7L6-UJTT] (noting early uncertainties about COVID-19 transmission); Harry Rutter, Miranda Wolpert & Trisha Greenhalgh, *Managing Uncertainty in the COVID-19 Era*, BMJ, Sept. 1, 2020, at 1, https://www.bmj.com/content/370/bmj.m3349 [https://perma.cc/62X7-4J8R] (noting persistent scientific uncertainty); Warren Pearce, *Trouble in the Trough: How Uncertainties Were Downplayed in the UK's Science Advice on COVID-19,* HUMANITIES & SOC. SCI. COMMC'NS., Oct. 13, 2020, at 1 (noting uncertainty about the virus doubling rate).

3. *See, e.g.*, Tandon v. Newsom, 141 S. Ct. 1294, 1297 (2021) (enjoining enforcement of limitations on in-home religious gatherings); S. Bay United Pentecostal Church v. Newsom, 141 S. Ct. 716, 716 (2021) (partially granting an injunction against California limitations on religious services due to COVID-19); Danville Christian Acad., Inc. v. Beshear, 141 S. Ct. 527, 528 (2020) (rejecting a challenge to a school closing order that petitioners asserted treated religious schools worse than other businesses); Roman Cath. Diocese of Brooklyn v. Cuomo, 141 S. Ct. 63, 69 (2020) (per curiam) (enjoining enforcement of occupancy limitations on certain religious services); *see also* Josh Blackman, *The "Essential" Free Exercise Clause*, 44 HARV. J.L. & PUB. POL'Y 637, 644 (2021) (analyzing court interpretations of the Free Exercise Clause as it applied to religious institutions during the pandemic).

4. *See* FDA v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 578, 578 (2021) (staying preliminary injunction against FDA's requirement that mifepristone be dispensed in person during the pandemic).

agency authority or protection of constitutional rights against government interference.

Judicial review of federal agency action is systematically deferential.[5] Courts defer to agency interpretations, policy judgments, and factual findings. Some would argue that such deference is necessary for the viability of the modern administrative state.[6] In many areas, agencies are tasked with assessing complex scientific questions in the course of promulgating rules and implementing federal programs. Judicial deference is arguably at its peak where agencies address scientific and highly technical matters within their area of expertise.[7] This is what some call "super deference."[8]

There are several reasons for applying a stronger form of deference where agencies are evaluating and applying scientific and technical information that relates to matters within their jurisdiction. Agencies have a comparative advantage over Article III courts in evaluating scientific information. Administrative agencies often have expert personnel who can be expected to have greater expertise than generalist judges. Agencies are often better positioned than courts or legislatures to assess new scientific information and incorporate evolving findings into their program. The evaluation of scientific information is often intricately bound up in policy determinations for which agencies are responsible. Moreover, insofar as Congress has delegated responsibility to federal agencies over certain matters, deference to agency determinations within their delegated jurisdiction would seem to follow.

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5. As Daniel Solove observed, "[i]t has become almost commonplace for the Court to declare that it will 'defer to the expert judgment' of a government official." Daniel J. Solove, *The Darkest Domain: Deference, Judicial Review, and the Bill of Rights*, 84 IOWA L. REV. 941, 947 (1995) (quoting Pell v. Procunier, 417 U.S. 817, 827 (1974)).

6. *See, e.g.*, Gillian E. Metzger, *The Supreme Court, 2016 Term—Foreword: 1930s Redux: The Administrative State Under Siege*, 131 HARV. L. REV. 1, 7 (2017) (arguing that deference is a necessary consequence of delegation to administrative agencies); Jacob Gersen & Adrian Vermeule, *Thin Rationality Review*, 114 MICH. L. REV. 1355, 1356 (2016) (arguing for extremely thin review of agency decisionmaking); David Zaring, *Reasonable Agencies,* 96 VA. L. REV. 135, 138–39 (2010) (arguing in favor of a general "reasonable agency" standard). Some also argue that existing "hard look" review is not deferential enough. *See, e.g.*, Sidney A. Shapiro & Richard W. Murphy, *Arbitrariness Review Made Reasonable: Structural and Conceptual Reform of the "Hard Look*,*"* 92 NOTRE DAME L. REV. 331, 333 (2016).

7. *See* Balt. Gas & Elec. v. Nat. Res. Def. Council, 462 U.S. 87, 103 (1983) (explaining that "a reviewing court must be . . . at its most deferential" to an agency's scientific determinations).

8. *See*, *e.g.*, Emily Hammond Meazell, *Super Deference, the Science Obsession, and Judicial Review as Translation of Agency Science*, 109 MICH. L. REV. 733, 734 (2011). The first description of *Baltimore Gas* deference as "super deference" appears to be Thomas O. McGarity & Wendy E. Wagner, *Legal Aspects of the Regulatory Use of Environmental Modeling*, 33 ENV'T L. REP. 10751, 10757 n.44 (2003).

While there may be strong arguments for deferential review of agency scientific determinations as a general matter, there are reasons to question such deference when agency action implicates constitutional constraints on government action. In particular, where agency actions trigger heightened scrutiny, such as when they intrude upon fundamental rights or adopt constitutionally suspect classifications, courts should not apply traditional levels of deference. In such contexts, super deference is not so super.

Deference to agency interpretations may well be perfectly appropriate where agencies are tasked with following legislative instruction and implementing legislatively authorized programs. Applying the level of deference Congress anticipated, or even that to which Congress may have acquiesced, is consistent with the effective operation of the administrative state. If Congress wants courts to apply more or less stringent forms of judicial review, Congress is capable of enacting such preferences, and Courts would be obliged to follow.[9] Where heightened scrutiny is triggered, however, the proper degree of deference is not a decision for Congress to make.[10]

While scholars have identified and evaluated arguments for granting deference to the scientific judgments and assessments made by federal agencies,[11] there has been no prolonged consideration of how such

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9. The Administrative Procedure Act is the source of the primary standards of review in administrative law. *See* 5 U.S.C. § 706. Other statutes prescribe different standards of review for different sorts of questions. *See, e.g.*, Religious Freedom Restoration Act, 42 U.S.C. § 2000bb-1 (prescribing a more stringent standard of review for federal actions that infringe upon religious liberty). Congress's power in this regard is limited by constitutional constraints. *See* City of Boerne v. Flores, 521 U.S. 507, 536 (1997) (holding that Congress cannot prescribe the level of review Article III courts apply to state action in constitutional cases).

10. In *FCC v. Fox Television Stations*, the Supreme Court held that review of agency action under the relevant statutory standard is distinct from any constitutional inquiry. 556 U.S. 502, 516 (2009) ("If the Commission's action here was not arbitrary or capricious in the ordinary sense, it satisfies the Administrative Procedure Act's 'arbitrary [or] capricious' standard; its lawfulness under the Constitution is a separate question . . . ."). As it happened, the FCC action upheld in that decision was subsequently held to be unconstitutional. *See* FCC v. Fox Television Stations, 567 U.S. 239, 259 (2012).

11. *See, e.g.*, Shannon Roesler, *Agency Reasons at the Intersection of Expertise and Presidential Preferences*, 71 ADMIN. L. REV. 491, 531–53 (2019); Meazell, *supra* note 8, at 737–38; Gersen & Vermeule, *supra* note 6, at 1387, 1406; Shapiro & Murphy, *supra* note 6, at 355, 359; Mark Seidenfeld, *The Role of Politics in a Deliberative Model of the Administrative State*, 81 GEO. WASH. L. REV. 1397, 1443–47 (2013); Kathryn A. Watts, *Proposing a Place for Politics in Arbitrary and Capricious Review*, 119 YALE L.J. 2, 13–16, 32–33 (2009); Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1711–19 (1995). *See generally* THOMAS O. MCGARITY, REINVENTING RATIONALITY: THE ROLE OF REGULATORY ANALYSIS IN THE FEDERAL BUREAUCRACY (1991) (examining and critiquing claims of regulatory reformers that regulatory analysis will result in better decisionmaking). On standards of judicial review of agency action more generally, see Sidney A. Shapiro & Richard E. Levy, *Heightened*

arguments fare when resulting agency action triggers heightened scrutiny.[12] Scholars have questioned deferential judicial review of agency fact-finding, particularly concerning "constitutional facts,"[13] but have not evaluated the particular concerns that arise under heightened scrutiny. Scholarship has considered the deference courts should, or should not, show to legislative findings,[14] including when constitutional values are at stake,[15] but has not examined how heightened scrutiny should affect judicial review of factual determinations made by federal agencies.[16]

This Article explains why the application of so-called "super deference" is inappropriate where federal agency action triggers heightened deference, either by threatening to infringe upon constitutionally protected rights or adopting suspect classifications. Part I describes the doctrine of "super deference," identifying its roots in *Baltimore Gas & Electric Co. v. Natural Resources Defense Council, Inc.*,[17] describing its application in federal courts, and identifying several arguments in favor of such a rule of deference in the regular course. Part II briefly explains the origins and rationale of applying heightened judicial scrutiny in particular contexts. Part III identifies particular risks

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Scrutiny of the Fourth Branch: Separation of Powers and the Requirement for Adequate Reasons for Agency Decisions, 1987 DUKE L.J. 387, 388 (1987).

12. Some scholars have, however, considered how courts should consider conflicts between civil liberties and COVID-19-related public health measures. *See, e.g.*, Wiley & Vladeck, *supra* note 1, at 187–91; Wendy E. Parmet, *Rediscovering* Jacobson *in the Era of COVID-19*, 100 B.U. L. REV. ONLINE 117, 130–31 (2020); Wendy E. Parmet & Michael S. Sinha, *Covid-19—The Law and Limits of Quarantine*, 382 NEW ENG. J. MED. e28(1), e28(2) (2020); Lawrence O. Gostin, Eric A. Friedman & Sarah A. Wetter, *Responding to Covid-19: How to Navigate a Public Health Emergency Legally and Ethically*, 50 HASTINGS CTR. REP. 8, 11 (2020). Others have suggested that relevant precedent on the permissibility of measures like forced vaccination has been misunderstood. *See generally, e.g.*, Josh Blackman, *The Irrepressible Myth of* Jacobson v. Massachusetts, 70 BUFF. L. REV. 113 (2021).

13. The most significant work in this vein is likely DAVID L. FAIGMAN, CONSTITUTIONAL FICTIONS: A UNIFIED THEORY OF CONSTITUTIONAL FACTS (2008). *See also* Evan D. Bernick, *Is Judicial Deference to Agency Fact-Finding Unlawful?*, 16 GEO. J.L. & PUB. POL'Y 27, 30 (2018); Martin H. Redish & William D. Gohl, *The Wandering Doctrine of Constitutional Fact*, 59 ARIZ. L. REV. 289, 327, 331 (2017); Mila Sohoni, *Agency Adjudication and Judicial Nondelegation: An Article III Canon*, 107 NW. U. L. REV. 1569, 1599 (2013) (arguing for less deferential review of agency adjudication concerning private rights); Martin H. Redish, *Legislative Courts, Administrative Agencies and the* Northern Pipeline *Decision*, 1983 DUKE L.J. 197, 205 (questioning substantial evidence review of agency factual determinations).

14. *See generally* Daniel A. Crane, *Enacted Legislative Findings and the Deference Problem*, 102 GEO. L.J. 637 (2014) (evaluating claims for judicial deference of legislative fact-finding).

15. *See generally* FAIGMAN, *supra* note 13 (examining the role of fact-finding in constitutional cases and the incorporation of contemporary facts in constitutional decisions).

16. For a brief discussion of how courts should approach constitutional fact-finding by agencies, see *id.* at 177–81. *See generally* Sohoni, *supra* note 13 (arguing for more stringent judicial review of agency adjudications in private rights contexts than in public rights contexts).

17. 462 U.S. 87 (1983).

of applying super deference where agency action intrudes upon constitutionally protected rights or implicates suspect classifications. Part IV identifies several reasons why heightened scrutiny should prevail over deference. Part V considers some questions of application and addresses some potential implications of the arguments made.

I. SUPER DEFERENCE

Federal courts generally defer to agency judgments about scientific and technical matters within their expertise. According to the Supreme Court, reviewing courts are to be "most deferential" about such scientific determinations,[18] and courts generally are. While giving a "hard look" to agency explanations so as to ensure they have engaged in reasoned decisionmaking, courts are reluctant to disturb an agency's conclusions about relevant scientific or technical matters. There are many good reasons for this general approach, including the comparative institutional competence of agencies over courts, the need to account for new information and understandings, the interconnectedness of scientific judgments with policy determinations, and Congress's delegation of the authority to make such determinations to federal agencies.

A. *Super Deference in the Courts*

Section 706 of the Administrative Procedure Act (APA)[19] instructs reviewing courts to "hold unlawful and set aside agency action" that is found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[20] As interpreted by the courts, Section 706 requires courts to subject agency actions to a "searching and careful" inquiry—a "hard look"—so as to ensure they were the product of reasoned decisionmaking.[21] This review is "narrow" and provides no warrant for the reviewing court to substitute its view for that of the agency.[22] Its focus is ensuring that the agency "examine[d] the relevant data," "articulate[d] a satisfactory explanation for its action," and identified a "rational connection between the facts found and the choice made."[23] Under this standard, an agency's decision to ignore relevant

18. *Id.* at 103.

19. Ch. 324, 60 Stat. 237 (1946) (codified as amended in scattered sections of 5 U.S.C.).

20. 5 U.S.C. § 706. It further provides that agency actions are to be set aside if "unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute." *Id.* § (2)(e).

21. *See* Citizens to Pres. Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971), *superseded by statute*, Pub. L. No. 94–574, 90 Stat. 2721 (1976), *as recognized in* Califano v. Sanders, 430 U.S. 99, 105 (1977); Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).

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

23. *Id.* (quoting Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962)).

scientific evidence or disregard relevant arguments presented in the rulemaking is grounds for reversal, but reaching a different conclusion than what the reviewing court or others would prefer is not.[24]

The hard look review described in *State Farm* and its progeny focuses on the agency's decisionmaking and its explanation, not on the substance of the agency's conclusions. Although such scrutiny can be searching, and inevitably results in some agency decisions being overturned, it leaves agencies with the ability to render judgments about how to interpret incomplete data, how to account for scientific uncertainty, which scientific arguments or technical analyses to credit, and which to reject. Thus, it should be no surprise that *State Farm* and *Baltimore Gas* were decided by the same Court, in the same year.[25]

Under *Baltimore Gas*, agencies receive what is often termed "super deference."[26] As Justice Sandra Day O'Connor explained for a unanimous Court, when considering a challenge to an agency's scientific judgment "within its area of special expertise, at the frontiers of science . . . a reviewing court must generally be at its most deferential."[27] Such deference is to be even greater than that provided to an agency's "simple findings of fact,"[28] and such deference is not to be diminished by the existence of scientific uncertainty.[29]

The central issue in *Baltimore Gas* was the "reasonableness" of the Nuclear Regulatory Commission's assumption that there eventually would be a nuclear waste repository capable of preventing any environmental contamination from the waste stored therein.[30] The Court understood that the soundness of this assumption was "surrounded with uncertainty."[31] It nonetheless concluded that the Commission, to which

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24. *See, e.g.*, Dep't of Homeland Sec. v. Regents of the Univ. of Cal., 140 S. Ct. 1891, 1910–13 (2020) (concluding that the Department of Homeland Security's decision to rescind the Deferred Action for Childhood Arrivals policy was arbitrary and capricious because the Acting Secretary "'failed to consider . . . important aspect[s] of the problem' before her" (quoting *State Farm*, 463 U.S. at 43)); Michigan v. EPA, 576 U.S. 743, 752 (2015) ("[A]n agency may not 'entirely fai[l] to consider an important aspect of the problem' when deciding whether regulation is appropriate." (quoting *State Farm*, 463 U.S. at 43)).

25. Jacob Gersen and Adrian Vermeule argue that *Baltimore Gas* is more representative of the Supreme Court's approach to reviewing agency action than is *State Farm*. *See* Gersen & Vermeule, *supra* note 6, at 1359–60. This may be so, but Supreme Court cases are unlikely to be representative of judicial review of agency actions generally, and this hypothesis does not appear to apply to the behavior of the circuit courts of appeals where most challenges to agency actions are heard, and to the U.S. Court of Appeals for the D.C. Circuit in particular.

26. *See* Meazell, *supra* note 8, at 756–63.

27. Balt. Gas & Elec. Co. v. Natural Res. Def. Council, Inc., 462 U.S. 87, 103 (1983).

28. *Id.*

29. *Id.* at 97.

30. *Id.* at 92 (noting "the reasonableness of [the 'zero-release'] assumption is at the core of the present controversy").

31. *Id.* at 96.

Congress had entrusted responsibility for addressing such matters, could assume that "the Nation is likely to develop methods to store the wastes with no leakage to the environment."[32] Further, the Court observed, making this sort of assumption entailed a "policy judgment" that was "within the bounds of reasoned decisionmaking."[33] As the Court had noted in prior cases, agencies were "free" to make assumptions in line with their policy orientation.[34]

Predicting whether technical capabilities would develop was not a simple question of fact. Rather, it required making a judgment "within [the] special expertise" of the agency "at the frontiers of science."[35] This sort of "scientific determination" should be entitled to even greater deference than "simple findings of fact," the Court reasoned, because of the agency's particular expertise and delegated responsibility to make these sorts of judgments.[36] Provided that the agency engaged in reasoned decisionmaking by acknowledging and detailing relevant "areas of uncertainty" and their relevance for the agency's ultimate determination, the resulting conclusion could not be deemed arbitrary and capricious.[37]

Baltimore Gas reaffirmed that courts should review agency scientific determinations deferentially. Even before *Baltimore Gas*, though, it was understood that agencies were not required to substantiate their findings "with anything approaching scientific certainty."[38] Yet the broad language of *Baltimore Gas* made clear that judicial review was not to be an opportunity for interest groups to relitigate scientific matters on which they had not prevailed before the agency. As one early commentator noted, the "broad and powerful deference language" of Justice O'Connor's opinion for the Court embodied a "heightened notion of deference" greater than had been applied traditionally.[39] Indeed, some would even refer to the *Baltimore Gas* approach as "no look" review.[40]

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32. *Id.* at 98.

33. *Id.* at 105.

34. *See, e.g.*, Indus. Union Dep't v. Am. Petrol. Inst., 448 U.S. 607, 656 (1980) (plurality opinion) ("[T]he [a]gency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than under protection.").

35. *Balt. Gas*, 462 U.S. at 103.

36. *Id.*

37. *Id.* at 104–06.

38. *See Indus. Union Dep't*, 448 U.S. at 656.

39. *See* Andrew D. Siegel, *The Aftermath of* Baltimore Gas & Electric Co. v. NRDC*: A Broader Notion of Judicial Deference to Agency Expertise*, 11 HARV. ENV'T L. REV. 331, 331–32 (1987).

40. *See* Donald W. Stever, Jr., *Deference to Administrative Agencies in Federal Environmental, Health and Safety Litigation—Thoughts on Varying Judicial Application of the Rule*, 6 W. NEW ENG. L. REV. 35, 59 (1983); E. Donald Elliott, Retiring "No Look" Judicial Review in Agency Cases Involving Science 4 (Jan. 14, 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3766372 [https://perma.cc/8JLH-65LY]. Most would characterize this as an overstatement. *See* Siegel, *supra* note 39, at 359.

Lower courts have generally heeded the Court's *Baltimore Gas* guidance, even if not always with reference to the decision.[41] The idea that an agency's scientific judgments receive broad deference is deeply ingrained in judicial review of agency action. Particularly in the U.S. Court of Appeals for the D.C. Circuit, judges are loathe to second-guess the scientific assumptions, judgments, and conclusions of regulatory agencies.[42] Where an agency's decision is "based upon highly complex and technical matters," it is "entitled to great deference."[43]

Consistent with the understanding that the purpose of judicial review under the APA (and equivalent provisions in other statutes[44]) is to ensure "that the choices made" by the agency are "reasonable and supported by the record," where a regulation concerns highly technical or complex scientific questions, judges routinely insist on an agency explanation that details what choices were made and why, but courts rarely overturn scientific determinations themselves.[45] Review in such cases does not entail resolving "disagreement among the experts" or evaluating "the merits of competing expert views."[46] Nor does it matter whether the evidence in the record could support conclusions at odds with those of the agency.[47] As the D.C. Circuit observed in 1987: "Our only role is to determine whether 'the agency has exercised a reasoned discretion, with reasons that do not deviate from or ignore the ascertainable legislative intent.'"[48]

Baltimore Gas deference is of particular importance where agencies are addressing matters where science is contested or uncertain—as is

41. *See, e.g.*, Nat'l Ass'n for Surface Finishing v. EPA, 795 F.3d 1, 7 (D.C. Cir. 2015) ("We afford special deference 'where the agency's decision rests on an evaluation of complex scientific data within the agency's technical expertise.'" (quoting Troy Corp. v. Browner, 120 F.3d 277, 283 (D.C. Cir. 1997))).

42. *See, e.g.*, Am. Lung Ass'n v. EPA, 134 F.3d 388, 391 (D.C. Cir. 1998) ("Generally speaking, we will not second-guess EPA in its area of special expertise."); Env't Def. Fund v. EPA, 598 F.2d 62, 83–84 (D.C. Cir. 1978) ("EPA, not the court, has the technical expertise to decide what inferences may be drawn from the characteristics of . . . substances.").

43. Appalachian Power Co. v. EPA, 249 F.3d 1032, 1051–52 (D.C. Cir. 2001) (per curiam) (quoting Pub. Citizen Health Rsch. Grp. v. Brock, 823 F.2d 626, 628 (D.C. Cir. 1987)); *see also* Hüls Am., Inc. v. Browner, 83 F.3d 445, 452 (D.C. Cir. 1996) ("[W]e will give an extreme degree of deference to the agency when it 'is evaluating scientific data within its technical expertise.'" (quoting Int'l Fabricare Inst. v. EPA, 972 F.2d 384, 389 (D.C. Cir. 1992))).

44. *See, e.g.*, 42 U.S.C. § 7607.

45. Lead Indus. Ass'n v. EPA, 647 F.2d 1130, 1160 (1980).

46. *Id.*; *see also* Am. Trucking Ass'ns, Inc. v. EPA, 175 F.3d 1027, 1054 (D.C. Cir.) (per curiam), *modified*, 195 F.3d 4 (D.C. Cir. 1999); Am. Trucking Ass'ns v. EPA, 283 F.3d 355, 362 (D.C. Cir. 2002); Nat. Res. Def. Council, Inc. v. EPA, 16 F.3d 1395, 1404 (4th Cir. 1993) ("[T]he court concludes that the best course of action is to leave this debate to the world of science to ultimately be resolved by those with specialized training in this field.").

47. *Lead Indus.*, 647 F.2d at 1160; *Am. Trucking*, 283 F.3d at 362.

48. Nat. Res. Def. Council, Inc. v. EPA, 824 F.2d 1146, 1163 (D.C. Cir. 1987) (quoting *Lead Indus.*, 647 F.2d, at 1145).

often the case where science is to be incorporated into agency rulemaking—or where agencies are required to make predictions or projections about the future. While the design of agency models and accuracy of agency projections can be contested, they represent the sorts of judgments agencies are entitled to make, provided they offer adequate explanation for the choices they make. As the D.C. Circuit explained in one illustrative case, courts will uphold agency models "as long as the agency explains the assumptions and methodology used in preparing the model and provides a complete analytic defense should the model be challenged."[49] It is not enough for those challenging a model's accuracy or design to show that it is "limited or imperfect."[50] Rather, petitioners must show the model "bears no rational relationship to the characteristics of the data to which it is applied" for a court to conclude its use was arbitrary and capricious.[51] Likewise, unless there is a specific statutory mandate dictating otherwise, agencies are entrusted with the authority to determine when "imperfect scientific information" is sufficient for the task at hand.[52]

Requiring reviewing courts to be particularly deferential to an agency's assessment of relevant scientific research—and the implications for matters within the agency's regulatory purview—does not mean that anything goes.[53] Such deference need not be abdication. Courts are still responsible for ensuring that an agency has engaged in reasoned decisionmaking, and has articulated a connection between any particular policy outcome or conclusion and the facts found or scientific conclusions reached. Super deference does not excuse an agency from its obligation to engage in reason-giving. Nor does super deference empower an agency to deny readily established scientific facts about the world.

In *American Trucking Ass'ns v. EPA*,[54] the D.C. Circuit rejected the EPA's failure to consider the potential health harms that could result from a *reduction* in ambient levels of tropospheric ozone when setting the ozone National Ambient Air Quality Standards (NAAQS) under the

49. Nat'l Ass'n for Surface Finishing v. EPA, 795 F.3d 1, 18 (D.C. Cir. 2015) (cleaned up); *see also* Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 535 (D.C. Cir. 1983) ("Ultimately, however, [courts] must defer to the agency's decision on how to balance the cost and complexity of a more elaborate model against the oversimplification of a simpler model.").

50. Appalachian Power Co. v. EPA, 249 F.3d 1032, 1052 (D.C. Cir. 2001) (per curiam).

51. *Id.* (quoting Appalachian Power Co. v. EPA, 135 F.3d 791, 802 (D.C. Cir. 1998)).

52. *See* Allied Loc. & Reg'l Mfrs. Caucus v. EPA, 215 F.3d 61, 71 (D.C. Cir. 2000) ("We generally defer to an agency's decision to proceed on the basis of imperfect scientific information, rather than to 'invest the resources to conduct the perfect study" (quoting Sierra Club v. EPA, 167 F.3d 658, 662 (D.C. Cir. 1999))).

53. *But see* Elliott, *supra* note 40, at 4 (stating that "[i]n 'no look' judicial review, courts merely assert that a subject is 'on the frontiers of science' . . . and affirm whatever the agency has done without addressing the challengers' arguments on the merits").

54. 175 F.3d 1027 (D.C. Cir. 1999).

Clean Air Act (CAA).[55] Under the Act, the EPA was obligated to base the NAAQS on air quality criteria that were to "reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities."[56]

Comments submitted to the rulemaking record indicated that ozone blocks ultraviolet radiation, and therefore a reduction in tropospheric ozone levels could produce an increase in human exposure to ultraviolet radiation with negative effects on human health.[57] In other words, reducing urban air pollution levels could *increase* the risks to public health along one dimension, however much such reductions could reduce health risks along other dimensions.[58]

In finalizing the ozone NAAQS revision, the EPA did not account for these effects, arguing that it was not required to consider potentially beneficial effects of pollutants in the ambient air.[59] In the EPA's view, the purpose of an NAAQS is to protect people against breathing unhealthy concentrations of regulated pollutants, so that is what the agency focused on. The D.C. Circuit rejected the EPA's arguments because the plain text of the CAA required the agency to consider "all identifiable effects" of regulated pollutants in the ambient air, not merely negative effects or those effects that come from the inhalation of pollutants.[60] Further, the court rejected the EPA's argument that it could ignore the relevant studies finding potential adverse health consequences from ozone reductions because the EPA had not simply discounted the results of such studies.[61] Rather, it "chose to give the studies no weight at all."[62] The EPA's failure was its refusal to engage with the arguments and evidence presented, not any particular conclusion about the robustness of the relevant studies or specific scientific conclusions.

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55. *See id.* at 1051–53. *See generally* Randall Lutter & Howard Gruenspecht, *Assessing Benefits of Ground-Level Ozone: What Role for Science in Setting National Air Quality Standards*, 15 TUL. ENV'T L.J. 85 (2001) (discussing the issue raised by "benefits" of ground-level ozone).

56. 42 U.S.C. § 7408(a)(2).

57. *See* Randall Lutter & Christopher Wolz, *UV-B Screening by Tropospheric Ozone: Implications for the National Ambient Air Quality Standards*, 31 ENV'T SCI. & TECH. 142A, 144A (1997) (noting that increased UV-B exposure due to the reductions in concentrations of tropospheric ozone anticipated by the EPA's then-proposed NAAQS could result in as many as 11,000 additional cases of melanoma skin cancer and as many as fifty melanoma related deaths per year, in addition to as many as 28,000 new cataract cases per year).

58. *See id.* at 144A–45A.

59. Am. Trucking Ass'ns, Inc. v. EPA, 175 F.3d 1027, 1051–52 (D.C. Cir.) (per curiam), *modified*, 195 F.3d 4 (D.C. Cir. 1999).

60. *Id.*

61. *Id.* at 1052–53.

62. *Id.* at 1052.

The *American Trucking* court was careful not to circumscribe how the EPA evaluated or weighted the import of such studies on remand.[63] To the contrary, the court made clear that it was up to the EPA to develop criteria for evaluating the potential effects of ozone reductions on ultraviolet radiation exposure and consequent health effects.[64] On remand, the EPA concluded that there was insufficient information on the connection between reduced levels of tropospheric ozone and patterns of exposure to ultraviolet radiation to justify any relaxation of the ozone NAAQS on the ground of public health.[65] Yet, because the EPA had addressed the issue, its decision was upheld.[66] Had the EPA made this argument in the first instance, it would likely have prevailed then too. There is a meaningful difference between choosing to provide different degrees of weight to particular findings or potential effects and refusing to consider them altogether. The former is entitled to great deference, whereas the latter is a failure to engage in reasoned decisionmaking.

Super deference does not allow an agency to completely ignore scientific claims with which it disagrees.[67] Nor does it allow agencies to simply deny readily established scientific claims.[68] When the EPA listed methylene diphenyl diisocyanate (MDI) as a "high risk" hazardous air pollutant, the Chemical Manufacturers Association challenged the listing because it was based upon assumptions and speculations that bore "no rational relationship to the physical properties of the chemical" at issue.[69] In reaching its judgment about MDI, the EPA had concluded that MDI posed a health risk from inhalation, despite uncontroverted evidence that "MDI is a solid" at the ambient temperatures at which the EPA assumed people might be exposed.[70] The EPA's mere "speculative factual assertion" that MDI might nonetheless be dispersed as a gas was plainly contradicted by scientific evidence in the record to which the agency had offered no substantive response.[71] It was as if the EPA had characterized day as night, or up as down.[72] Thus, the court had no difficulty concluding

63. *Id.* at 1053.

64. *Id.*

65. *See* National Ambient Air Quality Standards for Ozone: Final Response to Remand, 68 Fed. Reg. 614, 642 (Jan. 6, 2003).

66. *See* Am. Trucking Ass'ns v. EPA, 283 F.3d 355, 358 (D.C. Cir. 2002).

67. *See* Meazell, *supra* note 8, at 749.

68. *Id*.

69. Chem. Mfrs. Ass'n v. EPA, 28 F.3d 1259, 1261 (D.C. Cir. 1994).

70. *Id.* at 1266.

71. *Id.* (alteration in original) (quoting Edison Elec. Inst. v. EPA., 2 F.3d 438, 446 (D.C. Cir. 1993)).

72. Or, as occurred in one case, "daily" as "weekly." *See* Friends of Earth, Inc. v. EPA, 446 F.3d 140, 142–43 (D.C. Cir. 2006) (noting that the EPA could not set a "total maximum daily load" on a seasonal basis because "daily means daily").

that the EPA's MDI listing was arbitrary and capricious "[f]or want of a rational relationship between the model and the molecule."[73]

Rejecting the EPA's MDI listing did not require abandoning the traditional degree of deference given to an agency's scientific conclusions. The D.C. Circuit's review was still quite deferential.[74] The EPA was not required to "justify the model on an ad hoc basis for every chemical to which the model is applied, even when faced with data indicating that it is not a perfect fit."[75] Imposing such a burden on the agency, the court noted, would "defeat the purpose of using a model,"[76] and whether to use a predictive model was ultimately a choice left to the agency.[77] Likewise, the court noted that it should defer to "the determination of fit between the facts and the model . . . so that the agency rather than the court may balance marginal losses in accuracy against marginal gains in administrative efficiency and timeliness of decision making."[78] But deference was not to be "boundless."[79] Insofar as the agency adopted a model that bore "no rational relationship" to "the known behavior" of the chemical compound at issue, deference would become abdication.[80] To illustrate the point, the D.C. Circuit offered an illustration:

> [T]he reasonable assumption that a certain type of fish comes from the sea leads directly to the prediction that a fish of that type will die when put in an aquarium without salt water; but if one should learn that the particular fish comes from a lake, and thus that the prediction is certainly wrong and that the fish will die without fresh water, then it would be wrongheaded in the extreme to persist in the original assumption.[81]

The physical reality of the known world is a constraint on the findings and conclusions to which courts may be expected to defer. The fact that experts may disagree, or that there is persistent uncertainty or a degree of indeterminacy, is not. Provided that agencies can provide reasonable explanations for the scientific and technical research and assumptions upon which they rely, courts will tend to defer.

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73. *Chem. Mfrs. Ass'n*, 28 F.3d at 1266.

74. *Id.* at 1265–66. Among other things, the court rejected CMA's claims that EPA's model was a "poor fit" because it assumed MDI was emitted from point sources, rather than as fugitive emissions, easily concluding that EPA's choice here was "reasonable." *Id.* at 1265.

75. *Id.*

76. *Id.*

77. *Id.* at 1264.

78. *Id.* at 1265.

79. *Id.*

80. *Id.*

81. *Id.*

Courts are consistently—and fairly systematically—deferential to agency scientific judgments on matters related to agencies' delegated responsibilities and technical expertise. Such deference is not absolute, as agencies are still expected to demonstrate the underlying rationality of their choices, but agencies are rarely required to defend the substance of their scientific conclusions, particularly where there is some degree of scientific uncertainty.

B. *Rationales for Super Deference*

There are multiple arguments for deferential judicial review of agency factual determinations and assessments concerning scientific matters in particular, as is called for in *Baltimore Gas*. These include (a) the relative expertise of agencies when compared to courts; (b) the need to account for the accumulation of scientific evidence and changing evidence over time; (c) the intertwined relationship between agency scientific judgments and policy judgments; and (d) the fact that Congress has delegated responsibility for making scientific judgments to administrative agencies rather than to courts.

1. Expertise

It should be "obvious" that "expert agencies are better situated than generalist judges to make policy decisions in light of policy uncertainty."[82] Indeed, the utility of agency expertise is one of the reasons Congress opted to create administrative agencies in the first place.[83] Specialized agencies with specified jurisdiction have the ability to address complex and technical matters with greater felicity and understanding than either members of Congress or generalist federal

82. Meazell, *supra* note 8, at 734. After all, "technocrats do understand and judges clearly cannot understand." Martin Shapiro, *Administrative Discretion: The Next Stage*, 92 YALE L.J. 1487, 1507 (1983).

83. *See* Sidney A. Shapiro, *The Failure to Understand Expertise in Administrative Law: The Problem and the Consequences*, 50 WAKE FOREST L. REV. 1097, 1097 (2015) ("Congress establishes administrative agencies and often gives them substantial discretion because it lacks the expertise and political agreement to resolve the policy issues that are likely to arise under a statutory scheme."); *see also* MICHAEL A. LIVERMORE & RICHARD L. REVESZ, REVIVING RATIONALITY: SAVING COST-BENEFIT ANALYSIS FOR THE SAKE OF THE ENVIRONMENT AND OUR HEALTH 13–14 (2020) (discussing the need for agency expertise to meet the demand for rules to "structure commerce and regulate risk"); Anne Joseph O'Connell & Jacob Gersen, *Deadlines in Administrative Law*, 121 U. PA. L. REV. 923, 925–26 (2008) ("A central premise of the administrative state is that agencies have better information and greater expertise than the Congress, thus the need for delegation to agencies.").

judges.[84] "Judges are not experts in the field," observed the Court in *Chevron*.[85]

Agencies employ scientists, engineers, economists, and other technical experts who accumulate years of experience handling the particular sorts of matters and questions that lie within an agency's jurisdiction. Federal courts, on the other hand, lack these technical capacities and do not have the same degree of specialized experience.[86] For example, professional staff within the EPA's Office of Air and Radiation will have spent years figuring out how to incorporate scientific findings and ongoing research into the agency's assessment of the health risks posed by various types of air pollution and what sorts of measures may be adopted to control emissions, exposures, and ambient concentrations of various pollutants.[87] Their accumulated expertise is not simply a question of knowledge of the subject matter or training in a particular discipline, but also of operating in a given policy space, as well as developing, implementing, administering, and enforcing specific policy measures.[88] Judges on the D.C. Circuit, on the other hand, may only see a handful of air-pollution-related cases every few years.

In some cases, courts do hear and evaluate detailed scientific evidence, evaluate the admissibility of such evidence under the Federal Rules of Evidence, and rely upon such evidence to reach legal judgments. But the ability of courts to handle complex scientific evidence in such contexts (which is itself disputed[89]) does not mean courts are well-positioned to evaluate the scientific predicates of agency rulemakings.[90]

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84. *See* David B. Spence & Frank Cross, *A Public Choice Case for the Administrative State*, 89 GEO. L.J. 97, 136 (2000) ("[T]here is little that could be done to provide Congress with the engineering expertise of OSHA or EPA.").

85. Chevron U.S.A., Inc. v. Nat. Res. Def. Council, 467 U.S. 837, 865 (1984).

86. *See* Thomas O. McGarity, *On the Prospect of "*Daubert*izing" Judicial Review of Risk Assessment*, 66 LAW & CONTEMP. PROBS. 155, 156 (2003) ("Judges' limited competence in areas involving scientific data and analysis, complex modeling exercises, and large uncertainties is well recognized in administrative law.").

87. *See* Shapiro, *supra* note 83, at 1106.

88. *Id.* at 1099 ("[A]gency professionals (and some nonprofessionals) develop expertise in reconciling and accounting for conflicting evidence and arguments, disciplinary perspectives, political demands, and legal commands. This expertise is a 'craft' form of expertise . . . .").

89. *See generally* PETER W. HUBER, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM (1991) (explaining the problems with courts freely admitting "junk science," science without any substance, into trials).

90. David E. Bernstein, *What to Do About Federal Agency Science: Some Doubts About Regulatory* Daubert, 22 GEO. MASON L. REV. 549, 558 (2015) ("[W]hile judicial scrutiny of expert testimony is preferable to simply dumping a matter on a jury, there's little reason to think that judges will make better scientific decisions than agencies.").

Adopting a more skeptical view of judicial capacity only underscores the point.[91]

Agency expertise is not solely about what information or data is in the technical literature, or what science tells us about existing problems and potential solutions. Expertise also includes practical experience with implementing and administering a regulatory program in light of inherently uncertain and incomplete scientific information and technical knowledge.[92] The accumulated expertise that comes with operating in this space may also be a basis for judicial deference.

Whatever the limitations of agency expertise, agencies will generally have greater competence to address technical and scientific matters than will federal courts, as courts themselves often acknowledge.[93] Courts with specialized expertise, such as may result from specialized dockets, are a rarity.[94] Federal judges and their clerks are generalists with no particular technical training outside of the law.[95] As a comparative matter, it is difficult to dispute that agencies have comparative advantages in assessing scientific matters over courts.

2. Flexibility

Deference to agencies also helps preserve agency flexibility.[96] The need for agencies to be able to evaluate and incorporate new scientific

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91. As Peter Huber notes:

> The legal system has no special competence to assess and compare public risks, and the legal process is not designed or equipped to conduct the broad-ranging aggregative inquiries on which sensible public-risk choices are built. Expert administrative agencies, troubled and erratic though they may be, remain best able to regulate public risks in a manner calculated to advance the public health and welfare.

Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 329 (1985); *see also* LIVERMORE & REVESZ, *supra* note 83, at 14 ("[A]gencies largely derive their legitimacy from reputations for impartiality and expertise.").

92. *See* Shapiro, *supra* note 83, at 1099.

93. *See, e.g.*, Pub. Citizen Health Rsch. Grp. v. Brock, 823 F.2d 626, 629 (D.C. Cir. 1987) (per curiam) (noting OSHA "possesses enormous technical expertise we lack").

94. And a specialized docket is not enough to give judges technical or scientific expertise. *See* Jonathan S. Masur, *Regulating Patents*, 2010 SUP. CT. REV. 275, 307–11 (discussing how the U.S. Court of Appeals for the Federal Circuit's specialized docket may produce some degree of patent law expertise without conferring any expertise in the underlying technical or scientific subject matter upon which patents draw).

95. *See* SHEILA JASANOFF, SCIENCE AT THE BAR: LAW, SCIENCE, AND TECHNOLOGY IN AMERICA 43 (1995) ("Most U.S. judges are still generalists, without any special schooling in the sciences, and practices such as random assignment of cases prevent judicial specialization in areas requiring technical knowledge.").

96. *See* O'Connell & Gersen, *supra* note 83, at 927–28 (noting agency flexibility is a "running theme" in administrative law).

research and improved understandings into regulatory standards and agency actions further supports deferring to an agency's evaluation of uncertain scientific questions. One reason Congress delegates authority to administrative agencies is that such agencies are in a better position to respond to changes that may require new or modified policy responses.[97]

Scientific knowledge is not static. Over time, additional data is accumulated, new studies are conducted, and understandings are updated and reevaluated. While cumulative, scientific knowledge is not always linear. Marginal improvements and discoveries may ultimately shift or upset settled paradigms. Administrative agencies, more than legislatures or courts, are able to anticipate and account for such changes in a proactive fashion by revising standards or providing new guidance when improvements in scientific understandings so warrant. Forcing courts to resolve such questions could "fix" scientific judgments into place within the law and risk obsolescence.[98] As Professor Steph Tai warns, this would be bad for both science and the courts.[99] This is particularly so insofar as judicial decisions risk entrenching scientific judgments that are based upon limited or preliminary scientific assessments or research.[100]

Numerous regulatory statutes expressly anticipate the development of improved scientific understandings and require agencies to revise their rules and policies appropriately. Perhaps the most prominent example can be found in the CAA, which instructs the EPA to review and potentially revise the NAAQS every five years.[101]

The EPA is obligated to set NAAQS for criteria air pollutants at the level "requisite to protect the public health" with "an adequate margin of safety."[102] These standards are to be based upon air quality criteria that "accurately reflect the latest scientific knowledge."[103] This periodic

97. *Id.* at 925–26.

98. *See* Stephanie Tai, *Uncertainty about Uncertainty: The Impact of Judicial Decisions on Assessing Scientific Uncertainty*, 11 U. PA. J. CONST. L. 671, 696 (2009) ("The dangers of the Court making its own determinations on scientific and medical issues is that such determinations will fix into place 'science' that could be ultimately undermined by additional studies.").

99. *Id.* at 697 ("Permanent determination of the state of science . . . may create challenges for the legitimacy of courts, especially when later scientific developments call those earlier determinations into question. This danger is not as great for legislative determinations of science, given that legislatures are freer to revisit their determinations." (footnote omitted)).

100. *See id.* at 696–97 ("While additional research on a given issue may both refine and change the state of the science on a given issue before a court, judicial decisions . . . are often treated as permanent . . . given the doctrine of stare decisis.").

101. *See* 42 U.S.C. § 7409(a)(2), (d)(1) (requiring the establishment and five-year review of national ambient air quality standards).

102. *See id.* § 7409(b)(1).

103. *See id.* § 7408(a)(2).

review sometimes results in maintaining the status quo.[104] Other times it results in the tightening (or, in one instance, the loosening) of the applicable standards.[105] At still other times, it results in the EPA revising the way that standards are measured, such as by changing the time period over which compliance is to be assessed or redefining the relevant pollutants. The ozone NAAQS had previously required keeping ambient concentrations below 0.12 parts per million (ppm) as measured over a one-hour period.[106] In 1997, however, the EPA concluded that the "latest scientific knowledge" counseled a lower standard (0.08 ppm) but measured over a longer period of time (eight hours).[107]

The CAA also accommodates changes in what is considered a pollutant. New pollutants may be added as health effects are recognized.[108] Old pollutants may be recharacterized or redefined. At the same time the EPA tightened the ozone NAAQS from 0.12 ppm to 0.08 ppm, the Agency also revised the NAAQS for particulate matter needed to be refined so as to measure coarse and fine particles separately.[109] Whereas the relevant NAAQS previously focused on total suspended particulates in the ambient air, the EPA revised the standards to focus on those particles between 10 and 2.5 microns in diameter (PM_{10}), and those smaller than 2.5 ($PM_{2.5}$).[110]

3. Policy Discretion

That courts should defer to an agency's permissible policy determination is almost beyond question. The need for deference on normative policy questions further supports the argument for deference to scientific determinations, particularly those sorts of complex and evolving areas of science anticipated by *Baltimore Gas*.

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104. *See* National Ambient Air Quality Standards for Sulfur Oxides (Sulfur Dioxide)—Final Decision, 61 Fed. Reg. 25,566, 25,566 (May 22, 1996) (codified at 40 C.F.R. pt. 50) (retaining NAAQS for sulfur dioxide); National Ambient Air Quality Standards for Ozone—Final Decision, 58 Fed. Reg. 13,008, 13,008 (Mar. 9, 1993) (codified at 40 C.F.R. pt. 50) (retaining NAAQS for ozone).

105. *See* Revisions to the National Ambient Air Quality Standards for Photochemical Oxidants, 44 Fed. Reg. 8,202, 8,202 (Feb. 8, 1979) (codified at 40 C.F.R. pt. 50) (raising ozone NAAQS from 0.08 ppm to 0.12 ppm).

106. National Ambient Air Quality Standards for Ozone, 62 Fed. Reg. 38,856, 38,856 (July 18, 1997) (codified at 40 C.F.R. pt. 50) (noting that the "current primary and secondary standards" from March 1993 "are each set at a level of 0.12 ppm, with 1-hour averaging time").

107. *Id.* (tightening NAAQS for ozone and changing measurement time period from one hour to eight hours).

108. *See* Nat'l Res. Def. Council v. Train, 545 F.2d 320, 326, 328 (2d Cir. 1976) (concluding that the EPA was obligated to list lead as a criteria air pollutant).

109. *See* National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,652 (July 18, 1997) (codified at 40 C.F.R. pt. 50) (adding $PM_{2.5}$ standards to complement PM_{10} standards based upon available scientific evidence).

110. *Id.*

Many agency actions informed by science are, ultimately, normative policy judgments,[111] even if agencies are not quick to acknowledge that fact.[112] Policy-relevant science is, itself, grounded in and shaped by value judgments.[113] The rhetorical debate over whether a given regulatory or deregulatory agenda is grounded in "sound science" or "junk science" is typically a debate over the policy conclusions that should be drawn from what is often incomplete or uncertain scientific research. Purportedly scientific conclusions often mask normative judgments about how data should be interpreted and how uncertainties should be resolved. The conclusion that a particular confidence interval should be determinative is a value-based judgment, as are various policy-relevant inferences that are routinely drawn from scientific research.

Throughout the administrative state, "the formulation of standards involves choices that by their nature require basic policy determinations rather than resolution of factual controversies."[114] Science-dependent conclusions are not always purely scientific. Should a risk assessment adopt "conservative" assumptions about exposure pathways or dose-response curves?[115] How should such assessments account for the likelihood of acutely sensitive subpopulations in the absence of concrete evidence on the size or sensitivity of such groups? Should sparse data on species populations be construed as evidence of the species' absence? How should potential future harms be discounted, if at all? And so on. When the Fish & Wildlife Service assesses whether the "best scientific and commercial data available"[116] supports listing a given species as

111. *See* J.B. Ruhl, *Prescribing the Right Dose of Peer Review for the Endangered Species Act*, 83 NEB. L. REV. 398, 404 (2004) ("[S]cience, even sound science, usually does not lead to compelling answers about the questions posed in environmental law.").

112. *See* Wagner, *supra* note 11, at 1617 ("[C]ontemporary science can provide only partial answers to pressing environmental problems . . . ."). As Wagner documented, agencies often obscure the limits of science to answer policy questions. *See id.* at 1628–50; *see also* Edward J. Rykiel, *Scientific Objectivity, Value Systems, and Policymaking*, 51 BIOSCIENCE 433, 434 (2001) ("Scientists typically portray the information they provide to the public as objective and value free, with the implication that those traits confer greater weight to their opinions than should be accorded to the value laden opinions of nonscientists.").

113. *See* Roesler, *supra* note 11, at 526–27 ("Policy-relevant science will always incorporate value judgments."); Wagner, *supra* note 11, at 1618 (noting how agency science-based standard setting often requires an "express policy choice").

114. Indus. Union Dep't, AFL-CIO v. Hodgson, 499 F.2d 467, 475 (D.C. Cir. 1974). Wagner illustrates this point with reference to dose-response models used in toxic risk regulation. *See* Wagner, *supra* note 11, at 1625; *see also* James P. Leape, *Quantitative Risk Assessment in Regulation of Environmental Carcinogens*, 4 HARV. ENV'T L. REV. 86, 108 (1980).

115. *See* Wagner, *supra* note 11, at 1622 ("The search for a 'safe' concentration of a chemical, which poses only minimal risks to human health, immediately breaks down into a sequence of smaller sub-questions that often alternate between questions that can be resolved with science and others that cannot.").

116. *See* 16 U.S.C. § 1536(a)(2).

"threatened" or "endangered" under the Endangered Species Act,[117] it must still make judgments about how much risk to a species actually constitutes the degree of endangerment the law prohibits.[118]

The persistence of scientific uncertainty serves to underscore the extent to which agencies rely upon policy considerations when reaching scientific judgments. As Professor David Bernstein notes, federal agencies often have "no choice but to rely on a certain amount of speculation based on limited data."[119] When considering whether a given pollutant causes adverse health effects at various levels of exposure, the relevant research is rarely sufficient to identify the precise risks at each level of exposure.[120] Consequently, agencies are required to adopt simplifying assumptions, such as whether to assume that the pollutant's health effects are best modeled with a linear dose-response curve.[121] These assumptions will be based upon normative policy judgments, such as whether to adopt a more protective or precautionary interpretation of the relevant research.[122]

Persistent uncertainty means that policy-relevant scientific judgments will often be inherently intertwined with policy judgments, such that a failure to defer to an agency's assessment and application of the relevant science is, in effect, a failure to defer to the agency's policy judgment. Thus, upholding the principle that courts should defer to agency policy judgments that are not otherwise precluded by statute requires a fair amount of deference to agency assessments and applications of relevant scientific research.

4. Delegation

Perhaps a more fundamental reason for courts to be particularly deferential to the scientific judgments of administrative agencies is that

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117. *Id.* §§ 1531–1544.

118. *See* Michael S. Carolan, *Is It a Distinct Subspecies? Preble's Mouse and the "Best Available Science" Mandate of the Endangered Species Act*, 21 SOC'Y & NAT. RES. 944, 947 (2008) ("[D]eciding when a species is safe versus endangered (and thus in need of protection) is really a question of how much risk a society is willing to take with that species. And since there is no 'correct' level of risk, such decisions rest upon policy rather than scientific choices."); *see also* Holly Doremus, *Listing Decisions Under the Endangered Species Act: Why Better Science Isn't Always Better Policy*, 75 WASH. U. L.Q. 1029, 1035 (1997) ("[S]cience alone cannot answer all the relevant questions. Science cannot tell us whether a group of organisms has value to society, or what risk of extinction society should tolerate.").

119. Bernstein, *supra* note 90, at 562. As Bernstein notes, indeed, "agencies are often legally required" to make decisions based upon incomplete scientific evidence. *Id.* One example of this is the Endangered Species Act, which requires decisions be made upon the "best available" research, without regard for whether the evidence is particularly robust or reliable. *See* Jonathan H. Adler, *The Science Charade in Species Conservation*, 24 SUP. CT. ECON. REV. 109, 114 (2016).

120. *See, e.g.*, *supra* notes 55–65 and accompanying text.

121. *See* Wagner, *supra* note 11, at 1623 n.34.

122. *See* Ruhl, *supra* note 111.

Congress has delegated the responsibility to make such determinations to expert agencies instead of delegating such matters to the courts (or leaving such questions to themselves).[123] Congress creates administrative agencies and delegates the power to act.[124] Such delegation is the only source of agency power.[125] While authorizing judicial review of agency action, Congress has not instructed courts to be particularly searching in their review of agency assessments of scientific or technical information.[126] To the contrary, in many statutes, Congress has expressly anticipated broad deference to agency "judgment" about what sorts of reasonable inferences may be drawn from readily available research and analysis.[127] Further, insofar as scientific determinations are interlaced with policy determinations, as discussed above, Congress has likewise delegated the responsibility to agencies to make such policy judgments, subject only to requirements of adequate explanation and reasoned decisionmaking.[128]

Consider the various "endangerment" findings that the EPA Administrator is directed to make under the CAA. Under these provisions, the Administrator is required to adopt emission controls when "*in his judgment*," emissions of an identified pollutant causes or contributes to "air pollution which *may reasonably be anticipated to endanger* public health or welfare."[129] With this language, Congress has not required that the Administrator demonstrate a given quantum of harm or health risks, nor must the Administrator demonstrate that his finding is supported by a preponderance of evidence. Rather, it is a question of the Administrator's "judgment," and all that the Administrator must find is that it would be "reasonabl[e]" to "anticipate[]" a threat to public health or welfare.[130] This language is clearly precautionary. At the same time, it delegates to the Administrator a great deal of discretion to make the relevant determination, based upon the scientific evidence before the agency.

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123. *See* Shapiro, *supra* note 83, at 1097.

124. *See* Thomas W. Merrill, *Rethinking Article I, Section 1: From Nondelegation to Exclusive Delegation*, 104 COLUM. L. REV. 2097, 2101 (2004) ("Congress has created the administrative state and has given its far-flung agencies extensive powers to adopt legislative rules.").

125. *See* Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988) ("It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress."); *see also* La. Pub. Serv. Comm'n v. FCC, 476 U.S. 355, 374 (1986) ("[A]n agency literally has no power to act . . . unless and until Congress confers power upon it."), *superseded by statute*, Telecommunications Act of 1996, Pub. L. No. 104-104, 49 Stat. 1526.

126. *See supra* text accompanying notes 44–48.

127. *See, e.g.*, *supra* text accompanying notes 115–17 (discussing the Endangered Species Act).

128. *See supra* text accompanying notes 20–23.

129. *See, e.g.*, 42 U.S.C. § 7521(a)(1) (emphasis added).

130. *Id.*

Congress could have resolved key regulatory policy questions through legislation, as many have argued it should.[131] Yet Congress has not taken this course. The pervasive delegation of regulatory authority includes the delegation of responsibility to resolve matters implicating controversial and often uncertain scientific questions.[132] Federal regulatory statutes are replete with provisions that instruct federal agencies to consider and account for relevant scientific research in the promulgation and enforcement of regulatory standards, and that instruct courts to engage in fairly deferential review.[133]

Congress could also have required federal courts to resolve contested scientific questions in the context of administrative matters, perhaps even subjecting scientific research relied upon by agencies to Rule 702 of the Federal Rules of Evidence.[134] There are areas of law, such as antitrust, where the relevant statutory provisions require courts to consider competing technical analyses in resolving disputes, but in many other areas, Congress has delegated responsibility for making relevant scientific determinations to administrative agencies and provided for deferential judicial review.

Whatever one thinks of the administrative state, there is no denying that Congress has made the judgment that science-infused policy questions should be resolved by administrative agencies.

II. HEIGHTENED SCRUTINY

Federal administrative agencies may be entitled to substantial deference on scientific questions and science-informed policy judgments as a general matter, but what happens when agency actions intrude upon constitutionally protected rights or implicate constitutionally suspect classifications? The rationales sketched above may provide ample support for a general policy of judicial deference to agency fact-finding on scientific and technical matters, particularly where such matters are within an agency's core expertise and congressionally delegated realm of responsibility. Where heightened scrutiny is triggered, however, courts

131. *See, e.g.*, DAVID SCHOENBROD, POWER WITHOUT RESPONSIBILITY: HOW CONGRESS ABUSES THE PEOPLE THROUGH DELEGATION 14 (1993) (arguing that Congress should delegate less to administrative agencies); Ernest Gellhorn, Commentary, *Returning to First Principles*, 36 AM. U. L. REV. 345, 353 (1987) (arguing that "so long as the legislation . . . served primarily public purposes . . . Congress [should] exercise *its* lawmaking power").

132. *See supra* text accompanying notes 26–29.

133. *See, e.g.*, 42 U.S.C. § 7408(a)(2); 16 U.S.C. § 1536(a)(2).

134. For an argument in support of this approach, see Alan Charles Raul & Julie Zampa Dwyer, *"Regulatory* Daubert*": A Proposal to Enhance Judicial Review of Agency Science by Incorporating* Daubert *Principles into Administrative Law*, 66 LAW & CONTEMP. PROBS. 7 (2003). For a contrasting view, see Bernstein, *supra* note 90, at 558; *see also* McGarity, *supra* note 86, at 156 ("Assigning a Daubert-like gatekeeper role to courts engaged in judicial review of agency risk assessments is a profoundly bad idea.").

are generally instructed *not* to defer to government decision-makers. Therein lies the potential conflict.

Actions taken by federal agencies are generally subject to a "presumption of regularity."[135] Lawmakers and executive branch officers take an oath to uphold the Constitution and laws of the United States,[136] and courts generally start with the presumption that whatever actions they take are consistent with their understanding of their legal obligations.[137] This presumption is reflected in the baseline of rational basis review, which embodies a presumption of constitutionality and merely requires that governmental actions be rationally related to a legitimate governmental interest,[138] and not that they represent good policy[139] or even that such actions were undertaken for the reasons articulated by the relevant government decision-makers.[140] In practice, this means those wishing to argue that a governmental action lacks a rational basis face a "virtually insurmountable" burden.[141]

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135. *See* Citizens to Pres. Overton Park, Inc. v. Volpe, 401 U.S. 402, 415 (1971), *abrogated by* Califano v. Sanders, 97 S. Ct. 980 (1977); *see also* Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. U.S. Dep't of Agric., 415 F.3d 1078, 1093 (9th Cir. 2005) ("Regulations are presumed to be valid, and therefore review is deferential to the agency.").

136. U.S. CONST. art. VI, cl. 3.

137. Article VI provides, "Senators and Representatives . . . and all executive . . . Officers . . . shall be bound by Oath or Affirmation, to support this Constitution." *Id.* Whether the fact that legislators and agency officials take such an oath justifies the presumption of lawfulness has been subject to challenge. *See, e.g.*, F. Andrew Hessick, *Rethinking the Presumption of Constitutionality*, 85 NOTRE DAME. L. REV. 1447, 1463 (2010).

138. *See, e.g.*, City of New Orleans v. Dukes, 427 U.S. 297, 303 (1976) ("Unless a classification trammels fundamental personal rights or is drawn upon inherently suspect distinctions such as race, religion, or alienage, our decisions presume the constitutionality of the statutory discriminations and require only that the classification challenged be rationally related to a legitimate state interest."); Pennell v. City of San Jose, 485 U.S. 1, 14 (1988) (stating that the classification scheme in an ordinance must be "rationally related to a legitimate state interest").

139. *See* Williamson v. Lee Optical, 348 U.S. 483, 487 (1955) ("[I]t is for the legislature, not the courts, to balance the advantages and disadvantages of the new requirement.").

140. *See* FCC v. Beach Commc'ns, Inc., 508 U.S. 307, 315 (1993) (noting that invalidating a law under rational basis requires refuting "every conceivable basis which might support it" and that "it is entirely irrelevant for constitutional purposes whether the conceived reason for the challenged distinction actually motivated the legislature"); U.S. R.R. Ret. Bd. v. Fritz, 449 U.S. 166, 179 (1980) ("It is . . . 'constitutionally irrelevant whether this reasoning in fact underlies the legislative decision'" (quoting Flemming v. Nestor, 363 U.S. 603, 612 (1960))); *Williamson*, 348 U.S. at 487–88 ("It is enough that there is an evil at hand for correction, and that it *might be thought* that the particular legislative measure was a rational way to correct it." (emphasis added)); *see also* ERWIN CHEMERINSKY, CONSTITUTIONAL LAW 518 (2d ed. 2002) (noting the asserted state interest "need not be the actual purpose" that motivated enactment). As Professor Laurence Tribe observed, under this approach, the degree of deference afforded to economic regulation under this approach became "virtually complete judicial abdication." *See* LAURENCE H. TRIBE, AMERICAN CONSTITUTIONAL LAW § 8-7, at 582 (2d ed. 1988).

141. *See* FAIGMAN, *supra* note 13, at 102.

When governmental actions intrude upon fundamental rights or implicate suspect classifications, however, courts apply heightened forms of judicial scrutiny. The form such scrutiny takes may vary, but what all forms of heightened scrutiny have in common is a suspicion of governmental action that has particular types of effects or utilizes particular types of classifications in policy implementation.[142] Such outcomes are inherently suspect, and must be supported by more thorough and pervasive justifications than other governmental actions.[143] The governmental processes that can be generally trusted to produce legitimate outcomes must be scrutinized once heightened scrutiny is triggered.[144]

The basic rationale for heightened scrutiny was set forth in *United States v. Carolene Products*.[145] There, writing for the Court, Justice Harlan F. Stone explained that courts should generally presume that legislative actions are constitutional.[146] However, Justice Stone added in the famous Footnote 4 that "[t]here may be narrower scope for operation of the presumption of constitutionality" where governmental action infringes upon fundamental rights, such as those enumerated in the Constitution, and "restricts those political processes which can ordinarily be expected to bring about repeal of undesirable legislation," or is "directed" against "discrete and insular minorities" that may lack the ability to protect themselves within the political process.[147] In such cases, the presumption of constitutionality is no longer operable, and the government bears a greater burden to demonstrate the lawfulness of its action.[148] As explained in a leading treatise, *Carolene Products* outlined

142. *See* TRIBE, *supra* note 140, § 16-6, at 1451 ("[T]he idea of strict scrutiny acknowledges that other political choices—those burdening fundamental rights, or suggesting prejudice against racial or other minorities—must be subjected to close analysis in order to preserve substantive values of equality and liberty.").

143. *See id.* at 1453 (Heightened scrutiny entails "judicial wariness of interests such as these which can so easily and indiscriminately be invoked, and which almost never point uniquely to a challenged political choice.").

144. As the Court explained in *Vance v. Bradley*: "[W]e will not overturn [a statute that does not burden a suspect class or a fundamental interest] unless the varying treatment of different groups or persons is so unrelated to the achievement of any combination of legitimate purposes that we can only conclude that the legislature's actions were irrational." 440 U.S. 93, 97 (1979).

145. 304 U.S. 144 (1938).

146. *Id.* at 152 ("[T]he existence of facts supporting the legislative judgment is to be presumed, for regulatory legislation affecting ordinary commercial transactions is not to be pronounced unconstitutional unless in the light of the facts made known or generally assumed it is of such a character as to preclude the assumption that it rests upon some rational basis within the knowledge and experience of the legislators.").

147. *Id.* at 152–53 n.4.

148. *Id*.

"a framework of general judicial deference to the legislature, but with particular areas of more intensive judicial review."[149]

Rational basis review is not premised upon the idea that all—or even most—governmental actions represent "good" policy, however measured. Such review does not presume that enacted measures effectively advance the public good or necessarily represent the best accommodation of competing interests.[150] Rather, rational basis review rests upon the presumption that a legitimate process produces legitimate policy outcomes, and that such processes may again be used to modify, amend, or repeal those policies which prove to be unpopular or unwise. At least as far as the courts are concerned, that a given policy may be unwise, inefficient, or ineffectual is no basis for declaring it to be invalid.

Rational basis review presumes that some policies will make some people unhappy. Governmental action routinely produces winners and losers. Fiscal and regulatory measures alike have the potential to redistribute resources or impose constraints that benefit some at the expense of others. An implicit premise of *Carolene Products* is that such consequences are, as a general matter, perfectly acceptable outcomes of factional competition within the political process. The underlying facts of the case underscore the point. The federal government had adopted a law—the Filled Milk Act[151]—restricting the sale of "filled milk" in interstate commerce, on the ostensible grounds that such a restriction was necessary for public health.[152] In actuality, there was no scientific basis

149. *See* CHEMERINSKY, *supra* note 140, at 518.

150. *See, e.g.*, FCC v. Beach Commc'ns, Inc., 508 U.S. 307, 313 (1993) ("In areas of social and economic policy, a statutory classification that neither proceeds along suspect lines nor infringes fundamental constitutional rights must be upheld against equal protection challenge if there is any reasonably conceivable state of facts that could provide a rational basis for the classification."); Williamson v. Lee Optical, 348 U.S. 483, 487–88 (1955) ("The Oklahoma law may exact a needless, wasteful requirement in many cases. But it is for the legislature, not the courts, to balance the advantages and disadvantages of the new requirement . . . . [T]he law need not be in every respect logically consistent with its aims to be constitutional. It is enough that there is an evil at hand for correction, and that it might be thought that the particular legislative measure was a rational way to correct it."); Vance v. Bradley, 440 U.S. 93, 97 (1979) ("The Constitution presumes that, absent some reason to infer antipathy, even improvident decisions will eventually be rectified by the democratic process and that judicial intervention is generally unwarranted no matter how unwisely we may think a political branch has acted." (footnote omitted)); U.S. R.R. Ret. Bd. v. Fritz, 449 U.S. 166, 179 (1980) ("Where, as here, there are plausible reasons for Congress' action, our inquiry is at an end.").

151. Pub. L. No. 67-513, 42 Stat. 1486 (1923) (codified at 21 U.S.C. §§ 61–64).

152. *See* 21 U.S.C. § 62 (declaring filled milk to be "an adulterated article of food, injurious to public health"). The law defined "filled milk" as "any milk, cream, or skimmed milk, whether or not condensed, evaporated, concentrated, powdered, dried, or desiccated, to which has been added, or which has been blended or compounded with, any fat or oil other than milk fat, so that the resulting product is in imitation or semblance of milk, cream, or skimmed milk, whether or not condensed, evaporated, concentrated, powdered, dried, or desiccated." *Id.* § 61(c).

for the indictment against filled milk.[153] If anything, there was evidence that prohibiting filled milk could actually harm low-income consumers.[154]

The Filled Milk Act was "an utterly unprincipled example of special interest legislation," designed to protect the dairy industry from competition.[155] The public health justification was a convenient, public spirited veneer to disguise blatant rent seeking.[156] The *Carolene Products* Court did not care about such things, however, as governmental action was to be presumed constitutional in the regular course.[157] Producers and purveyors of filled milk could presumably fend for themselves in the political process. Whether they won or lost in a particular case was of no moment.[158]

What would matter, however, is if the policy design or outcome implicated constitutionally protected interests. That would be the case if those affected by the challenged legislation were singled out because of their race, sex, or national origin,[159] or where the regulatory measure to achieve the legislation's purpose treaded on a constitutional right.[160] Then the presumption of constitutionality would have to yield to greater scrutiny.[161] The government would need to show how the measure served a compelling or important governmental interest,[162] and was either

153. *See* Geoffrey P. Miller, *The True Story of* Carolene Products, 1987 SUP. CT. REV. 397, 416 ("[E]ven on the legislative record compiled in 1923 [the justifications for the prohibition] were a tissue of insubstantial rationalizations covering the real motivation of the statute . . . .").

154. *Id.* at 419 ("The fact was that filled milk undoubtedly improved the national health. Its lower price increased consumption of skimmed milk and vegetable fats, both wholesome and nutritious foods.").

155. *Id.* at 398.

156. *Id.* at 399 (noting "public interest" justifications were "patently bogus"); *id.* at 406 ("There was no question that filled milk, taken by itself was a healthful product, since it was simply a compound of skimmed milk and vegetable oil, two substances universally recognized as healthful.").

157. *See* United States v. Carolene Prods. Co., 304 U.S. 144, 152 (1938) ("[T]he existence of facts supporting the legislative judgment is to be presumed, for regulatory legislation affecting ordinary commercial transactions is not to be pronounced unconstitutional unless in the light of the facts made known or generally assumed it is of such a character as to preclude the assumption that it rests upon some rational basis within the knowledge and experience of the legislators.").

158. *See* Miller, *supra* note 153, at 399 (arguing that the *Carolene Products* footnote indicated that "the Court intended to keep its hands off economic regulation, no matter how egregious the discrimination or patent the special interest motivation"). As it happened, a lower court would eventually disagree. *See* Milnot Co. v. Richardson, 350 F. Supp. 221, 225 (N.D. Ill. 1972) (concluding that the Filled Milk Act was sufficiently irrational to violate the Due Process Clause).

159. *See supra* note 142 and accompanying text.

160. *See Carolene Prods.*, 304 U.S. at 152 n.4.

161. *Id.*

162. *See infra* notes 253–54 and accompanying text.

narrowly tailored or substantially related to that interest.[163] Heightened scrutiny would be reserved for those instances in which particular suspect outcomes were reached,[164] or there was reason to believe that the democratic process did not provide factions with the fair opportunity to advance or protect their interests.

Special interest pleading is not confined to the legislative process. In the regulatory context as well, economic interest groups often seek to camouflage anticompetitive measures with public-spirited justifications.[165] As with the Filled Milk Act, it is useful to defend such measures as protective of the public interest, and the language of science can be useful in this regard. But as with legislation, traditional notions of deference to agency judgments should yield when heightened scrutiny is triggered. Any presumption of regularity is forfeit in such instances. It is to this point this Article now turns.

III. SCRUTINY VS. DEFERENCE

Federal agency actions are routinely subject to judicial review for their compliance with the APA and the requirements of reasoned decisionmaking.[166] At times, however, courts are tasked with ensuring that agency actions are constitutional. Section 706 of the APA expressly instructs courts to "hold unlawful and set aside agency action" that is "found to be . . . contrary to constitutional right, power, privilege, or immunity."[167] And in fulfilling that charge, reviewing courts may need to consider whether agency actions withstand heightened scrutiny.

Agency actions informed by scientific determinations that implicate heightened scrutiny may arise in a wide range of contexts. Consider, just as an example, the regulatory purview of the Food and Drug Administration (FDA). For years, the FDA has maintained guidelines and policies concerning blood and sperm donation that rest upon sex-based

163. *See* Roe v. Wade, 410 U.S. 113, 155 (1973).

164. *See supra* text accompanying notes 142–43.

165. *See, e.g.*, Bruce Yandle & Stuart Buck, *Bootleggers, Baptists, and the Global Warming Battle*, 26 HARV. ENV'T L. REV. 177 (2002) (identifying examples of special interest policies in the context of climate change policy); POLITICAL ENVIRONMENTALISM: GOING BEHIND THE GREEN CURTAIN (Terry L. Anderson ed., 2000) (describing how special interests and rent seeking have influenced environmental policies); Todd J. Zywicki, *Environmental Externalities and Political Externalities: The Political Economy of Environmental Regulation and Reform*, 73 TUL. L. REV. 845 (1999) (same); Jonathan H. Adler, *Rent Seeking Behind the Green Curtain*, 19 REGUL. 26, 26 (1996) (same); ENVIRONMENTAL POLITICS: PUBLIC COSTS, PRIVATE REWARDS (Michael S. Greve & Fred L. Smith, Jr. eds., 2d ed. 1992) (same).

166. *See* 5 U.S.C. § 706 (defining the scope of review a reviewing court has over federal government agencies).

167. *Id.* § 706(2)(B).

characteristics.[168] Specifically, the FDA has limited donations made by men who have had sex with other men (termed "MSM") within given time periods.[169] The FDA has justified this policy on the grounds that donations from MSM pose a greater risk of HIV contamination than do donations from other individuals.[170] Yet the scientific and medical basis for this policy has been the subject of extensive criticism and debate.[171] Among other things, critics note that the exclusion is both over- and underinclusive, and is less effective than more focused screening and monitoring of blood supplies.[172] As a sex-based classification, however, the policy would seem to be subject to heightened scrutiny, albeit the intermediate scrutiny provided for sex-based classifications.[173]

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168. *See* Neiloy Sircar, *Good Health Policy, Better Public Health Law: Blood Donation, Individual Risk Assessments, & Lifting the Deferral For Men Who Have Sex with Men*, 73 FOOD & DRUG L.J. 103, 104 (2018) (noting that men who have sex with men (MSM) have been prohibited from giving blood since the 1980s). These guidelines were relaxed in 2020 due to COVID-19. *See* FDA, U.S. DEP'T HEALTH & HUMAN SERVS., REVISED RECOMMENDATION FOR REDUCING THE RISK OF HUMAN IMMUNODEFICIENCY VIRUS TRANSMISSION BY BLOOD AND BLOOD PRODUCTS: GUIDANCE FOR INDUSTRY (2020), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/revised-recommendations-reducing-risk-human-immunodeficiency-virus-transmission-blood-and-blood [https://perma.cc/6ZPZ-XU3F].

169. The FDA initially imposed a permanent ban on blood donations by MSM. This was subsequently revised to a twelve-month deferral period. In 2020, the FDA narrowed the deferral period for MSM to three months. *See* FDA, *supra* note 168; *see also* Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products, 85 Fed. Reg. 36,595, 36,596 (June 17, 2020) (revised recommendation). This revision has not eliminated criticism of the policy for lacking an adequate scientific basis. *See* Maggie L. Shaw, *FDA's Revised Blood Donation Guidance for Gay Men Still Courts Controversy*, AM. J. MANAGED CARE (Apr. 4, 2020), https://www.ajmc.com/view/fdas-revised-blood-donation-guidance-for-gay-men-still-courts-controversy [https://perma.cc/5UGS-HM6T]; Ayako Miyahita Ochoa, *Discriminatory Blood Donation Policies Defy Science*, REGUL. REV. (June 30, 2021), https://www.theregreview.org/2021/06/30/ochoa-discriminatory-blood-donation-policies/ [https://perma.cc/A5EH-N7Q6].

170. *See* FDA, U.S. DEP'T OF HEALTH & HUMAN SERVS., REVISED RECOMMENDATIONS FOR THE PREVENTION OF HUMAN IMMUNODEFICIENCY VIRUS TRANSMISSION BY BLOOD AND BLOOD PRODUCTS: GUIDANCE FOR INDUSTRY (2020). This policy has also been applied to sperm donation. *See* Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products, 69 Fed. Reg. 29,786, 29,789–90 (May 25, 2004) (codified at 21 C.F.R. pts. 210, 211, 820, and 1271).

171. *See* Sircar, *supra* note 168, at 112; John G. Culhane, *Bad Science, Worse Policy: The Exclusion of Gay Males from Donor Pools*, 24 ST. LOUIS PUB. L. REV. 129, 134 (2005).

172. *See* Sircar, *supra* note 168, at 119–20.

173. While the FDA's policy may appear to be based upon sexual orientation, and the consequences of this policy no doubt fall most heavily on gay men, the FDA expressly bases the policies on the sex of the prospective donor and his prior sexual partners, not upon any expressed sexual orientation or identity. This would appear to qualify as a sex-based distinction. *See* Bostock v. Clayton Cnty., 140 S. Ct. 1731, 1737 (2020) (noting that, for purposes of Title VII, if sex "plays a necessary and undisguisable role in the decision," it is sex-based). *Bostock* held that "it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based on sex," *id.* at 1741, but this holding was limited to

The FDA is also engaged in the extensive regulation of speech protected by the First Amendment, including product advertisements, labeling, and promotions.[174] While commercial speech is not subject to the same degree of protection as other forms of speech, such as political speech, it is nonetheless constitutionally protected.[175] Under *Central Hudson Gas & Electric v. Public Service Commission*,[176] commercial speech is governed by a form of intermediate scrutiny that is sometimes applied quite strictly.[177]

The FDA makes and enforces rules concerning what manufacturers may or must say about their products.[178] FDA regulations may prohibit manufacturers from making statements about their products that the producers believe are amply supported by the relevant science.[179] Because the FDA regulates newly developed pharmaceuticals, medical devices, and other products, it is routinely evaluating claims and research on the "frontiers of science" and evaluating what sorts of claims about regulated products do, or do not, have adequate scientific justification. In other cases, the FDA may limit the ability of manufacturers to make scientifically valid claims due to concerns that such claims will be misunderstood by consumers.[180]

Title VII, and has not yet been applied to Equal Protection claims under the Fourteenth Amendment. *See id.* at 1783 (Alito, J., dissenting). Further, unlike the employer conduct at issue in *Bostock*, the FDA policy only applies to men and is based upon the sex of the individuals engaged in the relevant behavior, not their sexual preference.

174. *See* Thompson v. W. States Med. Ctr., 535 U.S. 357, 360 (2002) (invalidating FDA prohibitions on pharmacy advertising for drug compounding); 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 489 (1996) (invalidating prohibition on price advertising for alcoholic beverages).

175. *See* United States v. United Foods, 533 U.S. 405, 410 (2001) ("The fact that the speech is in aid of a commercial purpose does not deprive [the speaker] of all First Amendment protection."). As the Court explained in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, commercial speech "is indispensable to the proper allocation of resources in a free enterprise system, it is also indispensable to the formation of intelligent opinions as to how that system ought to be regulated or altered." 425 U.S. 748, 765 (1976).

176. 447 U.S. 557 (1980).

177. *See, e.g.*, Sorrell v. IMS Health Inc., 564 U.S. 552, 565 (2011) (suggesting that a higher level of scrutiny is appropriate where a state imposes "content-based burden on protected expression").

178. *See, e.g.*, 21 C.F.R. § 202.1(2) (regulating the content of prescription drug advertising).

179. *See, e.g.*, *id.* § 101.14(1) (regulating health claims for foods and dietary supplements).

180. That is, the FDA justified its decision to "deem" electronic cigarettes and other vaping products to be tobacco products under the Family Smoking Prevention and Tobacco Control Act because a failure to regulate such products might mislead consumers via comparative health claims, even though the FDA itself claimed that e-cigarettes are likely to be less harmful than combustible tobacco produces. *See* Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,974, 28,976 (May 10, 2016) (codified at 21 C.F.R. pts. 1100, 1140, and 1143). For a discussion of why such regulation may harm public health, see Jonathan H. Adler, *Regulatory Obstacles to Harm-Reduction: The Case of Smoking*, 11 N.Y.U. J.L. & LIBERTY 712, 714–15 (2017).

The FDA also imposes mandatory disclosures and warnings on regulated products.[181] In some cases, this compelled speech covers noncontroversial, factual information, such as content-labeling requirements or an acknowledgement that a manufacturer's claims have not been approved by the FDA.[182] While courts are often quite permissive when considering compelled commercial speech, such requirements still implicate heightened constitutional scrutiny.[183]

The freedom of speech is not the only constitutionally protected right potentially constrained by FDA regulation. FDA regulation of contraceptives and pharmaceuticals that may be used to prevent or terminate a pregnancy implicate reproductive-autonomy rights protected by the Fourteenth Amendment under current doctrine.[184] While most laws and regulations governing abortion have been adopted at the state level,[185] the FDA regulates the use and prescription of mifepristone, commercially known as Mifeprex or the "abortion pill."[186] Mifepristone

181. *See, e.g.*, 21 C.F.R. § 202.1–2 (mandating content of prescription drug advertising).

182. *See id.* § 101.93 (requiring disclaimers for statements about nutritional supplements).

183. Many courts and commentators have interpreted *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), to require minimal scrutiny of purely factual disclosure requirements. *See, e.g.*, Am. Meat Inst. v. U.S. Dep't of Agric., 760 F.3d 18, 28 (D.C. Cir. 2014) (en banc) (Rogers, J., concurring) (explaining that *Zauderer* implies a less stringent view of disclosures); Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 113–14 (2d Cir. 2001) ("Commercial disclosure requirements are treated differently from restrictions on commercial speech because mandated disclosure of accurate, factual, commercial information does not offend the core First Amendment values of promoting efficient exchange of information or protecting individual liberty interests."); Robert Post, *Transparent and Efficient Markets: Compelled Commercial Speech and Coerced Commercial Associations in* United Foods*,* Zauderer*, and* Abood, 40 VAL. U. L. REV. 555, 560 (2006) (arguing that *Zauderer* "advanced an extraordinarily lenient test for the review of compelled commercial speech"). For a critique of that interpretation of *Zauderer*, see Jonathan H. Adler, *Compelled Commercial Speech and the Consumer "Right to Know*,*"* 58 ARIZ. L. REV. 421, 435 (2016).

184. *See* Griswold v. Connecticut, 381 U.S. 479, 485 (1965) (recognizing that married couples have a right to use contraception); Eisenstadt v. Baird, 405 U.S. 438, 453–55 (1972) (extending the right to contraception to individuals, "married or single"); Roe v. Wade, 410 U.S. 113, 153 (1973) (recognizing a "right to privacy . . . founded in the Fourteenth Amendment's concept of personal liberty" that encompasses "a woman's decision whether or not to terminate her pregnancy"). The Court narrowed the protection afforded to the right to terminate a pregnancy in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, but reaffirmed the right's constitutional protection. 505 U.S. 833, 845–46 (1992). For a discussion of how the rights in these cases, among others, may suggest a broader right to autonomy over important medical decisions, see B. Jessie Hill, *The Constitutional Right to Make Medical Treatment Decisions: A Tale of Two Doctrines*, 86 TEX. L. REV. 277, 281–82 (2007).

185. The primary exception is a federal prohibition on so-called "partial-birth abortion," but this was adopted through legislation, not agency action. 18 U.S.C. § 1531.

186. *Mifeprex (Mifepristone) Information*, FDA (Apr. 13, 2021), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information [https://perma.cc/R4FV-P7VL]; *The Facts on Mifepristone*, PLANNED PARENTHOOD FED'N OF

is a pharmaceutical that may be used in combination with misoprostol to terminate a pregnancy within the first ten weeks.[187]

Under current FDA regulations, mifepristone is subject to a "Risk Evaluation and Mitigation Strategy" (REMS), under which the drug must be obtained in person at a hospital, clinic, or medical office.[188] Few, if any, other medications that may be taken at home are subject to similar requirements.[189] This has led to claims that the FDA's regulatory treatment of mifepristone constitutes an unconstitutional "undue burden" on a woman's constitutional right to terminate a pregnancy under *Casey*.[190]

In response to the COVID-19 pandemic and the need to reduce disease transmission due to potential in-person exposures, the FDA suspended in-person dispensing requirements for some medications, but not mifepristone.[191] The FDA determined that the in-person dispensing requirements should remain in place.[192] Some outside medical experts,

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AM., INC. 1, 1 (Oct. 2019), https://www.plannedparenthood.org/uploads/filer_public/42/8a/428ab2ad-3798-4e3d-8a9f-213203f0af65/191011-the-facts-on-mifepristone-d01.pdf [https://perma.cc/UN4B-F37A].

187. PLANNED PARENTHOOD FED'N OF AM., INC., *supra* note 186, at 1.

188. FDA, *supra* note 186.

189. *Bad Medicine: The Government's Restriction on Medication Abortion*, NAT'L P'SHIP FOR WOMEN & FAMS. 1, 6 (Sept. 2020), https://www.nationalpartnership.org/our-work/resources/repro/abortion/bad-medicine-the-governments-restriction-on-medication-abortion.pdf [https://perma.cc/572J-ED9E] ("Out of the 16 medications that have an in-person distribution requirement, mifepristone is the only one the FDA requires to be picked up in a health care setting but also allows self-administration at home." (footnote omitted)).

190. *See, e.g.*, Complaint at 59–60, Chelius v. Wright, No. 1:17-cv-00493 (D. Haw. Oct. 3, 2017) (arguing that regulations governing dispensing and use of Mifeprex violated plaintiff's right to privacy by imposing an undue burden on a woman's right to abortion); *see also* Susannah Iles, Note, *Prescription Restriction: Why Birth Control Must Be Over-the-Counter in the United States*, 26 MICH. J. GENDER & L. 389, 411 (2019) (suggesting current regulatory requirements for oral contraception constitute an "undue burden" on reproductive rights). In 2017, a Hawaii doctor challenged these regulatory requirements. Complaint, *supra*, at 9. On May 7, 2021, the court granted the parties' joint motion to stay proceedings pending agency review until December 1, 2021. Order Granting Joint Motion to Stay Case Pending Agency Review at 2, Chelius v. Becerra, No. 1:17-cv-00493 (D. Haw. May 7, 2021). In the joint motion, the FDA announced that it was reviewing the REMS for mifepristone and stated that it would consider any relevant data and evidence from the plaintiffs. Joint Motion to Stay Case Pending Agency Review at 2, *Chelius*, No. 1:17-cv-00493.

191. Am. Coll. of Obstetricians & Gynecologists v. FDA, 472 F. Supp. 3d 183, 212–13 (D. Md. 2020). Mifepristone has been approved for use, in combination with misoprostol, to perform a "medication abortion" in which a pregnancy may be terminated without any form of surgery. *Id.* at 192. Mifepristone may also be prescribed to assist with the recovery from a miscarriage. *Id.* at 190.

192. *See The FDA's Decision Lifting the Burdensome Restriction on Mifepristone During the Pandemic: What You Need to Know*, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS 1 (Apr. 21, 2021), https://www.acog.org/news/news-articles/2020/07/courts-order-lifting-burdensome-fda-restriction-what-you-need-to-know [https://perma.cc/6PHY-RHLD].

however, disagreed that this decision was necessary or appropriate to safeguard public health.[193]

The American College of Obstetricians and Gynecologists (ACOG) sued the FDA, alleging that the maintenance of the in-person dispensing requirement amidst the COVID-19 pandemic would violate women's constitutional right to terminate a pregnancy.[194] In granting a preliminary injunction against the FDA's enforcement, a district court concluded that ACOG was likely to demonstrate that the maintenance of the in-person dispensing requirement would constitute an impermissible "undue burden" on a woman's right to an abortion, and that this restriction should be enjoined, notwithstanding the FDA's expert medical judgment.[195] On October 8, 2020, the Supreme Court denied a stay of the district court's injunction over the dissent of Justices Clarence Thomas and Samuel A. Alito.[196] The Court granted a subsequent stay request in January 2021.[197] Concurring in the order, Chief Justice John G. Roberts stressed the importance of judicial deference to expert agencies, writing that "courts owe significant deference to the politically accountable entities with the 'background, competence, and expertise to assess public health.'"[198]

The COVID-19 pandemic highlighted other instances in which the FDA and other administrative agencies may take actions that implicate uncertain questions on the "frontiers" of current understanding that could require heightened scrutiny. In December 2020, for example, the Department of Veterans Affairs (VA) indicated its intent to include race and ethnicity as factors in determining the priority for veterans to receive

193. *See id.*

194. *See id.* Although the right to an abortion has been characterized as a fundamental right, abortion rights are governed by the "undue burden" test, a *sui generis* form of heightened scrutiny, but a form of heightened scrutiny nonetheless. *See* Charles Stanley Ross, *The Right of Privacy and Restraints on Abortion Under the "Undue Burden" Test: A Jurisprudential Comparison of* Planned Parenthood v. Casey *with European Practice and Italian Law*, 3 IND. INT'L & COMP. L. REV. 199, 226 (1993) ("The United States, following *Casey*, views abortion as a *sui generis* fundamental liberty."); *The Undue Burden Standard After* Whole Woman's Health v. Hellerstedt, CTR. FOR REPROD. RTS. (2018), https://reproductiverights.org/wp-content/uploads/2020/12/WWH-Undue-Burden-Report-07262018-Edit.pdf [https://perma.cc/P5CD-7RXJ] ("The *Whole Woman's Health* decision clarified that the undue burden test is a form of heightened scrutiny.").

195. *Am. Coll. of Obstetricians & Gynecologists*, 472 F. Supp. 3d at 223, 233.

196. FDA v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 10, 11 (2020).

197. FDA v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 578, 578 (2021).

198. *Id.* at 578–79 (Roberts, C.J., concurring) (quoting South Bay United Pentecostal Church v. Newsom, 141 S. Ct. 1613, 1614 (2020)). In April 2021, the FDA announced it would use enforcement discretion regarding the in-person dispensing requirement. Letter from Janet Woodcock, Acting Comm'r, FDA, to Maureen G. Phipps, CEO, Am. Coll. of Obstetricians & Gynecologists, & William Grobman, President, Soc'y for Maternal-Fetal Med. (Apr. 12, 2021), https://prochoice.org/wp-content/uploads/FDA-Acting-Commissioner-Letter-to-ACOG-April-12-2021.pdf [https://perma.cc/K7FM-7DXX]. Following this announcement, the plaintiffs voluntarily dismissed the case with prejudice, which the district court ordered. Order at 1, Am. Coll. of Obstetricians & Gynecologists v. FDA, No. 8:20-cv-01320 (D. Md. May 13, 2021).

COVID-19 vaccines.[199] This decision was undoubtedly based upon research showing a higher COVID-19 incidence and mortality in certain racial and ethnic groups.[200] This caused some medical experts to call for the inclusion of race in vaccine eligibility criteria.[201] Other medical experts have argued that prioritizing other race-neutral criteria, such as preexisting health problems, conditions, and risk-factors, when combined with targeted outreach efforts to ensure greater vaccine distribution in underserved communities, would adequately account for racial imbalances in the threat posed by COVID-19.[202] Regardless, the VA's explicit use of race in the provision of medical services would trigger strict scrutiny as a race-based classification, as would the use of race by other public health related agencies.[203]

The point of these examples is not to prejudge whether the agency policies in question in each instance are correct or can be adequately

199. *See COVID-19 Vaccine Planning: Frequently Asked Questions for Veterans*, U.S. DEP'T VET. AFFS. (Dec. 2, 2020), https://content.govdelivery.com/attachments/USVHA/2020/12/08/file_attachments/1620107/3_VeteranFAQs_Chapter3_COVID-19VaccineAwareness_120220_Approved%20and%20Final.pdf [https://perma.cc/NB8P-T2C5]. *See also* Michael Conklin, *Racial Preferences in COVID-19 Vaccination: Legal and Practical Implications*, 5 HOW. HUM. & C.R.L. REV. 141, 150–51 (2021).

200. *See* Richard A. Oppel Jr., Robert Gebeloff, K.K. Rebecca Lai, Will Wright & Mitch Smith, *The Fullest Look Yet at the Racial Inequity of Coronavirus*, N.Y. TIMES (July 5, 2020), https://www.nytimes.com/interactive/2020/07/05/us/coronavirus-latinos-african-americans-cdc-data.html [https://perma.cc/Y76L-CMKS]. *See also*, Harald Schmidt, Lawrence O. Gostin & Michelle A. Williams, *Is It Lawful and Ethical to Prioritize Racial Minorities for COVID-19 Vaccines?*, 324 JAMA 2023 (Nov. 24, 2020) (noting arguments for prioritization of racial minorities for COVID-19 vaccines); Kristin Underhill & Olatunde C.A. Johnson, *Vaccination Equity by Design*, 131 YALE L.J. FORUM 53, 57–64 (2021) (discussing the sources of vaccine inequity).

201. *See* Megan Twohey, *Who Gets a Vaccine First? U.S. Considers Race in Coronavirus Plans*, N.Y. TIMES (July 9, 2020), https://www.nytimes.com/2020/07/09/us/coronavirus-vaccine.html [https://perma.cc/C8V7-4GTK] (noting federal health officials' consideration of prioritizing racial minorities in COVID-19 vaccine distribution). Some experts have called for the adoption of "race-explicit protocol changes" in medicine. *See* Bram Wispelwey & Michelle Morse, *An Antiracist Agenda for Medicine*, BOST. REV. (Mar. 17, 2021), https://bostonreview.net/science-nature-race/bram-wispelwey-michelle-morse-antiracist-agenda-medicine [https://perma.cc/JQF6-VGC9].

202. *See, e.g.*, Sally Satel, *Race for the Vaccine*, PERSUASION (Nov. 16, 2020), https://www.persuasion.community/p/race-for-the-vaccine [https://perma.cc/HH6R-VTEP].

203. *See* David E. Bernstein, *Two Decades Ago, the FDA and NIH Mandated the Use of Race to Categorize Subjects and Report Results in Medical and Scientific Research They Oversee. It Was a Huge Mistake*, YALE J. REG.: NOTICE & COMMENT BLOG (July 27, 2020), https://www.yalejreg.com/nc/two-decades-ago-the-fda-and-nih-mandated-the-use-of-race-to-categorize-subjects-and-report-results-in-medical-and-scientific-research-they-oversee-it-was-a-huge-mistake-by-david-e-bernstein/ [https://perma.cc/6U7U-AA8R].

justified.[204] In each case, the agencies have articulated plausible scientific rationales for the policies in question. In each case, however, the policy could also be challenged. And in each case, if the principles and premises of heightened scrutiny are to be upheld, the agencies should not be able to rely upon doctrines of administrative deference, and super deference in particular, to deflect careful judicial scrutiny of the scientific conclusions upon which their respective policies are based. This Article proceeds to address the reasons for placing heightened scrutiny over super deference.

IV. SCRUTINY OVER DEFERENCE

As the preceding Part shows, there are a range of instances in which agency actions may implicate various forms of heightened scrutiny, either because they rely upon suspect classifications or potentially infringe upon constitutionally protected rights. Such policies are not inherently unconstitutional. They are instead subject to a greater degree of judicial scrutiny when subject to judicial review. In practice, this means that agencies must do more in such circumstances to demonstrate that their policy measures are justified and, as this Part explains, insofar as such policies are predicated on technical or scientific judgments, those judgments should be subject to heightened scrutiny as well. Subjecting such judgments to heightened scrutiny is incompatible with affording deference to such agency judgments, let alone the super deference that is commonly invoked with respect to questions of science.

There are several reasons why heightened scrutiny should trump agency deference, including—perhaps especially—super deference. First, agency deference is a consequence of legislative and judicial choice, whereas heightened scrutiny is a constitutional demand.[205] Second, allowing agencies to evade the more demanding judicial review brought by heightened scrutiny by relying upon scientific determinations would encourage such evasion and the submersion of policy choices under a scientific façade. Third, while it may be appropriate to presume agencies are competent and able to assess matters within their expertise, there is little reason to suspect agencies will show adequate concern for constitutional matters beyond their mission or outside of their purview. And fourth, subjecting agency scientific determinations to heightened

204. Nor, as noted previously, does this Article take a position on the underlying soundness of existing constitutional law doctrine, the tiers of scrutiny as currently formulated, or decisions concerning which sorts of governmental decisions should be subject to heightened scrutiny.

205. As noted earlier, this Article takes the current contours of constitutional jurisprudence as a given to focus on the potential conflict between agency deference and heightened scrutiny. This argument is distinct from disputes over which sorts of governmental action should trigger heightened scrutiny and what levels of heightened scrutiny should be applied in a given context.

scrutiny is consistent with, and perhaps even compelled by, the constitutional fact doctrine.

A. *The Constitution Constrains Legislative Choice*

Judicial deference to administrative agencies is a product of legislative choice and judicial norms. The APA prescribes a limited set of procedural requirements[206] and identifies a limited set of bases upon which an agency action may be struck down.[207] By requiring judicial invalidation of those agency actions that are arbitrary or capricious, or that are based on facts not supported by substantial evidence, Congress has indicated its preference for relatively deferential and limited judicial review. Further, courts have recognized their relative lack of expertise over the subject matter about which most agency actions are concerned. Regulatory agencies have scientific and technical expertise, compounded by substantial administrative experience within the particular vineyards in which they toil. Reviewing courts are interlopers, capable of giving agencies a "hard look" to ensure relevant factors were considered and made subject to reasoned decisionmaking, but they are not capable of improving upon the agency's judgment, nor are they generally authorized to do so.[208]

This all makes sense, provided constitutional questions are not in play. To the same extent that the Constitution constrains legislative behavior, it must also constrain administrative behavior. Entities created by Congress and delegated power through legislation are in no way immunized from constitutional constraints by such delegation. To the contrary, courts have at times suggested agencies should be subject to greater scrutiny than legislatures.[209] Regardless, agencies only exercise that authority delegated to them by Congress, and such delegations are fully subject to the constitutional constraints under which Congress itself must operate.[210]

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206. *See, e.g.*, 5 U.S.C. § 553 (detailing the procedural requirements of informal rulemaking).

207. *See id.* § 706.

208. *See supra* Part I.

209. *See, e.g.*, Turner Broadcasting Sys., Inc. v. FCC, 520 U.S. 180, 195 (1997) (finding that review of legislative findings "is to be measured in this context by a standard more deferential than we accord to judgments of an administrative agency"). Some Justices have raised the concern that undue scrutiny of congressional findings, or the lack thereof, would be inappropriate. *See, e.g.*, Fullilove v. Klutznick, 448 U.S. 448, 502–03 (1980) (Powell, J., concurring) (cautioning against review that would "treat Congress as if it were a lower federal court" and "mark an unprecedented imposition of adjudicatory procedures upon a coordinate branch of Government").

210. *See* Shapiro & Levy, *supra* note 11, at 429 ("[A]dministrative agencies, unlike legislatures, are not entitled to the same presumption of correctness because they are neither politically accountable nor directly subject to checks and balances.").

It may well be that Congress would still prefer that agency actions retain a presumption of regularity or validity even when constitutional concerns are in play, but this does not matter. Insofar as the Constitution constrains governmental action, its constraints are no less limiting on federal agencies than on Congress. If Congress cannot regulate in ways that constrain fundamental rights or that rely upon suspect classifications without satisfying the needs of heightened scrutiny, neither can agencies.

Congress delegates to federal agencies the authority to make discretionary policy choices when promulgating regulations and implementing various programs. In such instances, federal agencies are free to prioritize one set of values or concerns over another. Where heightened scrutiny applies, however, the resolution of such trade-offs may be predetermined. If heightened scrutiny applies, then it effectively puts a thumb on the scales in favor of one value—protecting constitutional liberties, ensuring equal protection, etc.—over others.[211]

B. *Agency Competence and Tunnel Vision*

Beyond the built-in rationale that heightened scrutiny is antithetical to deference—let alone super deference—there are reasons to suspect that agencies are less likely to consider constitutional rather than political or legal constraints on their actions. However well-intentioned agencies may be—indeed, perhaps *due* to their good intentions—agencies are likely to undervalue exogenous constitutional constraints on their ability to achieve their stated missions.[212] As the Supreme Court has noted repeatedly, constitutional questions often lie outside the "competence and expertise" of regulatory agencies.[213]

Agencies are created to pursue and implement their organic visions. The FDA is focused on ensuring a safe supply of food and drugs, the EPA is focused on environmental protection, the Consumer Product Safety Commission is focused on the potential dangers posed by consumer products, and so on. Such focus facilitates the ability of agencies to achieve their statutorily prescribed missions, but may also produce

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211. *See* FAIGMAN, *supra* note 13, at 101 (noting that the constitutional inquiry allocates the "risk of error" and that the judicial inquiry "must be guided by the burdens of proof that correspond with the constitutional values at stake").

212. *See* David E. Bernstein, *Antidiscrimination Laws and the Administrative State: A Skeptic's Look at Administrative Constitutionalism*, 94 NOTRE DAME L. REV. 1381, 1400–06 (2019) (describing the ways in which administrative agencies "neglect limitations, constitutional or otherwise, on their power").

213. *See* Free Enter. Fund v. Pub. Co. Acct. Oversight Bd., 561 U.S. 477, 491 (2010) ("Petitioners' constitutional claims are also outside the Commission's competence and expertise."); *see also* Carr v. Saul, 141 S. Ct. 1352, 1354 (2021) (noting that constitutional questions "usually fall outside" an agency adjudicator's "areas of technical expertise"); Califano v. Sanders, 430 U.S. 99, 109 (1977) ("Constitutional questions obviously are unsuited to resolution in administrative hearing procedures . . . .").

"tunnel vision," which leads agencies to discount or ignore the consequences of their actions and the trade-offs adjacent to any policy choice.[214]

Justice Stephen G. Breyer explained why tunnel vision can be a problem in his book *Breaking the Vicious Circle*: "Tunnel vision, a classic administrative disease, arises when an agency so organizes or subdivides its tasks that each employee's individual conscientious performance effectively carries single-minded pursuit of a single goal too far, to the point where it brings about more harm than good."[215]

As Justice Breyer explained, when agencies experience tunnel vision, they will pursue their missions by embracing even more stringent or severe measures, despite diminishing marginal returns, potentially past the point at which net benefits may still be obtained.[216] In the context of hazardous waste cleanups under Superfund, for example, Justice Breyer noted that the EPA can be so focused on removing "the last little bit" of hazardous materials that it demands remediation past the point at which any benefit is justified by the resulting costs.[217]

Just as tunnel vision may induce agencies to ignore the consequences of otherwise desirable actions, it may blind agencies to the constitutional values with which the agency rarely has to deal.[218] The narrow focus many agencies have may enhance their technical expertise, but it may also come at the expense of competing constitutional values that lie outside of their core mission.[219] Moreover, it is not as if agencies are disinterested when the question at hand concerns the scope of their own authority.[220]

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214. *See* Paul N. Singarella & Marc T. Campopiano, *The Role of Economics in Environmental, Health, and Safety Regulation After* Entergy, 35 ENVIRONS 101, 105 (2011) ("Regulatory tunnel vision occurs when an agency over regulates a particular societal problem at an opportunity cost to other, potentially more pressing, problems."); *see also* Richard B. Stewart, *A New Generation of Environmental Regulation?*, 29 CAP. U. L. REV. 21, 36 (2001) (discussing the problem of "agency 'tunnel vision' and insensitivity to the broader range of interests, values and considerations at stake in their decisions"). *See generally* Govind Persad, *Beyond Administrative Tunnel Vision: Widening the Lens of Costs and Benefits*, 15 GEO. J.L. & PUB. POL'Y 941 (2017) (discussing the problem of agency tunnel vision and potential solutions).

215. STEPHEN BREYER, BREAKING THE VICIOUS CYCLE: TOWARD EFFECTIVE RISK REGULATION 11 (1993).

216. *Id.*

217. *Id.*

218. *See* FAIGMAN, *supra* note 13, at 134 (noting that agencies "cannot be fully relied upon to give due weight to countermajoritarian values").

219. *See* Solove, *supra* note 5, at 1013 ("[T]he expert rarely factors democratic liberal values into her decisions.").

220. For the classic articulation of the public-choice claim that agencies tend to seek greater power and funding, see WILLIAM A. NISKANEN, JR., BUREAUCRACY AND REPRESENTATIVE GOVERNMENT 38 (1971). For a more nuanced account, see generally Matthew C. Stephenson, *Statutory Interpretation by Agencies*, *in* RESEARCH HANDBOOK ON PUBLIC CHOICE AND PUBLIC LAW (Daniel A. Farber & Anne Joseph O'Connell eds., 2010).

Under the Clean Water Act (CWA),[221] the EPA and U.S. Army Corps of Engineers (Army Corps) are entrusted with the responsibility of protecting the "waters of the United States."[222] The "waters" subject to their jurisdiction undoubtedly include tributaries and wetlands bound up with the nation's navigable waters.[223] The scope of this jurisdiction is also subject to constitutional constraint.[224] Yet, throughout their administration of these responsibilities, the EPA and Army Corps have routinely failed to account for the extent to which limits on federal power may constrain their jurisdiction,[225] resulting in significant judicial losses.[226] The two agencies' understandable focus on maximizing their ability to protect environmental values has come at the expense of their attention to constitutional constraints, and the Supreme Court has pointedly refused to defer to their interpretations of the scope of their own authority.[227] If agency myopia and self-interest preclude deference to agencies concerning the constitutional limits of their authority, they should also preclude deference to the scientific or factual judgments upon which constitutional claims ultimately rest.[228]

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221. Pub. L. No. 95-217, 91 Stat. 1566 (codified in scattered sections of 33 U.S.C.).

222. *See* 33 U.S.C. § 1362(7).

223. *See* United States v. Riverside Bayview Homes, Inc., 474 U.S. 121, 129, 131 (1985) (upholding the application of the CWA to "wetlands adjacent to navigable bodies of water and their tributaries" as "part of the waters of the United States").

224. *See* Jonathan H. Adler, *Judicial Federalism and the Future of Federal Environmental Regulation*, 90 IOWA L. REV. 377, 417–20 (2005) (discussing the constitutional constraints on CWA jurisdiction).

225. For example, after the Supreme Court made clear it would enforce constitutional limits on the scope of federal power under the Commerce Clause, the Army Corps and EPA made no effort to modify or limit their regulations to account for this potential limit on their jurisdiction. *See* Richard Lazarus, *Corps Slips on Lopez, FWS Wins*, ENVTL. F., Mar.–Apr. 1998, at 8 (noting that the Corps' wetlands regulations were "clearly" constitutional prior to *Lopez*, but unconstitutional afterwards, and yet the regulations were not revised).

226. *See* Rapanos v. United States, 547 U.S. 715, 742, 757 (2006) (narrowing the definition of wetlands that can be considered part of the "waters of the United States"); Solid Waste Agency N. Cook Cnty. v. U.S. Army Corps of Eng'rs, 531 U.S. 159, 174 (2001) ("Permitting respondents to claim federal jurisdiction over ponds and mudflats falling within the 'Migratory Bird Rule' would result in a significant impingement of the States' traditional and primary power over land and water use."); *see also In re* EPA, 803 F.3d 804, 807 (6th Cir. 2015) (concluding that challenges to "waters of the United States" regulation were likely to succeed on the merits), *vacated by In re* U.S. Dep't of Def., 713 F. App'x 489 (6th Cir. 2018).

227. *See, e.g.*, *Solid Waste Agency*, 531 U.S. at 172 ("explaining that [w]here an administrative interpretation of a statute invokes the outer limits of Congress' power," no deference is due).

228. *See* Redish & Gohl, *supra* note 13, at 315 ("Because a regulator is insufficiently disinterested concerning questions about the scope of her authority, she cannot be permitted to make the final decision on that constitutional challenge. Because she cannot decide the very issue of constitutionality, she also should be denied final authority to decide factual issues or issues of mixed law-fact that are inherently intertwined with the determination of constitutionality."); *see*

In some cases, agencies are simply insufficiently attuned to or aware of external constraints on the pursuit of their statutorily authorized missions. In others, they are actually hostile to the suggestion that vague constitutional principles could limit their ability to fulfill their mission.[229] When FDA Chief Counsel Daniel Troy suggested his agency needed to be more attentive to First Amendment concerns, in part because the agency had been losing legal challenges to its regulatory policies, he was met with substantial resistance from agency veterans and personnel.[230] Constitutionally protected freedom of speech was important, to be sure, but for many in the FDA, the agency's public health missions were a higher priority.[231]

Just as judges may lack the technical expertise agencies enjoy within their delegated subject matter, agencies may lack the constitutional expertise of courts, which further justifies not deferring to agency determinations that lay the predicate for actions that trigger heightened scrutiny.

C. *Combatting the Science Charade*

Deferential judicial review of agency scientific determinations encourages agencies to characterize normative judgments and discretionary policy decisions as scientific determinations. Insofar as resorting to scientific justifications may enable agencies to evade constitutional limitations on their authority, maintaining deference in the face of heightened scrutiny will magnify the incentive for agencies to engage in the "science charade" and disguise their policy choices as scientifically determined conclusions.[232] In this way, allowing agency

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also Ernest Gellhorn & Paul Verkuil, *Controlling* Chevron*-Based Delegations*, 20 CARDOZO L. REV. 989, 994 (1999) ("When agency self-interest is directly implicated, such as when it must decide whether an area previously unregulated by the agency should now come within its jurisdiction, the justifications for deference fade. . . . It is here that concern about agency aggrandizement is at its highest.").

229. *See* Solove, *supra* note 5, at 1013 ("The expert judgments of agencies are often contorted by political needs; they are not always the product of an impartial analysis of factual data.").

230. *See* Marc Kaufman, *FDA Seeks Public Comment on Rules' Constitutionality*, WASH. POST, May 15, 2002, at A25 (quoting critics of the FDA's willingness to consider First Amendment limitations on its regulatory authority); *see also* Willam B. Schultz & Michael R. Taylor, *Hazardous Hucksters*, WASH. POST, May 28, 2002, at A17 (accusing the FDA of placing "public health protections in jeopardy" by acknowledging First Amendment concerns).

231. *See* Carl Wiersum, *No Longer Business as Usual: FDA Exceptionalism, Commercial Speech, and the First Amendment*, 73 FOOD & DRUG L.J. 486, 488 (2018) (noting that the FDA's response to repeated First Amendment losses in federal court "was not to reevaluate" its regulatory approach, but rather "generally attempting to carry on business as usual").

232. *Cf.* Wagner, *supra* note 11, at 1617 ("[C]amoflauging controversial policy decisions as science assists in evading various . . . legal . . . forces.").

scientific expertise to trump heightened scrutiny will also further serve to undermine the transparency of agency decisionmaking.[233]

The science charade refers to the phenomenon whereby "agencies exaggerate the contributions made by science" in resolving particular questions "in order to avoid accountability for the underlying policy decisions."[234] As described by Professor Wendy Wagner in her seminal article "The Science Charade in Toxic Risk Regulation," agencies evade political and legal accountability by "camouflaging controversial policy decisions as science."[235] This occurs, in part, because scientific conclusions are viewed as "objective," and are less easily attributed to the policy preferences of a given agency official or policymaker.[236]

The science charade not only enables agencies to avoid political accountability, it also helps to insulate agency actions from judicial review. Indeed, judicial deference to agency scientific judgments serves to exacerbate the science charade.[237] This is particularly true in the contexts identified in *Baltimore Gas*, as normative judgments made on the "frontiers of scientific knowledge" are most inescapable.[238] Residual uncertainty about the precise scope or scale of emergent risks and the full consequence of agency responses mean that agency policymakers will necessarily rely upon normative priors or preferences in reaching final determinations.[239] However, such judgments may be preferable to placing these decisions in the hands of judges, as disguising normative policy judgments as questions of science undermines political and legal accountability for the underlying choice.

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233. *Id.* at 1665–66 (arguing that courts are increasing the prevalence of the science charade, which inherently undermines agency transparency, by not scrutinizing the accuracy of technical explanations).

234. *Id.* at 1617. For a discussion of this phenomenon in the context of species conservation, see generally Adler, *supra* note 119.

235. Wagner, *supra* note 11, at 1617; *see also* Doremus, *supra* note 118, at 1038 ("[C]haracterizing a decision as strictly scientific can allow politicians to evade difficult value choices, placing those choices instead in the hands of technical experts.").

236. *See* Cary Coglianese & Gary E. Marchant, *Shifting Sands: The Limits of Science in Setting Risk Standards*, 152 U. PA. L. REV. 1255, 1264 (2004) ("Science has considerable rhetorical appeal when it comes to defending regulatory decisions, as it is often described and perceived as being 'objective.'").

237. *See* Wagner, *supra* note 11, at 1661 ("[C]ourts are exacerbating, rather than discouraging, the agencies' misidentification of toxic standard-setting as resolvable by science."). This is not an entirely new observation. *See* Thomas O. McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 GEO. L.J. 729, 750 (1979) ("[T]o the extent that a reviewing court is willing to defer to agency 'expertise' in choosing between the theories of equally respectable scientists, the court will simply force the agency to disguise policy decisions as factual determinations.").

238. *See* Wagner, *supra* note 11, at 1665 n.188.

239. *See* Rebecca N. Bratspies, *Human Rights and Environmental Regulation*, 19 N.Y.U. ENV'T L.J. 225, 228 (2012) (noting the importance of agency "background assumptions" in resolving scientific uncertainties).

In some cases, the charade may be deliberate, as when a scientific expert is playing the role of policy advocate, seeking to advance her own policy preferences. As Professor Wagner noted, "scientists have been shown to deliberately misidentify the hazy line between science and policy in the past."[240] In other instances, the charade may result from the incentives created by the underlying legal and policy framework.[241] Judicial deference to agency scientific determinations augments these incentives, particularly where—as in the context of heightened scrutiny—agency decisions are otherwise likely to face more searching judicial inquiries. Put another way, the presence of constitutional constraints on agency behavior will, if anything, further enhance the incentive to engage in the science charade, thereby placing the values heightened scrutiny is designed to protect in greater jeopardy.

D. *The Constitutional Fact Doctrine*

Deference to agency scientific assessments in the context of heightened scrutiny would also appear to conflict with the constitutional fact doctrine, which provides that "courts must independently decide factual issues whose resolution will be determinative of constitutional challenges."[242] This doctrine "recognizes that the need for adjudicatory independence is at its height when a decision-maker finds facts that bear on the constitutional limits of its own regulatory authority."[243] While not applied as consistently as some might hope,[244] the constitutional fact doctrine suggests that courts should not defer to agency determinations used to justify or defend policies that implicate heightened scrutiny.[245]

According to Professors Martin Redish and William Gohl, courts should be *most* willing to enforce this doctrine when reviewing the decisions of administrative agencies.[246] Whether this requires de novo review, as the Court had suggested in *Crowell v. Benson*,[247] it would seem

240. *See* Wagner, *supra* note 11, at 1628; *see also* Rykiel, *supra* note 112, at 434 ("Scientists typically portray the information they provide to the public as objective and value free, with the implication that those traits confer greater weight to their opinions than should be accorded to the value laden opinions of nonscientists.").

241. *See* Wagner, *supra* note 11, at 1650–51 ("[A]gencies are responding to multiple political, legal, and institutional incentives to cloak policy judgments in the garb of science.").

242. Redish & Gohl, *supra* note 13, at 290.

243. *Id.* at 311.

244. *See* Solove, *supra* note 5, at 986 n.241 ("[T]his mysterious doctrine has been practiced only sporadically."); Sohoni, *supra* note 13, at 1612 ("[T]he constitutional fact doctrine has been 'unevenly applied,' and its contours remain uncertain." (footnote omitted)).

245. *See* Redish & Gohl, *supra* note 13, at 317 ("Notwithstanding some commentators' doubts about the doctrine's vitality, the Court has continued to recognize Chief Justice Hughes's insight that 'constitutional courts,' not the legislative or executive branches, must have the final say on constitutional facts.").

246. *Id.* at 292.

247. 285 U.S. 22 (1932).

to preclude the degree of deference generally granted to agency scientific determinations.[248] Although often analyzed solely with regard to adjudicative facts, as opposed to the legislative facts that may form the basis for broad regulatory policy decisions,[249] there is no reason why these considerations should not apply with equal force when an agency has conducted a rulemaking.[250] Agency determinations of adjudicative facts may require greater procedural protections than findings of legislative facts do,[251] but neither the choice of agency process nor the facts found affect the substantive degree of constitutional scrutiny to be applied.

V. APPLICATION AND IMPLICATIONS

A bit more can be said about how the approach in this Article would be operationalized. The norm of judicial deference to agency scientific determinations is well established. Allowing for greater judicial scrutiny of such judgments when heightened scrutiny is implicated need not threaten judicial competence, meaningfully increase judicial workloads, or destabilize judicial review of agency actions more generally.

This Part addresses operationality as well as potential implications of abandoning super deference to agency scientific determinations in the context of heightened scrutiny.

A. *Application*

The evaluation of government action under heightened scrutiny requires attention to both means and ends. The end asserted by the government must be a sufficiently weighty and substantive interest to justify intruding into otherwise suspect space. Whereas the rational basis

248. *Id.* at 65.

249. *See, e.g.*, Henry P. Monaghan, *Constitutional Fact Review*, 85 COLUM. L. REV. 229, 230–31 & nn.16–17 (1985) (describing "adjudicative facts decisive of constitutional claims" as constitutional facts); Kenneth Culp Davis, *An Approach to Problems of Evidence in the Administrative Process*, 55 HARV. L. REV. 364, 402–04 (1942) (distinguishing between legislative and adjudicative facts).

250. *See* Redish & Gohl, *supra* note 13, at 295 n.18 (suggesting that a constitutional fact should be understood as a fact "asserted [as the] constitutional basis for the exercise of the *power* in question").

251. This is the lesson of the *Londoner*/*Bi-Metallic* dichotomy. *See* Londoner v. Denver, 210 U.S. 373, 385–86 (1908) (recognizing that due process requires an individualized hearing to determine individualized facts about individualized cases); Bi-Metallic Inv. Co. v. State Bd. of Equalization, 239 U.S. 441, 445 (1915) (finding that due process does not require an individualized hearing where "a rule of conduct applies to more than a few people"); *see also* Kimberly L. Wehle, *Defining Lawmaking Power*, 51 WAKE FOREST L. REV. 881, 891 (2016) ("*Londoner* and *Bi-Metallic* remain the leading cases on the definitional distinctions between legislation and adjudication, which are mirrored in the APA itself.").

test merely requires that the governmental interest be legitimate,[252] heightened scrutiny requires that it be "important" or "substantial" in the case of intermediate scrutiny,[253] or "compelling" where scrutiny is strict.[254] Protection of human life or health are generally accepted to be sufficient interests under heightened scrutiny, as is national security.[255] Mere government convenience, cost savings, or idiosyncratic political preferences, on the other hand, will not do.[256]

Heightened scrutiny also requires a focus on the means adopted to pursue the stated government end.[257] Although there are different formulations depending upon the precise context, heightened scrutiny invariably requires a degree of "fit" between the end sought and the means selected, ensuring that the policy at issue meaningfully advances the stated governmental interest and limits the extent to which the chosen policy or classification is over or under inclusive.[258] It may also require some demonstration that the government lacked available alternatives to

252. *See* Kimel v. Fla. Bd. of Regents, 528 U.S. 62, 83–84 (2000) (finding that under rational basis review, government classifications will be upheld if they are "rationally related to a legitimate state interest"); City of New Orleans v. Dukes, 427 U.S. 297, 303 (1976) (per curiam); *see also* Williamson v. Lee Optical, 348 U.S. 483, 488 (1955) ("It is enough that there is an evil at hand for correction, and that it might be thought that the particular legislative measure was a rational way to correct it."); Ry. Express Agency v. New York, 336 U.S. 106, 109–10 (1949) (upholding a local ordinance that limited which types of advertisements could be displayed on vehicles under rational basis review given the local government's interest in limiting distractions for motorists).

253. *See* Craig v. Boren, 429 U.S. 190, 197 (1976) ("[C]lassifications by gender must serve important governmental objectives . . . ."); Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 566 (1980) (requiring regulation of commercial speech to serve a "substantial" government interest).

254. *See* Plyler v. Doe, 457 U.S. 202, 217 (1982) (finding that strict scrutiny requires a "compelling governmental interest").

255. *See* Khiara M. Bridges, "*Life" in the Balance: Judicial Review of Abortion Regulations*, 46 U. CAL. DAVIS L. REV. 1285, 1289 (2013) (recognizing life and health as government interests); Note, *Let the End Be Legitimate: Questioning the Value of Heightened Scrutiny's Compelling- and Important-Interest Inquiries*, 129 HARV. L. REV. 1406, 1419 (2016) (noting that national security has been recognized as a compelling interest).

256. *See* TRIBE, *supra* note 140, § 16-6, at 1453 (noting that heightened scrutiny entails "judicial wariness of interests such as these which can so easily and indiscriminately be invoked, and which almost never point uniquely to a challenged political choice").

257. *See* FAIGMAN, *supra* note 13, at 137 ("The standard of 'strict scrutiny' would lose its meaning if the means chosen to effectuate arguably compelling ends . . . were not rigorously evaluated by a reviewing court.").

258. *See, e.g.*, Hassan v. City of New York, 804 F.3d 277, 305 (3d Cir. 2015) ("The higher the scrutiny required, the more persuasive must be the governmental objective and the snugger the means-ends fit.").

achieve its stated goal, or at least that no available alternative would be as effective.[259]

Scientific analysis may be relevant to evaluating both the means and ends of government policies, and if heightened scrutiny is to have meaning, it cannot be enough for an agency to offer a rote invocation of a sufficient interest. If an agency claims that public health is at stake, for example, it should be able to show the basis for that conclusion. If, for instance, the agency claims a food additive causes cancer or other disease, and therefore must be disclosed, it should have to show some modicum of evidence to substantiate that claim. Health-based pretexts, such as those used to prohibit filled milk, may be acceptable when regulating unprivileged economic conduct. They are impermissible when it comes to regulating speech or constitutionally protected rights. Similarly, if the FDA believes that a woman's mail access to mifepristone poses a risk that could justify constraining constitutionally recognized reproductive rights, it should be able to offer more than its say to establish that the risks involved are greater than those posed by other medications not subject to similar limitations.[260] In such cases, the FDA should be able to put forward medical evidence and assessments to substantiate that claim. Once a constitutional right is recognized, extreme judicial deference should be off the table.[261]

The same scrutiny should be applied to means as is applied to ends. Here again, agencies should not be able to hide behind an invocation of their technical expertise to avoid demonstrating or justifying their choice. If the FDA claims that allowing blood or sperm donations by MSM poses health risks in the blood or sperm supplies due to the potential presence of HIV that justify limits on donation, the FDA should have to show that scientific evidence supports this conclusion, as well as that there are not viable alternatives to safeguard the nation's blood and sperm donation supplies, so as to ensure the policy is not simply the result of stereotypes or prejudice. If the FDA believes more targeted risk-based measures are not viable, it should be able to explain why. If it cannot provide such an

259. *See id.* ([W]hile it usually matters little for the purposes of rational-basis review that . . . 'other means are better suited to the achievement of governmental ends,' heightened scrutiny demands a much stronger justification . . . ." (quoting Twan Anh Nguyen v. INS, 533 U.S. 53, 77–78 (2001) (O'Connor, J., dissenting))).

260. This discussion assumes that the FDA's stated interest in restricting the use of mifepristone is in protecting women from risks posed by the medication, as opposed to another asserted interest, such as the protection of fetal life, which may be beyond the FDA's statutory purview.

261. Note that the argument in this Article proceeds on the assumption that the Court's constitutional jurisprudence has properly identified the contexts in which heightened scrutiny should apply. Should one conclude that, for example, commercial speech or reproductive choice should not be subject to heightened scrutiny, this would not change the underlying argument but only the contexts in which it would apply.

explanation, that would simply show that heightened scrutiny is serving its purpose.

If the government claims that a particular measure substantially advances the asserted interest, or is the least restrictive means of achieving that interest, here again this must be demonstrated without the benefit of deference. For instance, the FDA cannot merely assert that graphic warning labels of a given size or design reduce the likelihood of smoking.[262] This too must be substantiated. Similarly, if the FDA wants to bar producers of smokeless tobacco from advertising that their products are less risky than cigarettes,[263] it would have to cite evidence that such advertisements would mislead consumers and that less onerous regulations, such as the requirement of a qualifying disclosure, would be insufficient to advance its regulatory interest.

An inevitable question is what degree of evidence would be enough? Does the rejection of super deference merely mean a more ordinary arbitrary and capricious or substantial evidence review? Or should judicial review of agency determinations be something more akin to de novo?

In *Turner Broadcasting System v. FCC*,[264] the Supreme Court explained that heightened scrutiny required the Court to determine whether Congress had "drawn reasonable inferences based upon substantial evidence."[265] At the same time, the Court stressed that this was to be a more deferential review than would be afforded to an administrative agency.[266] Subsequently, in *FCC v. Fox Television Stations, Inc.*,[267] the Court noted that the question of whether a given agency action satisfied the relevant constitutional scrutiny was a distinct inquiry from whether it satisfied the reasoned decision making requirements of the APA.[268]

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262. *See, e.g.*, R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205, 1219 (D.C. Cir. 2012) (noting that the agency could not "satisfy its First Amendment burden with 'mere speculation and conjecture'" (citing Rubin v. Coors Brewing Co., 514 U.S. 476, 487 (1995), *overruled by* Am. Meat Inst. v. U.S. Dep't of Agric., 760 F.3d 18 (2014))).

263. *See, e.g.*, Brad Rodu & Philip Cole, *Smokeless Tobacco Use and Cancer of the Upper Respiratory Tract*, 93 ORAL SURGERY, ORAL MEDICINE, ORAL PATHOLOGY, ORAL RADIOLOGY & ENDODONTOLOGY 511, 512, 514 (2002) (reporting that powdered dry snuff use resulted in elevated risk of oral cancer, while use of moist snuff and chewing tobacco conferred minimal to no excess risk).

264. 520 U.S. 180 (1997).

265. *Id.* at 195.

266. *Id.* at 196.

267. 556 U.S. 502 (2009).

268. *Id.* at 516 ("If the Commission's action here was not arbitrary and capricious in the ordinary sense, it satisfies the Administrative Procedure Act's 'arbitrary [or] capricious' standard; its lawfulness under the Constitution is a separate question to be addressed in a constitutional challenge.").

Under current law, if the FTC concludes that an advertiser is engaged in false, misleading, or unsubstantiated claims, it must be able to demonstrate the basis for these conclusions. At present, such conclusions are to be upheld if they satisfy "substantial evidence."[269] As defined by the Supreme Court, this requires "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion,"[270] upon consideration of the whole record and taking into account "whatever in the record fairly detracts from its weight."[271] As understood in the administrative law context, the substantial evidence test is quite deferential—not much, if at all, more stringent than typical arbitrary and capricious review. Substantial evidence is "something less than the weight of the evidence."[272]

Is this standard sufficiently protective? In *POM Wonderful v. FTC*,[273] the D.C. Circuit applied substantial evidence review when evaluating the health claims POM Wonderful made about its products.[274] As discussed above, this standard of review is unduly deferential given that restrictions on product claims and other commercial speech are subjected to heightened scrutiny under existing doctrine. Yet in upholding the FTC's judgment against POM's First Amendment and other challenges, the court concluded that it would have upheld the FTC action even if it had reviewed the claims de novo, and had no difficulty evaluating the scientific claims at issue.[275] This would suggest that the effective enforcement of prohibition on false or unsubstantiated claims is not dependent upon deferential judicial review of agency action. The FTC remains an expert agency with greater understanding of the relevant scientific information and technical literature. Insofar as *POM Wonderful* is representative, it would suggest that requiring the FTC to explain and defend its interpretation of relevant scientific findings is unlikely to be unduly burdensome.

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269. *See, e.g.*, POM Wonderful, LLC v. FTC, 777 F.3d 478, 490 (D.C. Cir. 2015).

270. Consol. Edison v. NLRB, 305 U.S. 197, 229 (1938). It may also be understood as sufficient evidence to justify refusing to direct a verdict in the context of a jury trial. *See* NLRB v. Columbian Enameling & Stamping Co., 306 U.S. 292, 300 (1939).

271. Universal Camera Corp. v. NLRB, 340 U.S. 474, 488 (1951). As described by Professor Richard Pierce, the requirement is that "the evidence in support of an agency finding must be sufficient to support the conclusion of a reasonable person after considering all of the evidence in the record as a whole, not just the evidence that is consistent with the agency's finding." 2 RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE § 11.2, at 770 (4th ed. 2002).

272. Consolo v. Fed. Mar. Comm'n, 383 U.S. 607, 619–20 (1966).

273. 777 F.3d 478 (D.C. Cir. 2015).

274. *Id.* at 499.

275. *Id.* at 500.

B. *Implications*

The foregoing arguments raise potential implications for the applicability of *Baltimore Gas* super deference outside of those contexts in which governmental action is subject to heightened scrutiny, as well as whether courts should be deferential to scientific determinations or findings made by legislatures, as opposed to federal agencies. There are countervailing interests that should be addressed, including the nature of the burden this approach would impose on agencies. The arguments sketched above do not suggest that strong deference to agency scientific conclusions is inappropriate where the interpretations do not implicate constitutional questions, but instead suggest that courts should not be particularly deferential to legislative findings concerning scientific questions where government action is subject to heightened scrutiny.

1. Ossification and other Constraints on Regulation

One obvious concern with subjecting agency scientific determinations to greater scrutiny is that this will further the ossification of the regulatory process.[276] The development and promulgation of agency rules touching on complex and contested scientific matters already takes years.[277] By some accounts, existing standards of review have already "burdened, dislocated, and ultimately paralyzed" agency rulemaking, at least in some contexts.[278] Might subjecting an agency's ultimate scientific conclusions to greater scrutiny induce further conflict and delay? Might greater judicial scrutiny of agency scientific judgments risk judicial entrenchment of contingent scientific conclusions?[279]

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276. *See* Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1386 (1992) (noting that "ossification" of the rulemaking process is one of the most serious problems currently facing regulatory agencies). For an overview of the debate over regulatory "ossification," see Richard J. Pierce, Jr., *Rulemaking Ossification Is Real: A Response to "Testing the Ossification Hypothesis,"* 80 GEO. WASH. L. REV. 1493, 1494 (2012) ("[Ossification] must be understood so that we can effectively discuss potential means through which we can enhance the efficacy and efficiency of regulation by federal agencies.").

277. *See* PIERCE, *supra* note 271, at 1496 (noting that EPA rulemaking may take six to eight years for a single rule); *see also* Cass R. Sunstein & Adrian Vermeule, *Interpretation and Institutions*, 101 MICH. L. REV. 885, 932 (2003) ("[Judicial] review has contributed to the 'ossification' of notice-and-comment rulemaking, which now takes years, in part as a result of the effort to fend off judicial challenges. In light of the risk of invalidation, many agencies have turned away from notice-and-comment rulemaking altogether . . . .").

278. Jerry L. Mashaw & David Harfst, *Inside the National Highway Traffic Safety Administration: Legal Determinants of Bureaucratic Organization and Performance*, 57 U. CHI. L. REV. 443, 443 (1990).

279. *See* Tai, *supra* note 98, at 696 ("The dangers of the Court making its own determinations on scientific and medical issues is that such determinations will fix into place 'science' that could ultimately be undermined by additional studies.").

Concerns about ossification are real, but perhaps overstated.[280] Nonetheless, it is possible that subjecting agency scientific determinations to less deferential review will force agencies to devote greater time and attention to establishing the scientific predicate for policies that implicate such constitutional concerns. It might also induce agencies to embrace more fulsome procedures in order to justify their ultimate conclusions.[281] Agency willingness to subject proposed policies to greater scrutiny within the administrative process might induce greater confidence from reviewing courts.[282] Subjecting agency claims to cross-examination, for example, can "help illuminate agency sleight-of-hands."[283] Insofar as abandoning super deference encourages more formal policymaking processes, it would also encourage more transparent agency policymaking.[284]

It is also possible that the prospect of more demanding judicial review may induce agencies to be more attentive to constitutional concerns and more wary of rules and orders that implicate constitutional values, in effect creating an incentive for agencies to engage in a form of constitutional avoidance. In this way, less deferential review under heightened scrutiny would push agencies away from regulatory measures that infringe upon constitutionally protected rights and toward measures that do not implicate such rights. So, for example, it might induce regulatory agencies to focus less on the regulation of commercial speech, and more on the qualities and characteristics of underlying products. Or it might further incentivize agencies to consider alternative bases for regulatory measures than reliance upon constitutionally suspect classifications. This may make it more difficult to achieve some regulatory priorities, but it may also reinforce the underlying purpose heightened scrutiny is supposed to serve: an extra degree of protection

280. *See, e.g.*, Cary Coglianese, *The Search for Slowness*, JOTWELL (Apr. 11, 2012), http://adlaw.jotwell.com/the-search-for-slowness/ [https://perma.cc/9PQP-GY2X] (reviewing Jason Webb Yackee & Susan Webb Yackee, *Administrative Procedures and Bureaucratic Performance: Is Federal Rule-making "Ossified"?*, 20 J. PUB. ADMIN. RSCH. & THEORY 261 (2010)). *But see* Pierce, *supra* note 276, at 1494 (criticizing Jason Webb Yackee & Susan Webb Yackee, *Testing the Ossification Thesis: An Empirical Examination of Federal Regulatory Volume and Speed, 1950–1990*, 80 GEO. WASH. L. REV. 1414 (2012), for misunderstanding the ossification hypothesis).

281. Some would suggest such changes would, in and of themselves, be a good thing. *See* Aaron L. Nielson, *In Defense of Formal Rulemaking*, 75 OHIO ST. L.J. 237, 291 (2014) (defending formal rulemaking as improving the quality of rules and public respect for the rulemaking process).

282. *See* Crane, *supra* note 14, at 653 ("In ordinary litigation, reviewing courts purport to give greater or lesser scrutiny to facts found by others based on the stringency and character of the processes that produced them.").

283. Nielson, *supra* note 281, at 266.

284. Sohoni, *supra* note 13, at 1599 ("Reduced judicial deference to agency adjudications of private rights . . . will encourage better and more transparent agency decisionmaking.").

against governmental action in discrete areas of distinct constitutional concern.[285]

2. Super Deference Without Heightened Scrutiny

If super deference to scientific conclusions is inappropriate in the context of heightened scrutiny, it is fair to ask whether super deference is appropriate at all. Indeed, some have argued, quite forcefully, that super deference represents judicial abdication and provides federal agencies with too much leeway.[286] Professor Emily Hammond lays out the particulars of this indictment:

> Super deference is not grounded in realistic notions of agency science; it may contribute to ossification and the science charade; and it appears to have a disparate impact on environmental law. Measured against broader administrative-law values, super deference also inhibits transparency; undermines deliberation; fails to accord with political accountability; and generally abdicates the courts' role in the constitutional scheme by encouraging outcome-oriented review.[287]

These are all reasons for Congress to reconsider the extent to which courts should defer to agency judgments about science or, in the alternative, to create structures and processes that channel the assessment and evaluation of scientific matters in helpful ways.[288]

Outside of the constitutional context, judicial review of agency action is governed by Congress. The APA and relevant judicial review provisions in other regulatory statutes authorize and define the extent to which litigants may go to court to challenge agency action.[289] The standard of review anticipated by the text of Section 706 is quite deferential, and it has long been understood as such by courts and Congress alike.[290] If this is to be changed, that is the job of the legislature, not of reviewing courts.

Professor Aaron Nielson has argued that one benefit of formal rulemaking is that it provides interested parties with greater opportunity to challenge an agency's assessment of the science, particularly when compared to informal rulemakings.[291] Formal rulemakings also provide

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285. It is worth reiterating here that this analysis is independent of which rights or classifications are subject to heightened scrutiny. That is, the argument and effects will correspond with whatever rights or classifications are deemed sufficiently sensitive or important to merit such treatment.

286. *See* Elliott, *supra* note 40, at 23.

287. Meazell, *supra* note 8, at 737–38 (footnotes omitted).

288. The Clean Air Scientific Advisory Committee may be an example of this.

289. *See* 5 U.S.C. §§ 702, 704.

290. *See id.* § 706.

291. *See* Nielson, *supra* note 281, at 280.

greater opportunity for those who suspect an agency is shading or misrepresenting the relevant evidence to make their case, and salt the record with contrary assessments. This may all be true, but just as there is no warrant for courts to abandon super deference on their own, there is no warrant for courts to impose greater procedural requirements on agencies than Congress has opted to impose.[292]

3. Deference to Legislative Findings

If constitutional values should preclude super deference to agency scientific judgments where agency actions implicate fundamental rights or suspect classifications, it is not clear why the same should not be true for legislative actions. Legislatures may be the source of agency authority, but legislatures are no more free from constitutional constraint than agencies.[293] Further, administrative agencies at least have a plausible claim to technical or other expertise on relevant subject matter. Legislators, as a general rule, have little such expertise and, at least at the federal level, receive minimal technical support, particularly since legislative staffs were downsized and entities such as the Office of Technology Assessment were closed. Mere legislative recitation of important or substantial state interests should not be sufficient to satisfy the standard of review. For the reasons sketched above, legislative findings on disputed questions of scientific effect should likely not escape the critical examination heightened scrutiny demands.

CONCLUSION

Conscious of their own institutional limitations, it is understandable why judges may tend to defer to the scientific judgments of expert administrative agencies. In the usual course, such deference may be appropriate, if even compelled under prevailing administrative law norms. Yet when constitutional values are at stake, such deference must yield to the requirements of heightened scrutiny. The very premise of such scrutiny is that government actors must be held to a higher standard,

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292. *See* Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc., 435 U.S. 519, 524–25 (1978) (noting that, as a general rule, courts may not impose procedural requirements beyond those required by Congress).

293. Courts do, however, generally presume that legislatures have considered the constitutionality of their actions as a coordinate branch of government. *See* United States v. Carolene Prods. Co., 304 U.S. 144, 152 (1938) ("[T]he existence of facts supporting the legislative judgment is to be presumed, for regulatory legislation affecting ordinary commercial transactions is not to be pronounced unconstitutional unless in the light of the facts made known or generally assumed it is of such a character as to preclude the assumption that it rests upon some rational basis within the knowledge and experience of the legislators."). As noted earlier, that assumption is not always appropriate for administrative agencies. *See supra* Part IV.

and such a standard is incompatible with the extreme super deference federal courts tend to show federal agencies on scientific matters.

This argument does not depend upon the embrace of a particularly capacious or restrained conception of constitutional rights. It is not about what sorts of activities should receive constitutional protection or what sorts of classifications are particularly suspect. Rather, it is about the way in which courts should evaluate agency actions that cross established constitutional boundaries. It is an argument about how courts should ensure that those rights and classifications deemed worthy of heightened scrutiny receive the degree of constitutional protection such scrutiny necessarily demands. It is, in the end, simply a call for courts to recognize that when heightened scrutiny is invoked, super deference is not so super.