

Open the Floodgates: The Potential Impact on Litigation Against FDA if the Supreme Court Reverses or Curtails *Chevron* Deference

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ABSTRACT

The Supreme Court is drastically shifting, and several Supreme Court precedents may get a fresh look. The focus of this paper is on *Chevron* deference and what it could mean for FDA-regulated companies if FDA no longer has this powerful weapon in its arsenal. This paper is not an argument for or against *Chevron* deference, but simply provides an analysis of how certain cases could have turned out and what the future may look like with an even playing field.

INTRODUCTION

Suing the U.S. Food and Drug Administration (FDA) while playing by *Chevron*'s¹ rules is a David versus Goliath-like battle. Except here, David almost never wins.² These disputes might not be one-sided forever, however, and this losing storyline may change if *Chevron* deference is curtailed or eliminated.³ This Article addresses the intersection of FDA and *Chevron* deference.

Part I describes the current climate of battles against FDA and how *Chevron* deference makes court challenges against FDA difficult to win and often fruitless.⁴ Part II analyzes Supreme Court Justices and their perspective on *Chevron* through the

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¹ See *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984).

² See *id.*

³ The Supreme Court may become increasingly willing to grant certiorari in cases like *Kisor v. Wilkie*, in which the petitioner asked the Court to discard highly-deferential standards accorded to federal agencies. See Peter J. Wallison, *The Supreme Court May Begin to Tame the Administrative State*, WALL ST. J. (Dec. 13, 2018, 6:43 PM), <https://www.wsj.com/articles/the-supreme-court-may-begin-to-tame-the-administrative-state-11544744606> [<https://perma.cc/38BT-4VAV>]; see also *Kisor v. Wilkie*, 139 S.Ct. 657 (Mem) (2018).

⁴ On the other hand, when drug developers join FDA in defending a position, *Chevron* deference can increase the likelihood of success.

lens of their writings.⁵ Part III forecasts alternate outcomes in select cases if they had been decided in the absence of *Chevron* deference.⁶ This Article will conclude that, if *Chevron* deference is overturned or curtailed by the Supreme Court, FDA's decisions will come under increasing judicial scrutiny, and the floodgates will be opened to litigation against FDA and other agencies.

I. INTRODUCTION TO *CHEVRON* AND FDA

Because the Federal Food, Drug, and Cosmetic Act (FDCA)⁷ and *Chevron* are well known to *Food and Drug Law Journal* readers, only a brief discussion is necessary.

A. FDA & Its Power

FDA regulates a wide range of products in the food,⁸ medical, dietary supplement, cosmetic, and tobacco⁹ industries.¹⁰ The FDCA gave FDA broad power to develop advisory regulations, which were later construed to be binding and have the force of law—as long as they underwent the notice and comment procedure.¹¹ But “[a]s informal rulemaking became more difficult, the FDA shifted from promulgating binding rules to issuing nonbinding guidelines.”¹² FDA routinely relies on these guidelines as if they were binding rules, despite never having subjected them to the notice and comment procedure. Further, both Congress and the courts have supported this kind of action, and the deference afforded by *Chevron* has made it difficult to successfully challenge FDA's application of these guidelines.¹³

⁵ The Court may seek to overrule *Auer v. Robbins*, which establishes *Auer* deference. *See Auer v. Robbins*, 519 U.S. 452, 461 (1997) (*Auer* deference provides that an agency's interpretation of its own regulations is controlling unless plainly erroneous or inconsistent with the regulations being interpreted).

⁶ Potential challenges to *Auer* deference make the possibility of the Court further overruling *Chevron* deference appear to be not that far-fetched. *See Wallison, supra* note 3.

⁷ Federal Food, Drug, and Cosmetic Act, ch. 675, sec. 701(a), 52 Stat. 1040, 1055 (1938) (codified at 21 U.S.C. § 371(a) (2000)).

⁸ The U.S. Department of Agriculture regulates some aspects of meat, poultry, and egg products rather than the FDA.

⁹ *See Family Smoking Prevention and Tobacco Control Act*, Pub. L. No. 111-31, § 910, 123 Stat. 1776 (2009). FDA initially sought to regulate tobacco products through the general authority granted to it by the FDCA, but the United States Supreme Court found that there was no clear statutory authorization for FDA to regulate the tobacco industry generally. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000) (invalidating FDA's rule, stating that it was “confident that Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion”).

¹⁰ *See Regulated Products*, FOOD & DRUG ADMIN. (Aug. 3, 2018), <https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/default.htm> [<https://pe.rma.cc/4X67-8CU9>].

¹¹ *See* 21 U.S.C. § 371(a); *Nat'l Ass'n of Pharm. Mfrs. v. FDA*, 637 F.2d 877, 884 (2d Cir. 1981) (Although “pre-1962 case law established that any substantive regulations issued under § 701(a) could be interpretive only,” as long as regulations undergo the notice and comment procedure, they are considered to have the force of law.); *see also* Thomas W. Merrill & Kathryn Tongue Watts, *Agency Rules With the Force of Law: The Original Convention*, 116 HARV. L. REV. 467 (2002).

¹² Lars Noah, *The Little Agency That Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 CORNELL L. REV. 901, 904 (2008).

¹³ *See, e.g., Amneal Pharms. LLC v. FDA*, 285 F. Supp. 3d 328 (D.D.C. 2018) (applying *Chevron* and concluding that FDA's reliance on guidance was not arbitrary and capricious).

The FDCA demonstrates that “Congress chose for the most part to express its mandate [giving FDA authority] in broad and general terms, rather than in narrow and specific terms.”¹⁴ FDA has often pushed the bounds of its authority, however, and has stated that “the fact that Congress simply has not considered or spoken on a particular issue certainly is no bar to the [FDA] exerting initiative and leadership in the public interest.”¹⁵ In fact, FDA has been described as showing “little compunction about occasionally crossing a statutory or constitutional line when necessary to accomplish some valuable end.”¹⁶

The application of *Chevron* has allowed courts to rely heavily on FDA’s expertise and to withstand scrutiny. Although courts have, at times, found that FDA’s arguments are “almost frivolous,”¹⁷ “preposterous,”¹⁸ “tautological,”¹⁹ and “exaggerate[] [FDA’s own] overall place in the universe,”²⁰ courts have nonetheless frequently granted deference to the agency under *Chevron*.

B. What Does Chevron Deference Look Like?

As with the FDCA, judicial review, agency interpretation, and the *Chevron* test need little introduction, so only a quick refresher is provided. Article III of the U.S. Constitution vests the power of interpreting the law in the Supreme Court and the inferior courts established by Congress.²¹ Nevertheless, federal courts are courts of limited jurisdiction and they must possess statutory jurisdiction to adjudicate a lawsuit.²²

The Administrative Procedure Act (APA) grants federal courts jurisdiction to review administrative actions. The APA states that “the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action.”²³ The APA further provides that the court will “hold unlawful and set aside agency action” if it is found to be “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.”²⁴ The APA thus makes judges the decision-makers of all questions of law properly before them and contemplates some level of deference if the

¹⁴ Peter Barton Hutt, *Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act*, 28 FOOD DRUG COSM. L.J. 177, 178 (1973); see *Heckler v. Chaney*, 470 U.S. 821 (1985) (finding FDA’s decision not to act unreviewable under the Administrative Procedure Act).

¹⁵ Hutt, *supra* note 14, at 179.

¹⁶ Noah, *supra* note 12, at 903; see *United States v. Parkinson*, 240 F.2d 918, 921 (9th Cir. 1956) (“The record of the past few decades is replete with examples of the tendency of executive agencies to expand their field of operations. . . . These are warning signs that zeal for the noblest causes should not be translated into uncontrolled power of suppression of the contraries. The courts are charged with the duty of compelling restraint.”).

¹⁷ *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999).

¹⁸ *Washington Legal Found. v. Henney*, 56 F. Supp. 2d 81, 85 (D.D.C. 1999).

¹⁹ *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 66 (D.D.C. 1998).

²⁰ *Id.*

²¹ See U.S. CONST. art. III, § 1 (“The judicial Power of the United States, shall be vested in one Supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish.”).

²² See *Ruhrgas AG v. Marathon Oil, Co.*, 526 U.S. 574, 583 (1999).

²³ 5 U.S.C. § 706 (2012).

²⁴ *Id.* § 706(2)(A).

agency's interpretation of the statute is reasonable, i.e., not arbitrary, capricious, or an abuse of discretion.²⁵

This is where *Chevron* comes in. The *Chevron* test “accord[s] dispositive effect to an agency’s reasonable interpretation of ambiguous statutory language.”²⁶ This is done by a two-step analysis. First, the court determines whether “Congress has directly spoken to the precise question at issue” because “[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.”²⁷ Second, if Congress has not directly addressed the question at issue, then the court determines whether the “agency’s answer is based on a permissible construction of the statute.”²⁸

Even before *Chevron*, however, courts granted deference to agency decisions. In *United States v. Rutherford*, for example, the Supreme Court explained that “[t]he construction of a statute by those charged with its administration is entitled to substantial deference Such deference is particularly appropriate where, as here, an agency’s interpretation involves issues of considerable public controversy, and Congress has not acted to correct any misperception of its statutory objectives.”²⁹ In deferring to FDA, the Supreme Court implied that its hands were tied unless Congress were to correct FDA’s interpretation of statutory objectives. Further, even in the face of an unreasonable interpretation, the Supreme Court has been “reluctant to disturb a longstanding administrative policy that comports with the plain language, history, and prophylactic purpose of the Act.”³⁰

Following *Chevron*, courts have expanded the amount of deference afforded agencies to include an agency’s interpretation of its own ambiguous regulation. Thirteen years after *Chevron*, the Supreme Court issued its decision in *Auer v. Robbins*,³¹ announcing that an agency’s interpretation of its own regulation is “controlling unless ‘plainly erroneous or inconsistent with the regulation.’”³² This expansion has created a potential for federal agencies to draft intentionally ambiguous regulations to skirt procedural safeguards that could later be expanded through interpretive rules.³³

II. A TEXTUALIST COURT DOESN’T LOOK GOOD FOR *CHEVRON*

Notable textualists on the Supreme Court, like Justice Clarence Thomas, have criticized the *Chevron* doctrine, but have lacked the support to overturn it.³⁴ But the

²⁵ Ronald A. Cass, *Auer Deference: Doubling Down on Delegation’s Defects*, 87 *FORDHAM L. REV.* 531, 537 (2018).

²⁶ *EPA v. EME Homer City Generation, L.P.*, 572 U.S. 489, 512 (2014).

²⁷ *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984).

²⁸ *Id.*

²⁹ *United States v. Rutherford*, 442 U.S. 544, 545 (1979) (citation omitted).

³⁰ *Id.*

³¹ *Auer v. Robbins*, 519 U.S. 452 (1997).

³² *Id.* at 461 (quoting *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 359 (1989)).

³³ *See, e.g.*, John F. Manning, *Constitutional Structure and Judicial Deference to Agency Interpretations of Agency Rules*, 96 *COLUM. L. REV.* 612, 655–56, 659–60, 663–64 (1996).

³⁴ *See infra* Part II; *see, e.g.*, *Michigan v. EPA*, 135 S. Ct. 2699, 2712 (2015) (Thomas, J., concurring).

confirmations of Justices Neil Gorsuch and Brett Kavanaugh have shifted the Supreme Court towards becoming, at the very least, a “fairly textualist court.”³⁵ With this shift, the Supreme Court is likely to more closely inspect statutory language during disputes over an administrative agency’s interpretation. As discussed above, interpretive authority is reserved to the courts under Article III of the Constitution. The *Chevron* doctrine arguably deviates from both Article III and the APA in that it offers Article II agencies (i.e., the executive branch of government) authority to interpret the statutes from which they receive power. This can raise serious separation of powers questions under the Constitution. Although all judges have had to face the question of whether *Chevron* deference is compatible with the oft-quoted command that “the court shall decide all relevant questions of law,” some important actors are now saying “no.”

The trajectory of the courts—and especially the Supreme Court—has recently been pointing away from *Chevron* and towards a narrower standard. Legal commentary is buzzing in anticipation of a textualist Supreme Court majority that will potentially kill the *Chevron* doctrine once and for all.³⁶ Commentators have particularly focused their attention on the Supreme Court’s newest additions, Justices Gorsuch and Kavanaugh. Justice Gorsuch’s textualist persuasion and distaste for the *Chevron* doctrine are no secret. In the recent case, *SAS Institute, Inc. v. Iancu*,³⁷ the appellant attempted to persuade the Court to “use this case as an opportunity to abandon *Chevron* and embrace the ‘impressive body’ of pre-*Chevron* law recognizing that ‘the meaning of a statutory term’ is properly a matter for ‘judicial rather than administrative judgment.’”³⁸ Although the Court declined to bite,³⁹ there is reason to believe that it someday will—and soon. Justice Kennedy’s retirement from the Court has helped keep the Trump Administration’s promise of a textualist majority (enter Justice Kavanaugh) and provided reason to believe that Justices Gorsuch and Thomas may have finally gained the votes they need to put *Chevron* to rest.

Alternatively, the Supreme Court’s current trend of dodging questions of *Chevron*’s validity at least implies a desire to narrow the doctrine.⁴⁰ The Court has shown a distinct preference to end the *Chevron* inquiry at step one—ambiguity—so as not to reach the second question of agency deference. The late Justice Scalia favored this approach and advocated for a step one-heavy analysis on a number of occasions.⁴¹ Given this trend, the Court may forego revisiting the test and instead continue to find

³⁵ Ryan Lovelace, *Elena Kagan: The Supreme Court is a ‘Textualist Court’ That Reasons More Like Scalia Than Breyer*, WASH. EXAMINER (Oct. 16, 2017, 7:04 PM), <https://www.washingtonexaminer.com/elena-kagan-the-supreme-court-is-a-textualist-court-that-reasons-more-like-scalia-than-breyer> [https://perma.cc/2UDK-96YU].

³⁶ Kimberly Strawbridge Robinson, *High Court Could Take First Step to Chevron Doctrine’s Demise*, BLOOMBERG L. (March 28, 2019, 4:56 AM), <https://news.bloomberglaw.com/us-law-week/high-court-could-take-first-step-to-chevron-doctrines-demise> [https://perma.cc/6FPA-8EAH].

³⁷ See *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348 (2018).

³⁸ See *id.* at 1358 (citation omitted).

³⁹ See *id.* (“[W]hether *Chevron* should remain is a question we may leave for another day.”). Justice Gorsuch delivered the opinion of the Court and declined to explore the question of *Chevron*’s validity as a judicial tool.

⁴⁰ See, e.g., *Lucia v. SEC*, 138 S. Ct. 736 (2018); *Wisconsin Cent. Ltd. v. United States*, 138 S. Ct. 2067 (2018); *Mellouli v. Lynch*, 135 S. Ct. 1980 (2015).

⁴¹ See, e.g., Antonin Scalia, *Judicial Deference to Administrative Interpretations of Law*, 3 DUKE L.J. 511, 515 (1989).

in every case that “the statute is not ambiguous.”⁴² This remains to be seen. For now, the textualist-heavy court is making proponents of the *Chevron* doctrine—particularly lawyers at federal agencies—concerned about future legal challenges.

A. A Textualist Chevron Framework

Chevron deference may not go down without a fight. Proponents of the doctrine argue that, given the policy-determinative nature of administrative decisions, agencies are better positioned as “experts” to say what the law is.⁴³ Others simply favor policy decisions by executive-accountable agencies rather than life-tenured judges, presuming that Congress intended for agencies to fill statutory gaps, not the courts.⁴⁴ Legal scholars like Richard J. Pierce, Jr., further argue that the goal of *Chevron* is to separate legal questions, which courts are good at resolving, from policy questions, which they are not.⁴⁵

The late Justice Scalia was a proponent of the *Chevron* framework but employed a textualist approach to the doctrine. Justice Scalia’s *Chevron* analysis attempted to decide most cases at step one, believing that most cases would never get to step two because, using the traditional tools of statutory construction, many of Congress’s directives have only one possible meaning.⁴⁶ Justice Scalia argued that, if *Chevron* is to have any meaning, “congressional intent must be regarded as ‘ambiguous’ not just when no interpretation is even marginally better than any other, but rather when two or more reasonable, though not necessarily equally valid, interpretations exist.”⁴⁷

The Court attempted to further narrow the *Chevron* analysis in the early 2000s, implementing what some have called a “step zero” to assess whether Congress gave the agency the authority in this particular instance to make an interpretation that carries the force of law.⁴⁸ In an opinion by Justice David Souter, the Court held that “administrative implementation of a particular statutory provision qualifies for

⁴² See, e.g., *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438 (2002).

⁴³ Compare *Marbury v. Madison*, 5 U.S. 137, 177 (1803) (“It is emphatically the province and duty of the judicial department to say what the law is.”), with *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 843–44 (1984).

⁴⁴ Cass R. Sunstein, *Chevron Step Zero*, 92 VA. L. REV. 187, 189 (2006) (“*Chevron* seemed to declare that in the face of ambiguity, it is emphatically the province and duty of the administrative department to say what the law is.”).

⁴⁵ See Richard J. Pierce, Jr., *Chevron and Its Aftermath: Judicial Review of Agency Interpretations of Statutory Provisions*, 41 VAND. L. REV. 301, 306 (1988) (“In a high proportion of cases . . . an honest analysis of the language, the congressional goals, and the legislative history of the statute will not support a holding that Congress actually resolved the policy issue presented to the court . . . these courts are resolving a policy issue that Congress raised but declined to resolve.”); see also Lisa Schultz Bressman, *Chevron’s Mistake*, 58 DUKE L.J. 549, 561 (2009) (“*Chevron* recognizes that Congress may intend for agencies rather than courts to fill gaps in regulatory statutes . . . Agencies possess more expertise than courts for handling regulatory schemes that are ‘technical and complex’ and for reconciling the ‘competing interests’ that regulatory decisions often involve. Agencies are also accountable to the people, not directly but through the president, and ‘it is entirely appropriate for this political branch of Government to make such policy choices.’”) (citation omitted).

⁴⁶ See Antonin Scalia, *Judicial Deference to Administrative Interpretations of Law*, 3 DUKE L.J. 511, 515 (1989) (*Chevron* does not implicate separation of powers issues because the “traditional tools of statutory construction” are performed rigorously and “include not merely text and legislative history but also, quite specifically, the consideration of policy consequences.”).

⁴⁷ *Id.* at 520.

⁴⁸ See *United States v. Meade Corp.*, 533 U.S. 218, 221 (2001).

Chevron deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law and that the agency interpretation claiming deference was promulgated in the exercise of that authority.”⁴⁹ If an agency failed at “step zero,” the lower courts were instructed to use either *Skidmore* deference⁵⁰ or de novo review.⁵¹ As will be discussed below, attempts to narrow the doctrine have since developed and are evidence of the Court’s desire to take back some of its interpretative power.

B. *Chevron According to Gorsuch: It Is the Exclusive Province of Article III Courts to “Emphatically Say What the Law Is”*

Justice Gorsuch’s skepticism of the *Chevron* doctrine predates his time on the Supreme Court and can be examined through his opinion in *De Niz Robles v. Lynch*.⁵² In a 2015 opinion delivered by then-Judge Gorsuch, the Tenth Circuit considered whether a court was required to defer to an agency’s policy choice even when doing so meant that the court must overrule its own preexisting and governing statutory interpretation.⁵³ In light of *Chevron*,⁵⁴ Justice Gorsuch reluctantly answered: “These decisions mean that there are indeed some occasions when a federal bureaucracy can effectively overrule a judicial decision.”⁵⁵ In what followed, however, Justice Gorsuch described the “second-order constitutional protections sounding in due process and equal protection, as embodied in our longstanding traditions and precedents addressing retroactivity in the law” that constrain the retroactive application of administrative decisions despite the *Chevron* directive.⁵⁶

First, Justice Gorsuch distinguished judicial from legislative power, and the disparate sources of authority for each. Legislative power is derived from the people, and judicial power is derived from the Constitution, in isolation of “partisan influence and retribution.”⁵⁷ The role of a legislator is instead to announce new rules of general applicability, effectively forbidding retroactive application, while the role of a judge is to apply preexisting rules of general applicability to individual circumstances, necessitating retroactive application.⁵⁸ When Congress seeks to delegate legislative policymaking authority to an agency, an agency effectively parrots the legislative persona, therefore precluding the use of retroactive decision-making.⁵⁹ According to

⁴⁹ *Id.* at 226–27.

⁵⁰ When assessing how much deference to afford an agency under *Skidmore*, the court “look[s] to the degree of the agency’s care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency’s position[.]” *Id.* at 24 (citing *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944)).

⁵¹ *See Flores-Molina v. Sessions*, 850 F.3d 1150 (10th Cir. 2017) (applying de novo review when the agency’s action is not persuasive and is not reviewed under *Skidmore* deference).

⁵² *De Niz Robles v. Lynch*, 803 F.3d 1165, 1167 (10th Cir. 2015).

⁵³ *See Id.*

⁵⁴ *See Nat’l Cable & Telecomms. Ass’n v. Brand X Internet Service*, 545 U.S. 967, 969 (2005) (“The Commission’s construction of § 153(46)’s ‘telecommunications service’ definition is a permissible reading of the Communications Act at both steps of *Chevron*’s test.”).

⁵⁵ *De Niz Robles*, 803 F.3d at 1167.

⁵⁶ *Id.* at 1171–72.

⁵⁷ *Id.* at 1171.

⁵⁸ *See id.* at 1172.

⁵⁹ *See id.*

Justice Gorsuch, “their rules too should be presumed prospective in operation unless Congress has clearly authorized retroactive application.”⁶⁰

Justice Gorsuch’s opinion in *De Niz Robles* is rife with language suggesting that executive agencies’ desire for power, and that their actions upset the carefully calibrated constitutional design without restriction or reservation. He writes that in a *Chevron* step two analysis, “it’s easy to see the ‘ill effect[s]’ of retroactivity: upsetting settled expectations with a new rule of general applicability, penalizing persons for past conduct, doing so with a full view of the winners and losers—all with a decisionmaker driven by partisan politics.”⁶¹ According to Justice Gorsuch, there seems to be a corrupting influence when the executive agencies are free to use a legislative-like power retroactively and judges are unable to correct use of that power to ensure that it is free from partisan influence. The opinion describes agency deference as intrusive,⁶² exploitative,⁶³ and constitutionally evasive.⁶⁴

Justice Gorsuch’s opinion in *De Niz Robles* is not the only example of his distaste for *Chevron* deference. Perhaps the most scathing of his opinions is his concurrence in *Gutierrez-Brizuela v. Lynch*,⁶⁵ drafted as a supplement to his more neutral majority opinion. Drawing much attention, then-Judge Gorsuch’s concurrence in *Gutierrez* addresses the “elephant in the room”⁶⁶ by condemning *Chevron* as “no less than a judge-made doctrine for the abdication of the judicial duty.”⁶⁷ He opens his opinion by stating, as a matter of fact, that *Chevron* “permit[s] executive bureaucracies to swallow huge amounts of core judicial and legislative power and concentrate federal power in a way that seems more than a little difficult to square with the Constitution of the framers’ design.”⁶⁸ That design, he explains, was an intentional reservation of distinct, yet overlapping powers over three branches of government—a distinction enacted as “a vital guard against governmental encroachment on the people’s liberties, including all those later enumerated in the Bill of Rights.”⁶⁹ It is the job of the judiciary to “say what the law is”⁷⁰ and to insulate the adjudication of individual rights from “majoritarian politics” and “grave due process (fair notice) and equal protection

⁶⁰ *Id.*

⁶¹ *Id.* at 1176.

⁶² *Id.* at 1171 (“Indeed, one might question whether *Chevron* step two muddles the separation of powers by delegating to the Executive the power to legislate generally applicable rules of private conduct.”).

⁶³ *Id.* at 1177 (“By definition, the agency in the *Chevron* step two . . . scenario isn’t seeking to enforce the law as it is but instead seeks to exploit a gap in the law to implement its own (current but revisable) vision of what the law should be.”).

⁶⁴ *Id.* at 1173 (“Allowing agencies the benefit of retroactivity always and automatically whenever they choose adjudication over rulemaking would create a strange incentive for them to eschew the Court’s stated preference for rulemaking . . .”).

⁶⁵ *Gutierrez-Brizuela v. Lynch*, 834 F.3d 1142 (10th Cir. 2016).

⁶⁶ *Id.* at 1149.

⁶⁷ *Id.* at 1151–52.

⁶⁸ *Id.* at 1149.

⁶⁹ *Id.*

⁷⁰ *Marbury v. Madison*, 5 U.S. 137, 177 (1803).

problems.”⁷¹ According to Justice Gorsuch, disagreements with the interpretations of the court are properly remedied in the legislature, not the executive branch.⁷²

The *Chevron* doctrine implies that silence or gaps in a statute point to Congress’s intent to delegate “reasonable” legislative authority to the executive branch.⁷³ But, as then-Judge Gorsuch’s concurrence in *Gutierrez* suggests, this authority is found nowhere in express directives from Congress.⁷⁴ To the contrary, Congress has explicitly reserved to the courts the duty to interpret statutory provisions and overturn agency actions inconsistent with those interpretations.⁷⁵ Even if Congress did expressly reserve such power to agencies, it’s difficult to find any place in the Constitution where Congress is vested with the authority to delegate its legislative authority to executive agencies. In fact, in *Marshall Field & Co. v. Clark*,⁷⁶ the Supreme Court expressly stated that “[C]ongress cannot delegate legislative power to the president” and that this “principle [is] universally recognized as vital to the integrity and maintenance of the system of government ordained by the constitution.”⁷⁷ Nonetheless, *Chevron*’s purpose and effect do exactly that—“delegate legislative authority to the executive branch.”⁷⁸ Although not the “very definition of tyranny,” *Chevron* deference “certainly seems to have added prodigious new powers to an already titanic administrative state—and spawned along the way more than a few due process and equal protection problems of the sort documented in the court’s [*Gutierrez*] opinion today and in *De Niz Robles*.”⁷⁹

Then-Judge Gorsuch concluded his *Gutierrez* concurrence by imagining a world without *Chevron*.⁸⁰ This world, he states, would not look much different than it does today.⁸¹ Congress would continue to pass regulatory statutes, and agencies would continue to enforce them. Although courts would maintain discretion to “consult” agency interpretations regarding these statutes, courts would exercise their constitutionally-ordained power to independently “say what the law is.” Judge Gorsuch wrote:

Of course, courts could and would consult agency views and apply the agency’s interpretation when it accords with the best reading of a statute. But de novo judicial review of the law’s meaning would limit the ability of an agency to alter and amend existing law. It would avoid the due

⁷¹ *Gutierrez-Brizuela*, 834 F.3d at 1152 (“Transferring the job of saying what the law is from the judiciary to the executive unsurprisingly invites the very sort of due process (fair notice) and equal protection concerns the framers knew would arise if the political branches intruded on judicial functions.”).

⁷² *See id.* at 1151 (“When the political branches disagree with a judicial interpretation of existing law, the Constitution prescribes the appropriate remedial process. It’s called legislation.”).

⁷³ *See Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 843-44 (1984).

⁷⁴ *Gutierrez-Brizuela*, 834 F.3d at 1153. (“[W]here exactly has Congress expressed this intent? Trying to infer the intentions of an institution composed of 535 members is a notoriously doubtful business under the best of circumstances. And these are not exactly the best of circumstances.”).

⁷⁵ *See* 5 U.S.C. § 706.

⁷⁶ *Marshall Field & Co. v. Clark*, 143 U.S. 649 (1892).

⁷⁷ *See Gutierrez-Brizuela*, 834 F.3d at 1143-53 (quoting *Marshall Field*, 143 U.S. at 692).

⁷⁸ *Id.*

⁷⁹ *See id.* at 1155.

⁸⁰ *See infra* Part III.

⁸¹ *See Gutierrez-Brizuela*, 834 F.3d at 1158.

process and equal protection problems of the kind documented in our decisions. It would promote reliance interests by allowing citizens to organize their affairs with some assurance that the rug will not be pulled from under them tomorrow, the next day, or after the next election. And an agency's recourse for a judicial declaration of the law's meaning that it dislikes would be precisely the recourse the Constitution prescribes—an appeal to higher judicial authority or a new law enacted consistent with bicameralism and presentment. We managed to live with the administrative state before *Chevron*. We could do it again. Put simply, it seems to me that in a world without *Chevron* very little would change—except perhaps the most important things.⁸²

In a final blow to *Chevron*, he wrote that the *Chevron* doctrine is deserving of less precedential consideration than Supreme Court opinions are otherwise afforded because it is a procedural rule that proves problematic in its administration.⁸³

The *De Niz Robles* majority and *Gutierrez* concurrence are only two instances in which Justice Gorsuch criticized the *Chevron* doctrine as a procedural rule. In his short tenure on the Supreme Court, Justice Gorsuch has already drafted several opinions suggesting that his skepticism about the doctrine has not faded.⁸⁴ During the October 2017 term, in *Wisconsin Central Ltd. v. United States*,⁸⁵ Justice Gorsuch authored the majority opinion, finding that the Railroad Retirement Tax Act was not ambiguous with regard to whether employee stock options were taxable “compensation” for “services rendered.”⁸⁶ To find as much, Justice Gorsuch looked outside the statutory text, using “all the textual and structural clues before [the Court]” to find that it was “clear enough that the term ‘money’ excludes ‘stock,’” leaving no ambiguity for the agency to fill.⁸⁷ Some commentators are referring to this assessment as a “muscular *Chevron* step one inquiry,” alluding unmistakably to Justice Scalia's approach of rarely finding regulatory statutes ambiguous, relegating the question of whether the agency's interpretation is reasonable and should be given deference.⁸⁸ The same commentators suggest that lower courts may interpret Justice Gorsuch's “clear enough” ruling as a more searching inquiry than “clear” or “unambiguous,” effectively limiting the scope of *Chevron* deference rather than eviscerating it altogether.

C. *The Gorsuch Contingency*

Of course, one justice is not enough to eliminate *Chevron*, but several sitting justices have opined on the *Chevron* issue, suggesting that Justice Gorsuch may have the contingency he needs to at least narrow the procedural standard in the near future. Perhaps most notable is Justice Thomas, who shares Justice Gorsuch's preference for

⁸² *Id.* at 1158.

⁸³ *See id.* at 1157–58.

⁸⁴ These opinions, however, are certainly less scathing than his previous Tenth Circuit reviews.

⁸⁵ *See Wisconsin Central Ltd. v. United States*, 138 S. Ct. 2067 (2018).

⁸⁶ *Id.*

⁸⁷ *Id.* at 2074.

⁸⁸ *See* Chris Walker, *Gorsuch's “Clear Enough” & Kennedy's Anti-“Reflexive Deference”*: Two Potential Limits on *Chevron* Deference, 36 YALE J. ON REG.: NOTICE & COMMENT (June 22, 2018), <http://yalejreg.com/nc/gorsuchs-clear-enough-kennedys-anti-reflexive-deference-two-potential-limits-on-Chevron-deference> [<https://perma.cc/AYT6-U24F>].

eliminating the standard. In his dissent in *Michigan v. EPA*,⁸⁹ Justice Thomas remarked that *Chevron* deference “wrests from the Courts the ultimate interpretative authority to ‘say what the law is,’ and hands it over to the Executive.”⁹⁰ Echoing then-Judge Gorsuch’s *Gutierrez* concurrence, Justice Thomas stated that “[s]uch a transfer is in tension with Article III’s Vesting Clause, which vests the judicial power exclusively in Article III courts, not administrative agencies.”⁹¹

Also notable is Chief Justice John Roberts’s opinion of *Chevron* deference as embodied in his *City of Arlington v. FCC* dissent.⁹² There, Chief Justice Roberts proposed that, even where general rulemaking authority is clear, every agency rule must be subject to a *de novo* judicial determination of whether the particular issue was committed to agency discretion.⁹³ Chief Justice Roberts remarked that the analysis known as *Chevron* “step zero” was a high standard.

Perhaps most telling, however, is Chief Justice Roberts’s opinion in *King v. Burwell*,⁹⁴ the statutory challenge to the Affordable Care Act (ACA), which applied an exception to *Chevron* deference known as the “major questions” doctrine. The major questions doctrine provides that a court should not consider “statutory opacity” as a delegation of authority by Congress when the interpretation implicates a major question of social, economic, or political policy.⁹⁵

At issue in *King* was whether the ACA permitted subsidies for federal health insurance exchanges despite explicitly indicating that the subsidies were for exchanges “established by the State.”⁹⁶ The Court determined that although the ACA defined “State” to include all fifty states and the District of Columbia, the term was ambiguous and might be applied to federal exchanges when read in context of the ACA’s other provisions.⁹⁷ Despite finding the term ambiguous, the Court refused to apply *Chevron* deference because the statutory provision implicated “a question of deep ‘economic and political significance’ that is central to this statutory scheme” and “[i]t is especially unlikely that Congress would have delegated this decision to the IRS, which has no expertise in crafting health insurance policy of this sort.”⁹⁸

Further criticism of the *Chevron* doctrine has been made by Justice Brett Kavanaugh, the most recent addition to the Supreme Court. In Justice Kavanaugh’s view, “the doctrine is so indeterminate—and thus can be antithetical to the neutral, impartial rule of law[]”⁹⁹ and is “a judicially orchestrated shift of power from Congress

⁸⁹ *Michigan v. E.P.A.*, 135 S. Ct. 2699, 2713 (2015) (Thomas, J., concurring).

⁹⁰ *Id.* at 2712 (citation omitted).

⁹¹ *Id.*

⁹² *City of Arlington v. FCC*, 569 U.S. 290, 312 (2013) (Roberts, C.J., dissenting).

⁹³ *Id.*

⁹⁴ *King v. Burwell*, 135 S. Ct. 2480 (2015).

⁹⁵ Jeffrey Pojanowski, *Cabining the Chevron Doctrine the Kavanaugh Way*, LAW & LIBERTY (June 12, 2017), <https://www.lawliberty.org/2017/06/12/cabining-the-chevron-doctrine-the-kavanaugh-way> [https://perma.cc/V2PA-EKXR].

⁹⁶ *King*, 135 S. Ct. at 2490.

⁹⁷ *Id.* at 2497.

⁹⁸ *Id.* at 2489.

⁹⁹ Brett M. Kavanaugh, *Fixing Statutory Interpretation*, 129 HARV. L. REV. 2118, 2154 (2016).

to the Executive Branch.”¹⁰⁰ He took a harsher tone during a keynote address at Notre Dame Law School in 2017, stating that “the *Chevron* doctrine encourages agency aggressiveness on a large scale[.]” and that “[t]he result is that the agency wins” even if the judges disagree with the agency.¹⁰¹

According to Justice Kavanaugh, the root of the problem is the ambiguity prong of the *Chevron* test¹⁰²:

The legality of a major agency rule may . . . turn not on whether the judges think the agency’s interpretation of the statute is the best interpretation, but rather on whether the statute is ambiguous. That is true even though there is no real objective guide for determining whether a statute is ambiguous.¹⁰³

Justice Kavanaugh asserted that the solution is for courts to “simply determine the best reading of the statute[.]” without “defer[ing] to the agency interpretations.”¹⁰⁴

Perhaps pulling away from a call for *Chevron*’s demise, then-Judge Kavanaugh advocated for the major questions doctrine in his dissent in *United States Telecom Association v. FCC*.¹⁰⁵ *United States Telecom* involved the Federal Communications Commission’s (FCC) interpretation of the Telecommunications Act to subject internet providers to net-neutrality regulations.¹⁰⁶ FCC argued for, and the D.C. Circuit applied, *Chevron* deference in upholding the agency’s action to implement and enforce the net-neutrality rule.¹⁰⁷ The majority held that the Telecommunications Act was ambiguous but that FCC was empowered to resolve the ambiguity.¹⁰⁸ In his dissent, Justice Kavanaugh asserted that *Chevron* applies to “ordinary agency rules,” not “major agency rules of great economic and political significance.”¹⁰⁹ Having determined that net-neutrality was “one of the most consequential regulations ever issued by any executive agency in the history of the United States[.]”¹¹⁰ the rule should be deemed unlawful absent clear authority from Congress.¹¹¹

Despite his criticisms, however, Justice Kavanaugh has acknowledged the merits behind the *Chevron* doctrine and has defended it when there is clear congressional delegation.¹¹² For example, Justice Kavanaugh wrote that “Congress might assign an agency to issue rules to prevent companies from dumping ‘unreasonable’ levels of

¹⁰⁰*Id.* at 2150.

¹⁰¹Brett M. Kavanaugh, *Keynote Address: Two Challenges for the Judge as Umpire: Statutory Ambiguity and Constitutional Exceptions*, 92 NOTRE DAME L. REV. 1907, 1911 (2017).

¹⁰²*Id.* at 1912.

¹⁰³*Id.* at 1911–12.

¹⁰⁴*Id.* at 1912.

¹⁰⁵*United States Telecom Ass’n v. FCC*, 855 F.3d 381 (D.C. Cir. 2017).

¹⁰⁶*Id.* at 382.

¹⁰⁷*Id.* at 386.

¹⁰⁸*Id.* at 387.

¹⁰⁹*Id.* at 419.

¹¹⁰*Id.* at 417.

¹¹¹*Id.* at 418.

¹¹²See Andrea Driggs & Christopher Thomas, *Kavanaugh’s Chevron Skepticism May Impact Enviro Regs*, LAW360 (Sep. 10, 2018), <https://www.law360.com/articles/1080830/kavanaugh-s-chevron-skepticism-may-impact-enviro-regs> [<https://perma.cc/2B3R-G2QL>].

certain pollutants. In such a case, what rises to the level of ‘unreasonable’ is a policy decision. So courts should be leery of second-guessing that decision.”¹¹³ He offered a similar opinion in a keynote address discussing “unreasonable rates” charged by utilities.¹¹⁴ Although Justice Kavanaugh’s writings suggest that he has some conflicting views on *Chevron* deference, this history suggests that he is in favor of at least substantially narrowing *Chevron*’s application—perhaps only to determine what “unreasonable” means—as opposed to eliminating the doctrine entirely.

III. *CHEVRON* OVERTURNED: A LEVEL PLAYING FIELD

Many companies currently see courts’ reliance on *Chevron* as an insurmountable hurdle and choose not to sue FDA even when they have legitimate legal arguments.¹¹⁵ If the newly-constituted Supreme Court overrules or curtails *Chevron* deference, however, it will open up the floodgates to lawsuits and unleash a new wave of litigation against FDA on a host of issues. Part III addresses how the courts may act in the absence of *Chevron* deference. This Part also describes notable cases applying *Chevron* and hypothesizes about possible alternate outcomes had they been decided in a regime devoid of *Chevron* deference.

A. *Fewer FDA Wins Under Skidmore*

In the absence of *Chevron* deference, courts might turn to *Skidmore* for guidance when analyzing FDA decisions.¹¹⁶ Under *Skidmore*, a court “look[s] to the degree of the agency’s care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency’s position” in assessing the degree of deference to apply to the agency’s decision.¹¹⁷ Parties seeking to reverse an agency’s decisions have fared somewhat better under *Skidmore* than they have under *Chevron*. Courts have upheld agency decisions in fifty-five percent to seventy-one percent of cases under *Skidmore*, whereas courts have upheld agency decisions in sixty-four percent to eighty-one percent of cases under *Chevron*.¹¹⁸ Disputed FDA decisions have rarely been subject to *Skidmore* deference because *Chevron* has almost always been applied. Courts have almost always found that Congress “intended to confer [] authority on the agency to issue interpretations having force-of-law effect.”¹¹⁹

¹¹³Brett M. Kavanaugh, *Fixing Statutory Interpretation*, 129 HARV. L. REV. 2118, 2154 (2016).

¹¹⁴Kavanaugh, *supra* note 101, at 1912.

¹¹⁵See Jeff Overley, *Wave of FDA Suits Awaits if Kavanaugh Helps Trim Chevron*, LAW360 (July 10, 2018), <https://www.law360.com/articles/1061797/wave-of-fda-suits-awaits-if-kavanaugh-helps-trim-chevron> [<https://perma.cc/KKZ3-VN8V>].

¹¹⁶There has been some suggestion that *Chevron* obliterated *Skidmore* deference, but at least some circuit courts still address the doctrine. See *Flores-Molina v. Sessions*, 850 F.3d 1150 (10th Cir. 2017).

¹¹⁷*United States v. Mead Corp.*, 533 U.S. 218 (2001) (citing *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944)).

¹¹⁸Richard J. Pierce, Jr., *What do the Studies of Judicial Review of Agency Actions Mean?*, 63 ADMIN. L. REV. 77, 84 (2011) (fifty-five percent to seventy-one percent under *Skidmore* between 1965 and 2005 and sixty-four percent to eighty-one percent under *Chevron* between 1985 and 2006). See *supra* Section 0.

¹¹⁹Mitchell M. Gans, Damien Rios & Jonathan G. Blattmachr, *Deference: When the Court Must Yield to the Government’s Interpretation*, CIRCULAR 230 DESKBOOK 1–12 (Practising Law Inst. ed., 2006), www.thecre.com/oira/wp-content/uploads/2015/03/ABA-Deference.pdf [<https://perma.cc/DM6J-MYZZ>].

At times, however, courts have found that an agency is not entitled to any deference. For example, in *PhotoCure ASA v. Dudas*,¹²⁰ the court declined to apply *any* deference when the U.S. Patent and Trademark Office (PTO) “applied the active moiety approach [as discussed more fully below] at the formal agency adjudication stage of th[e] case,” even though the Manual of Patent Examining Procedures instructed the use of the active ingredient approach.¹²¹ The court cited the PTO’s inconsistent and careless analysis in declining to give the PTO’s interpretation any deference: “[a]ny amount of deference earned as a result of [understanding the chemistry of drug products], however, would be insufficient to convince the Court to follow the [PTO] in adopting an inconsistent and unreasonable statutory construction contrary to plain meaning.”¹²²

Although FDA would likely be seen as persuasive, particularly on scientific matters,¹²³ *Skidmore* deference might provide a platform from which FDA-regulated industries can more effectively attack any arbitrary or contradictory decisions by FDA. If a developer can demonstrate that FDA’s decision deviated from prior practices, FDA’s persuasiveness would likely be diminished. This might lead the court to apply a less deferential standard—that is, if the court were to apply any deferential standard at all.

B. Battles With FDA Post-Chevron

In a world without deference, regulated companies might have greater success when challenging FDA decisions in court. This Section looks to some of the issues addressed in Part I and hypothesizes outcomes for select cases in the absence of *Chevron* deference. Many of these cases would have had vastly different outcomes, potentially leading to significant changes in the way that FDA-regulated companies behave.

For example, for some time, new chemical entities (NCE) have been desirable targets for drug developers. Under the Hatch-Waxman Act, FDA grants five years of market exclusivity for a drug that is considered a new chemical entity.¹²⁴ What distinguishes an NCE from a “previously approved active ingredient,” however, has been the subject of much debate even long after FDA’s win in *Actavis Elizabeth v. FDA*.¹²⁵ Pediatric exclusivity is another way that drug developers can seek to maintain control of the market and maximize the return on research and development expenses. By conducting pediatric studies, drugs can earn additional exclusivity to extend other marketing exclusivity and the term of certain patents.¹²⁶ In reviewing all of these

¹²⁰*PhotoCure ASA v. Dudas*, 622 F. Supp. 2d 338 (E.D. Va. 2009).

¹²¹*Id.* In *PhotoCure*, plaintiff applied to the PTO for a patent term extension, which the agency denied because, applying the active moiety approach, it ruled that the plaintiff’s methyl ester aminolevulinic HCL (MAL HCL) product was the same product as an already commercially available aminolevulinic acid HCL (ALA HCL) because of its shared aminolevulinic molecule. *Id.* at 342.

¹²²*Id.* at 350.

¹²³*See, e.g.*, *Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir. 1995) (“[FDA’s] judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of FDA’s expertise.”); *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1325 (D.C. Cir. 1998) (Courts are “bound to show deference to the agency’s fact-finding in this area of its technical expertise.”).

¹²⁴*See* 21 U.S.C. § 355(c)(3)(E)(ii) (2006).

¹²⁵*Actavis Elizabeth LLC v. FDA (Actavis I)*, 689 F. Supp. 2d 174, 178–79 (D.D.C. 2010); *Actavis Elizabeth LLC v. FDA (Actavis II)*, 625 F.3d 760, 762 (D.C. Cir. 2010).

¹²⁶*See* 21 U.S.C. § 355a(b)(1)(A) (2006).

issues, the courts have given significant deference to FDA, but that could change if *Chevron* deference is abolished.

The present makeup of the Supreme Court suggests that alternative outcomes might not remain confined to the theoretical musings of academics or counsel.¹²⁷ The degree to which there might be changes will likely “depend[] on whether a policy is based primarily on statutory interpretation or on evidence and reasoning.”¹²⁸ An agency’s statutory interpretation is more likely than an agency’s fact-finding to be subject to changes in the absence of *Chevron* deference. Using the following cases as examples, it becomes evident that strategy changes will be required by challengers to successfully advance positions if and when *Chevron* deference is minimized or erased.

i. Drawing Arbitrary Lines for New Chemical Entities

Market exclusivity is highly coveted and can result in hundreds of millions of dollars in profits every year during which a drug is marketed.¹²⁹ The difference between receiving three years of exclusivity and five years of exclusivity can amount to the potential gain or effective loss of hundreds of millions of dollars. It is unsurprising that drug developers frequently dispute the duration of exclusivity granted by FDA, and these disputes largely focus on the definitions of “active ingredient” and “active moiety.” “[A] drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application” is entitled to only three years of exclusivity,¹³⁰ whereas a drug that does not include a previously approved active ingredient (i.e., an NCE) is entitled to five years¹³¹ of exclusivity.¹³²

FDA has interpreted the term “active ingredient” to mean “active moiety.” “The regulatory history makes clear that the [FDA] adopted the ‘active moiety’ approach to address . . . the availability of exclusivity for multiple closely related forms of the same basic molecule.”¹³³ Instead of looking at the drug or active ingredient as a whole, FDA focuses on the molecule and considers only the active moiety.

FDA “identif[ied] structural modifications to previously approved molecules that [were] likely to change the activity of the drug and represent a significant innovation,

¹²⁷The Separation of Powers Restoration Act of 2017, which was referred to the Subcommittee on Regulatory Reform, Commercial and Antitrust Law, could also radically change how agency actions are disputed. H.R. 76, 115th Cong. (2017). This Act would subject all agency actions and interpretations of constitutional and statutory provisions to de novo review.

¹²⁸Phillip Dane Warren, *The Impact of Weakening Chevron Deference on Environmental Deregulation*, 118 COLUM. L. REV. ONLINE 62, 72 (2018).

¹²⁹For example, Gilead Sciences’ Sovaldi sold \$139.4 million in the first month it was approved. See Gilead Sciences, Inc., 2013 Form 10-k Annual Report (filed Feb. 25, 2014), <http://investors.gilead.com/static-files/f2c2758c-31b2-4964-8e3c-54e987ba4df1> [<https://perma.cc/6QNC-VFVQ>].

¹³⁰21 U.S.C. § 355(j)(5)(F)(iii) (2012).

¹³¹Of course, NCE exclusivity has the practical effect of expanding market exclusivity well beyond the five-year period because it is a prohibition on the filing of an abbreviated new drug application (ANDA) at least for four years (the so-called “NCE-1” date applicable to ANDAs filed with patent challenges). See 21 CFR § 314.108(b)(2). As a result, the NDA holder’s market exclusivity is extended even beyond the five years as the ANDA undergoes FDA review (and potential delays through patent litigation) before receiving FDA approval.

¹³²See 21 U.S.C. § 355(j)(5)(F)(ii).

¹³³*Amarin Pharms. Ir. Ltd. v. FDA*, 106 F. Supp. 3d 196, 200 (D.D.C. 2015).

such as a non-ester, covalent derivatives, and those that are not likely to reflect a significant change, such as salts and esters.”¹³⁴ Active moiety is therefore defined as:

[T]he molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.¹³⁵

Using this construction, FDA may “withhold exclusivity . . . from other derivative molecules that it concludes are insufficiently innovative to merit five-year exclusivity.”¹³⁶ Despite the intent to exclude molecules that are not sufficiently innovative, “[s]ome might question the merits of a structure-based interpretation of active moiety instead of an activity-based interpretation.”¹³⁷ Assessing the molecule based solely on its structure could lead to a grant of five-year exclusivity for “small structural changes with relatively little therapeutic benefit.”¹³⁸ Potentially even more problematic (at least for innovator companies) is that, contrary to the intent of Congress, non-structural changes that potentially provide significantly improved therapeutic effects are not eligible for five-year exclusivity.¹³⁹

In 2007, Shire Pharmaceuticals, Inc.’s lisdexamfetamine dimesylate drug Vyvanse[®] was granted five years of NCE exclusivity because FDA determined it was a new chemical entity.¹⁴⁰ According to FDA, Vyvanse[®] does not include an “active ingredient (including any ester or salt of the active ingredient) [that] has been approved in any other application.”¹⁴¹ A generic drug developer, Actavis Elizabeth, LLC (Actavis) sued FDA, arguing that Vyvanse[®] was not entitled to five years of exclusivity because the drug is not a new active ingredient; therefore, under Section 355(j)(5)(F)(iii), Actavis argued that Vyvanse[®] should only have been entitled to three years of exclusivity.¹⁴²

Vyvanse[®] is a prodrug—a biologically *inactive* compound that is metabolized by the body into an *active* compound. The product insert for Vyvanse[®] indicates that “lisdexamfetamine is rapidly absorbed from the gastrointestinal tract and converted to dextroamphetamine, which is responsible for the drug’s activity.”¹⁴³ It is metabolized via hydrolysis of the covalent amide linkage, which results in the amino acid lysine

¹³⁴Actavis Elizabeth LLC v. FDA (*Actavis I*), 689 F. Supp. 2d 174, 179 (D.D.C. 2010).

¹³⁵21 C.F.R. § 314.3(b) (2017); *see* Actavis Elizabeth LLC v. FDA, 625 F.3d 760, 762 (D.C. Cir. 2010) (*Actavis II*).

¹³⁶*Amarin Pharms. Ir. Ltd.*, 106 F. Supp. 3d at 200.

¹³⁷DONALD O. BEERS & KURT R. KARST, *GENERIC AND INNOVATOR DRUGS: A GUIDE TO FDA APPROVAL REQUIREMENTS*, at 4–20 (8th ed., 2017 Supp.).

¹³⁸*See id.*

¹³⁹*Id.*

¹⁴⁰*See* Drug Approval Package: Vyvanse, FDA, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2007/021977s000TOC.cfm; *see also* Actavis I, 689 F. Supp. 2d at 175–76.

¹⁴¹21 U.S.C. § 355(j)(5)(F)(ii).

¹⁴²Axinn, Veltrop & Harkrider LLP represented Actavis Elizabeth, LLC in this lawsuit against FDA.

¹⁴³Vyvanse Product Insert (July 2008), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021977s006s007lbl.pdf [<https://perma.cc/72V5-AGE2>].

and dextroamphetamine, an active molecule that had been approved by FDA for decades.¹⁴⁴

Applying *Chevron*, the court found that the phrase “no active ingredient . . . of which has been approved” is ambiguous and that deference to FDA’s interpretation was warranted so long as that interpretation is based on a reasonable construction of the statute.¹⁴⁵ Even though the court in *Abbott Laboratories v. Young*¹⁴⁶ determined that an “active moiety” is “the substance that creates the actual therapeutic effect within the body,”¹⁴⁷ FDA did not focus on dextroamphetamine, the active substance. Instead, FDA focused on lisdexamfetamine’s “amide bond, [and] . . . FDA properly treated it as an ‘active moiety’ of its own.”¹⁴⁸ As mentioned previously, even Shire acknowledged through labeling and disclosures to FDA that dextroamphetamine is responsible for the drug’s effects in the body and is, therefore, the active molecule.¹⁴⁹ Still, the court applied *Chevron* deference and refused to second-guess FDA’s determination that lisdexamfetamine was not a previously approved “active moiety.”¹⁵⁰

FDA categorizes active and inactive moieties based on a distinction between covalent and non-covalent bonds. All non-covalent derivatives, salts, and (covalent) esters are categorized as “inactive moieties,” while all covalent derivatives (except esters) are “active moieties.”¹⁵¹ These distinctions are somewhat arbitrary because the statute does not mention distinctions between covalent and non-covalent bonds, and there is nothing to suggest that Congress ever intended to make such a distinction. Congress has offered no explanation for “not us[ing] the term ‘new chemical entity’ or the term ‘new molecular entity’” instead of the phrase “no active ingredient (including any ester or salt of the active ingredient).”¹⁵²

Instead of deferring to FDA’s distinctions, however, the court could have applied the following reasoning: (1) an inactive prodrug is metabolized into an active ingredient; (2) lisdexamfetamine is an inactive prodrug that is metabolized into the active ingredient dextroamphetamine, which is the only molecule that has activity in the body; (3) dextroamphetamine is an active ingredient that was previously approved by FDA in an application; (4) therefore, lisdexamfetamine’s active ingredient has been previously approved in another application. The court also could have found the regulation’s language merely illustrative and might have determined that an amide of an active ingredient should be treated in the same manner as an ester or salt of an active

¹⁴⁴Dextroamphetamine is the active ingredient in drugs such as Dexedrine, Adderall®, and Biphentamine, all of which were approved prior to Vyvanse®. *See, e.g.*, Approval Letter from Gary Buehler, Director, Office of Generic Drugs, to Barr Laboratories, Inc. (Jan. 31, 2001), https://www.accessdata.fda.gov/drugsatfda_docs/anda/2001/40-361_Dextroamphetamine%20Sulfate_Approv.pdf [<https://perma.cc/c/2GVS-329Q>].

¹⁴⁵*Actavis Elizabeth LLC v. FDA (Actavis I)*, 689 F. Supp. 2d 174, 178–79 (D.D.C. 2010).

¹⁴⁶*Abbott Labs. v. Young*, 920 F.2d 984 (D.C. Cir. 1990).

¹⁴⁷*Id.* at 986.

¹⁴⁸*Actavis II*, 625 F.3d 760, 762 (D.C. Cir. 2010).

¹⁴⁹*See* Vyvanse Product Insert (July 2008), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021977s006s0071bl.pdf [<https://perma.cc/72V5-AGE2>].

¹⁵⁰*Actavis II*, 625 F.3d at 763.

¹⁵¹*See* 21 C.F.R. § 314.3(b).

¹⁵²*See* BEERS, *supra* note 137 at 4–18.

ingredient. That construction would have closely aligned with the regulation's plain and unambiguous language. In fact, FDA made this very argument in *Abbott Laboratories*:¹⁵³ “[B]y using the word ‘including’ in the statute, . . . Congress meant to introduce an illustrative list of the sorts of chemical derivations of an active ingredient that . . . would deprive a new drug of the maximum” period of exclusivity.¹⁵⁴ The *Abbott* court, however, disagreed, effectively pushing FDA to abandon the construction it argued before the court and adopt its current interpretation.

It is hard to believe that Congress intended to grant FDA the power to assign exclusivity periods based on covalent and non-covalent bonds.¹⁵⁵ Although FDA may claim that a structural modification that does not create a salt or ester of the active ingredient is “likely to change the activity of the drug and represent a significant innovation,”¹⁵⁶ this generalization undoubtedly causes inconsistencies. Nonetheless, the *Actavis* court found that this generalization was not unreasonable.¹⁵⁷

Many scientists disagree with FDA's active ingredient and functional group categorizations. In fact, scientists at the PTO have disagreed. Scientists at the PTO instruct that “[a]n active ingredient of a drug is the ingredient in the drug product that becomes therapeutically active when administered.”¹⁵⁸ Further, Chapter 2751 of the Manual of Patent Examining Procedures states that “[t]he ester form is a different active ingredient from the salt form.”¹⁵⁹ While FDA treats some ester and salt derivatives as equivalents for the purpose of establishing an exclusivity period, the PTO acknowledges that they are different active ingredients for a patent term extension determination. FDA is not bound or even advised to align with other agencies' interpretations. This, however, simply illustrates FDA's contradictory interpretation of “active ingredient” and “active moiety.”

It is true that many salts and esters might not be “likely to reflect a significant change” in the pharmacological properties of a drug.¹⁶⁰ Still, many non-salt and non-ester derivatives—some amides for example—might be just as unlikely to reflect a significant change in the properties of a drug. This generalization demonstrates a fundamental over-simplification of the complex nature of organic chemistry and

¹⁵³*Abbott Labs. v. Young*, 920 F.2d 984 (D.C. Cir. 1990).

¹⁵⁴*Id.* at 992.

¹⁵⁵The current interpretation also opens the door to companies making insignificant chemical changes to a prodrug for the sole purpose of gaining five years of exclusivity. See Jeff Overley, *FDA's Abilify Smack-Down Boosts Imitator Drugs*, LAW360 (Oct. 9, 2015), <https://www.law360.com/articles/711945/fda-s-abilify-smack-down-boosts-imitator-drugs> [<https://perma.cc/2K8D-QD79>] (“FDA's reasoning on prodrugs has been criticized in the past, with some saying it will encourage trivial tweaks to familiar products in order to acquire fresh exclusivity.”).

¹⁵⁶*Actavis Elizabeth LLC v. FDA (Actavis I)*, 689 F. Supp. 2d 174, 179 (D.D.C. 2010).

¹⁵⁷*See id.*; see also *Ethyl Corp. v. EPA*, 541 F.2d 1, 36 (D.C. Cir. 1976) (The Court “must look at the [agency] decision not as the chemist . . . that we are qualified neither by training nor experience to be, but as a reviewing court exercising our narrowly defined duty of holding agencies to certain minimum standards of rationality.”).

¹⁵⁸U.S. PATENT & TRADEMARK OFF., U.S. DEP'T OF COM., MANUAL OF PATENT EXAMINING PROCS., ch. 2751, at 2700–31 (8th ed. 2001, Sept. 2007 revision).

¹⁵⁹*Id.*; see *PhotoCure ASA v. Dudas*, 622 F. Supp. 2d 338, 349 (E.D. Va. 2009).

¹⁶⁰*Actavis I*, 689 F. Supp. 2d at 179.

pharmacology. Instead of arbitrarily focusing on the type of chemical bond, the question should be whether the active molecule in the drug product is new.¹⁶¹

In the absence of *Chevron* deference, the court would not have had to defer to FDA's interpretation of "active ingredient." The court might have agreed with Actavis and could have revisited the rejection of FDA's argument in *Abbott Laboratories* that Congress intended esters and salts to be merely illustrative of the types of derivative drugs that lack the novelty and creativity to warrant five years of exclusivity.¹⁶² Although the ultimate outcome may be difficult to predict with certainty, one thing is clear: *Chevron* deference led the court to defer heavily to FDA without independently interpreting the statute.

ii. *Disputing "Fairly Respond" for Pediatric Exclusivity*

Obtaining pediatric exclusivity is another means by which a drug developer can extend its market exclusivity. Pediatric exclusivity is tacked on to any existing patent or regulatory exclusivity and can be important to a drug developer desiring to maintain its market dominance. Although the profits due to this exclusivity are highly variable, they should not be overlooked: one study performed in 2007 "found that among a subset of drugs granted pediatric exclusivity in the early 2000s, the net economic return for the six-month exclusivity averaged \$134.3 million" and was as high as \$507.9 million.¹⁶³

To begin the process, a drug developer may prompt FDA to issue a written request. FDA and the drug developer then negotiate the terms of the written request, including the specifics of the study or studies. To obtain pediatric exclusivity, the statute provides that the study data must "fairly respond" to the written request: "The Secretary's only responsibility in accepting or rejecting the reports shall be to determine . . . whether the studies *fairly respond* to the written request, have been conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with the requirements of the Secretary for filing."¹⁶⁴ There is a dearth of information as to how precisely data must comply with the written request in order to "fairly respond." But a review of at least one of the cases to have addressed this issue demonstrates the impact of *Chevron* deference to any challenge to FDA's decision-making.

Specifically, in *Amgen, Inc. v. Hargan*,¹⁶⁵ an FDA letter decision attempted to clarify FDA's interpretation of "fairly respond."¹⁶⁶ In evaluating whether the studies "fairly respond," FDA considers several factors: (1) the purpose of the pediatric

¹⁶¹*Amarin Pharms. Ir. Ltd. v. FDA*, 106 F. Supp. 3d 196, 200 (D.D.C. 2015) (explaining that with the active moiety approach, "FDA was able to withhold exclusivity not only from esters or salts of a previously approved molecule, but also from other derivative molecules that it concludes are insufficiently innovative to merit five-year exclusivity"); see Letter from Congressman Henry A. Waxman to Frank E. Young, Commissioner, FDA, Aug. 5, 1985 ("Congress wanted to assure that drug companies were rewarded for major *innovations* involving . . . a new drug . . . by guaranteeing them a period of market exclusivity.").

¹⁶²See *Abbott Labs. v. Young*, 920 F.2d 984, 992 (D.C. Cir. 1990).

¹⁶³Jeanie Kim, Joseph S. Ross, & Amy Kapczynski, *Pediatric Exclusivity and Regulatory Authority*, 319 J. AM. MED. ASS'N 21, 21 (2017).

¹⁶⁴21 U.S.C. § 355a(d)(4) (emphasis added).

¹⁶⁵*Amgen, Inc. v. Hargan*, 285 F. Supp. 3d 351 (D.D.C. 2018).

¹⁶⁶See Letter from Peter Stein, Deputy Director, Office of New Drugs, Center for Drug Evaluation and Research, to Amgen, Inc. (May 22, 2017).

exclusivity provision, which is to “generate clinical information on the use of drugs in children that will result in a health benefit to pediatric populations,” (2) “whether the studies were designed and carried out by the sponsor in a way likely to meet . . . objectives specified in the [written request],” and (3) “whether the submission is sufficient to enable [FDA] to approve pediatric labeling.”¹⁶⁷

In response to FDA’s written request, Amgen had difficulty recruiting pediatric patients between twenty-eight months and six years of age with chronic kidney disease who were also receiving dialysis. In several proposed amendments to the written request, FDA relaxed the requirements and reduced the number of required study participants. The studies were placed on a temporary suspension, however, due to the death of one patient. During the suspension, Amgen and FDA discussed the fate of the studies, and Amgen decided to continue. FDA, however, never informed Amgen that it would be in jeopardy of failing to “fairly respond” based on the number of participants remaining in the studies. Although the written request “required a minimum of 15 patients[,] Amgen enrolled 18 [b]ut only 11 patients exceeded 12 weeks of treatment, and even fewer—just four patients—completed the full 26-week study.”¹⁶⁸ Ultimately, FDA denied Amgen pediatric exclusivity, concluding that Amgen “fail[ed] to provide sufficient safety data” and that “it could not draw ‘any conclusions about the safety’ of the drug in a key age group.”¹⁶⁹ Still, Amgen argued that the data provided fairly responded to the written request.

According to the 2017 letter decision to resolve Amgen’s appeal issued by the Deputy Director for Clinical Science, Center for Drug Evaluation and Research, there are two ways that data will “fairly respond” to a written request: (1) “if the sponsor’s studies meet the ‘specific terms’ of the written request”; or (2) “if the studies deviate from the ‘specific terms’ of the written request,” they may still “fairly respond” if the studies “yield ‘clinically meaningful’ information ‘across all age groups and uses cited in the’ written request.”¹⁷⁰

Although Amgen conceded that the studies did not meet the “specific terms,” it argued that the second prong “is both narrower than the statute mandates and ‘incompatible’ with the ‘limited role’ Congress accorded to . . . FDA.”¹⁷¹ Further, Amgen argued that “fairly respond” means “answer reasonably well” and that “reasonableness includes both the extent of the data [provided] and the amount of the effort [undertaken].”¹⁷² Employing *Chevron*, the court found that “fairly responds” is ambiguous and that FDA has the authority to interpret this term. Assessing whether FDA’s interpretation was reasonable, the court noted that the goal of the statute is to provide information that “may produce health benefits.” The court also noted that FDA’s second prong, requiring a yield of “clinically meaningful information,” is consistent with information that “may produce health benefits.”¹⁷³ Based on what it determined to be FDA’s reasonable interpretation and FDA’s claim that the data

¹⁶⁷*Id.* at 2–3.

¹⁶⁸*Amgen, Inc.*, 285 F. Supp. 3d at 362.

¹⁶⁹*Id.*

¹⁷⁰*Id.* at 364.

¹⁷¹*Id.*

¹⁷²*Id.* at 369.

¹⁷³*Id.* at 372.

provided was insufficient to draw conclusions about the drug's safety, the court upheld FDA's determination that Amgen failed to "fairly respond" to the written request.

In the absence of *Chevron* deference, one of Amgen's arguments might have successfully led to an award of pediatric exclusivity. Amgen asserted that FDA's interpretation "injects 'deep uncertainty into the process' and thus 'radically undermines the terms of Congress's bargain.'"¹⁷⁴ A court might have found that Amgen's efforts to solicit an adequate number of adolescent participants and its efforts in maintaining communication with FDA were sufficient to satisfy the "fairly respond" requirement. It is also possible that Amgen's inability to complete the study with more than four of the agreed-to fifteen participants did not necessarily preclude the finding that the data was clinically meaningful. Importantly, FDA had not informed Amgen that the number of participants was insufficient for clinically meaningful information, and Amgen relied on FDA's silence in continuing the studies.

Chevron deference can play a large role in any challenge to an award of pediatric exclusivity. If courts simply find that "fairly respond" is intrinsically ambiguous, courts will continue to defer to FDA on any grant or denial of pediatric exclusivity under *Chevron*. A reversal or scaling back of *Chevron* deference will likely open up challenges to FDA's pediatric exclusivity decisions, allowing courts to fully evaluate the facts to determine whether a given study "fairly respond[s]" to FDA's request.

V.—CONCLUSION

Chevron deference has played a significant role in courts repeatedly deferring to FDA and upholding its decisions without a detailed consideration as to whether the agency actions were consistent with congressional purpose, as set out in the statutes. As the balance of the Supreme Court shifts in favor of textualist judges—some of whom have openly criticized the legal underpinnings of *Chevron*—the continued viability of judicial deference to agencies may be coming to an end. In such a world, the floodgates will open to court challenges to FDA and other federal agencies. We can then picture a world where Goliath may not be able to call on *Chevron* for every battle, and these battles might soon follow the biblical storyline where David prevails.

¹⁷⁴ *Id.*