

FDA and *Chevron* Deference: A Case Review

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ABSTRACT

Courts granted the U.S. Food and Drug Administration (FDA) considerable deference to carry out its mission throughout the twentieth century, recognizing the agency's scientific expertise and public health mission. Recent Supreme Court decisions such as *West Virginia v. EPA*, however, have eroded this longstanding practice and cast doubt on the future of deference accorded to administrative agencies when they act pursuant to statutory language that is not always clear-cut. To understand the state of judicial deference to FDA, this Article investigates how federal appellate courts have applied the framework set forth in *Chevron v. Natural Resources Defense Council* in litigation involving FDA actions since 2000.

INTRODUCTION

FDA has historically been the gold standard for health care regulation and evidence-based decision making relating to drugs, devices, and other medical products.¹ Since its inception, the agency has used its specialized expertise to regulate complex markets and protect the public's health.² Today, roughly 15% of American consumer spending falls within FDA's ambit.³

Because the scope of FDA's jurisdiction is so broad, the question of how FDA construes its own regulatory power has enormous implications for consumers, the global economy, regulated industries, and patients. The Federal Food, Drug, and Cosmetic Act (FDCA) is the primary federal law that authorizes FDA's regulatory activities.⁴ As part of its charge to carry out the provisions of the FDCA,⁵ FDA

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¹ DANIEL P. CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA 301 (Princeton Univ. Press, 2010).

² Theodore Ruger, *After the FDA: A Twentieth-Century Agency in a Postmodern World*, in FDA IN THE TWENTY-FIRST CENTURY: THE CHALLENGES OF REGULATING DRUGS AND NEW TECHNOLOGIES 77 (Holly Fernandez Lynch and I. Glenn Cohen eds., 2015) ("Few agencies have been as successful at achieving their stated regulatory goals, and few have enjoyed the reputation for technocratic expertise that the FDA has long held among the press and the public. The regulatory regime overseen by FDA has produced sizeable public health gains over the past sixty years by virtue of ensuring safer food and therapeutic products for U.S. consumers.").

³ U.S. FOOD & DRUG ADMIN., FACT SHEET: FDA AT A GLANCE (Apr. 2023), <https://www.fda.gov/media/168049/download> ("FDA-regulated products account for about 15 cents of every dollar spent by U.S. consumers.").

⁴ 21 U.S.C. §§ 301 et seq.

performs tasks as wide-ranging as inspecting facilities that manufacture cosmetics and reviewing the results of clinical trials to ensure the safety and efficacy of prescription drugs before they enter the market.⁶

Like most federal statutes,⁷ the language of the FDCA is not always clear-cut. When FDA acts on the basis of possibly ambiguous statutory text, courts must decide whether federal law permits the agency's activity. In the 1984 case *Chevron v. Natural Resources Defense Council*,⁸ the Supreme Court established the principle that courts should defer to agencies' reasonable interpretations of the statutes they administer. *Chevron* established a two-step framework for courts to evaluate agencies' claims of statutory authority. When parties sue FDA, arguing that FDA's actions have exceeded the bounds of its statutory authority, judges first determine whether the plain text of the law is clear (Step One). If the text is clear, the court applies the law as written regardless of the positions of FDA or other parties. When the statutory language at issue is ambiguous, however, *Chevron* instructs courts to determine whether FDA's interpretation of the law is reasonable and if so, defer to the agency's decision (Step Two).

Courts deferred to FDA's expertise before the Supreme Court handed down *Chevron*. In the twentieth century, the judiciary overwhelmingly decided lawsuits involving FDA in the agency's favor.⁹ As one prominent lawyer who often represented pharmaceutical companies put it in 1963, "in this field what the agency concludes, the court approves."¹⁰ FDA's reputation as a scientific decisionmaker and a champion of public health led to deference in the courts.¹¹

In recent decades, however, courts have grown increasingly skeptical of agency authority in many different contexts. To date, the high-water mark of this shift was the Supreme Court's decision in *West Virginia v. EPA* in June 2022.¹² *West Virginia*, a case concerning the Environmental Protection Agency's (EPA's) authority to regulate power plants' carbon emissions, seemed like a textbook candidate for *Chevron* deference.¹³ Rather than using the familiar *Chevron* framework, however, the Supreme Court ruled that EPA and agencies like it do not have power over

⁵ *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000) ("Because this case involves an agency's construction of a statute it administers, the Court's analysis is governed by *Chevron U.S.A. Inc. v. Natural Resources Defense Council* . . ."); 21 U.S.C. § 393(d)(2) ("The Secretary, through the Commissioner, shall be responsible for executing this chapter.").

⁶ 21 U.S.C. § 374; 21 U.S.C. § 355.

⁷ *Muscarello v. United States*, 524 U.S. 125, 138 (1998) ("[M]ost statutes are ambiguous to some degree.").

⁸ *Chevron v. Nat. Res. Def. Council*, 467 U.S. 837 (1984).

⁹ See CARPENTER, *supra* note 1, at 729 ("[T]he twentieth-century FDA received nearly unparalleled judicial deference in its regulation of drugs.").

¹⁰ H. Thomas Austern, *Sanctions in Silhouette: An Inquiry into the Enforcement of the Federal Food, Drug, and Cosmetic Act*, 51 CAL. L. REV. 38, 43 (1963).

¹¹ See CARPENTER, *supra* note 1, at 300 ("In such a pattern of political echo and social reverberation did the public myth of Frances Kelsey and terms like 'gold standard' and 'guardian of health' take shape The Administration stood as one of the world's most admired public organizations—with surprisingly high name recognition and approval in national surveys, admiration and emulation from dozens of foreign governments and hundreds of scientific communities, and deference from pharmaceutical and biomedical companies.").

¹² *West Virginia v. Env't Prot. Agency*, 142 S. Ct. 2587 (2022).

¹³ *Id.* at 2.

questions of major economic and political significance unless federal law explicitly states that they do.¹⁴ The *West Virginia* majority deployed this “major questions doctrine” to deny EPA the authority it had claimed.¹⁵

While *West Virginia* did not formally overrule *Chevron*, it invites a broader erosion in judicial deference to administrative agencies.¹⁶ An April 2023 order issued by a federal judge in Texas that sought to suspend FDA’s approval of mifepristone, a medication abortion drug, drew public attention to the public health implications of a weakened system of drug regulation.¹⁷ Other high-profile cases involving the public health authority of administrative agencies, such as a challenge to the Affordable Care Act’s preventive care mandate for insurers and the Supreme Court’s decision to strike down a requirement that large employers mandate testing or vaccination for their workers, are further evidence of this erosion.¹⁸

If the Supreme Court overrules *Chevron* outright or otherwise instructs judges to grant less deference to agencies in statutory interpretation cases, FDA’s ability to protect public health may be substantially diminished. To examine the potential implications of a legal landscape in which actions by federal agencies do not receive *Chevron* deference, we conducted a review of recent appellate challenges to FDA’s authority under federal law. We sought to evaluate how the *Chevron* regime has affected FDA’s regulatory conduct and shaped FDA’s efforts to protect the public health and make policy within the bounds of the law.

METHODS

Data Sources

We searched Westlaw to identify written opinions issued between January 1, 2000, and August 31, 2022, by Federal Courts of Appeals and the U.S. Supreme Court that referenced the U.S. Food and Drug Administration (FDA) and cited *Chevron v. Natural Resources Defense Council*. We limited our search to written opinions as a means of ensuring we could determine whether the majority opinion employed a *Chevron* analysis. We limited our review to appellate opinions due to the binding force of appellate rulings over federal district courts and their persuasive authority over other appellate courts. The study did not require institutional review board approval because it did not involve human subjects research.

¹⁴ *Id.* at 11. See generally Daniel Deacon & Leah Litman, *The New Major Questions Doctrine*, 109 VA. L. REV. 1009, 1032 (2023).

¹⁵ Deacon & Litman, *supra* note 14, at 1032 (“In *West Virginia v. EPA*, the Court declared that the Clean Power Plan was not authorized by statute.”).

¹⁶ C. Joseph Ross Daval, Liam Bendicksen & Aaron S. Kesselheim, *Eroding Judicial Deference to the FDA—Consequences for Public Health*, 388 NEW ENG. J. MED. 11 (2023); Julian Davis Mortenson & Nicholas Bagley, *Delegation at the Founding*, 121 COLUM. L. REV. 277 (2021); Gundy v. United States, 139 S. Ct. 2116, 2130 (2019) (Gorsuch, J., dissenting).

¹⁷ Adam Liptak, *Supreme Court Briefly Preserves Broad Availability of Abortion Pill*, N.Y. TIMES, Apr. 14, 2023, at A1.

¹⁸ Michelle Mello & Anne Joseph O’Connell, *The Fresh Assault on Insurance Coverage Mandates*, 388 NEW ENG. J. MED. 1, 2 (2023); Nat’l Fed’n of Indep. Bus. v. Dep’t of Lab., 142 S. Ct. 661, 666–67 (2022).

Case Identification and Selection

We sought to identify written opinions by federal appeals courts that employed a *Chevron* analysis to decide the scope of FDA's statutory authority (**Figure 1**). From an initial cohort of 458 opinions that cited *Chevron* and referenced FDA, we manually excluded 407 cases that did not involve a challenge to FDA's statutory authority. Using the text of the remaining fifty-one opinions, we excluded twenty-five cases because the majority did not employ a *Chevron* analysis. Because the case collection process involved objective inclusion criteria, minimal subjective judgment was involved, and double coding was not required.

Case Categorization

All included cases were reviewed by one of two investigators (L.B. and C.J.R.D.) to determine the following characteristics: which federal statutory provisions were central to the court's analysis, whether the court decided for or against FDA, whether the court found the statutory provision at issue ambiguous (*Chevron* Step One) and, if so, whether the court found FDA's interpretation permissible (*Chevron* Step Two). One investigator (L.B.) then extracted case date, court, and type of named plaintiff or defendant opposing the federal government.

We separated cases into two groups: cases concerning the bounds of FDA's regulatory jurisdiction and cases concerning market exclusivity periods. We also organized cases into the following categories: dietary supplements, tobacco products, generic exclusivity, pioneer exclusivity, orphan drug exclusivity, and miscellaneous. We characterized illustrative cases and compared them to cases in the same category.

RESULTS

There were twenty-six federal appellate opinions in which courts applied *Chevron* to cases concerning statutory authority claimed by FDA. Courts found statutes unambiguous in sixteen cases. The remaining ten cases, in which courts found statutes to be ambiguous, were all decided in FDA's favor after courts found FDA's interpretation reasonable and deferred to the agency's view of the law. Of the sixteen cases for which courts found statutes unambiguous, courts adopted FDA's preferred statutory interpretation in six cases, the opposing party's preferred interpretation in nine cases, and neither party's preferred interpretation in one case (**Figure 2**). Cases were distributed uniformly across our study period; 2021 was the modal year that courts issued opinions in our cohort.

The federal government, federal agencies, or federal officials were the named defendants in all but two cases (*FDA v. Brown & Williamson, United States v. Genendo*). The majority of named parties opposing the named federal defendant or plaintiff were drug manufacturers (15). The remaining named parties were dietary supplement manufacturers (3), a compounding pharmacy (1), a manufacturer of diagnostic contrast agents (1), a dietary supplement trade organization (1), a tobacco company (1), a tobacco trade organization (1), a pharmaceutical services organization (1), and a mental health facility (1).

One court, the D.C. Circuit, issued rulings in half of the cases. The other thirteen cases were dispersed across many appeals courts: the Fourth Circuit issued four opinions, the Federal Circuit issued two, the Tenth Circuit issued two, the Supreme Court issued one, the Second Circuit issued one, the Fifth Circuit issued one, the Seventh Circuit issued one, and the Eleventh Circuit issued one.

FDA Product Jurisdiction Cases

Ten cases concerned the scope of FDA's authority over particular products (**Table 1**). In these cases, courts were called upon to review whether FDA regulatory actions had exceeded the agency's statutory mandate. Courts found statutes ambiguous in three cases. Courts ruled in FDA's favor in half the cases. Four cases involved FDA's authority to regulate dietary supplements; two involved FDA's authority over tobacco products; and the four remaining cases dealt with imported drugs, pharmacy compounding of drugs, a diagnostic contrast agent, and certain uses of electrical stimulation devices.

Dietary Supplements (4)

Four cases concerned FDA's jurisdiction over dietary supplements under the Dietary Supplement Health and Education Act of 1994 (DSHEA).¹⁹ The DSHEA ensured that dietary supplements would not be regulated like drugs by deeming them to be foods without need for premarket efficacy or safety testing. These supplement cases hammered out the boundaries of FDA's authority under the DSHEA.

In three of the four cases, courts granted FDA the authority it asserted, affirming FDA's authority to ban unsafe products (*Nutraceutical*) and subject claims of health benefit to pre-market approval review (*Whitaker*).²⁰ In two of the three FDA victories, *Pharmanex* and *Whitaker*, courts found the statute ambiguous and deferred to FDA's interpretation.²¹ In *Pharmanex*, the Tenth Circuit upheld FDA's regulation of Cholestin as a new drug because it contained mevinolin, a natural substance chemically identical to the active ingredient in a prescription drug.²² Applying *Chevron*, the court concluded that the FDCA's definition of "dietary supplement" was ambiguous as applied to this product, and that FDA's interpretation was reasonable, allowing FDA to regulate the product as a new drug rather than a supplement.

Tobacco (2)

In *FDA v. Brown & Williamson* (2000), the Supreme Court held that Congress had not granted FDA authority over tobacco products as a drug or device under the FDCA.²³ The Court ruled that "[a] fundamental precept of the FDCA is that any product regulated by the FDA—but not banned—must be safe for its intended use."²⁴ Because tobacco products are inherently unsafe, FDA could not regulate them. In 2009, Congress responded by passing the Family Smoking Prevention and Tobacco Control Act (TCA), granting FDA the power to regulate tobacco products.

With the benefit of an explicit grant of authority under the TCA, the D.C. Circuit in *Cigar Association of America* (2021) sided with FDA in its *Chevron* analysis,

¹⁹ Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994).

²⁰ *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033, 1043 (10th Cir. 2006); *Whitaker v. Thompson*, 353 F.3d 947, 953 (D.C. Cir. 2004).

²¹ *Pharmanex v. Shalala*, 221 F.3d 1151, 1160 (10th Cir. 2000); *Whitaker*, 353 F.3d at 951–52.

²² *Pharmanex*, 221 F.3d at 1160.

²³ *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

²⁴ *See id.* at 142.

upholding an FDA rule deeming tobacco pipes and cigars to be subject to the TCA.²⁵ FDA had classified pipes as a “component or part” of tobacco products, which the TCA subjected to certain regulatory controls, rather than as an “accessory.”²⁶ Trade organizations contested this definition, arguing that the TCA’s plain language required a “component” of a tobacco product to be “integrated into such a product[.]”²⁷ The court found that the TCA did not compel this interpretation and deferred to FDA’s classification.²⁸

Other Product Jurisdiction Cases

Judge Rotenberg Educational Center v. FDA concerned whether FDA possessed the authority to ban some, but not all, uses of electrical stimulation devices.²⁹ Citing statutory power to ban medical devices that present “an unreasonable and substantial risk of illness or injury” to patients, FDA tried to selectively ban uses of electrical stimulation devices that posed a high risk to patients, such as for self-injurious or aggressive behavior.³⁰ The D.C. Circuit ruled two-to-one against FDA, concluding that federal law unambiguously required FDA to either ban electrical stimulation devices outright or allow the use of electrical stimulation devices for any condition.³¹ Federal legislation enacted in December 2022 effectively overturned *Rotenberg* by explicitly granting FDA the authority to selectively ban medical devices.³²

In *Genus Medical Technologies v. FDA* (2021), the D.C. Circuit considered whether FDA may regulate products as drugs if they also meet the statutory definition of the term “device.”³³ The product at issue was a diagnostic contrast agent. FDA had interpreted the FDCA as implicitly allowing it to regulate products meeting the definitions of both a “drug” and a “device” under either regulatory regime.³⁴ The court found that the FDCA unambiguously foreclosed FDA’s interpretation, stating, “it is not textually possible to say that an item *is* a drug (or device) but need not be regulated as such.”³⁵ The court reasoned that allowing FDA to exercise the authority it had claimed would contravene Congress’s choice to set up different regulatory regimes for drugs and devices. Congress deemed diagnostic contrast agents to be drugs in late 2022.³⁶

²⁵ *Cigar Ass’n of Am. v. FDA*, 5 F.4th 68, 78 (D.C. Cir. 2021).

²⁶ *Id.* at 76.

²⁷ *Id.* at 77.

²⁸ *Id.* at 78.

²⁹ *Judge Rotenberg Educ. Ctr., Inc. v. FDA*, 3 F.4th 390 (D.C. Cir. 2021).

³⁰ Banned Devices; Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior, 85 Fed. Reg. 13,312 (Mar. 6, 2020) (In a final rule issued on March 6, 2020, banning the use of electrical stimulation devices for self-injurious or aggressive behavior, FDA noted that these devices had previously been used, often without consent, on people with limited ability to communicate. “FDA recognizes that . . . legal consent is obtained to use the devices. However, the person who provides legal consent is typically not the person subject to the risks of the use of the device.”).

³¹ *Judge Rotenberg Educ. Ctr., Inc.*, 3 F.4th at 400.

³² Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, Div. FF, Tit. III, Sec. 3306.

³³ *Genus Med. Techs. LLC v. FDA*, 994 F.3d 631, 632 (D.C. Cir. 2021).

³⁴ *Id.* at 637.

³⁵ *Id.* at 639.

³⁶ Consolidated Appropriations Act, 2023, Div. FF, Tit. III, Sec. 3621(h)(1).

Market Exclusivity Cases

The majority (16) of the cases in the cohort were disputes over how FDA's interpretation of law had influenced its decision to grant or deny market exclusivity periods to drug manufacturers (**Table 2**). Courts found statutes ambiguous in seven (44%). Courts ruled in FDA's favor in eleven (69%). Nine cases involved disputes over generic exclusivity, another four cases concerned orphan drug exclusivity, two cases concerned new drug exclusivity, and one case involved animal drugs.

Generic Exclusivity (9)

Most market exclusivity cases related to the approval process for generic drugs established by the Hatch–Waxman Act of 1984, in which the first generic manufacturer to successfully challenge a patent on a brand-name drug is entitled to a 180-day period of generic market exclusivity (creating a market duopoly).³⁷ By providing a limited period of enhanced protection from competition for generic drugs, this system rewards generic manufacturers for undertaking patent challenges that bring generics to market.

Most of the nine cases involved efforts to deprive competitors of the benefits of market exclusivity. Competitors harmed by these efforts challenged the scope of FDA's discretion to administer the Hatch–Waxman regime. In *Ranbaxy v. Leavitt* (2006), for example, the D.C. Circuit struck down a strategy in which brand-name manufacturers would ask FDA to de-list patents reported to FDA that served as the basis for Hatch–Waxman Act patent challenges.³⁸ De-listing a patent effectively denied prospective generic manufacturers the 180-day incentive after they brought a challenge. FDA agreed to de-list patents at the brand manufacturer's request, arguing that it had only a "ministerial" role.³⁹ The D.C. Circuit disagreed, finding that FDA's policy was at odds with the Hatch–Waxman Act.⁴⁰

Another legal strategy brand-name manufacturers employ to limit generic competition is by releasing authorized generics, which are versions of brand-name drugs sold under generic labels. Two cases, *Teva v. Crawford* and *Mylan v. FDA*, upheld marketing of authorized generics under a *Chevron* analysis, addressing whether brand-name manufacturers can market authorized generics during the Hatch–Waxman Act's 180-day exclusivity period.⁴¹ In both cases, generic manufacturers sued FDA, arguing that allowing authorized generics during the 180-day exclusivity period undermined their incentives.⁴² The D.C. Circuit sided with FDA, holding that the Hatch–Waxman Amendments do not prevent NDA holders

³⁷ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

³⁸ *Ranbaxy Lab'ys Ltd. v. Leavitt*, 469 F.3d 120, 126 (D.C. Cir. 2006); Bryan S. Walsh, Jonathan J. Darrow & Aaron S. Kesselheim, *Recent Orange and Purple Book Legislation Suggests a Need to Bridge Drug and Biologic Patent Regimes*, 40 NATURE BIOTECHNOLOGY 167, 167 (2022).

³⁹ *Ranbaxy Lab'ys Ltd.*, 469 F.3d at 125.

⁴⁰ *Id.* at 126.

⁴¹ *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 55 (D.C. Cir. 2005); *Mylan Pharms., Inc. v. FDA*, 454 F.3d 270, 276–77 (4th Cir. 2006).

⁴² *Teva Pharm. Indus. Ltd.*, 410 F.3d at 53–54; *Mylan Pharms., Inc.*, 454 F.3d at 276.

from marketing their approved products however they see fit, including as authorized generics.⁴³

Orphan Drug Act (4)

Four cases involved the market exclusivity provisions in the Orphan Drug Act of 1983, which grants seven years of exclusivity to drugs approved for indications affecting fewer than 200,000 people in the United States.⁴⁴ During this exclusivity period, FDA may not approve other related products that treat the same condition.

The cases involved challenges to FDA's decision to approve competitors' drugs or to deny Orphan Drug Act exclusivity. In *Catalyst Pharmaceuticals v. Becerra*, for example, a brand-name rare disease drug manufacturer sued FDA for approving another drug with the same active ingredient for use in pediatric patients with the same disease.⁴⁵ Catalyst's drug was only approved for use in adults. FDA responded that it had "administratively divided" the second approval into a pediatric indication and an adult indication, reasoning that the second drug did not infringe upon Catalyst's exclusivity because the condition it aimed to treat was not the same disease.⁴⁶ The Eleventh Circuit disagreed, concluding that the plain language of the Orphan Drug Act precluded FDA's approval of the second drug, because the two products contained the same active ingredient, and the disease affected adults and children equally.⁴⁷

DISCUSSION

Courts adopted FDA's preferred statutory interpretation in most cases in our cohort, including every case in which courts reached Step Two of a *Chevron* analysis. Appellate opinions employing a *Chevron* analysis to determine the proper scope of FDA's authority concerned two types of disputes: FDA's jurisdiction over medical products and the administration of exclusivities. While the implications of eroding *Chevron* are unclear regarding the allocation of exclusivities, a diminished deference regime could adversely affect public health practice if courts curtail FDA's discretion to regulate medical products.

The Value of Chevron at FDA

If the Supreme Court overrules *Chevron*, the most likely changes for FDA would occur in areas of the law in which courts have found statutory ambiguity. This is because deference does not play a role in courts' analysis under *Chevron* Step One; instead, it only comes into play at *Chevron* Step Two, in which judges determine whether the agency's interpretation is reasonable. We found ten such *Chevron* Step Two cases, in which courts defer to FDA because the statute does not clearly speak to the question at issue.

⁴³ *Teva Pharm. Indus. Ltd.*, 410 F.3d at 55.

⁴⁴ Ameet Sarpatwari, Reed F. Beall, Abdurrahman Abdurrob, Mengdong He & Aaron S. Kesselheim, *Evaluating the Impact of the Orphan Drug Act's Seven-Year Market Exclusivity Period*, 37 HEALTH AFFS. 732, 732 (2018).

⁴⁵ *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299, 1305 (11th Cir. 2021).

⁴⁶ *Id.* at 1304–05.

⁴⁷ *Id.* at 1312–13.

The ambiguous product jurisdiction cases illustrate the substantial public policy benefits of deference to FDA's reasonable interpretations of its statute. In *Pharmanex*, *Whitaker*, and *Genendo*, courts faced genuine statutory ambiguity in the scope of FDA's authority to regulate drugs.⁴⁸ In *Whitaker*, it was overlapping statutory definitions, while *Pharmanex* and *Genendo* involved disputes over the interpretation of key textual provisions. In each case, FDA presented arguments for why its interpretations best aligned with its mission to protect public health and safety, and courts deferred. Without the *Chevron* framework, it is unclear how courts will resolve these sorts of statutory ambiguities. As a result, fundamental aspects of FDA's authority may be in jeopardy, including its ability to regulate active drug ingredients,⁴⁹ claims about a product's ability to treat disease,⁵⁰ and the labeling of imported drug products.⁵¹

In addition to product jurisdiction cases, the area of FDA law most subject to change under the judiciary's current trajectory is the administration of exclusivities. Unlike product jurisdiction disputes, the exclusivity outcomes were more closely related to competition incentives than public health and safety per se. In contrast to when it asserts authority over a particular product, exclusivity cases often force FDA to choose sides between different manufacturers, implementing statutory provisions intended to balance the development of useful drugs against competition among manufacturers. Since Article III judges have more relevant expertise in adjudicating financial disputes and making sense of statutory regimes than they do with regard to public health, the policy implications of overruling *Chevron* would be far less clear in the context of cases that deal with exclusivity.

The Limits of Deference

Courts employing a *Chevron* analysis proved frequently willing to strike down FDA's actions as inconsistent with the relevant statute. Among the FDA actions struck down in this way (under *Chevron* Step One) were two exclusivity cases in which FDA sided with brand-name drug manufacturers over prospective generic entrants. In the *Teva v. Sebelius*⁵² and *Ranbaxy* cases, FDA argued to allow brand manufacturers to de-list patents after paragraph IV certification, supporting brand manufacturers' strategic attempt to prevent generic manufacturers from benefiting from the statutory 180-day exclusivity period. In both cases, the D.C. Circuit blocked a brand manufacturer's attempt to deny a generic manufacturer a lucrative 180-day exclusivity period, arguing that the plain text and purpose of the Hatch–Waxman Act precluded FDA from allowing brand firms to engage in such anticompetitive behavior.⁵³

Courts' willingness to strike down FDA actions that appeared to inhibit meaningful competition suggests a practical benefit of judicial scrutiny—mitigating or precluding the harmful effects of potential agency influence by established

⁴⁸ See *supra* text accompanying notes 19–21.

⁴⁹ See generally *Pharmanex v. Shalala*, 221 F.3d 1151 (10th Cir. 2000).

⁵⁰ See generally *Whitaker v. Thompson*, 353 F.3d 947 (D.C. Cir. 2004).

⁵¹ See generally *United States v. Genendo Pharm.*, 485 F.3d 958 (7th Cir. 2007).

⁵² 595 F.3d 1303 (D.C. Cir. 2010).

⁵³ See *Teva v. Sebelius*, 595 F.3d 1303, 1318 (D.C. Cir. 2010); see also *Ranbaxy Lab's Ltd. v. Leavitt*, 469 F.3d 120, 126 (D.C. Cir. 2006).

industry.⁵⁴ Indeed, several exclusivity cases pitted FDA against generic manufacturers attempting to win approval under the Hatch–Waxman Act, including *Ranbaxy v. Leavitt* and *Mylan v. Thompson* (2004).⁵⁵ Each case granted a generic firm the opportunity to advance its preferred statutory construction in a forum not subject to FDA’s institutional incentives or oversight.

In other cases, however, it did not appear that the *Chevron* framework encouraged courts to police FDA’s relationship with the industries it regulates. Indeed, the ambiguities in the complex Hatch–Waxman regime sometimes meant that courts deferred to FDA interpretations that clearly contravened competition policy. In *aaiPharma v. Thompson* (2002) and *Apotex v. Thompson* (2003), courts held that FDA was not responsible for ensuring the accuracy of listed patents.⁵⁶ Both courts concluded that FDA’s interpretation of its role under the Hatch–Waxman Act as purely ministerial was reasonable, even though this interpretation enabled brand manufacturers to stave off generic competition.⁵⁷

At times, FDA appeared to intentionally test the limits of judicial deference, and when losing highlighted gaps in FDA’s authority, it inspired congressional action. For example, the Supreme Court’s decision in *Brown & Williamson* led to the subsequent enactment of the TCA.⁵⁸ Though five justices did not believe that FDA’s pre-TCA authority included the authority to regulate tobacco products, the media coverage and public discourse that resulted from *Brown & Williamson* helped galvanize lawmaking in service of public health objectives.⁵⁹ Even though FDA lost in court, it ultimately gained substantial power to regulate cigarettes and other tobacco products—perhaps even more authority than it was ready to exert under the FDCA. After FDA failed to convince the D.C. Circuit in *Rotenberg* (2021) that the agency could ban some uses of electrical stimulation devices, Congress granted FDA authority to selectively ban medical devices the following year.⁶⁰ In this sense, FDA appears to occasionally use litigation as a platform to appeal to Congress to obtain product jurisdiction authority.

FDA may be attempting something similar by defying the Eleventh Circuit’s 2021 ruling in *Catalyst*.⁶¹ Even after the court found that “FDA’s interpretation of Orphan Drug Act [was] contrary to the clear statutory language enacted by Congress,” FDA

⁵⁴ See generally Jason Webb Yackee & Susan Webb Yackee, *A Bias Towards Business? Assessing Interest Group Influence on the U.S. Bureaucracy*, 68 J. POLITICS 128 (2006).

⁵⁵ See *Ranbaxy Lab’ys Ltd.*, 469 F.3d; see also *Mylan Lab’ys v. Thompson*, 389 F.3d 1272 (D.C. Cir. 2004).

⁵⁶ *aaiPharma Inc. v. Thompson*, 296 F.3d 227 (4th Cir. 2002); *Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003).

⁵⁷ *aaiPharma Inc.*, 296 F. 3d at 243; *Apotex, Inc.*, 347 F.3d at 1349.

⁵⁸ See *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 121 (2000).

⁵⁹ See, e.g., CONG. RSCH. SERV., R40475, *FDA TOBACCO REGULATION: THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT OF 2009* (May 28, 2009), <https://crsreports.congress.gov/product/pdf/R/R40475/7>.

⁶⁰ See *supra* note 32; 21 U.S.C. § 360f (2023).

⁶¹ *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299, 1299 (11th Cir. 2021); see also Ed Silverman, *Despite Court Ruling, FDA Will Continue With Its Approach to Approving Orphan Drug Exclusivity*, STAT (Jan. 23, 2023), <https://www.statnews.com/pharmalot/2023/01/23/fda-orphan-drug-rare-disease-catalyst-exclusivity/>.

announced that it would continue to implement those same regulations.⁶² FDA's notification in the Federal Register came after a bill seeking to codify the agency's position stalled in the Senate.⁶³ By drawing renewed attention to this issue, FDA may yet obtain statutory reforms.

The Risk of Eroding Deference

Decisions like *Rotenberg* and *Nutritional Health Alliance* illustrate the potential public health implications of eroding judicial deference to FDA. These cases represent a departure from courts' twentieth century practice of deferring to FDA's expertise on matters central to the agency's mission. In the twentieth century, courts largely avoided striking down FDA actions intended to protect the public's health.⁶⁴ In today's legal landscape, FDA no longer enjoys such discretion. If the Supreme Court further erodes agency deference or dismantles the *Chevron* regime altogether in *Loper Bright Enterprises v. Raimondo*, as the petitioners in that case have requested, decisions limiting FDA actions intended to protect public health may become the norm.⁶⁵

Our analysis provides some insight into the possible consequences of this shift. The *Rotenberg* majority, for instance, held that FDA could not ban electrical stimulation devices for some uses under its statutory authority to ban devices and "establish and enforce restrictions on the sale or distribution . . . of a device that are . . . promulgated through regulations."⁶⁶ The D.C. Circuit panel held that this language unambiguously foreclosed the power to implement a selective ban.⁶⁷ A more deferential approach proposed by the dissent would have recognized "FDA's ability to tailor a ban to a device's most problematic uses . . . to avoid affecting state regulation of the practice of medicine more than is necessary."⁶⁸ The *Rotenberg* majority's decision glossed over statutory ambiguity, impeded nuanced public health action, and prevented FDA from tailoring its actions to address federalism concerns. Fortunately, Congress granted FDA the authority to selectively ban the use of medical devices for non-medically indicated purposes in December 2022.⁶⁹

⁶² *Catalyst*, 14 F.4th at 1312; see 21 C.F.R. § 316 (2023).

⁶³ Ed Silverman, *Lawmakers Wade Into a Contentious Battle Over Orphan Drug Monopolies*, STAT (May 11, 2022), <https://www.statnews.com/pharmalot/2022/05/11/jacobus-catalyst-cassidy-orphan-drug-monopolies-baldwin/>; S. 4185, 117th Cong., 2d Sess. (2022).

⁶⁴ *United States v. Bacto-Unidisk*, 394 U.S. 784, 791–92 (1969) ("It is enough for us that the expert agency charged with the enforcement of remedial legislation has determined that such regulation is desirable for the public health, for we are hardly qualified to second-guess the Secretary's medical judgment. Our sole concern is whether the statute's definition of 'drug' authorizes the disc regulations contested here[.]"); *United States v. Rutherford*, 442 U.S. 544, 577 (1979) ("[A]s the Commissioner concluded, to exempt from the Act drugs with no proved effectiveness in the treatment of cancer 'would lead to needless deaths and suffering among . . . patients characterized as 'terminal' who could actually be helped by legitimate therapy.'").

⁶⁵ Brief for Petitioner, *Loper Bright Enters. v. Raimondo*, No. 22-451 (July 17, 2023).

⁶⁶ *Judge Rotenberg Educ. Ctr., Inc. v. FDA*, 3 F.4th 390, 395 (D.C. Cir. 2021) (quoting 21 U.S.C. § 396 (2023)).

⁶⁷ *Id.* at 400.

⁶⁸ *Id.* at 403 (Srinivasan, C.J., dissenting).

⁶⁹ Consolidated Appropriations Act, Pub. L. No. 117-328, 136 Stat. 4459 (2022).

Nutritional Health Alliance presented another instance of courts declining to find ambiguity in ambiguous statutes.⁷⁰ Despite FDA's authority to set forth good manufacturing practices for dietary supplements, the Second Circuit held at *Chevron* Step One that FDA unambiguously lacked the power to require manufacturers of drugs and supplements containing 30mg or more of iron to package their products in containers holding only one dosage unit.⁷¹ Even after considering FDA's robust showing that its regulations could prevent thousands of children from becoming seriously ill or dying from iron poisoning, the court foreclosed FDA's action.⁷²

Recommendations

A tiered deference system would grant a higher degree of deference to FDA in cases that directly implicate issues such as product safety and public health, while applying less deference to cases that implicate issues such as how to apportion statutory entitlements. A context-specific approach that employs different "degrees" of deference depending on the facts of the case has been advocated by some administrative law scholars (most notably by then-Judge Stephen Breyer) since *Chevron* was decided.⁷³ Such an approach would also better align the courts and FDA with their respective strengths. In contrast to cases in which questions of statutory incentives dominate and strengthen the judiciary's hand, product-jurisdiction disputes are more ready candidates for judicial deference, since FDA wields scientific and public health expertise. FDA's mandate should be at its peak when the agency acts "to protect aspects of 'the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection.'"⁷⁴

Congress could also pass more frequent legislation to give FDA the authority it needs to respond to developing public health threats. As its responses to *Brown & Williamson*, *Rotenberg*, and other cases demonstrate, Congress can occasionally act on FDA's requests for additional, or clearer, statutory authority.⁷⁵ More frequent and specific delegations of power to FDA would improve the democratic legitimacy of FDA action and help address concerns about the impact of eroding deference on public health practice. In the current political climate, however, reactive lawmaking may not be feasible or appropriate.

⁷⁰ *Nutritional Health All. v. FDA*, 318 F.3d 92 (2d Cir. 2003).

⁷¹ *Id.* at 99–101.

⁷² *United States v. Dotterweich*, 320 U.S. 277, 280 (1943) (The court failed to heed Justice Frankfurter's statement that the public health purpose of the FDCA "should infuse construction of the legislation if it is to be treated as a working instrument of government, and not merely as a collection of English words.").

⁷³ See Lisa Schultz Bressman, *The Jurisprudence of "Degree and Difference": Justice Breyer and Judicial Deference*, 132 YALE L.J. FORUM 729 (2022) (discussing Stephen Breyer, *Judicial Review of Questions of Law and Policy*, 38 ADMIN. L. REV. 363 (1986)). Courts have adopted a tiered approach when adjudicating disputes over the scope of the Federal Reserve's authority. See Steffi Ostrowski, *Judging the Fed*, 131 YALE L.J. 726, 733 ("Courts tend to take a narrow view of the Fed in any given dispute, analyzing the mechanism or statute the Fed is implementing in isolation, rather than considering the Fed in a cross-functional way. As a result, courts have developed a series of deference doctrines that they apply to the Fed depending on its role in a given dispute.").

⁷⁴ See *United States v. Genendo Pharm.*, 485 F.3d 958, 965 (7th Cir. 2007) (citing *Amer Co. v. United States*, 142 F.2d 730, 736 (1st Cir. 1944)).

⁷⁵ Anne K. Walsh & Rachael E. Hunt, *Eagle Pharms., Inc. v. Azar*, FOOD & DRUG L. INST., <https://www.fdpi.org/2019/05/eagle-pharms-inc-v-azar/> (last visited Apr. 21, 2023).

In response to an eroding *Chevron* regime, FDA may increase its use of informal guidance as a regulatory tool. As opposed to notice-and-comment rulemaking under the Administrative Procedure Act, informal guidance is generally not considered to carry the force of law, and thus cannot form the basis for a *Chevron* analysis.⁷⁶ To avoid non-deferential judicial scrutiny, FDA could issue non-binding guidance to industry and other stakeholders and use its enforcement discretion to influence industry behavior.

Limitations

Our review excluded cases decided in district courts. Several factors shape the characteristics of litigation that reaches federal appellate courts. Due to the considerable legal fees that parties must pay to have any chance of succeeding on appeal, private appellants must weigh whether their financial interests in the matter are sufficient to warrant further legal action. This is a likely reason why most of the cases in our review involved disputes over lucrative market exclusivities. FDA, for its part, may seek to avoid negative press related to litigation, particularly when disputes concern hot-button political issues. FDA also does not have independent litigating authority.⁷⁷ Accordingly, when FDA officials want to appeal a district court ruling, the Department of Justice must concur; this does not always happen, since the Department of Justice has competing institutional priorities that may determine whether the government appeals and the positions it takes on appeal. In addition, we excluded appellate case opinions that did not result in a written opinion, since we could not analyze opinions without access to judges' reasoning.⁷⁸

CONCLUSION

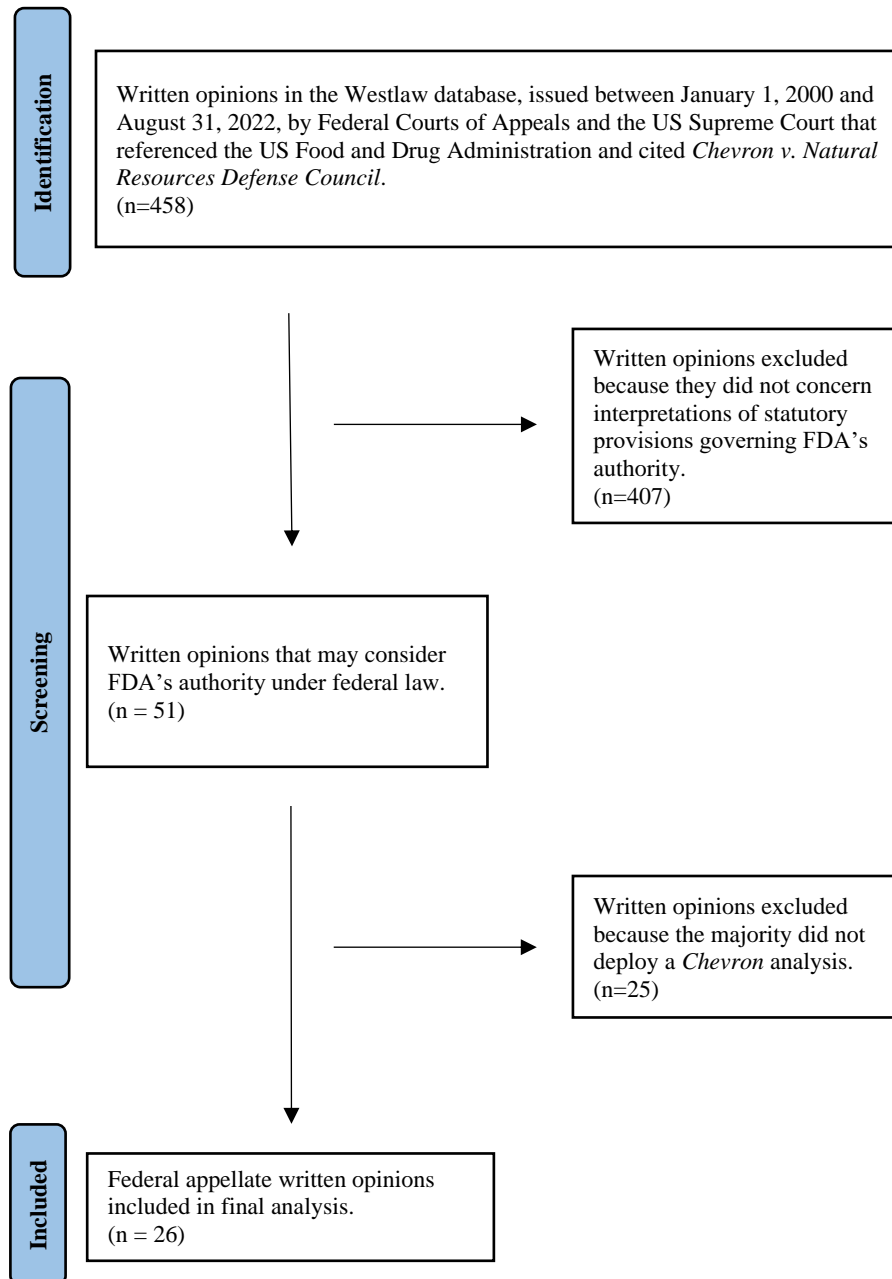
The Supreme Court's recent moves toward eroding deference to administrative agencies have cast doubt on the fate of the *Chevron* regime. Our findings suggest that although robust deference to FDA may not always be appropriate in cases concerning exclusivity periods and financial incentives, eroding deference threatens appropriate public health action in cases concerning FDA's authority over medical products. While growing skepticism has thus far been limited to non-generalizable cases like *Rotenberg*, this may change for FDA in the wake of *West Virginia v. EPA*. Lawmakers, FDA, and the Supreme Court will have to adapt to ensure that FDA has the legal capacity and regulatory tools it needs to act in service of public health.

⁷⁶ See *United States v. Mead Corp.*, 533 U.S. 218, 221 (2001).

⁷⁷ See C. Joseph Ross Daval, *Litigating Authority for the FDA*, 100 WASH. U. L. REV. 175 (2022) (discussing the Department of Justice's role in litigating on behalf of FDA).

⁷⁸ *Appellate Procedure Guide*, U.S. CT. OF APPEALS FOR THE FOURTH CIR., https://www.ca4.uscourts.gov/AppellateProcedureGuide/Decision_Post-Decision/APG-opinionandjudgment.html (last visited Apr. 21, 2023).

Figure 1: Identification of Federal Appellate Opinions Employing a *Chevron* Analysis to Decide the Scope of FDA’s Statutory Authority⁷⁹



⁷⁹ Matthew J. Page et al., *The PRISMA 2020 statement: an updated guideline for reporting systematic reviews*, 372 *BMJ* n71 (2021).

Figure 2. Frequency of Appellate Courts Adopting FDA's Preferred Interpretation After Applying a *Chevron* Analysis, January 2000-August 2022

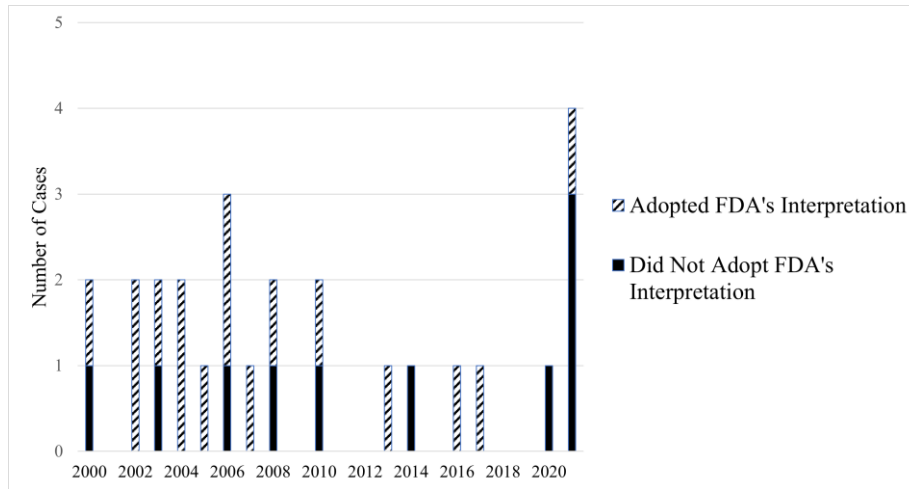


Table 1. Federal Appellate Opinions Employing a <i>Chevron</i> Analysis to Determine FDA's Jurisdiction over Products, January 2000–August 2022						
Case	Court (Year)	Category	For or Against FDA	Decision Summary	Ambiguity	FDA's Interpretation Permissible
FDA v. Brown & Williamson	Supreme Court (2000)	Tobacco	Against	FDA may not regulate tobacco products as a "drug" or "device"	No	N/A
Cigar Ass'n of Am. v. FDA	D.C. Circuit (2021)	Tobacco	For	FDA rule deeming cigars and pipes subject to the Tobacco Control Act was lawful	No*	Yes
Pharmanex v. Shalala	Tenth Circuit (2000)	Dietary supplements	For	FDA may regulate unfinished drug products (i.e., active ingredients) as new drugs	Yes	Yes
Nutritional Health All. v. FDA	Second Circuit (2003)	Dietary supplements	Against	FDA may not regulate the packaging of solid dosage dietary supplements under its authority to prevent "adulteration"	No**	No
Whitaker v. Thompson	D.C. Circuit (2004)	Dietary supplements	For	FDA may reasonably regulate saw palmetto extract as a "drug" due to statutory overlap in the definitions of "health claims" and "drug claims"	Yes	Yes
Nutraceutical v. Von Eschenbach	Tenth Circuit (2006)	Dietary supplements	For	FDA properly banned the sale of ephedrine after concluding it had no safe dosage in the cost-benefit analysis required by the DSHEA	No	N/A
United States v. Genendo Pharm.	Seventh Circuit (2007)	Imported drugs	For	An imported drug that does not comply with packaging and labeling requirements in that drug's NDA is an "unapproved new drug"	Yes	Yes

Table 1. Federal Appellate Opinions Employing a <i>Chevron</i> Analysis to Determine FDA’s Jurisdiction over Products, January 2000–August 2022						
Case	Court (Year)	Category	For or Against FDA	Decision Summary	Ambiguity	FDA’s Interpretation Permissible
Med. Ctr. Pharmacy v. Mukasey	Fifth Circuit (2008)	Compounded drugs	Against ***	FDA may regulate compounded drugs that differ in composition from approved drugs as “new drugs” except for certain statutory exceptions	No	N/A
Genus Med. Techs. LLC v. FDA	D.C. Circuit (2021)	Diagnostic agents	Against	FDA may not regulate a product as a drug if it also meets the statutory definition of a device	No	N/A
Judge Rotenberg Educ. Ctr. v. FDA	D.C. Circuit (2021)	Selective device bans	Against	FDA may not implement a selective ban on certain uses of electrical stimulation devices	No	N/A

* The court noted that FDA’s interpretation survives *Chevron* Step Two because it is a reasonable interpretation.

** The court further noted that “FDA’s dubious construction . . . is not reasonable” even under *Chevron* Step Two.

*** The court did not adopt either party’s preferred interpretation, instead offering its own distinct interpretation of the statute.

Table 2. Federal Appellate Opinions Employing a *Chevron* Analysis to Adjudicate FDA's Application of Market Exclusivity Periods, January 2000-August 2022

Case	Court (Year)	Category	For or Against FDA	Decision Summary	Ambiguity	FDA's Interpretation Permissible
Sigma-Tau Pharms. v. Schwetz	Fourth Circuit (2002)	Orphan drugs	For	FDA may approve a generic version of an orphan drug for an indication during the originator's market exclusivity for a different indication	No	N/A
Spectrum Pharms. v. Burwell	D.C. Circuit (2016)	Orphan drugs	For	FDA may approve a generic version of an orphan drug for an indication during the originator's market exclusivity for a different indication (same as <i>Sigma-Tau</i>)	Yes	Yes. Court left open the question of "whether the statute unambiguously requires FDA's interpretation."
Eagle Pharms. v. Azar	D.C. Circuit (2020)	Orphan drugs	Against	FDA may not deny Orphan Drug Act exclusivity to a drug with the same active moiety as a previously approved rare disease drug	No	N/A
Catalyst Pharms. v. Becerra	Eleventh Circuit (2021)	Orphan drugs	Against	FDA unlawfully construed the pediatric and adult versions of a disease as different conditions for purposes of orphan exclusivity	No	N/A
aaipharma Inc. v. Thompson	Fourth Circuit (2002)	Generic exclusivity	For	FDA is not required to enforce the accuracy of Orange Book filings, such as by requiring NDA holders to list relevant patents	Yes	Yes
Apotex v. Thompson	Federal Circuit (2003)	Generic exclusivity	For	FDA is not required to screen Orange Book filings for correctness (same outcome as <i>aaipharma</i>)	Yes	Yes

Table 2. Federal Appellate Opinions Employing a <i>Chevron</i> Analysis to Adjudicate FDA's Application of Market Exclusivity Periods, January 2000-August 2022						
Case	Court (Year)	Category	For or Against FDA	Decision Summary	Ambiguity	FDA's Interpretation Permissible
Mylan Lab'ys v. Thompson	D.C. Circuit (2004)	Generic exclusivity	For	When two statutory provisions led to two different dates for a single ANDA approval, FDA reasonably resolved the conflict by changing the types of approval and certification to account for "a factual situation not fully foreseen . . . by the Congress"	Yes	Yes
Teva Pharm. Indus. v. Crawford	D.C. Circuit (2005)	Generic exclusivity	For	A brand manufacturer may sell "authorized generics" (made by the brand manufacturer but marketed as generic) during a first-to-file generic manufacturer's 180-day exclusivity	No	N/A
Mylan Pharms. v. FDA	Fourth Circuit (2006)	Generic exclusivity	For	A brand manufacturer may license the sale of authorized generics to a third party during a first-to-file generic manufacturer's 180-day exclusivity	No	N/A
Ranbaxy Lab'ys v. Leavitt	D.C. Circuit (2006)	Generic exclusivity	Against	FDA cannot remove patents from the Orange Book at the brand manufacturer's request, as a strategy to deny generic manufacturers the benefit of the 180-day exclusivity, after the paragraph IV certification has been filed	No	N/A
Teva Pharms. v. Leavitt	D.C. Circuit (2008)	Generic exclusivity	For	FDA may remove patents from the Orange Book at brand manufacturer's request, denying generic manufacturers the 180-day exclusivity, if the paragraph IV certification has not yet been filed	No	N/A

Table 2. Federal Appellate Opinions Employing a <i>Chevron</i> Analysis to Adjudicate FDA's Application of Market Exclusivity Periods, January 2000-August 2022						
Case	Court (Year)	Category	For or Against FDA	Decision Summary	Ambiguity	FDA's Interpretation Permissible
Teva Pharms. v. Sebelius	D.C. Circuit (2010)	Generic exclusivity	Against	The Medicare Modernization Act of 2003 and its list of "forfeiture events" did not change the holding of <i>Ranbaxy</i> . FDA still cannot delist Orange Book patents after paragraph IV certification at the brand manufacturer's request	No	N/A
Mylan Pharms. v. FDA	Fourth Circuit (2014)	Generic exclusivity	Against	The generic exclusivity period can begin with a court's decision to invalidate any certified patent; generic applicants do not have to file another paragraph IV certification	No	No (court stated that FDA's "interpretation is contrary to the plain statutory language.")
AstraZeneca Pharms. v. FDA	D.C. Circuit (2013)	Pioneer exclusivity	For	FDA has discretion under the FDCA to determine what constitutes an exclusivity-eligible "change approved" in a supplement	Yes	Yes
Otsuka Pharm. v. Price	D.C. Circuit (2017)	Pioneer exclusivity	For	FDA reasonably determined that pioneer exclusivity is only infringed by a drug with the same "active moiety"	Yes	Yes
Wyeth Holdings v. Sebelius	Federal Circuit (2010)	Patent term extensions	For	FDA's method of calculating patent term extensions for patent life lost during phased review of new animal drugs was reasonable	Yes	Yes