How Courts Reviewed FDA Action Before *Chevron* and May Again After *Loper Bright*

DANIEL E. ORR, JONATHAN TRINH & EVA F. YIN*

ABSTRACT

The U.S. Supreme Court's decision in *Loper Bright Enterprises v. Raimondo* overruled *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc*. *Chevron* had required federal courts to defer to agencies' reasonable interpretations of the statutes they administered for over 40 years. This Article examines the potential impact of *Loper Bright* on the U.S. Food and Drug Administration (FDA) and how courts reviewed the agency's actions before and after *Chevron*. It finds that FDA's "win-rate" was unchanged but that courts came to rely heavily on *Chevron* as a key basis for their decisions. We identify some possible explanations for these findings and predictions for what litigation against FDA will look like in the future.

I. INTRODUCTION

On June 28, 2024, in *Loper Bright Enterprises v. Raimondo*,[1] the U.S. Supreme Court overruled *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*[2] *Chevron*, and the cases that followed it, had established the *Chevron* doctrine that required federal courts to defer to the agency's reasonable interpretation of an ambiguous statute that the agency administers. *Loper Bright* rejected this deferential framework and held that courts must instead exercise their "independent judgment" and "decide all relevant questions of law."[3]

Chevron served as a cornerstone of administrative law for four decades. In her dissent in *Loper Bright*, Justice Kagan warned "the majority's decision today will

* Daniel E. Orr is senior counsel in Wilson Sonsini Goodrich & Rosati's FDA & healthcare regulatory practice group. He previously served as a Regulatory Counsel at the U.S. Food & Drug Administration where he developed national policy for drugs and biologics. J.D., Vanderbilt University Law School, M.A., B.A. *with distinction*, University of Pennsylvania; B.S. *cum laude*, City University of New York.

Jonathan Trinh is a Senior Associate in the Life Sciences and Healthcare Regulatory practice group at Arnold & Porter. Jonathan advises life sciences companies on navigating pre- and post-market challenges throughout their products' lifecycles, enabling them to launch and commercialize their products. J.D., The George Washington University Law School; B.A., *with honors*, University of California, Berkeley.

Eva F. Yin is a partner in Wilson Sonsini Goodrich & Rosati's FDA & healthcare regulatory practice group. She advises life sciences companies at all stages of growth, including medical device, digital health, pharmaceutical, diagnostic, cosmetic, dietary supplement, and general wellness companies. J.D., University of California College of the Law, San Francisco, M.P.H., Johns Hopkins Bloomberg School of Public Health, Ph.D., Molecular Biophysics and Biochemistry, Yale University, B.S., Chemistry and Biology, Emory University.

1 144 S. Ct. 2244 (2024).

2 467 U.S. 837 (1984).

3 *Loper Bright*, 144 S. Ct. at 2261, 2273 (quoting 5 U.S.C. § 706) (internal punctuation omitted).

cause a massive shock to the legal system, casting doubt on many settled constructions of statutes and threatening the interests of many parties who have relied on them for years."[4] Media reports have described *Chevron*'s overruling as a "legal earthquake" that calls into question as many as 19,000 prior court decisions.[5]

We assess the potential impact of *Loper Bright* on FDA by examining how *Chevron* affected judicial review of the agency's decisions. We compared a sample of 164 decisions in litigation against FDA before *Chevron* was decided in 1984 with 100 decisions after. We find that *Chevron* had little effect on whether FDA won litigation against it, with the agency prevailing in about two-thirds of cases in both samples.

Chevron did, however, have a significant effect on how courts reached their decisions. Before *Chevron*, federal courts relied primarily on statutory interpretation (34.7%) and the Administrative Procedure Act (APA) (34.1%) to review FDA's actions. After *Chevron*, the focus shifted dramatically, with courts applying *Chevron* in 86% of cases against FDA.

II. *CHEVRON* AND *LOPER BRIGHT*

Chevron reviewed a challenge to how the Environmental Protection Agency (EPA) interpreted the Clean Air Act (CAA). The EPA's CAA "bubble" policy treated all pollution sources within a single industrial complex as one source.[6] The Natural Resources Defense Council argued that this approach was contrary to the CAA and that each source should be regulated separately.[7] The U.S. Supreme Court found that the CAA was ambiguous and supported EPA's interpretation.[8] This decision created the so-called *Chevron* doctrine that a court must defer to an executive agency's reasonable interpretation of an ambiguous statute that the agency administers.[9]

Courts applied the *Chevron* doctrine in two steps. First, a court decided whether "Congress has directly spoken to the precise question at issue."[10] If so, the court's inquiry ended and the court enforced the "unambiguously expressed intent of Congress."[11] But if the statute was ambiguous or silent on the issue, then the court moved to step two where it determined whether the agency's interpretation was "reasonable" and, if so, accepted it.[12]

A dispute concerning commercial fishermen in *Loper Bright* caused the U.S. Supreme Court to reconsider *Chevron*. The fishermen challenged a rule by the National Marine Fisheries Service (NMFS) that required them to fund at-sea

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[4] *Loper Bright*, 144 S. Ct. at 2307 (Kagan, J., dissenting) (quoting Kisor v. Wilkie, 588 U.S. 558, 587 (2019)) (internal punctuation omitted).

[5] *See, e.g.*, Josephine Rozzelle, *With* Chevron *Reversal, Supreme Court Paves Way for a 'Legal Earthquake'*, CNBC (July 10, 2024, 1:28 PM), https://www.cnbc.com/2024/07/10/supreme-court-post-chevron-legal-chaos.html; Cary Coglianese, *The Supreme Court's Judicial Earthquake Will Shake the Administrative State*, BARRON'S (July 2, 2024, 1:14 PM), https://www.barrons.com/articles/supreme-court-decision-chevron-administrative-state-a3fcb801.

[6] *Chevron*, 467 U.S. at 854–55.

[7] *Id.* at 839–42.

[8] *Id.* at 866.

[9] *Chevron*, 467 U.S. at 843.

[10] *Id.* at 842.

[11] *Id.* at 843.

[12] *Id.* at 844–45.

monitoring programs at a significant cost.[13] The fishermen argued the requirement was illegal under the Magnuson-Stevens Fishery Conservation and Management Act of 1976 and that the NMFS' regulations were invalid as a result.[14] Two circuit courts applied *Chevron* and upheld the NMFS' interpretation.[15]

But *Loper Bright* rejected *Chevron*'s directive that an ambiguous statute should be construed in favor of an agency's interpretation. Citing precedents as far back as 200 years, the majority opinion emphasized that "it is emphatically the province and duty of the judicial department to say what the law is."[16] According to the majority, the APA requires courts to decide "all relevant questions of law" when reviewing agency action.[17] A court should consider an agency's interpretation only based on "those factors [that] give it [the] power to persuade" as described in *Skidmore v. Swift & Co*.[18]

In her dissent, Justice Kagan, joined by Justices Sotomayor and Jackson, criticized the majority's opinion as "judicial hubris."[19] She argued that *Chevron* enabled agency expertise to fill statutory gaps left by Congress and that Congress prefers that agencies fill those gaps instead of courts.[20] She emphasized that "*Chevron* is about respecting that allocation of responsibility—the conferral of primary authority over regulatory matters to agencies, not courts."[21]

Justice Kagan cited examples of the importance of agency expertise under *Chevron*, including FDA's determination of what qualifies as a "protein" under the Public Health Service Act:

> When does an alpha amino acid polymer qualify as a "protein"? I don't know many judges who would feel confident resolving that issue. (First question: What even *is* an alpha amino acid polymer?) But the FDA likely has scores of scientists on staff who can think intelligently about it, maybe collaborate with each other on its finer points, and arrive at a sensible answer.[22]

Although *Loper Bright* explicitly overruled *Chevron*, it did not overturn other precedents that rely on it.[23] The majority noted that those decisions remain valid under

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[13] *Loper Bright*, 144 S. Ct. at 2255–56.

[14] *Id.*

[15] Relentless, Inc. v. Dep't of Com., 62 F.4th 621, 628 (1st Cir. 2023); Loper Bright Enters. v. Raimondo, 45 F.4th 359, 368 (D.C. Cir. 2022).

[16] *Loper Bright*, 144 S. Ct. at 2257 (quoting Marbury v. Madison, 1 Cranch 137, 177 (1803)) (internal punctuation omitted).

[17] *Id.* at 2261 (quoting 5 U.S.C. § 706).

[18] *Id.* at 2259 (quoting Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944)).

[19] *Id.* at 2294 (Kagan, J., dissenting).

[20] *Id.* at 2300–2301 (Kagan, J., dissenting).

[21] *Id.* at 2311 (Kagan, J., dissenting).

[22] *Id.* at 2298 (Kagan, J., dissenting) (internal citations omitted).

[23] *Id.* at 2272–73 ("By [overruling *Chevron*] we do not call into question prior cases that relied on the *Chevron* framework. The holdings of those cases that specific agency actions are lawful—including the Clean Air Act holding of *Chevron* itself—are still subject to statutory *stare decisis* despite our change in interpretive methodology.").

the doctrine of stare decisis.[24] Nonetheless, *Loper Bright* raises questions about how the legal issues in those precedents will be decided if they come to court again.

According to the *Loper Bright* majority, absent an explicit delegation in a statute, "Courts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority, as the APA requires."[25] But it also leaves room for deference other than *Chevron* deference. The majority endorses *Skidmore* deference as appropriate in some circumstances.[26] Both the majority and the dissent rely on *Kisor v. Wilkie*,[27] which reaffirmed that a court should defer to an agency's reasonable interpretation of its own regulations (so-called *Auer* deference).[28]

III. METHODOLOGY

We used Westlaw to find decisions where a court reviewed FDA action. Our search included all cases where FDA, HHS, or the FDA Commissioner or HHS Secretary was a named party. The search found a total of 3,021 cases. 233 of these cases were decided before June 25, 1984—the date of the *Chevron* decision—and 2,788 were decided after that date.[29]

We reviewed all 233 pre-*Chevron* cases, which yielded a usable sample of 164 decisions that reviewed FDA action.[30] We compared these with a random sample of 100 decisions citing *Chevron*[31] that also reviewed FDA action. We coded both samples for whether the court found for the agency or the adverse party[32] (FDA's "win-rate") and what rule of decision the court applied to the case.

In coding for the rule of decision, we used the following categories:

- **Statutory Interpretation:** The court decided the case according to the text of the controlling statute (typically the FDCA) or according to rules of statutory construction.

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[24] *Id.*

[25] *Id.* at 2273.

[26] *Id.* at 2259.

[27] 588 U.S. 558 (2019).

[28] *Id.* at 563; *Loper Bright*, 144 S. Ct. at 2267–68, 2306–10.

[29] Fifty-three percent of decisions after June 24, 1984, were unreported as compared to less than 5% of decisions before that date. However, we did not find any significant differences in unreported cases as compared to reported cases.

[30] The excluded pre-*Chevron* decisions reviewed administrative actions by other HHS components, such as the Centers for Medicare and Medicaid Services, and not FDA.

[31] The random sample of decisions citing *Chevron* was selected in August 2024 from the initial sample of 3,021 using a random number generator. *See* RANDOM.ORG, https://www.random.org (last visited June 1, 2025). We acknowledge that selecting a random sample of decisions from those that cite *Chevron* introduces a potential source of bias, but we believe this comparison provides a better measure of *Chevron*'s effects as a precedent than an entirely random sample. If anything, measuring cases citing *Chevron* would tend to overestimate its effect on FDA's win-rate. Accordingly, we do not believe this potential bias could affect our findings.

[32] The "winner" was obvious in cases where the court found for the agency or its opponent on all issues. For mixed decisions, we applied the "prevailing party" standard to determine whether FDA won the case. *See, e.g.*, Hensley v. Eckerhart, 461 U.S. 424, 433 (1983) (establishing the prevailing party standard). If the plaintiff did not obtain "substantial relief" requested in the complaint, then FDA was coded as the winner. *See id.* at 437–40.

- **Administrative Procedure Act:** The court decided the case according to the requirements of the APA, such as invalidating a regulation for insufficient notice-and-comment.
- **Jurisdiction:** The court found that it lacked subject-matter jurisdiction or that FDA had primary jurisdiction.
- **Deference:** The court deferred to FDA's opinion on some grounds other than the *Chevron* doctrine.
- **Substantial Evidence:** The court upheld or reversed FDA's decision on the basis that it was or was not supported by substantial evidence.
- **Ripeness:** The court dismissed the case because it was not ripe for adjudication.
- **Reversible Error:** An appellate court reversed a decision of a lower court because of an abuse of discretion or procedural error.
- **Standing:** The reviewing court dismissed the case because the plaintiff lacked standing.
- ***Chevron*:** The court decided the case primarily under the *Chevron* doctrine (either at step one or step two).
- **Other:** One of several rules of decision accounted for less than 1% of cases in the sample, such as res judicata, mootness, and executive privilege.

IV. RESULTS

We found little difference in FDA's "win-rate" before and after *Chevron*. The agency prevailed in about two-thirds of cases in both samples: 68% of cases before *Chevron* and in 69% of cases after. These differences are not statistically significant.[33]

There were, however, significant differences in how courts decided litigation against FDA before and after *Chevron*. The results are summarized in Table 1, below.

Table 1—Rules of Decision Before and After *Chevron*

	Before Chevron n=164	**After Chevron n=100**
Statutory Interpretation	34.7% (57)	6.0% (6)
APA	34.1% (56)	2.0% (2)
Jurisdiction	12.8% (21)	1.0% (1)
Deference	6.1% (10)	2.0% (2)
Substantial Evidence	4.2% (7)	0.0% (0)
Ripeness	2.4% (4)	1.0% (1)
Reversible Error	1.8% (3)	0.0% (0)
Standing	1.2% (2)	0.0% (0)
Chevron	--	86.0% (86)
Other	2.4% (4)	2.0% (2)

[33] ($z = -0.11$, $p \geq 0.9$).

After 1984, *Chevron* supplanted the top four rules of decision combined—Statutory Interpretation, the APA, Jurisdiction, and Deference—in 86% of cases.

V. DISCUSSION

A. Why Didn't Chevron Have a Greater Effect on FDA's "Win-rate"?

Our results surprised us initially. We expected FDA would win significantly more cases after *Chevron* than before, but the agency prevailed in about two-thirds of the litigation against it in both samples. We can think of several potential explanations.

The first is that courts applying *Chevron* did not blindly afford deference to agency interpretations of the law. When reviewing agency action, some courts found that the statutory language was not ambiguous or silent with respect to the specific issue.[34] These courts resolved the case at step one and gave effect to the "unambiguously expressed intent of Congress."[35] That put an end to their inquiry. In many cases, the courts' resolution at step one resulted in favor of the parties challenging the agency's action.[36] Even when courts reached step two, some still found that the agency's interpretation was not reasonable and entered judgment for the challengers as a result.[37]

The second is that courts deferred to FDA's interpretations of ambiguous statutory language even before *Chevron*. For example, in the 1974 case *Federation of Homemakers v. Schmidt*,[38] the court considered a challenge to FDA's definition of a food "imitation" for purposes of misbranding under the FDCA.[39]

The court found that the statute was ambiguous and, foreshadowing *Chevron*, held that it should defer to FDA's interpretation. Judge Waddy wrote, "[u]nless there are compelling indications to the contrary, the construction of a statute by the agency charged with its enforcement is entitled to great deference."[40] Because "the FDA's interpretation of the misbranding provision at issue here is not clearly inconsistent with the language of the statute . . . this Court should accept the agency's judgment."[41]

Other courts implicitly deferred to FDA's expertise when they dismissed cases on jurisdictional grounds. For example, several dismissed challenges to the agency's

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[34] *See, e.g.*, Genus Med. Techs., LLC v. FDA, 427 F. Supp. 3d 74, 82–84 (D.D.C. 2019); Mylan Pharms., Inc. v. FDA, 594 Fed. Appx. 791, 797 (4th Cir. 2014).

[35] *Id.*

[36] *E.g.*, *Genus Med. Techs.*, 427 F. Supp. 3d at 84 (determining that the agency's interpretation was contrary to the unambiguous statutory language under *Chevron* step one); *Mylan Pharms.*, 594 Fed. Appx. at 797 (same); Teva Pharms. USA, Inc. v. Sebelius, 595 F.3d 1303, 1318 (D.C. Cir. 2010) (same); Nutritional Health All. v. FDA, 318 F.3d 92, 101 (2d Cir. 2003) (same).

[37] *See, e.g.*, Texas v. Becerra, 623 F. Supp. 3d 696, 725–30 (N.D. Tex. 2022) (determining that the agency's interpretation was unreasonable under *Chevron* step two); Braeburn Inc. v. FDA, 389 F. Supp. 3d 1, 27–28 (D.D.C. 2019) (same).

[38] 385 F. Supp. 362 (D.D.C. 1974), *aff'd*, 539 F.2d 740 (D.C. Cir. 1976).

[39] *Id.* at 363.

[40] *Id.* at 365 (citing Red Lion Broad. v. FCC, 395 U.S. 367 (1969) and Udall v. Tallman, 380 U.S. 1 (1965)).

[41] *Id.*

findings that products were "new drugs" regulated under the FDCA.[42] One court explained, "[t]he heart of the new procedures designed by Congress is the grant of primary jurisdiction to FDA, the expert agency which it created."[43]

A third explanation is that judges often reach their decisions inductively, then identify the precedent and reasoning that supports their chosen outcome. This explanation finds significant support in prior research concerning judicial decisionmaking.[44] Pre-*Chevron* courts chose from a variety of precedents and reasoning to support an intuited decision that FDA's actions were correct. But *Chevron* gave them a shortcut and became the predominant rule of decision as a result.

Finally, prior research has found that courts are more deferential to FDA than to other administrative agencies. "In the twentieth century, the judiciary overwhelmingly decided lawsuits involving FDA in the agency's favor."[45]

A recent case review by Liam Bendicksen, Aaron Kesselheim, and C. Joseph Ross Daval examined how the U.S. Supreme Court and federal circuit courts applied *Chevron* in ligation against FDA.[46] They found that in the twenty-six opinions since 2000, federal appellate courts adopted FDA's preferred statutory interpretation most of the time.[47] When a court found that the statute was unambiguous, the court agreed with FDA's preferred interpretation in six out of sixteen cases (37%).[48] When a court determined that the statute was ambiguous, the court found the agency's interpretation to be reasonable and deferred to FDA's preferred interpretation in ten out of ten cases (100%).[49] Overall, FDA's interpretation prevailed in 61.5% of the cases they reviewed.[50]

Although our methods differ, our results are consistent with these findings.[51]

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[42] Tutoki v. Celebrezze, 375 F.2d 105, 107 (7th Cir. 1967); IMS, Ltd. v. Califano, 453 F. Supp. 157, 159 (C.D. Cal. 1977); Nat'l Ethical Pharm. Ass'n v. Weinberger, 365 F. Supp. 735, 737 (D.S.C. 1973), *aff'd*, 503 F.2d 1051 (4th Cir. 1974); Carolina Brown, Inc. v. Weinberger, 365 F. Supp. 310, 311 (D.S.C. 1973).

[43] *Nat'l Ethical*, 365 F. Supp. at 737 n.2 (applying Weinberger v. Bentex Pharms., Inc., 412 U.S. 645 (1973)).

[44] Chris Guthrie, Jeffrey J. Rachlinski & Andrew J. Wistrich, *Blinking on the Bench: How Judges Decide Cases*, 93 CORNELL L. REV. 1, 43 (2007).

[45] Liam Bendicksen, Aaron S. Kesselheim & C. Joseph Ross Daval, *FDA and* Chevron *Deference: A Case Review*, 78 FOOD & DRUG L.J. 371, 372 (2023).

[46] *Id.* at 371, 373.

[47] *Id.* at 374; Bendicksen et al.'s methodology differed from ours in that they looked only at decisions after January 1, 2000, and excluded district court opinions.

[48] *Id.*

[49] *Id.*

[50] *Id.*

[51] These results are also consistent with Barnett and Walker's broader 2017 study of *Chevron* deference to all federal agencies. The study found that circuit courts upheld 71% of agency interpretations and applied *Chevron* deference 77% of the time. *See* Kent Barnett & Christopher J. Walker, Chevron *in the Circuit Courts*, 116 MICH. L. REV. 1 (2017). These results are within the upper limits of confidence intervals in our post-*Chevron* sample.

B. What Effects Will Loper Bright Have on Litigation Against FDA?

In 2019, a prescient article by Chad Landmon, Alexander Alfano, and Michelle Divelbiss predicted that *Chevron* may be overruled and "the floodgates will be opened to litigation against FDA and other agencies."[52] The article did not necessarily view this as bad, complaining that "[s]uing the U.S. Food and Drug Administration (FDA) while playing by *Chevron*'s rules is a David versus Goliath-like battle. Except here, David almost never wins."[53]

The U.S. Supreme Court's recent decision in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*[54] also expands the potential for litigation against federal agencies. The case concerned a challenge to the Federal Reserve's regulation that set maximum interchange fees for debit card transactions.[55] The regulation was finalized in 2011, and the lower courts found the suit was time-barred under the APA's six-year statute of limitations.[56] But the U.S. Supreme Court reversed, holding that the limitations period accrued not from the agency's final regulation but from the date of the plaintiff's injury.[57] A pointed dissent from Justice Jackson summarized the effects of this holding as "there is effectively no longer any limitations period for lawsuits that challenge agency regulations on their face."[58]

While our data does not support the conclusion that loss of *Chevron* deference will 'level the playing field,' we agree that litigation against FDA is likely to increase. *Corner Post* expands the number of agency decisions that can be challenged, and *Loper Bright* creates the perception that litigation against an agency is more winnable. The two cases together will likely increase litigation against all federal agencies.

Landmon, Alfano, and Divelbiss also accurately predicted that the U.S. Supreme Court would endorse continued use of *Skidmore* deference and reasoned that FDA would win fewer cases under *Skidmore*.[59] While it is possible that courts may apply *Skidmore* deference to suits against FDA more often in future cases, we did not find any cases decided under *Skidmore* in our pre-*Chevron* sample and only one in our post-*Chevron* sample.[60]

As a result, we anticipate that litigation against FDA after *Loper Bright* will look a lot like litigation against the agency before *Chevron*. Consistent with *Loper Bright*'s instructions to lower courts, we expect most cases against FDA will be decided under rules of statutory interpretation and APA requirements.

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[52] Chad Landmon, Alexander Alfano & Michelle Divelbiss, *Open the Floodgates: The Potential Impact on Litigation Against FDA if the Supreme Court Reverses or Curtails* Chevron *Deference*, 74 FOOD & DRUG L.J. 358, 359 (2019).

[53] *Id.* at 358.

[54] Corner Post, Inc. v. Bd. of Governors of the Fed. Rsrv. Sys., 144 S. Ct. 2440 (2024).

[55] *Id.* at 2448.

[56] *Id.* at 2248–49.

[57] *Id.* at 2460.

[58] *Id.* at 2470.

[59] Landmon et al., *supra* note 352, at 371.

[60] Orton Motor, Inc. v. HHS, 884 F.3d 1205, 1211 (D.C. Cir. 2018). *Skidmore* was decided eighty-one years ago but has been cited fewer than 4,400 times, as compared to over 18,000 citations to *Chevron*. It's likely that *Skidmore* has been eclipsed by *Chevron* for much of its history.

Although we do not believe FDA will lose significantly more cases without *Chevron* deference, the loss of deference as a judicial shortcut will likely increase the time required and cost of litigation for all parties. Former FDA Chief Counsel Stacy Cline Amin made the same prediction in 2023, that if *Chevron* is overruled "we're going to see a lot more resources diverted to providing the justification for decisions and interpretations so that they have a greater chance of survival in litigation and . . . this is going to make FDA's job harder."[61]

VI. CONCLUSION

Loper Bright made a major change in administrative law by overturning *Chevron*. But although *Chevron* had a significant effect on how courts reviewed FDA's decisions, it did not alter how often FDA won litigation against it. The agency's success rate in court stayed about the same before and after *Chevron*.

With *Chevron* no longer in place, courts will have to rely more on their "independent judgment" when they review FDA's decisions. We express no opinion on whether this is good or bad and expect that courts will return to the same analytical methods that they used before *Chevron*. But these methods will require more analysis, more evidence, and more time and expense for the courts, the litigants, and the agency. While FDA may not lose more cases, it will need to be better prepared to defend its actions.

[61] Stacy Cline Amin, Partner, Morrison and Foerster, LLP, FDA Under Fire: What Recent Cases Mean for FDA Regulation, Panel Presentation at the Food and Drug Law Institute's 2023 FDLI Annual Conference (May 17, 2023) (timestamp 39:22) (recording on file with author).