Litigation Against FDA in a Post-*Chevron* World

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ATTORNEYS who defend pharmaceutical and medical device manufacturers in product liability litigation know that changes in state tort law can have significant consequences for their clients. But pharmaceutical and medical device manufacturers (and other federally regulated companies) can also be greatly affected by changes in federal administrative law.

Recent changes to the composition of the Supreme Court have resulted in significant developments in administrative law. These developments have constrained the authority of federal agencies to regulate parties through rulemaking and adjudication.

For example, the Court has recently made greater use of the "major questions doctrine" to set aside federal agency actions.[1]

[1] *See, for example*, West Virginia v. EPA, 597 U.S. 697 (2022) (holding that the Clean Air Act did not include an implicit delegation of authority to EPA to adopt regulations that, in effect, restructured the electricity industry); Biden v. Nebraska, 600 U.S. 477 (2023) (setting aside a Department of

Under that doctrine, courts require "an agency to point to clear congressional authorization when" the agency "asserts an enormous and transformative expansion of its regulatory authority by making a decision of vast economic and political significance."[2]

The Court also recently ruled that the six-year statute of limitations to bring a facial challenge to an agency regulation does not begin to run until the plaintiff is injured by the regulation.[3] The practical effect of this ruling is that a party may bring a facial challenge to an agency regulation that was adopted decades ago if that party can show it was not injured by the regulation until less than six years ago.[4]

As another example, the Supreme Court recently held that a statute that permits the Securities and Exchange Commission to use administrative law judges to adjudicate civil money penalty cases against persons the SEC accuses of fraud violates the Seventh Amendment right to a jury trial.[5] As the dissent in that case noted, dozens of agencies use administrative proceedings to adjudicate civil money penalties, and the constitutionality of those proceedings "may now be in peril."[6] Indeed, as of December 8, 2024, Seventh Amendment challenges to FDA's administrative civil money penalty scheme have been filed in three federal district courts.[7]

But the Supreme Court's most significant recent decision in the field of administrative law is *Loper Bright Enterprises v. Raimondo*.[8] In *Loper Bright*, the Court overruled *Chevron v. National Resources Defense Council*—the case that had governed agency interpretations of their enabling statutes for the past forty years.[9] In *Chevron*, the Court held that courts should defer to a federal agency's "reasonable" construction of an ambiguous statutory term, even if the court does not believe the agency's construction is the best one. In overruling *Chevron*, the Court stated that courts are required to exercise their independent judgment to determine the best interpretation of a statute.

Education student loan forgiveness program).

[2] United States v. Navarro, 2024 U.S. App. LEXIS 7683, *7-8 (D.C. Cir. Apr. 1, 2024) (internal citations and quotations omitted).

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

[4] The plaintiff in *Corner Post* was a corporation that did not even exist at the time the regulation at issue was adopted.

[5] SEC v. Jarkesy, 144 S. Ct. 2117 (2024).

[6] *Id.* at 2174 (Sotomayor, J., dissenting).

[7] *See* Huff & Puffers, LLC v. FDA, No. 24-cv-02110 (C.D. Cal. Sept. 27, 2024); Vape Central Group, LLC v. FDA, No. 24-cv-03354 (D. D.C. Nov. 27, 2024); Wulferic, LLC v. FDA, No. 24-cv-01183 (N.D. Tex. Dec. 3, 2024). The author represents the plaintiffs in each of these cases.

[8] 144 S. Ct. 2244 (2024).

[9] 467 U.S. 837 (1984).

However, the Court made clear that courts may, as they did in the pre-*Chevron* era, consider the views and expertise of the agency when determining the best interpretation of a statute.

Some commentators have predicted that the fall of *Chevron* will make it much easier to bring legal challenges to FDA decisions.[10] To be sure, the Court's decision to overrule *Chevron* is a positive development for parties who want to challenge an FDA interpretation of the Food, Drug, and Cosmetic Act ("FDCA"). But even in the post-*Chevron* world, many courts will probably continue to afford some deference to FDA, much as they did prior to *Chevron*. So, FDA-regulated companies who wish to challenge FDA interpretations of the FDCA will need to have strong arguments as to why their interpretation of the FDCA is the best one.

I. Background on Administrative Procedure Act Litigation

Most legal challenges to federal agency actions are brought under the Administrative Procedure Act ("APA").[11] Under the APA, a court may (1) "compel agency action unlawfully withheld or unreasonably delayed," and (2) "hold unlawful and set aside agency action" that is, *inter alia*, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law."[12]

APA lawsuits are brought in federal district courts. Discovery is not permitted in most APA cases, and the court does not conduct a trial in APA cases. Rather, the "district judge sits as an appellate tribunal" to review the agency's decision.[13] The court's "review is limited to the administrative record" because "it is black letter administrative law that in an APA case a reviewing court should have

[10] *See, for example*, Chad Landmon, Alexander Alfano, and 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) (stating that "if *Chevron* deference is overturned or curtailed by the Supreme Court, FDA's decisions will come under increasing scrutiny, and the floodgates will be opened to litigation against FDA and other agencies."); Liam Bendicksen, Aaron S. Kesselheim, and C. Joseph Ross Daval, *FDA and* Chevron *Deference: A Case Study*, 74 FOOD & DRUG L. J. 371, 379 (2023) ("Without the *Chevron* framework, it is unclear how courts will resolve [various] statutory ambiguities. As a result, fundamental aspects of FDA's authority may be in jeopardy, including its ability to regulate active drug ingredients, claims about a product's ability to treat disease, and the labeling of imported drug products.").

[11] *See* 5 U.S.C. §§ 701-706.

[12] 5 U.S.C. § 706.

[13] Teva Pharms. USA, Inc. v. FDA, 514 F. Supp.3d 66, 85 (D. D.C. 2020) (internal quotation omitted). The author was agency counsel for FDA in this case.

before it neither more nor less information than did the agency when it made its decision."[14]

Through various other statutes, Congress has authorized legal challenges to certain agency actions by filing a petition for review in the United States Court of Appeals for the D.C. Circuit or the petitioner's home circuit.[15] Those statutes typically require the circuit court to apply the APA's "arbitrary and capricious" standard of review.[16] Although petitions brought under these statutes are not brought under the APA, administrative law practitioners consider them to fall within the field of "APA litigation" because courts hearing the cases apply the APA standard of review.

APA litigation can involve a challenge to an agency "rulemaking" (an agency's adoption of a regulation).[17] APA litigation can also involve a challenge to an agency "adjudication" (a decision by an agency administrative law judge or a decision by an agency on a licensing or product approval application).[18]

Of course, when someone challenges an agency's decision, there may be companies or other organizations that want the court to affirm that decision. In those situations, the companies or organizations that support the agency's decision may be able to intervene as co-defendants under Federal Rule of Civil Procedure 24. This often happens in APA challenges to FDA decisions regarding drug approvals. For example, where a drug manufacturer sues FDA alleging that its generic version of a drug is entitled to 180-day Hatch-Waxman marketing exclusivity, manufacturers of other generic versions of the drug typically intervene as co-defendants in the litigation to defend FDA decision's because they do not want to be kept off the market during an exclusivity period.[19]

The government officially "takes no position" in response to a third-party Rule 24 motion to intervene as a co-defendant.

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[14] *Id.* (internal quotations omitted).

[15] *See*, *for example*, 21 U.S.C. § 360g(a) (authorizing petitions for review to challenge certain FDA decisions regarding medical devices).

[16] *See, for example*, 21 U.S.C. § 360g(c).

[17] *See, for example*, Cigar Association of Am. v. FDA, 16-cv-01460, 2022 U.S. Dist. LEXIS 139035 (D. D.C. Aug. 9, 2023) (challenge to FDA regulation deeming "premium cigars" as falling within the FDCA definition of "tobacco products").

[18] *See, for example*, Orton Motor, Inc. v. HHS, 884 F.3d 1205 (D.C. Cir. 2018) (challenge to ALJ decision assessing civil money penalty against a cigarette retailer); Amneal Pharms. LLC v. FDA, 285 F. Supp.3d 328 (D. D.C. 2018) (challenge to FDA decision denying generic drug manufacturer's request for Hatch-Waxman 180-day marketing exclusivity). The author was agency counsel for FDA in *Amneal*.

[19] *See, for example,* Teva Pharms. USA, Inc. v. Azar, 369 F. Supp.3d 183 (D. D.C. 2019). The author was agency counsel for FDA in this case.

However, in the author's experience, the government often finds the involvement of intervenor defendants to be advantageous for various reasons.[20]

II. The *Chevron* Two-Step Framework

Chevron involved a challenge to an EPA regulation that implemented the Clean Air Act's permitting requirements for certain "stationary sources" of air pollution.[21] The Clean Air Act did not define the term "stationary source," and the EPA regulation allowed states to adopt a plantwide definition of that term.[22] In other words, even if a plant included several separate stationary pollution emitting devices, the entire plant could be considered a single "stationary source."[23] Such a definition gave plant owners more flexibility in modifying their pollution emitting devices.[24]

The Supreme Court found that EPA's definition of "stationary source" was a permissible construction of the statute.[25] In doing so, the Court set forth a two-step inquiry for judicial review of "an agency's construction of the statute which it administers."[26]

At step one, a court asks, "whether Congress has directly spoken to the precise question at issue."[27] If the step one inquiry determines that "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."[28] If, however, "the statute is silent or ambiguous with respect to the specific issue," the court moves to step two, where "the question for the court is whether the agency's answer is based on a reasonable construction of the statute."[29] If the agency's construction of the statute is a reasonable one, the court defers to the agency, even if the agency's construction is not the best one (*i.e.*, the one the court would have reached in the absence of deference to the agency).[30]

In setting forth this two-step inquiry, the Court reasoned that Congress often "explicitly" or "implicitly" leaves "gaps" in a statute for the agency to fill as a

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[20] For example, intervenor defendants may be able to make arguments that an agency cannot make because the argument may be used against the agency in other cases.
[21] 467 U.S. at 839-840.
[22] *Id.* at 840.
[23] *Id.*
[24] *Id.*
[25] *Id.* at 866.
[26] *Id.* at 842.
[27] *Id.*
[28] *Id.* at 842-843.
[29] *Id.* at 843.
[30] *Id.* at 843 and 843 n.11.

matter of "policy."[31] Such "gaps" are explicit or implicit "delegation[s] of authority" to the agency.[32] And where there has been such a delegation, "a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of the agency."[33]

III. Litigation against FDA under *Chevron*

Critics of *Chevron* offered several complaints about the decision and its subsequent consequences. For example, critics contended that judges were often too quick to find a statute "ambiguous" at step one so that they could defer to the agency at step two.[34]

However, even under *Chevron*, courts frequently ruled in favor of plaintiffs who challenged FDA decisions. And they did so at both step one and step two.[35]

In fact, even in the D.C. Circuit, hardly known for being a "conservative" jurisdiction, FDA often lost APA challenges at step one.[36] And such cases were not

[31] *Id.* at 843.
[32] *Id.* at 843-844.
[33] *Id.* at 844; *see also id.* at 845 (stating that if the agency's "choice represents a reasonable accommodation of conflicting policies that were committed to the agency's care by statute, we should not disturb it unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned") (internal quotations omitted).

[34] *See, for example*, Solar Energy Industries Ass'n v. FERC, 59 F.4th 1287, 1297 (D.C. Cir. 2023) (Walker, J., concurring in part and dissenting in part) ("[w]hen no express text makes the answer immediately obvious, some [*Chevron*] maximalists make a beeline to agency deference—before any inquiry into statutory structure, cross-references, context, precedents, dictionaries, or canons of construction" and then "use the tools of statutory interpretation not to find the best reading of the text but instead to test whether the agency's interpretation is 'reasonable.'").
[35] *See, for example*, Catalyst Pharms, Inc. v. Becerra, 14 F.4th 1299, 1312 (11th Cir. 2021) ("Courts do not defer to an agency's interpretation of a statute when the text is clear. And here, the FDA's interpretation of the Orphan Drug Act is contrary to the clear statutory language enacted by Congress." (internal citations omitted)).
[36] *See, for example*, Judge Rotenberg Educ. Ctr., Inc. v. FDA, 3 F.4th 390, 396 (D.C. Cir. 2021) (finding that FDA's construction of an FDCA provision failed at step one); Genus Med. Techs. LLC v. FDA, 994 F.3d 631, 638 (D.C. Cir. 2021) ("We conclude that the FDCA's text unambiguously forecloses the FDA's interpretation."); Eagle Pharms., Inc.

limited to those decided by judges appointed by Republican presidents.[37] Even a finding of ambiguity at step one did not necessarily mean that FDA would win at step two.[38]

IV. The *Loper Bright* Decision

Loper Bright involved a challenge to a federal regulation adopted by the National Marine Fisheries Service ("NMFS"), an agency within the Department of Commerce. The regulation required commercial fishing vessels operating in United States coastal waters in the Atlantic Ocean to cover the costs of having government observers on board to collect conservation and other data.[39] Owners of vessels operating in the Atlantic challenged this regulation on the grounds that the agency did not have the statutory authority to require them to cover the costs of the observers.[40]

The NMFS administers the Magnuson-Stevens Fishery Conservation Act ("MSA"). The MSA allows the NMFS to adopt regulations requiring commercial fishing vessels operating in U.S. coastal waters to carry agency observers on board to collect data necessary for management and conservation purposes.[41] The MSA states that the NMFS may adopt regulations requiring commercial fishing vessels operating in the *North Pacific* to pay the costs associated with having observers

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v. Azar, 952 F.3d 323, 341 (D.C. Cir. 2020) (finding that FDA's construction of an FDCA provision failed at step one); Teva Pharms. USA, Inc. v. Sebelius, 595 F.3d 1303, 1318 (D.C. Cir. 2010) (holding that "the interpretation of the statute that FDA has adopted . . . fails at *Chevron* step one"); Amarin Pharms. Ireland Ltd. v. FDA, 106 F. Supp.3d 196, 217 (D. D.C. 2015) ("In this case, the Court concludes that [FDA] has exceeded the bounds of its statutory authority to interpret the exclusivity provision, and that its interpretation, accordingly, fails at *Chevron*'s first step."); Stat-Trade, Inc. v. FDA, 869 F. Supp.2d 95, 107 (D. D.C. 2012) (finding that FDA's construction of an FDCA provision failed at step one).

[37] *See, for example*, Depomed, Inc. v. HHS, 66 F. Supp.3d 217, 229 (D. D.C. 2014) (Brown Jackson, J.) (finding "no need to proceed beyond *Chevron*'s step one" because FDA's construction of the FDCA provision at issue conflicted with "the plain language" of that provision).

[38] *See, for example*, Braeburn, Inc. v. FDA, 389 F. Supp.3d 1, 23, 27 (D. D.C. 2019) (noting that a statutory "ambiguity is not a license for the FDA to adopt any interpretation it chooses," and finding at step two that "FDA has not reasonably interpreted the statute"); *Amarin Pharms. Ireland*, 106 F. Supp.3d at 217 ("Even if the statute were in relevant respects ambiguous, the FDA's interpretation would still fail at *Chevron*'s second step, which requires the Court to determine whether FDA has permissibly exercised its delegated authority.").

[39] 144 S. Ct. at 2255.

[40] *Id.* at 2256.

[41] *Id.* at 2254-2255.

on board.[42] But the MSA does not say whether the NMFS may adopt regulations requiring commercial fishing vessels operating in the *Atlantic* to pay the costs for observers.[43] Despite the MSA's silence on whether fishing vessels operating in the Atlantic can be required to pay the costs of observers, the NMFS adopted a regulation requiring vessels operating in the Atlantic to cover those costs.[44]

In a 2-1 decision, the D.C. Circuit applied *Chevron*, found that the MSA was "ambiguous" on the issue of whether the NMFS had the authority to require vessels in the Atlantic to cover the costs of observers, and found the NMFS had "reasonably" interpreted the MSA as giving the agency that authority.[45]

The Supreme Court reversed the D.C. Circuit in a 6-3 decision.[46] The Court did not address whether the NMFS acted within its authority in requiring vessels in the Atlantic to cover the costs of observers. Instead, the Court overruled *Chevron* and remanded the case for further proceedings.[47]

In overruling *Chevron*, the Court reasoned that it has always been the role of the judiciary to have the final say on the proper interpretation of federal statutes, and courts are required to determine the "best" interpretation of a statute using the traditional tools of statutory construction.[48] The Court also reasoned that granting deference to federal agency interpretations of federal statutes is inconsistent with the APA, which states that "the reviewing court shall decide all relevant questions of law."[49]

But the Court made clear that, just like in the pre-*Chevron* era, courts may "seek aid from the interpretations of [agencies] responsible for implementing particular statutes."[50] A court's reliance on such interpretations is referred to as *Skidmore* deference.[51] Under *Skidmore* deference, "the rulings, interpretations and opinions" of an agency are "not controlling upon the courts by reason of their authority," but they "do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance."[52]

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[42] *Id.* at 2255.
[43] *Id.*
[44] *Id.*
[45] *Id.* at 2256. In a separate challenge, the First Circuit also upheld the regulation at issue. *Id.*
[46] *Id.* at 2273.
[47] *Id.*
[48] *Id.* at 2257-2258.
[49] *Id.* at 2255 (quoting 5 U.S.C. § 706).
[50] *Id.* at 2262
[51] Skidmore v. Swift & Co., 323 U.S. 134 (1944).
[52] *Id.* at 140.

V. Post-*Chevron* Litigation Against FDA

Going forward, FDA-regulated companies that wish to challenge FDA interpretations of the FDCA should keep in mind that courts may still be inclined to afford some deference to FDA. Courts frequently afforded such deference in the pre-*Chevron* era.

Most notably, in *United States v. Rutherford*, when ruling in FDA's favor, the Court said that FDA's interpretation of the FDCA provision at issue was "entitled to substantial deference."[53] And in *United States v. Article of Drug Bacto-Unidisk*, when ruling in FDA's favor, the Court said that "remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health."[54]

But the Court did not simply rubber stamp FDA's decisions in *Rutherford* and *Bacto-Unidisk*. In both cases, the Court first looked to determine congressional intent through traditional tools of statutory construction, such as examination of the structure and legislative history of the statute.[55] In other words, the Court did the same thing courts did when *properly* applying *Chevron* step one.[56] It was only after the Court employed traditional tools of statutory construction in *Rutherford* and *Bacto-Unidisk* that the Court considered the issue of deference or the remedial nature of the statute.[57] That is similar to the path courts followed when they *properly* applied *Chevron* step two.[58]

Importantly, many lower courts in the pre-*Chevron* era did not read *Rutherford* or *Bacto-Unidisk* to mean that courts should reflexively defer to FDA's interpretation of the FDCA. For example, in *United States v. Generix Drug Corp.*, the Fifth Circuit acknowledged the "general proposition" that "FDA's interpretation of the Act's new drug provisions is entitled to considerable deference since the FDA is the agency charged with the responsibility of administering the Act," but the court then went on to

[53] 442 U.S. 544, 553 (1979).
[54] 394 U.S. 784, 798 (1969).
[55] *See Rutherford*, 442 U.S. at 552-553; *Bacto-Unidisk*, 394 U.S. at 793.
[56] *See Chevron*, 467 U.S. at 843 n.9 ("If a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect.").
[57] *See Rutherford*, 442 U.S. at 553-554; *Bacto-Unidisk*, 394 U.S. at 798.
[58] *See Chevron*, 467 U.S. at 844-845.

state that "this principle does not mandate that we ignore the plain language and history of the Act."[59] In *Becton, Dickinson & Co. v. FDA*, the Second Circuit found that in light of the clear congressional intent reflected in the text of the FDCA, the FDA's construction of the Act was "not warranted by the principle requiring that due regard be given to agency interpretation, or by decisions that a 'liberal construction' should be given to the [FDCA] in the interest of public health."[60]

VI. Conclusion

The Supreme Court's overruling of *Chevron* is a positive development for parties who want to challenge an FDA interpretation of the FDCA. But FDA-regulated companies that wish to challenge FDA interpretations of the FDCA will still need to have strong arguments as to why their interpretation of the FDCA is the best one.

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[59] 654 F.2d 1114, 1117 n.4 (5th Cir. 1981).

[60] 589 F.2d 1175, 1182 (2d Cir. 1978) (internal citations omitted); *see also, for example*, National Nutritional Foods Assoc. v. Mathews, 557 F.2d 325, 336 (2d Cir. 1977) ("The drug definition is to be given a liberal interpretation in light of the remedial purposes of the [the FDCA], but when an FDA determination that an article is a 'drug' is so directly in conflict with the statutory definition, it must be invalidated as arbitrary and capricious and not in accordance with law."); United States v. Phelps Dodge Mercantile Co., 157 F.2d 453, 456 (9th Cir. 1946) (holding that FDA's "clearly erroneous" interpretation of the FDCA "need not and should not be followed by the courts").