Business Litigation Update

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FDA Litigation in a Post-*Chevron* World

In *Loper Bright Enterprises v. Raimondo*, 2024 U.S. LEXIS 2882 (June 28, 2024), the U.S. Supreme Court overruled *Chevron v. National Resources Defense Council*, 467 U.S. 837 (1984), a case in which the Supreme Court held that courts should defer to a federal agency's "reasonable" construction of an "ambiguous" statute, even when a court does not believe an 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, and that courts should not simply defer to an agency's reasonable interpretation of an ambiguous statute. However, the Court made clear that courts may, as they did in the pre-*Chevron* era, consider an agency's views and expertise when determining the best interpretation of a statute.

Some commentators have predicted that *Chevron's* fall will make it much easier to bring legal challenges to FDA decisions. To be sure, the Court's decision to overrule *Chevron* is a positive development for parties who want to challenge FDA's 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 that wish to challenge the agency's interpretation of the FDCA will need to have strong arguments as to why their own interpretation is the best one.

Legal Challenges to FDA Actions

Most legal challenges to federal agency actions are brought under the Administrative Procedure Act (APA). See 5 U.S.C. §§ 701-706. Under the APA, a court may "compel agency action unlawfully withheld or unreasonably delayed" and "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." 5 U.S.C. § 706.

APA litigation can involve a challenge to an agency "rulemaking" (i.e., an agency's adoption of a regulation). See, e.g., *Teva Pharms. USA, Inc. v. FDA*, 514 F. Supp. 3d 66 (D.D.C. 2020) (challenge to an FDA regulation defining the term "protein" as that term is used to classify a medical product as a biological product). APA litigation can also involve a challenge to an agency "adjudication" (i.e., a decision by an agency administrative law judge or by an agency on a license or product application). See, e.g., *Orton Motor, Inc. v. HHS*, 884 F.3d 1205 (D.C. Cir. 2018) (challenge to an ALJ decision assessing a civil money penalty against a cigarette retailer); *Amneal Pharms. LLC v. FDA*, 285 F. Supp. 3d 328 (D.D.C. 2018) (challenge to an FDA decision denying a generic drug manufacturer's request for Hatch-Waxman 180-day marketing exclusivity).

Chevron Decision

Chevron involved a challenge to an EPA regulation that implemented the Clean Air Act's permitting requirements for certain stationary sources of air pollution. *Chevron*, 467 U.S. at 839-40. 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. *Id.* at 840. In other words, even if a plant included several separate stationary pollution-emitting devices, the entire plant could be considered a single stationary source. *Id.* Such a

definition gave plant owners more flexibility in modifying their pollution-emitting devices. *Id.*

The Supreme Court found that EPA's definition of stationary source was a permissible construction of the statute. *Chevron*, 467 U.S. at 866. 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." *Id.* at 842.

At step one, a court asks "whether Congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842. 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." *Id.* at 842-43. If, however, "the statute is silent or ambiguous with respect to the specific issue," the court moves to step two. At step two, "the question for the court is whether the agency's answer is based on a reasonable construction of the statute." *Id.* at 843. 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). *Id.* at 843 and 843 n.11.

Chevron's Practical Effects in FDA Litigation

Critics of *Chevron* offered several complaints about the decision and its subsequent consequences. For example, they 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.

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. See, e.g., *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 [FDCA] is contrary to the clear statutory language enacted by Congress.").

In fact, even in the D.C. Circuit, hardly known for being a "conservative" jurisdiction, FDA often lost APA challenges at step one. See, e.g., *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."). And such cases were not limited to those decided by judges appointed by Republican presidents. See, e.g., *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).

Moreover, even a finding of ambiguity at step one did not necessarily mean that FDA would win at step two. See, e.g., *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 v. FDA*, 106 F. Supp. 3d 197, 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.").

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 U.S. coastal waters in the Atlantic Ocean to cover the costs of having government observers on board to collect conservation and other data. Vessel owners 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.

The NMFS administers the Magnuson-Stevens Fishery Conservation and Management Act (MSA), which 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. 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 on board. 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. 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.

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. (In a companion case called *Relentless*, the First Circuit also upheld the NMFS regulation.)

The Supreme Court reversed in a 6-3 decision. It 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 cases for further proceedings.

In overruling *Chevron*, the Court reasoned that it has always been the judiciary's role 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. 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." 5 U.S.C. § 706. But the Court made clear that, just like in the pre-*Chevron* era, a federal agency's interpretation of a statute may be informative, and even persuasive, on the proper interpretation of a statute. See, e.g., *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944) (stating that although "the rulings, interpretations and opinions" of an agency are "not controlling upon the courts by reason of their authority," they "do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance").

Post-*Chevron* FDA Litigation

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, as they frequently did in the pre-*Chevron* era.

Most notably, in *United States v. Rutherford*, 442 U.S. 544, 553 (1979), when ruling in FDA's favor, the Court said that FDA's interpretation of the FDCA provision at issue was "entitled to substantial deference." And in *United States v. Article of Drug Bacto-Unidisk*, 394 U.S. 784, 798 (1969), 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."

But the Court did not simply rubber-stamp FDA's decisions in *Rutherford* and *Bacto-Unidisk*. In both cases, it first looked to determine congressional intent through traditional tools of statutory construction, such as examination of the statute's structure and legislative history. In other words, the Court did the same thing courts did when **properly** applying *Chevron*. 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."). It was only after the court employed traditional tools of statutory construction in *Rutherford* and *Bacto-Unidisk* that it considered the issue of deference or the statute's remedial nature. That is similar to the path courts followed when they **properly** applied *Chevron*. See *Chevron*, 467 U.S. at 844-45.

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. See, e.g., *United States v. Generix Drug Corp.*, 654 F.2d 1114, 1117 n.4 (5th Cir. 1981) (acknowledging the "general principle" 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 stating that "this principle does not mandate that we ignore the plain language and history

of the Act."); *Becton, Dickinson & Co. v. FDA*, 589 F.2d 1175, 1181-82 (2d Cir. 1978) (stating that in light of the clear congressional intent reflected in the FDCA's text, FDA's construction 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").

Summary

The Supreme Court's overruling of *Chevron* is a positive development for parties who want to challenge FDA's interpretation of the FDCA. But an FDA-regulated company that wishes to challenge the agency's interpretation will still need a strong argument to support its own interpretation.

FOR MORE INFORMATION

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