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A Loper Bright(er) Future?

Consideration of the US Supreme Court's Recent Changes to Administrative Law and Their Impact on US Food and Drug Administration (FDA) Law

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At the end of the 2023-2024 Term, the Supreme Court issued four key decisions that have potentially wide-ranging consequences on federal agency rulemaking, adjudication and regulatory compliance. In this article we consider the impact of these decisions on matters involving the US Food and Drug Administration (FDA), including pending rules, ongoing litigation and enforcement.

The Supreme Court's Quartet

Most significantly, *Loper Bright v. Raimondo*[1] overruled the "*Chevron*" doctrine, which for years has generally afforded deference to government agencies with respect to reasonable interpretation of ambiguous statutes. Under the *Chevron* doctrine, when there was an ambiguity in the statute, courts were sometimes required "to defer to "permissible" agency interpretations of the statutes those agencies administer—even when a reviewing court read[] the statute differently."[2] *Loper Bright* eliminates that form of deference. It is still the case that "when a particular statute delegates authority to an agency consistent with constitutional limits, courts must respect the delegation."[3] It also remains true that the APA "does mandate that judicial review of agency policymaking and factfinding be deferential."[4] However, courts are now directed to "exercise their independent judgment in deciding whether an agency has acted within its statutory authority, as the APA requires," and courts "may not defer to an agency interpretation of the law simply because a statute is ambiguous."[5]

Although somewhat overshadowed by *Loper Bright*, *Corner Post v. Board of Governors*[6] is equally important for regulated entities. Before *Corner Post*, most circuits held that for a facial challenge to agency action, the six-year statute of limitations for suing the federal government (under 28 U.S.C. § 2401(a)) runs from the time of the agency's action. *Corner Post* radically changed this understanding by holding that the six-year period for a facial challenge starts after the date of the action, when the plaintiff is injured by it.[7]

This opens the door for an entity regulated by an agency to potentially bring facial challenges to rules and regulations issued more than six years ago if the entity itself was first injured by the agency action within the last six years, such as when the entity is a newly-formed company that did not exist when the agency took the original action.

In *SEC v. Jarkesy*,[8] the Supreme Court struck down as unconstitutional the US Securities and Exchange Commission's (SEC) use of internal agency adjudications to impose civil monetary penalties for securities fraud.[9] After *Jarkesy*, defendants facing SEC civil monetary penalties have a right to a jury trial under the Seventh Amendment and Article III of the Constitution, and they must be given the opportunity to defend themselves in court, as opposed to an administrative adjudication.[10] As pointed out in Justic Sotomayor's dissent, *Jarkesy* could similarly affect at least two dozen other agencies, including the FDA, that are authorized by statute to impose civil monetary penalties in administrative proceedings.[11]

Ohio v. EPA[12] granted a stay of a US Environmental Protection Agency (EPA) rule pending juridical review of the rule by the DC Circuit. The decision made a change in the court's assessment of the four-part test used for injunctive relief, and it suggests that the likelihood of success can be enough to warrant a stay when all other factors have "strong arguments" on "[e]ach side," even on a matter that is within the agency's authority and plaintiff's only claim is that the agency action was arbitrary and capricious.[13] While the decision was based on the specific EPA rule being challenged, it may affect how lower courts assess requests to stay agency action pending review, across the board.

1 603 U.S. ___, 144 S. Ct. 2244, 219 L. Ed. 2d 832 (2024).
2 *Id.* at 2254, 2273.
3 *Id.* at 2273.
4 *Id.* at 2261 (emphasis in original).
5 *Id.* at 2273.
6 603 U.S. ___, 144 S. Ct. 2440, 219 L. Ed. 2d 1139 (2024).
7 *Id.* at 2460.
8 603 U.S. ___, 144 S. Ct. 2117, 219 L. Ed. 2d 650 (2024)
9 *Id.* at 2131-34.
10 *Id.* at 2139.
11 *Id.* at 2173-74 (Sotomayor, J., dissenting).
12 603 U.S. ___, 144 S. Ct. 2040, 219 L. Ed. 2d 772 (2024).
13 *Id.* at 2052-53.

FDA is the federal agency responsible for regulating human and veterinary drugs, vaccines and other biological products, medical devices, our nation's food supply, cosmetics, dietary supplements, electronic radiation-emitting products and tobacco products. The FDA's wide-ranging regulatory authority primarily stems from the federal Food, Drug and Cosmetic Act (FDCA). Since 1969, the Supreme Court has generally afforded FDA significant deference in interpreting the FDCA with an eye towards protecting public health.[14] Consistent with this understanding, even before the *Chevron* framework was established in 1984, courts rarely substituted their own judgment for FDA's. However, like most federal agencies, the principles of *Chevron* deference have significantly influenced the scope of FDA's authority over time. While the full impact of the *Loper Bright, Corner Post, Ohio v. EPA* and *Jarkesy* will take years to unfold, the following examines some of the current and potential effects of these cases on matters within FDA's purview.

Pharmaceutical Regulation

Federal appellate courts have found language in the FDCA related to FDA's drug regulation ambiguous in at least three cases. In *Pharmanex*, the Tenth Circuit deemed the definition of "dietary supplement" ambiguous and upheld the FDA's decision that a product with an active ingredient did not qualify, making it subject to regulation as a new drug.[15] In *Whitaker*, the DC Circuit found the overlapping FDCA definitions of "drug claim" and "health claim" ambiguous, deferring to the FDA's conclusion that a product's claim to treat a disease was a "drug claim," thus requiring regulation as a drug.[16] In *Genendo*, the Seventh Circuit found the FDCA's language on exempting certain repackaged drugs from labeling and packaging requirements ambiguous and supported the FDA's decision not to exempt these products from all requirements.[17]

These specific sections of the FDCA where the courts found ambiguity are especially vulnerable to renewed challenges in a post-*Chevron* world. Although *Loper Bright* took pains to emphasize the role of *stare decisis* for past decisions reviewing agency action, the binding nature of such precedent is jurisdictionally limited. However, it is worth noting that pre-*Chevron*, the "FDA received nearly unparallel judicial deference in its regulations of drugs."[18]

And even though courts are no longer required to defer to an agency's interpretation, as was required under *Chevron*, courts are still directed to give due consideration to the views of the relevant agency under *Skidmore v. Swift & Co.*,[19] a precedent that remains untouched by *Loper Bright*. *Skidmore* acknowledges that an agency's "rulings, interpretations and opinions … constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance," and that "[t]he weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements and all those factors which give it power to persuade, if lacking power to control."[20]

Loper Bright itself explained the role that an agency's technical expertise still plays within a *Skidmore* and post-*Chevron* framework: "[A]lthough an agency's interpretation of a statute "cannot bind a court," it may be especially informative 'to the extent it rests on factual premises within [the agency's] expertise.'"[21] "Such expertise has always been one of the factors which may give an Executive Branch interpretation particular 'power to persuade, if lacking power to control.'"[22]

While courts may be more inclined to grant *Skidmore* deference to the FDA on complex scientific or technical matters, they will not be required to do so. For example, in *Medical Center Pharmacy v. Mukasey*, the Fifth Circuit adopted its own independent interpretation of the FDCA -- separate from the FDA's and the plaintiffs' preferred interpretations-- to hold that compounded drugs are not subject to a general exemption from the definitions of "new drug" and "new animal drug."[23]

Pharmaceutical Exclusivity

In both *aaiPharma24* and *Apotex*,[25] federal circuit courts found that the Hatch-Waxman Amendments of the FDCA were ambiguous about FDA's role in the Orange Book listing process, ruling that the agency is not required to verify the correctness of Orange Book filings. However, in separate cases, the courts also determined that the Hatch-Waxman Amendments unambiguously prohibit the FDA from allowing brand manufacturers to de-list patents after paragraph IV certification,[26] but allow the FDA to do so before any paragraph IV certification is filed with the FDA.[27] In general, these cases consistently keep the FDA's role in managing the Orange Book listings ministerial. *Loper Bright* likely would not disrupt courts' recognition of FDA's ministerial role that has been established since the 2000s.

14 *U.S. v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969).

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

16 *Whitaker v. Thompson*, 353 F.3d 947, 953 (D.C. Cir. 2004).

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

18 Liam Bendicksen et al., FDA and Chevron Deference: A Case Review, 78 Food & Drug L. J. 371 (2023) (quoting DANIEL P. CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA (Princeton Univ. Press, 2010)).

19 323 U.S. 134 (1944).

20 *Id.* at 140.

21 *Loper Bright*, 144 S.Ct. at 2267 (quoting *Bureau of Alcohol, Tobacco and Firearms v. FLRA*, 464 U.S. 89, 98, n. 8 (1983)).

22 *Id.* (quoting *Skidmore*, 323 U.S. at 140).

23 536 F.3d 386 (5th Cir. 2008).

24 *aaiPharma Inc v. Thompson*, 269 F.3d 227 (4thCir. 2002).

25 *Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003).

26 *Teva v. Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010); *Ranbaxy Lab'ys Ltd. v. Leavitt*, 469 F.3d 120, 126 (D.C. Cir. 2006).

27 *Teva Pharms., USA, Inc. v. Leavitt*, 548 F.3d 103 (D.C. Cir. 2008).

The availability of alternative avenues to challenge the Orange Book listings—such as filing a counterclaim for delisting in Hatch-Waxman litigation under the 2003 MMA Amendment[28] or pursuing an increasingly popular antitrust claim as the Federal Trade Commission (FTC) intensifies its focus on improper listings[29]—further diminishes the likelihood that plaintiffs will directly contest the FDA's listing decisions, thereby limiting *Loper Bright*'s potential impact.

Several FDA decisions regarding pioneer exclusivity have been upheld under *Chevron* deference, including determinations on what constitutes an exclusivity-eligible change approved in a supplement, infringement determinations, and the agency's method for calculating patent term extensions.[30] In *Wyeth Holdings v. Sebelius*,[31] the court found FDA's method of calculating patent term extensions for patent life lost during the phased review of new animal drugs was reasonable. In *AstraZeneca Pharmaceuticals v. FDA*,[32] the court held that FDA has discretion under the FDCA to determine what constitutes an exclusivity-eligible "change approved" in a supplement. In *Otsuka Pharmaceutical Co. v. Price*,[33] the court held that FDA reasonably found that pioneer exclusivity is only infringed by a drug with the same "active moiety." These cases could be decided differently today, and there are argued cases awaiting decision which raise *Chevron* issues and may soon begin to define the limits of deference after *Loper Bright*.[34] While the court made clear in *Loper Bright* that cases decided under *Chevron* remain good law, those prior cases do not prevent parties from seeking the same relief in other courts. And, under *Corner Post,* there now is a renewed opportunity for plaintiffs to file challenges that before would have been time-barred.

Lawsuits challenging FDA's decision-making have also been prevalent in the context of rare disease treatments. However, in most of those cases, courts declined to find any ambiguity in the governing statutory provisions;[35] therefore, theoretically those cases would be decided the same way today.

Pharmaceutical/Biological Product Approvals

Cases involving challenges to FDA's scientific and medical judgment in approving new drugs and biological products have been rare, and we would expect courts to remain reluctant to wade into these highly scientific and medical matters to substitute their judgment for FDA's. However, at least one federal court was willing to do so in the context of FDA's approval of an abortion-inducing drug, mifepristone.[36] Similar challenges might be more successful in the wake of *Loper Bright* and certainly would have a longer runway to be filed under *Corner Post.*

Biosimilar Approvals and Interchangeability Determinations

In 2010, Congress enacted the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which amends the Public Health Service Act to create an abbreviated approval pathway for biological products. Under the BPCIA, a sponsor may seek approval of a "biosimilar" product if data show that the product is "highly similar" to the referenced product. The FDA may also deem such product "interchangeable," which signals to the pharmacist that the biosimilar may be substituted for the reference product without the intervention of the prescribing health care provider.

Since the adoption of the BPCIA, FDA has approved dozens of biosimilar applications and designated a handful of those products as interchangeable. The FDA's implementation of the BPCIA remains in progress, and its application of the statute and interpretation thereof has evolved over time. The FDA's interpretations of the BPCIA have the potential to significantly impact biological product sponsors and, therefore, could invite challenges, similar to those that have been raised under the Orphan Drug Act, and the Hatch-Waxman Amendments to the FDCA. *Loper Bright* and *Corner Post* could make those potential challenges more attractive means for obtaining relief.

Medical Device Regulation

In *Genus Medical Technologies v. FDA*, the DC Circuit found the FDCA, with the exception of combination products, unambiguously precluded the FDA from classifying any product that meets the statutory definition of "device" as a "drug."[37] The court stated that with the exception of combination products, "devices must be regulated as devices and drugs—if they do not also satisfy the device definition—must be regulated as drugs." Because the court declined to find any ambiguity in the FDCA, its decision would not have been altered by the Supreme Court's ruling in *Loper Bright*.

On May 6, 2024, the FDA published a final rule making explicit that in vitro diagnostic products (IVDs) are devices under the FDCA.[38] In separate letters to the Department of Health and Human Services (HHS) and FDA, Senator Cassidy (R-LA), Ranking Member of the Senate Committee on Health, Education, Labor and Pensions (HELP) requested that FDA reconsider this rule and its lawfulness under *Loper Bright*. It is foreseeable that this controversial and impactful rule could be the subject of litigation and one of the first test cases for application of the new framework of judicial review. Indeed, shortly after the rule was promulgated, industry groups filed suit against FDA seeking to vacate the rule, arguing that *Loper Bright* forecloses deference to FDA's interpretation.[39]

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28 The Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

29 FTC Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in Orange Book, issued September 14, 2023; FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book, published November 7, 2023; FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs, published April 30, 2024.

30 *See* Bendicksen, *supra* note 6, at 390.

31 *Wyeth Holdings v. Sebelius,* 603 F.3d 1291 (Fed. Cir.2010).

32 *AstraZeneca Pharm. LP v. FDA,* 713 F.3d 1134 (D.C. Cir. 2013).

33 *Otsuka Pharm. Co., Ltd. v. Price,* 869 F.3d 987 (D.C. Cir. 2017).

34 *Jazz Pharm., Inc. v. FDA,* 23-cv-01819 (D.D.C.).

35 *See Sigma-Tau Pharms., Inc. v. Schwetz,* 288 F.3d 141 (4th Cir. 2002); *Eagle Pharms., Inc. v. Azar,* 952 F.3d 323, 325 (D.C. Cir. 2020); *Catalyst Pharms., Inc. v. Becerra,* 14 F.4th 1299 (11th Cir. 2021); *c.f., Spectrum Pharms., Inc. v. Burwell,* 824 F.3d 1062 (D.C. Cir. 2016).

36 *See All. for Hippocratic Med. v. U.S. Food & Drug Admin.,* 668 F. Supp. 3d 507 (N.D. Tex.), *aff'd in part, vacated in part*, 78 F.4th 210 (5th Cir. 2023).

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

38 *Medical Devices; Laboratory Developed Tests,* 89 Fed. Reg. 37,286 (May 6, 2024).

39 *Am. Clinical Lab. Assoc. v. FDA,* 4:24-cv-479 (E.D. Tex.).

Combination Product Regulation

Product center jurisdictional matters are often the subject of litigation between industry and FDA, particularly when industry representatives challenge FDA's determination that a combination product must be classified as a drug. Such classification inherently poses more regulatory requirements on the product sponsor, including the quantum of evidence that is needed to support premarket approval. Notably, in *Prevor v. FDA*, the DC District Court found that FDA acted arbitrarily and capriciously in designating a skin wash product designed to treat chemical burn injuries as a drug-device combination product.[40] The court explained that although courts typically defer to the FDA when it is evaluating scientific data within its technical expertise, here, the agency failed to provide an explanation based on qualitative analysis or scientific information as to why it determined the primary purpose of the product was achieved by chemical action. In a post-*Chevron* world, plaintiffs may bring more challenges to FDA decisions on combination products seeking similar rulings.

Dietary Supplements

In *Nutritional Health Alliance*, the Second Circuit ruled that the FDCA did not grant the FDA authority to regulate packaging for drugs and solid dose dietary supplements for poison prevention.[41] The court found that an FDA rule requiring unit-dose packaging for supplements and drugs with thirty milligrams or more of iron per dose exceeded the FDA's authority to regulate conditions, under which a product may be adulterated. Despite the FDA's argument that the rule addressed a widespread issue of iron poisoning in children, the court stated that "the risk of accidental poisoning ... is unrelated to adulteration under any reasonable interpretation of that term."[42] Conversely, in *Nutraceutical Corp.*, the Tenth Circuit held that the FDCA "unambiguously required the FDA to conduct a risk-benefit analysis" to determine if a dietary supplement presents a significant or unreasonable risk of adulteration.[43] Because the court found the relevant FDCA provisions were unambiguous, the parameters on FDA's authority to determine when a dietary supplement is adulterated is less likely to face renewed challenges.

Regulation of Tobacco Products

In 2009, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) after the Supreme Court held the FDCA unambiguously precluded the FDA from asserting jurisdiction to regulate tobacco products. In 2021, the DC Circuit found the Tobacco Control Act unambiguously permitted the FDA to regulate cigars and pipes.[44] However, questions concerning the scope of FDA's authority to regulate novel products, such as non-tobacco nicotine (NTN) products, have received limited judicial review. Because it is an evolving legislative regulatory landscape, the industry may use the *Loper Bright* decision to challenge unfavorable FDA actions in the area.

Cosmetics

In December 2022, the Modernization of Cosmetics Regulation Act of 2022 (MOCRA) overhauled the FDA framework for the regulation of cosmetics. MOCRA imposes a series of new requirements on the cosmetics industry, including with respect to adverse event recordkeeping and reporting, facility registration and product listing, good manufacturing practices (GMPs), safety substantiation and labeling. MOCRA also requires FDA to promulgate several new regulations to implement the law, such as regulations establishing GMPs for cosmetics facilities. In the wake of *Loper Bright* and *Ohio v. EPA*, the agency will likely seek to include ample justification for any proposed rules. While more clarity in the rulemaking record may help regulated parties, it may also further slow the rulemaking process. For more details on key changes and issues under MOCRA, see our detailed post on this issue here.

OTC Drugs

FDA has recently undertaken several actions related to over the counter (OTC) drug reform. Specifically, it has been implementing the 2020 Coronavirus Aid, Relief and Economic Security (CARES) Act, which changed OTC drug regulation. Under the CARES Act, OTC monograph drugs can be marketed without an approved drug application if they meet specific requirements. Additionally, the CARES Act replaced the rulemaking process for OTC monographs with an administrative order process and allowed the FDA to establish an OTC monograph drug user fee program. In 2022, FDA proposed new requirements for nonprescription drug products with an additional condition for nonprescription use. These requirements would require applicants to implement certain measures to ensure appropriate self-selection or use without a healthcare practitioner's supervision. If these rules are challenged, they will be subject to the new *Loper Bright* framework, and not the *Chevron* deference framework the FDA anticipated when designing them.

Conventional Foods

FDA is undergoing a reorganization involving the creation of a unified Human Foods Program (HFP) to improve its oversight of the human food supply. Under this new organization—targeted for a fall 2024 implementation—FDA plans to finalize an updated definition for the nutrient content claim "healthy," as well as issue proposed regulations for front-of-package nutrition labeling. The food sector may leverage the *Loper Bright* decision to challenge these rules on grounds not previously considered under the prior *Chevron* regime. Further, FDA heavily relies on the use of guidance documents across all program areas, including conventional foods. While *Loper Bright* did not directly address guidance documents, it may have the effect of making guidance documents easier to challenge by ensuring that the agency's interpretation of a statute, contained in a guidance document or elsewhere, does not receive deference.

40 *Prevor v. Food & Drug Admin,* 895 F. Supp. 2d 90, 97 (D.D.C. 2012).
41 *Nutritional Health All. v. FDA,* 318 F.3d 92 (2d Cir. 2003).
42 *Id.* at 95.
43 *Nutraceutical Corp. v. Von Eschenbach,* 459 F.3d 1033 (10th Cir. 2006).
44 *Cigar Ass'n of Am. v. FDA,* 5 F.4th 68 (D.C. Cir. 2021).

Administrative Enforcement Through Civil Penalties

FDA has expansive authority to issue civil penalties in administrative proceedings and has most recently used that authority in enforcement against tobacco manufacturers.[45] There is one significant exception from the *Jarkesy* rule—the amorphous "public rights" exception for certain limited categories of issues historically adjudicated outside of Article III courts. (For example, administrative proceedings to penalize certain immigration offenses.) It remains to be seen to what extent FDA's administrative scheme survives *Jarkesy*. Some regulated parties have already begun challenging FDA's use of administrative proceedings; the first challenge to FDA's use of administrative proceedings was filed in late September, *Huff and Puffers, LLC v. FDA*, 8:24-cv-02110 (C.D. Cal.), challenging FDA's use of administrative proceedings to impose civil monetary penalties for violations of the FDCA.

Conclusion

In the 2023-2024 term, the Supreme Court significantly changed the legal landscape for challenging agency action, creating new opportunities to challenge agency actions in court and to bypass an agency's internal adjudication for enforcement actions. But we caution that the death of Chevron does not mean the end of all judicial deference. Courts still owe deference to agency interpretations under Skidmore, and it is difficult to imagine courts not deferring—at least in part—to FDA on highly complex and technical matters. The playing field between agencies and regulated entities is far from even, but this Supreme Court term creates new opportunities and risks to challenging agency action in court.

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45 *See* FDA News Release FDA Files Civil Money FDA Files Civil Money Penalty Complaints Against Four E-Cigarette Product Manufacturers (https://www.fda.gov/news-events/press-announcements/fda-files-civil-money-penalty-complaints-against-four-e-cigarette-product-manufacturers) (February 22, 2023).