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FDA After Chevron

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By: Aaron Savit and Ian Swan
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Under the Supreme Court's *Chevron* doctrine, courts will defer to a federal agency's interpretation of an ambiguous statute unless that interpretation is unreasonable. *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U. S. 837 (1984). In recent years, however, the Supreme Court has hinted at a shift away from *Chevron*. Several recent cases addressing agency interpretations have ignored *Chevron* entirely. See, e.g., *American Hosp. Ass'n. v. Becerra*, 142 S. Ct. 1896 (2022). And, in January of 2024, the Supreme Court heard two cases challenging *Chevron*'s viability, raising expectations that the doctrine will be overturned or significantly curtailed. See *Loper Bright Enters. v. Raimondo*, No. 22-451 (U.S.); *Relentless, Inc. v. Dep't of Commerce*, No. 22-1219 (U.S.).

Many lower courts have likewise moved away from *Chevron* and instead have more strictly applied "traditional tools of statutory interpretation." *American Hosp. Ass'n.*, 142 S. Ct. at 1906. With many jurists and industry players advancing a narrower deference doctrine, it is time to consider what limiting or eliminating *Chevron* may look like for the Food and Drug Administration and the industries it regulates.

Here, we briefly examine *Chevron*'s impact on FDA before discussing what types of FDA decisions may be subject to greater scrutiny if *Chevron* is narrowed or overturned. The

industries that FDA regulates will certainly need to be prepared for tackling FDA issues – and tackling FDA itself – in a post-*Chevron* or *Chevron*-lite world.

Chevron's Impact on FDA

The Food, Drug, and Cosmetic Act (FDCA) empowers FDA to make regulations that have the force of law provided that they are subject to public notice and comment. But FDA often treats informal guidance documents, letter rulings, and policy statements—which are not subject to notice and comment—as equally binding. FDA thus tends to exert far more authority in practice than the letter of the law would suggest.

Under *Chevron*, courts have regularly upheld FDA's statutory interpretations. For example, in *Athenex v. Azar*, the court upheld FDA's standard for nominations to its bulk substance list, rejecting a challenge to the agency's interpretation of "clinical need" as used in Section 503B of the FDCA. 397 F. Supp. 3d 56, 63-74 (D.D.C. 2019).

Similarly, the court in *Sanofi-Aventis U.S. v. Food and Drug Administration* adopted FDA's interpretation of the "full description" requirement of 21 U.S.C. § 355(b)(1)(D), which allowed FDA to require immune response data as part of an abbreviated new drug application. 842 F. Supp. 2d 195, 210 (D.D.C. 2012). It likewise upheld as reasonable the FDA's five-pronged approach to determining active ingredient "sameness" for proposed generic drugs. Id. at 212-14.

These cases are two of the many examples in which *Chevron* has allowed FDA's statutory interpretations to carry the day. By directing courts to defer to any reasonable agency interpretation of an ambiguous statutory provision, *Chevron* often gives broad discretion to FDA. Eliminating or scaling back *Chevron* would thus expose FDA's decisions and interpretations to greater judicial scrutiny.

Likely Challenges to FDA Decisions

Eliminating or modifying *Chevron* will likely increase scrutiny of FDA actions across the board, but FDA interpretations that do not involve the Agency's scientific or technical knowledge will be particularly vulnerable to legal challenges absent agency deference. For example, the Supreme Court has previously held that, for an agency's interpretation of its own rule to be entitled to deference, "the agency's interpretation must in some way implicate its substantive expertise." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2404 (2019).

In this context, the point is frequently made that judges must decide legal questions but avoid policy-making. But in the recent oral arguments for *Relentless* and *Loper Bright*, the Justices disagreed as to where to draw the line between questions of policy and questions of law.

More liberal Justices, like Justice Kagan, stressed that agency experts were suited to make tough, policy-influenced calls when a statute doesn't provide a clear answer. On the other hand, more conservative Justices, like Justice Gorsuch, suggested that courts can use the traditional tools of statutory interpretation to resolve most questions of regulatory authority without deferring to an agency. Justices Alito and Kavanaugh, fellow *Chevron* skeptics, noted that courts never seem to find statutes overly ambiguous in cases that do not involve federal agencies.

The Justices' questions at oral argument made clear that technical issues are more likely to need the expert input that agencies provide. Thus, if the Supreme Court limits or overturns *Chevron*, agency interpretations involving legal or factual issues will come under closer judicial scrutiny compared to those that deal solely with scientific or technical questions.

Challenges to FDA's Legal Interpretations

Certain legal or factual questions that do not implicate agency expertise will be particularly vulnerable to challenges if *Chevron* is narrowed or eliminated. One example is FDA's interpretation of the forfeiture provisions relating to the 180-day exclusivity marketing period available to generic drug applicants. The first generic applicant to file an abbreviated new drug application (ANDA) challenging a patent owned by a brand company can receive a 180-day period of marketing exclusivity, during which the FDA is barred from approving any later-filed ANDAs.

This exclusivity period begins on the date that the first applicant begins to market its generic drug. Following a 2002 report by the Federal Trade Commission (FTC) that detailed certain anticompetitive abuses of the exclusivity period, Congress amended the FDCA in 2003, in the Medicare Modernization Act (MMA), to specify instances in which first applicants would forfeit the 180-day exclusivity period. 21 U.S.C. § 355(j)(5)(D) ; Pub. L. No. 108-173 .

There are multiple forfeiture provisions in the MMA, and FDA's interpretations of those forfeiture provisions have repeatedly been upheld by courts applying *Chevron* deference. For instance, one court rejected a challenge to FDA's determination that the forfeiture trigger in 21 U.S.C. § 355(j)(5)(D)(i)(IV) could be applied retroactively, in an instance where a grant of tentative approval was later rescinded. See *Ranbaxy Lab'ys, Ltd v. Burwell*, 82 F. Supp. 3d 159, 198 (D.D.C. 2015).

Courts have also upheld FDA's forfeiture determinations under 21 U.S.C. § 355(j)(5)(D)(i)(IV) regarding whether a change occurred in the requirements for approval of an ANDA, and whether that change "caused" an ANDA applicant's failure to obtain tentative approval. See *Amneal Pharms. LLC v. Food & Drug Admin.*, 285 F. Supp. 3d 328, 350 (D.D.C. 2018); *Mylan Lab'ys Ltd. v. U.S. Food & Drug Admin.*, 910 F. Supp. 2d 299, 306-310 (D.D.C. 2012).

Despite relatively frequent challenges to FDA's interpretations of exclusivity forfeiture provisions, the Agency has prevailed many times in court, thanks in no small part to *Chevron* deference. If *Chevron* is weakened or overturned, FDA's success rate in court may decline at the same time that challenges to its decisions pick up. Because FDA's forfeiture determinations are based largely on its statutory interpretation and not on its scientific expertise, those decisions would be particularly vulnerable to legal challenges if the Supreme Court limits *Chevron* or dispenses with it entirely.

Challenges to FDA's Scientific Determinations

Expertise-based agency determinations may still face increased scrutiny without *Chevron*, but they would likely be less vulnerable than law-based determinations. FDA regularly makes scientific decisions involving substantive agency expertise. Even before *Chevron*, courts recognized that FDA had valuable, field-specific knowledge. See, e.g., *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 654 (1973) (noting that "[t]he determination of whether a

drug is . . . effective . . . necessarily implicates complex chemical and pharmacological considerations" and is "the kind of issue[ ] peculiarly suited to initial FDA determination").

Notably, in the *Relentless* oral argument, Justice Kagan highlighted the importance of agency expertise. Justice Kagan questioned whether judges were fit to answer scientific or technical questions in the absence of explicit statutory guidance, asking whether a court should determine if a new product that promotes healthy cholesterol levels is a "dietary supplement" or a "drug." *Relentless Tr.* at 30:17-31:6.

Fish oil-based products are a prime example of how FDA distinguishes between drugs and supplements. FDA has approved two new drug applications (NDAs) for fish-oil based products (Vascepa® and Lovaza®), as well as a number of generic equivalents. But, there are also myriad fish oil-based dietary supplements that are not subject to the same regulatory requirements and cannot make the same efficacy claims.

Drug labels may claim that their product will diagnose, cure, mitigate, treat, or prevent a disease. But FDA limits health claims that can be made by supplements to reciting a "reduced risk of a disease or health-related condition . . . ." A drug must undergo an extensive FDA approval process, including clinical trials, to be legally marketed in the United States, while a supplement does not.

Perhaps unsurprisingly, courts have deferred to FDA's approach to differentiating fish oil-based drugs from fish oil-based supplements. In *Amarin Pharmaceuticals v. International Trade Commission*, for example, the NDA holder for Vascepa sought relief from the International Trade Commission (ITC) to stop imports of synthetic omega-3 dietary supplements derived from fish oil. *Amarin Pharma, Inc. v. Int'l Trade Comm'n*, 923 F.3d 959 (Fed. Cir. 2019). Amarin accused other companies of "falsely labeling and deceptively advertising" their imported products containing synthetic omega-3 as "dietary" supplements when they were actually "new drugs" under the FDCA. When the ITC refused to investigate, Amarin sued the Commission.

On appeal, the Federal Circuit affirmed the Commission's refusal and was generally deferential to FDA's technical assessment of the difference between drugs and dietary supplements. The Court noted that FDA approval is not required for dietary supplements and refused to recognize Amarin's claim "under § 337 where that claim is based on proving violations of the FDCA and where the FDA has not taken the position that the articles at issue do, indeed, violate the FDCA." Although the Federal Circuit deferred to FDA's substantive expertise on the issue, if *Chevron* is significantly narrowed, even decisions that involve Agency expertise may be subjected to closer scrutiny.

Without its *Chevron* advantage, FDA's more scientific or technical determinations will likely continue to receive a greater degree of deference than its purely legal determinations. Agency decisions that do not implicate FDA's substantive expertise will be challenged more frequently and likely overturned at greater rates.

Some Supreme Court Justices have asserted that almost any agency interpretation can be assessed by looking at the text, structure, and purpose of a statute, suggesting that deference to agencies should be the exception rather than the rule. See, e.g., *Relentless Tr.* at 82:25-83:5. But courts have historically been hesitant to second-guess the determinations of subject-

matter experts regarding the underlying science. If *Chevron* deference is significantly curtailed, courts will certainly be more active in scrutinizing FDA's determinations – both scientific and legal – and question more closely whether FDA deviated from statutory proscriptions.

Will FDA's Informal Rulemaking Survive?

If *Chevron* is limited or overturned, FDA's informal rulemaking practices could also come under close scrutiny. FDA routinely treats informal guidance documents, letter rulings, and policy statements as having the force of law, even though they are not subject to the public notice and comment process that such enforceability requires. If *Chevron* is narrowed or eliminated, regulated industry may be emboldened to challenge FDA's routine use of interpretive rules to make decisions with relatively little public input.

At oral argument, comments from Justice Gorsuch appeared to criticize FDA's routine reliance on informal guidance. During the *Loper Bright* oral argument, he noted that "agencies rely on informal adjudications and informal rulemakings. And really now today, perhaps as a product of *Chevron* . . . agencies have . . . abdicated that and are moving more and more toward interpretive rules where they don't have to provide notice-and-comment." *Loper Bright Tr.* At 73:4-73:16. Justice Gorsuch thus seemed to imply that *Chevron* has been interpreted by the agencies as granting them overbroad rulemaking power.

But Justice Gorsuch was clearly signaling to lower courts and regulated industry that he views such practices with suspicion. A decision narrowing or overturning agency deference would leave FDA's rulemaking practices more vulnerable to legal challenges. In the long run, greater scrutiny of FDA's reliance on interpretive rulemaking could cause the Agency to more regularly move forward with formal notice-and-comment rulemaking.

Without the advantage it has historically enjoyed from *Chevron*, FDA may also become more responsive to input from the public and regulated industry. Given that the days of *Chevron* in its current state are likely numbered, pre-litigation advocacy before FDA may become more important and may have a greater chance of success.

Conclusion

With the Supreme Court poised to limit or overturn *Chevron* deference, FDA will likely face an influx of litigation challenging its decisions. Legal and regulatory-based decisions that do not implicate the agency's substantive expertise will be the most vulnerable to scrutiny. But science-based determinations may not be fully insulated from judicial scrutiny, either. Courts will closely assess whether FDA's science-based determinations conform to the letter of the law. And without *Chevron* to protect it, FDA may be less willing to try its luck in court and thus more responsive to proactive advocacy by regulated industry and the general public.

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