Kisor May Be A New Dawn For Challenges To FDA Actions

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In Kisor v. Wilkie[1] — a closely watched case decided in a closely divided opinion toward the end of the U.S. Supreme Court's last term — the court upheld the doctrine of Auer deference, much to the surprise of many given the court's new conservative majority. Although technically a win for the government, the decision recast Auer deference in a manner likely to have the practical effect of eroding the ability of administrative agencies to rely upon the doctrine as a complete defense to legal challenges.

This article examines the potential impact of Kisor on firms regulated by the U.S. Food and Drug Administration and other agencies that rely heavily on scientific and technical expertise. While Kisor does not represent a fatal blow to administrative agencies seeking to invoke deference, the opinion provides heavily regulated entities with more ammunition to push back on arguments for deference, particularly when bringing certain kinds of Administrative Procedure Act claims.

The case also provides additional cover for judges conceptually uncomfortable with Auer to examine agency actions more closely. Future cases citing Kisor may continue to undermine the jurisprudence the FDA and other agencies have long relied upon to insulate their actions from substantive judicial scrutiny. That said, Kisor and related cases also highlight the types of circumstances in which courts are likely to continue to rely on Auer, notwithstanding the directional shift.

Key Takeaways for FDA-Regulated Entities

Few administrative agencies oversee as technically complex and broad-reaching a body of regulations as the FDA. The FDA has primary responsibility for regulating the development, manufacture and distribution of human and animal drugs, biologics, and medical devices; most processed and unprocessed foods; tobacco products; and cosmetics.

Its oversight requires significant scientific and medical expertise to establish, among other responsibilities, the requirements and standards for developing new products and evaluating their safety and efficacy; to assess and respond appropriately to health risks posed by products once they are on the market; and to evaluate whether manufacturers' claims about various regulated products are supported by scientific evidence.

Similarly, few agencies have been the subject of as much litigation as the FDA in recent years. Cases range from First Amendment challenges to the constitutionality of restrictions on pharmaceutical promotion; to APA and other statutory challenges to FDA rules and adverse administrative actions (including clinical trial holds, complete response letters, and marketing application denials); to basic jurisdictional challenges to the agency's ability to regulate certain products.

As FDA-regulated entities consider the feasibility of challenges to adverse FDA actions, Kisor will likely impact the analysis in several ways.

There are now multiple avenues to attack the applicability of Auer.

The Supreme Court's decision in Kisor means that the FDA can continue to invoke Auer deference as one of its defenses during litigation. However, even the opinion upholding Auer in principle sets forth a number of (relatively stringent) requirements that must be met in order for Auer to apply.

In seeking to reassure skeptics that Auer is not boundless — and, perhaps, to secure needed support from Chief Justice John Roberts — the opinion delivered by Justice Elena Kagan for the court gives those challenging FDA action multiple avenues to assert that Auer deference is not appropriate in a given situation.

For example, Kisor makes clear that "a court cannot wave the ambiguity flag just because it found the regulation impenetrable on first read" and must instead, before determining a rule to be genuinely ambiguous, consider "the text, structure, history, and purpose of a regulation, in all the ways it would if it had no agency to fall back on."[2] Similarly, if the FDA's position appears to be merely a "'convenient litigating position' or 'post hoc rationalizatio[n] advanced' to 'defend past agency action against attack,'" no deference is due.[3]

Further, Auer may be harder for the FDA to invoke in response to a claim that the FDA's interpretation of the regulation is inconsistent with the regulation's plain meaning, or with a position the FDA has taken in the past. In post-Kisor cases involving such challenges to other agencies' actions, courts have cited Kisor and refused to apply Auer deference (though, to be fair, the cases citing Kisor in this context have thus far tended to involve strained readings of regulations or overt changes in agency policy that courts may have rejected even before Kisor clarified the scope of Auer deference).[4]

Nevertheless, guardrails set forth in Kisor will likely operate to prevent the FDA from taking convenient litigating positions not supported by its specialized technical expertise, and more generally from taking actions inconsistent with FDA regulations. For this reason, Kisor may limit the extent to which an agency's interpretation of a regulation can evolve in the absence of further rulemaking.

The FDA will very likely continue to receive deference in certain cases.

While Kisor therefore may lead to more challenges to the applicability of Auer deference, there are many situations where the FDA is likely to continue to prevail in invoking this form of judicial deference. In particular, the plurality opinion in Kisor observes that most judges "probably have no idea of what a [technical FDA] rule means," and that where "a rule is technical" or "implicate[s] policy expertise," it remains appropriate to defer to the agency.[5]

In other words, where an issue is a technical one that is best judged by experts at an agency (e.g., scientific experts at the FDA who understand the implications of a particular data set on a drug's potential safety or efficacy, or who understand what kind of testing must be conducted to demonstrate the biocompatibility of materials used to manufacture an implanted device), and are not instead "interpretive issues [that] fall more naturally into a judge's bailiwick," Kisor suggests that Auer deference continues to be warranted.[6]

This distinction between legal interpretation and factual expertise is not new to Kisor. For example, in National Cable & Telecommunications Association v. Brand X Internet Services,[7] a Chevron case dealing with the Federal Communication Commission's interpretation of the Communications Act of 1934 (as amended by the Telecommunications Act of 1996), Justice Clarence Thomas, writing for the court, noted that Chevron deference was appropriate in part because the relevant question "[turned] not on the language of the Act, but on the factual particulars of how Internet technology works and how it is provided, questions Chevron leaves to the Commission to resolve in the first instance."[8]

In other words, the Supreme Court has signaled for some time that agencies are entitled to more deference under Chevron (and Auer) when they are dealing with factual issues uniquely within their expertise.

As a result, arguments that the FDA has erred by failing to abide by the plain meaning of its regulations may be more likely to gain traction post-Kisor. However, arguments that the FDA should defer to a challenger's superior interpretation of clinical data or scientific conclusions may continue to face hurdles, as the Kisor plurality opinion suggests that such technical and scientific inquiries are often best resolved by administrative agencies.[9]

The FDA will be forced to justify its actions.

Regardless of whether a court ultimately finds that Auer deference is warranted, Kisor suggests that courts must conduct a more careful review to ensure that Auer applies.[10] This, in turn, means that the FDA will be required to more fully justify any invocation of deference.

Post-Kisor, the FDA may face difficulty invoking Auer deference where it cannot demonstrate that its actions are evidence-based and that they comported with prescribed administrative processes. For example, Kisor clarifies that no deference is warranted when an interpretation advanced by an agency does not "emanate from those actors, using those vehicles, understood to make authoritative policy in the relevant context."[11]

Kisor also approvingly cites a case from the U.S. Court of Appeals for the Seventh Circuit declining to defer to a statement in an agency regulatory guide that the agency itself had disclaimed as authoritative.[12] Accordingly, should a litigant challenge the application of a nonbinding guidance document, the FDA may be hard-pressed — given the disclaimers it typically attaches to such guidance documents as well as the characterization of guidance documents in the FDA's own Good Guidance Practice regulations[13] — to assert that Auer deference is warranted based on the guidance alone.

It is possible that Kisor could lead the FDA to reconsider the method by which it issues rules, regulations, warning letters and other documents. And, for prospective litigants that feel they have been given the runaround by the agency — or are seeking explanations the FDA is reluctant to provide — Kisor may make it easier to obtain those answers in court.

The assigned judge is more key than ever.

Justice Neil Gorsuch's de facto dissent in Kisor asserts that the "decision to adorn Auer with so many new and ambiguous limitations" guarantees further litigation over Auer's scope, and expresses the "hope that ... judicial colleagues on other courts will take courage from today's ruling and realize that [Kisor] has transformed Auer into a paper tiger."[14] At the very least, the fragmented Kisor opinion gives lower court judges room to take varying tacks.

A judge sympathetic to the rationales supporting Auer deference must now contend with the limitations set forth in Kisor, but remains free to apply Auer deference if the judge, following a thorough and reasoned consideration of those enumerated factors, believes that deference is warranted. By contrast, a judge with a perspective similar to that of Justice Gorsuch may now indeed take courage from Kisor, and accept the invitation set forth in several of the Kisor opinions to apply a rigorous textual review to regulations and defer only where the agency's interpretation has "the power of persuasion."[15]

One recent case may foreshadow the transformed but still very present fault lines in administrative litigation following Kisor. In Alon Refining Krotz Springs Inc. v. U.S. Environmental Protection Agency,[16] the U.S. Court of Appeals for the D.C. Circuit considered the EPA's obligation under the Clean Air Act to publish renewable fuel standards each year and disputed language in the EPA's implementing regulations regarding how often it must actually reevaluate such standards.

The majority cited Justice Brett Kavanaugh's concurring opinion in Kisor for the proposition that the State Farm standard of review, rather than Chevron or Auer, supports the principle that agencies can use broad language in regulations and then exercise their discretion to select from multiple reasonable interpretations supported by the text. The majority ultimately found reasonable the EPA's interpretation.[17]

The concurring judge, on the other hand, cited Kisor in his criticism of what he viewed as the majority's reflexive deference to the EPA, arguing that the majority had failed to apply any of the "'traditional tools' of statutory construction" before waving "'the ambiguity flag.'"[18] The majority, inclined to defer to the EPA, shied away from embracing Auer; the concurrence, inclined not to defer, found support in Kisor. While Kisor thus does not resolve the divergence in opinions with respect to administrative deference, it may ultimately shift the center of the conversation away from deference.

In short, Kisor will almost certainly provoke more litigation, and the outcome of post-Kisor challenges will likely vary. If a litigant challenges an FDA action and is assigned a judge sympathetic to Auer, there may now be a more reasoned opinion that arrives at the same outcome of deference.

If a litigant challenges an FDA action and is assigned a judge unsympathetic to Auer, by contrast, there is a greater probability than in the past that the judge will decline to grant the FDA deference (and, in turn, rule against the FDA on the merits if the FDA's arguments are not persuasive). Administrative litigation may therefore become, at least for a time, both more ideological and more unpredictable. As a result, challenging the FDA in court could become an even more attractive proposition.

Chevron could be in the crosshairs.

Auer was saved by the vote of Justice Roberts, who elected to side with Justice Kagan in determining that "overruling those precedents is not warranted."[19] Justice Roberts cites the invocation of agency expertise as a potential rationale for retaining Auer deference in certain cases, because it is the agency that writes the regulations.

He then notes that "[issues] surrounding judicial deference to agency interpretations of their own regulations are distinct from those raised in connection with judicial deference to agency interpretations of statutes enacted by Congress," and he stresses that the decision in Kisor to preserve Auer does not address the latter question (governed by Chevron).[20]

One interpretation of this aside is that the chief justice simply wished to signal that Auer and Chevron are not doctrinally identical. Another interpretation is that the note communicates the view of the court's conservative majority that certain policy arguments for upholding Auer do not apply to statutory interpretation.

Indeed, the court conceded that legal interpretations (as opposed to issues dependent on scientific or technical expertise) are within the bailiwick of judges. Thus, Kisor could signal that Chevron — which sets forth a rule of deferring to agencies on precisely these seemingly more legal questions — would be vulnerable to the kind of head-on challenge that Auer ultimately (albeit narrowly) survived.[21]

Were Chevron to fall, the FDA would no longer be entitled to deference on its interpretation of the Federal Food, Drug and Cosmetic Act. That would be a dramatic development that could invite an open season on challenges to administrative agency action.

We are not at that point yet, but Kisor suggests that the future of deference to agency interpretations of statutes is not bright. FDA-regulated parties — and the FDA itself — should take note, and hone their powers to persuade.

Conclusion

While not a blockbuster win for either side, Kisor created a series of new ambiguities that will take some time to iron out. In the four months since the decision has issued, the case has been cited frequently, and with mixed results.

However, Kisor has not yet been cited by a court assessing a direct challenge to an FDA interpretation of its own regulation. Further cases, particularly those with more challenging facts and a direct focus on the FDA, will provide greater clarity regarding the ongoing vitality of Auer, and the magnitude of Kisor's impact on FDA-regulated entities.

What does seem clear already, however, is that the FDA faces a more uncertain future than it did pre-Kisor. Although the FDA will often continue to receive deference in cases involving application of its specialized scientific knowledge to specific factual circumstances, plaintiffs will be empowered to demand that the FDA justify its actions, conform to administrative formalities and apply consistent reasoning throughout the administrative process. Where the FDA fails to do so, its actions have never been more vulnerable to legal challenge.

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[1] 139 S. Ct. 2400 (2019).

[2] Id. at 2415.

[3] Id. at 2417 (quoting Christopher, 567 U.S. at 155).

[4] See, e.g., Romero v. Barr, No. 18-1850, 937 F.3d 282, 292, 295-96 (4th Cir. 2019) (holding that the regulation at issue unambiguously conferred the Board of Immigration Appeals ("BIA") with the authority to administratively close cases and that BIA's new interpretation to the contrary would create "unfair surprise" and disrupt the expectations of the parties.); Sec'y of Labor v. Seward Ship's Drydock, Inc., 937 F.3d 1301, 1308-10 (9th Cir. 2019) (refusing to defer to an Occupational Safety and Health Review Commission ("OSHRC") interpretation of an OSHA regulation that conflicted with its own previous interpretations of the regulation, as well as the interpretation of the Secretary of Labor, in connection with the obligation of employers to evaluate respiratory hazards in the workplace to determine whether respirators must be provided, because the regulation was unambiguous and the purpose of the regulation was clear from the regulatory history).

[5] Kisor, 139 S. Ct. at 2413, 2417 (plurality opinion).

[6] Id. at 2417.

[7] 545 U.S. 967 (2005).

[8] Id. at 991.

[9] This distinction has been borne out in at least some, post-Kisor decisions. Compare United States v. Brace, No. 1:17-cv-00006 (BR), 2019 WL 3378394, at *20-21 (W.D. Pa. Aug. 12, 2019) (deferring to the Army Corps of Engineers' definition of what constitutes "wetlands" because of the ambiguity of the relevant regulation, because "the determination of whether wetlands exist on a given site is a highly technical matter of science" and because the Corps' interpretation was reasonable) with Braeburn Inc. v. FDA, 389 F. Supp. 3d 1 (D.D.C. 2019) (finding that FDA's interpretation of the new drug exclusivity provisions under 21 U.S.C. § 355(c)(3)(E)(iii) was unreasonable and inconsistent with historical precedent, and, accordingly, should not be afforded deference despite the fact that such interpretation concerned an issue of scientific judgment).

[10] This review may in a given case include, inter alia, assessment of the regulatory language and history, prior agency interpretations of the same language, and the substantive arguments supporting an agency's interpretation.

[11] Kisor, 139 S. Ct. at 2416. By contrast, where an agency is speaking authoritatively, it may continue to receive deference. See, e.g., Am. Tunaboat Ass'n v. Ross, 391 F. Supp. 3d 98, 114-15 (D.D.C. 2019) (affording deference because "the Service's interpretation here is the 'official position' of the agency" and concluding that, "[g]iven that deference, it follows that the Service's decision was not arbitrary or capricious").

[12] Kisor, 139 S. Ct. at 2417 (quoting Exelon Generation Co. v. Local 15, Int'l Bhd. of Elec. Workers, 676 F.3d 566, 576-78 (7th Cir. 2012)).

[13] 21 C.F.R. § 10.115.

[14] Kisor, 139 S. Ct. at 2426 (Gorsuch, J., concurring in the judgment).

[15] Id. at 2424-26.

[16] 936 F.3d 628 (Aug. 10, 2019).

[17] Id. at 648-59, 668.

[18] Id. at 675 (quoting Kisor, 139 S. Ct. at 2415).

[19] Kisor, 139 S. Ct. at 2424.

[20] Id. at 2425.

[21] Notably, Chief Justice Roberts did not join Section II-A of Justice Kagan's opinion, describing fact-intensive circumstances where deference is warranted, but did join Section II-B, where the Court observes that deference is less warranted for purely legal matters.