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Implications of Loper Bright & Relentless for HHS-Regulated Entities

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The U.S. Department of Health and Human Services (HHS), and its agencies the Centers for Medicare & Medicaid Services (CMS) and the Federal Food and Drug Administration (FDA), are repeat defendants in federal court actions challenging their statutory interpretations. For decades, HHS appeared to have an upper hand in these cases, as federal courts employed the *Chevron* two-step framework in determining when to defer to HHS agencies' statutory interpretations. The Supreme Court has recently moved away from applying that doctrine, however, and is poised to decide its future this term as it decides a pair of cases directly challenging it: *Loper Bright Enters. v. Raimondo*, No. 21-5166 (filed Nov. 10, 2022); and *Relentless, Inc. v. Dept. of Commerce*, No. 22-1219 (filed Jun. 14, 2023).

Parties regulated by HHS might relish a further move away from judicial deference to agency interpretations. However, a review of recent jurisprudence involving challenges to federal agencies' statutory interpretations suggests the impact of such a ruling may be more limited than expected at first blush. Following recent precedent of the Supreme Court, some appellate courts have already refrained from applying *Chevron*. A diminished *Chevron* would most affect district courts that have been continuing to follow *Chevron* and would potentially need to dust off traditional tools of statutory interpretation to determine the best statutory reading themselves.

Depending on the exact nature of the Court's decision, all courts could face a new standard for reviewing statutory constructions. Agencies that cannot convince courts of their statutory interpretations may more often need to seek Congressional support for their policy priorities that, given the political environment, may not exist. Not likely to reverse the trend away from judicial deference to agencies' statutory constructions, the real impact of the two cases now before the Supreme Court depends on the precise nature of the Court's ultimate analysis.

Declining Deference to Agency Interpretations

In *Chevron USA, Inc.* v. *NRDC*, the Supreme Court considered whether challenged Environmental Protection Agency (EPA) regulations were "based on a reasonable construction of the statutory term, 'stationary source.'" **467 U.S. 837**, **850** (1984). The Court upheld the EPA regulations, introducing a two-step framework for reviewing disputed statutory interpretations.

At step one, *Chevron* instructs courts to determine whether Congress has "directly spoken to the precise question at issue." If the answer is yes, the inquiry ends, and the court "must give effect to the unambiguously expressed intent of Congress." If, however, the statute is "silent or ambiguous" on the issue in question, the court proceeds to step two, wherein it must defer to the agency's statutory interpretation if it is "based on a permissible construction of the statute."

In the early 2000s, the Supreme Court began to limit *Chevron*'s scope by instructing federal courts to engage in what legal scholars, including **Professor Cass Sunstein**, have called "*Chevron* Step Zero—the initial inquiry into whether the *Chevron* framework applies at all." For example, in *FDA* v. *Brown & Williamson Tobacco Corp.*, **529 U.S. 120**, **159**–60 (2000), the Court suggested *Chevron* deference may be inappropriate when the statutory ambiguity pertains to "major questions." In *U.S.* v. *Mead Corp.*, **533 U.S. 218**, **226** (2001), the Court opined that agency statutory interpretation is only entitled to *Chevron* deference when it is declared with "the force of law," such as in regulations promulgated through notice-and-comment rulemaking.

The Court directed that interpretations that fail to qualify for *Chevron* deference, such as those contained in non-binding guidance documents, may still "deserve[] some deference under *Skidmore*." In the pre-*Chevron* case, *Skidmore v. Swift*, **323 U.S. 134**, **140** (1944), the Supreme Court addressed whether "waiting time" constituted "working time" under the Fair Labor Standards Act, and held that "the weight" the agency's interpretation should be accorded depends on "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."

Over the past decade, *Chevron* has largely disappeared from the Supreme Court's jurisprudence. In 2019, the Court expressly declined to consider the application of *Chevron* when the government failed to invoke it. See *HollyFrontier Cheyenne Refin., LLC* v. *Renewable Fuels Ass'n,***141**

S. Ct. 2172 (2021). The following year, the Court issued a ruling which stated that although the government did not ask for *Chevron* deference, the agency's views were still entitled to some respect under *Mead* and *Skidmore*. See *City of Maui v. Haw. Wildlife Fund*, 140 S. Ct. 1462, 1474 (2020).

The doctrine's diminished role became very evident in 2022, when the Court decided a trio of cases involving questions of statutory interpretation without referencing *Chevron*.

• ***West Virginia*** v. *EPA*, 142 S. Ct. 2587, 2610 (2022). Relying on the "major questions" doctrine in a dispute over EPA's statutory authority.

• ***Am. Hosp. Ass'n*** ("*AHA*") v. *Becerra*, 142 S. Ct. 1896, 1904 (2022). Concluding the "text and structure of the statute" foreclosed the challenged HHS interpretation without addressing *Chevron*).

• ***Becerra*** v. *Empire Health Found. ("Empire")*, 142 S. Ct. 2354, 2362 (2022). "[A]pprov[ing] HHS' understanding of the Medicare fraction" without engaging in a *Chevron* analysis.

Another sign of the Supreme Court's growing skepticism of judicial deference to agencies came with its ruling in *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019). The case involved *Auer v. Robbins*, 519 U.S. 452 (1997), which directs federal courts to defer to reasonable agency interpretations of ambiguous regulations. The Court did not abandon *Auer*, instead narrowing it by introducing new guardrails around its application, including requiring the exhaustion of all "traditional tools of statutory construction" before finding a regulatory provision ambiguous, and clarifying the reasonableness standard.

While the Supreme Court has recently declined to apply *Chevron*, federal district and appellate courts generally have followed the precedent in challenges to agency statutory interpretations.

• **Avon Nursing & Rehab. v. Becerra**, 667 F. Supp. 3d 47, 60 (S.D.N.Y. 2023). Finding HHS rule consistent and reasonable and holding it "must be afforded deference under the *Chevron* framework."

• **Cigar Ass'n of Am. v. FDA**, 5 F.4th 68, 77 (D.C. Cir. 2021). Affirming the grant of summary judgment to FDA after "appl[ying] the familiar *Chevron* two-step framework" to the agency's interpretation of the Tobacco Control Act.

When lower courts have declined to defer under *Chevron* in adjudicating disputes over statutory interpretation, they have rooted their reasoning in other Supreme Court precedent.

• **Torres v. Del Toro**, 2022 BL 35742, *6 (D.D.C. 2022). Holding *Chevron* deference not warranted because the statutory provision is unambiguous on the point at issue.

• **Residents of Gordon Plaza, Inc. v. Cantrell**, 25 F.4th 288, 298 (5th Cir. 2022). Declining to grant *Chevron* deference to an agency interpretation contained in a proposed rule not "carrying the force of law."

Of note, appellate court reversals of district court decisions to defer to agency interpretations often have arisen when the appellate court has disagreed on the step-one ambiguity question, or because the government did not renew calls for *Chevron* deference on appeal. See, e.g., *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021); *Texas v. Becerra*, 89 F.4th 529, 541 (5th Cir. 2024).

Outside of the courts, regulated parties and their legislators have **sought to overturn** *Chevron* through amending the Administrative Procedure Act to authorize courts reviewing agency actions to decide interpretive questions, whether arising in statutes, regulations or interpretive rules, *de novo*, but have yet to be successful.

Loper Bright* & *Relentless

Both *Loper Bright* and *Relentless* involve challenges to a National Marine Fisheries Service (NMFS) rule requiring commercial fishing vessels to pay fees associated with carrying mandatory compliance monitors on their boats in the Atlantic. Plaintiffs allege the governing statute did not authorize this mandate. Although both Courts of Appeals upheld the challenged rule, their reasoning differed. The D.C. Circuit deferred to NMFS under *Chevron* step two, finding the agency's interpretation to be a "reasonable interpretation of its authority" amid statutory ambiguity. *Loper Bright Enters. v. Raimondo*, 45 F.4th 359, 363 (D.C. Cir. 2022). The First Circuit

upheld the agency's interpretation without classifying the decision "as a product of *Chevron* step one or step two." *Relentless, Inc. v. Dept. of Commerce*, **62 F.4th 621**, **634** (1st Cir. 2023).

In November 2022, Loper Bright Enterprises filed a petition for a writ of certiorari, asking the Supreme Court to overrule or limit *Chevron* given constitutional deficiencies inherent in the doctrine. The petitioner argued that *Chevron* deference impermissibly delegates core judicial and legislative powers to executive agencies and undermines the constitutional commitment to ensure fair trials and tribunals for private litigants. Given variability in the application of *Chevron*, the Court granted certiorari in April 2023 to consider the narrow question of whether to "overrule *Chevron* or at least clarify that statutory silence concerning controversial powers expressly but narrowly granted elsewhere in the statute does not constitute an ambiguity requiring deference to the agency." A few months later, the Court granted certiorari in *Relentless* to consider the same question.

During oral arguments on *Loper Bright* and *Relentless*, the Court grappled with the implications of *Chevron* deference. Justice Kavanaugh **suggested** that deference was an "abdication" of judicial authority that could lead "the executive branch [to] run[] roughshod over limits established in the Constitution, or, in this case, by Congress."

Justice Gorsuch appeared **skeptical** of *Chevron*'s presumption that statutory ambiguity "always and necessarily" means that Congress intended to delegate interpretative authority to the Executive. Other Justices, however, raised constitutional concerns with delegating interpretive authority to Article III courts.

Justice Jackson **expressed concern** that losing *Chevron* would turn courts into "uber-legislators" called on to make policy determinations in situations where statutes could be construed in multiple reasonable ways. Justices Kagan and Barrett **queried** whether courts should independently adjudicate questions requiring scientific expertise, such as those related to "whether a new product is a dietary supplement or a drug."

Most Justices appeared ready to reform (if not replace) the existing Chevron framework. Although Justice Kavanaugh suggested reversal might have limited impact, the Court spent significant time considering what would fill the void left by Chevron. Justices Roberts, Gorsuch, Kagan, and Kavanaugh, and Thomas, each raised questions regarding whether *Skidmore* could

play a broader role in agency statutory interpretation. Justice Barrett seemed to **indicate** the Court should take a *Kisor*-like approach by limiting, rather than overturning, *Chevron*. The Court's ruling is expected by late June.

Implications for Health Care & Life Sciences Industries

Disputes over the statutory basis for CMS, FDA, and other HHS agency actions will continue with or without *Chevron*. Following a decision in *Roper Light* and *Relentless* curtailing the doctrine, regulated parties facing adverse agency statutory interpretations may be all the more likely to challenge them. Given recent trends, however, changes to *Chevron* would not necessarily alter the course of Administrative Procedure Act (APA) challenges in the health care and life sciences industry significantly.

As highlighted above, the most pressing matters do not get finally decided at the district court level, and appellate courts are already bypassing *Chevron*. A Supreme Court ruling overturning or narrowing *Chevron* would most affect decisions in district courts, which until now have been generally applying the traditional two-step framework. If the Court took a *Kisor*-like approach to statutory interpretations, heightening the standard for finding statutory ambiguity, there would likely to be fewer instances of courts at *any level* proceeding to *Chevron* step two to consider whether the interpretation warrants deference. *See Kisor*, **139 S. Ct. at 2415**. Given current trends, the precise contours of this term's decision would determine whether potential litigants against HHS might fare any better going forward.

As noted above, in *AHA,* rather than conducting a *Chevron* inquiry as requested by the government, the Supreme Court used traditional interpretive tools to reject HHS's application of the Medicare reimbursement formula. Shortly thereafter, the Court again neglected to invoke *Chevron* in *Empire*, instead "approv[ing]" CMS's interpretation without mentioning the doctrine.

Appellate courts have also decided disputes related to calculating appropriate compensation for hospitals under the Medicare Act without applying *Chevron*. See e.g., *Silverado Hospice, Inc. v. Becerra*, **42 F.4th 1112** (9th Cir. 2022), upholding the agency's interpretation as "the much better one" without addressing Chevron. The D.C. Circuit expressly rejected the district court's use of *Chevron* in considering a reimbursement dispute, citing *Empire* for the proposition that

"[reviewing courts] need not apply the *Chevron* framework." See *Advocate Christ Med. Ctr.* v. *Becerra*, **80 F.4th 346**, **351** (D.C. Cir. 2023).

In the wake of the Supreme Court's *Dobbs* decision, HHS issued **guidance** interpreting the Emergency Medical Treatment and Active Labor Act (EMTALA) to require abortions in certain circumstances even when doing so would violate state law. Plaintiffs challenged this guidance, alleging HHS had exceeded its statutory authority. The district court struck down HHS' interpretation at *Chevron* step two, as an impermissible construction of statutory ambiguity. See *Texas v. Becerra*, **623 F. Supp. 3**d 696, 725 (N.D. Tex. 2022). The Fifth Circuit affirmed, applying the "traditional tools of statutory interpretation" as HHS had not invoked *Chevron* in its appellate arguments. See *Texas v. Becerra*, **89 F.4th 529**, **541** (5th Cir. 2024).

Reversing or significantly limiting *Chevron* may embolden plaintiffs who might have opted against challenging adverse agency regulatory and enforcement decisions in court. For example, limitations on *Chevron* may increase challenges to pharmaceutical exclusivity determinations.

In *Catalyst v. Becerra*, **14 F.4th 1299**, **1301** (11th Cir. 2021), the Eleventh Circuit rejected FDA's interpretation of the Orphan Drug Act, holding that exclusivity tied to the first approval for any indication of a designated orphan drug bars approval of any another drug for the same disease. FDA had interpreted the bar as applicable only to the specific indication for which the first drug was approved. Although the district court deferred to the agency's interpretation under *Chevron*, the appellate court found the text unambiguously foreclosed the agency's statutory construction.

Congress seemed prepared to codify the agency's interpretation, but the effort stalled. Rather than wait for Congressional action, FDA published a Federal Register **Notice** announcing that it would apply its preferred interpretation to matters beyond the scope of [the court's] order." The D.C. District Court is currently reviewing another Orphan Drug Act challenge, filed by **Jazz Pharmaceuticals**, in which the government seeks *Chevron* deference. The Supreme Court's *Loper* and *Relentless* rulings are likely to impact how the D.C. District Court evaluates the disputed provision.

If the loss of traditional *Chevron* led to courts rejecting more agency statutory interpretations, HHS may be forced to appeal to Congress for more explicit authority. For example, the

Supreme Court's decision in *FDA v. Brown & Williamson*, **529 U.S. 120** (2000) **prompted Congress** to enact the Tobacco Control Act. Similarly, Congress recently granted FDA the explicit authority to ban medical devices for specific indications after the D.C. Circuit rejected the agency's argument that it had existing authority to do so in *Judge Rotenberg Ed. Ctr., Inc. v. FDA*, **3 F.4th 390** (D.C. Cir. 2021).

Further, agencies may look to Congress to include statutory provisions explicitly precluding judicial review of certain agency actions. Congress has already precluded some aspects of CMS decision-making. See, e.g.,

• **42 U.SC. §§ 1395l.** Stating that "[t]here shall be no administrative or judicial review" of certain CMS decisions regarding Medicare reimbursement for outpatient services under Medicare Part B.

• **42 U.SC. §§ 1395x(kkk).** Precluding review over enumerated agency determinations regarding payments for "rural hospital services."

Of course, Congress does not always provide agencies with the legislative fixes they may seek, and the trend away from judicial deference to agencies may thus be hard to reverse in the near term.

Looking Forward

While the Supreme Court will soon decide *Chevron's* fate, narrowing or reversing the doctrine may have a less-than-expected impact considering judicial trends. That said, a further diminished *Chevron* could lead to more crowded federal dockets as regulated entities perceive more upside to litigating administrative law challenges on a more level playing field.