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The End of *Chevron* Deference: What It Means For MedTech

July 9, 2024

AGENDA

- **Welcome**
- **What Was *Chevron* Deference?**
- **Vehicles for Challenging *Chevron*: *Loper Bright/Relentless***
- **The Supreme Court's Decision**
- **Implications of *Chevron's* End**
- **Opportunities of *Chevron's* End**
- **Discussion/Questions**

What Was *Chevron* Deference?

The *Chevron* Two-Step:

- Courts apply *Chevron* to determine whether to defer to an agency's interpretation of a statute
- Step One: Was Congress ambiguous?
 - If yes, move to step two
- Step Two: Was the agency's interpretation reasonable?
 - If yes, defer to agency – even if the court disagrees with how the agency interpreted the statute





Vehicles for Challenging *Chevron* Deference: The *Loper Bright* and *Relentless* cases

Vehicles For Challenging *Chevron*

Loper Bright Enters. v. Raimondo, No. 22-451

Relentless, Inc. v. U.S. Dept. of Commerce, No. 22-1219

Issue: Challenge under the Administrative Procedure Act (APA) to an agency requiring fishing companies to pay for statutorily mandated monitors on boats

Question for the Court: Whether the Court should overrule or modify *Chevron* to clarify that certain statutory silences are not ambiguities requiring deference

Date of Decision: June 28, 2024



The Supreme Court's Decision

- **Landmark 6-3 decision overruling *Chevron* deference**
 - Chief Justice Roberts delivered the opinion of the Court, in which Justices Thomas, Alito, Gorsuch, Kavanaugh, and Barrett joined
 - Justices Thomas and Gorsuch filed concurring opinions
 - Justice Kagan filed a dissenting opinion, in which Justices Sotomayor and Jackson joined (as to the case in which she did not need to recuse herself)



Principal Holding

- “***Chevron* is overruled**”
- “Courts must exercise their ***independent judgment*** in deciding whether an agency has acted within its statutory authority, as the APA requires”
- “[W]hen a particular statute delegates authority to an agency consistent with constitutional limits, courts must respect the delegation, while ensuring that the agency acts within it”
- “**But courts need not and under the APA may not defer to an agency interpretation of the law simply because a statute is ambiguous**”

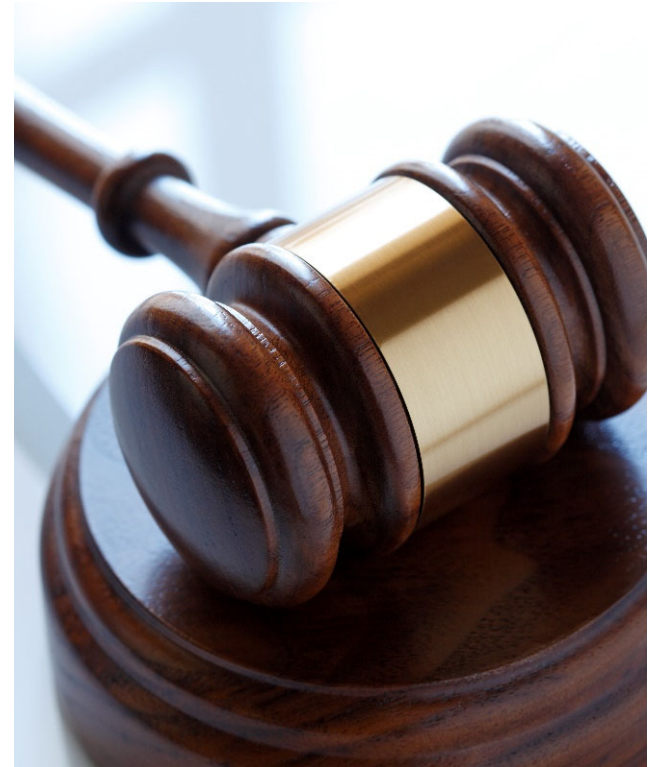
All emphasis added

Courts' Role to Say What the Law Is

- **Emphasis on the courts' unique role to interpret statutes:**
 - “It is emphatically the province and duty of the judicial department to say what the law is”
 - APA, 5 U.S.C. § 706, specifies that courts, not agencies, will decide “all relevant questions of law” arising on review of agency action—it sets no deferential standard
 - “*Chevron* defies the command of the APA that ‘the reviewing court’—not the agency whose action it reviews—is to ‘decide all relevant questions of law’” and “requires a court to ignore, not follow, ‘the reading the court would have reached’ had it exercised its independent judgment as required by the APA”

Rejection of General Intent of Congress to Defer to Agencies

- **Rejected the government's argument that Congress must generally intend for agencies to resolve statutory ambiguities based on their subject-matter expertise**
 - Interpretive issues in a regulatory scheme “may fall more naturally into a judge's bailiwick” than an agency's
 - Even when an ambiguity implicates a technical matter, it does not follow that Congress took the power to interpret the statute from the courts
 - Congress expects courts to handle technical statutory questions



Role of and Respect for Agencies

- ***Skidmore* Respect Replaces Deference; Congress Can Also Delegate Authority to Agencies**
 - Will consider agency's "body of experience and informed judgment"
 - Agency's interpretation "may be especially informative," may have the "power to persuade" and under *Skidmore*, is "entitled to respect," although it will not control
 - Dissent raises concerns about future arguments about what "respect" requires
 - Future statutes can delegate authority to an agency consistent with constitutional limits, and courts must respect the delegation, while ensuring that the agency acts within it

But FDA Already Under Scrutiny

The Honorable Robert Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20933

United States Senate
COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS
WASHINGTON, DC 20510-6300

- “[G]iven your agency’s track record, I am concerned about whether and how FDA will adapt to and faithfully implement . . . this decision”
 - FDA has “asserted jurisdiction over laboratory developed tests . . . without Congress granting FDA that authority”
 - FDA has “ignored multiple court rulings on the Orphan Drug Act”
- “FDA guts this process, and thumbs its nose at the Constitution, every time it ignores the decisions that Congress makes”
- Asks for answers to questions by July 19, including:
 - “How will FDA change its current practices to enforce the laws as Congress writes them, and not to improperly legislate via agency action?”
 - “Will FDA be conducting a systematic, action-by-action review of its ongoing activities to identify opportunities where FDA needs to make changes to comply with or otherwise account for the decision?”
 - “Will FDA pause or stop any existing rulemaking activities in light of the Court’s decision? If so, what rule(s) is FDA halting? If not, why does FDA feel it is legally able to continue existing rulemakings without considering the impacts of the Court’s decision?”

Prior Cases Still Good Law . . . For Now

- Court stated its decision does not call into question prior cases that relied on the *Chevron* framework
 - Those holdings are subject to statutory *stare decisis*
 - But a “special justification” may result in overturning a prior decision that had relied on *Chevron*
 - Dissent noted: “Courts motivated to overrule an old *Chevron*-based decision can always come up with something to label a ‘special justification’”
- Timing Considerations: Can challenge within the APA’s six-year statute of limitations, which runs from when a plaintiff is injured by the agency action, even if the injury was years or even decades after the agency’s action, per the *Corner Post* decision from the Supreme Court issued days after this one
- Did not overrule “*Auer* deference” for agencies interpreting their own ambiguous regulations

Implications for MedTech After *Chevron's* End

- May chill agencies from issuing swift or expansive rules or regulations
- Will likely increase litigation challenging agency rules and regulations, and could lead to splits if judges take different approaches
- May leave state regulations to fill gaps, creating a patchwork of laws for compliance across states
- May result in challenges to beneficial agency decisions (e.g., FDA approvals) and may open technical decisions to reevaluation
- May hamper bringing the latest innovations to patients, as long-standing regulatory agency decisions may be litigated and may change, and could potentially chill investment in innovation
- Will place more emphasis on technical legislative drafting, if clarity is achievable through efforts of Congress and stakeholder support



Opportunities for MedTech After *Chevron's* End

- Easier to challenge agency rules and regulations that burden the industry, as courts need not defer to agency interpretations
 - Easier to challenge restraints, including on patient access
 - Higher likelihood of success without *Chevron* deference
- More opportunities to support lawmakers and agencies by providing support during the legislative drafting process
- Industry support for approaches that benefit MedTech could help agencies receive “respect” (e.g., comment on favorable rules; consider amicus filings when regulations are challenged)
- Possible role for industry self-regulation



Spotlight on Opportunities to Challenge Burdensome Rules

The Court's ruling presents opportunities to challenge, or re-challenge, with a "special justification," burdensome rules and regulations from:

- FDA
- CMS
- EPA

Statistics on Success:

- Agencies won over **77%** of cases when circuit courts apply *Chevron* at all
 - When circuit courts applied *Chevron* deference (step 2), agencies won over **93%** of cases
- Agencies won **56%** when courts apply *Skidmore*
- Agencies won only **38.5%** when courts review agency action *de novo*
- Since 2000, FDA won in every appellate opinion that applied *Chevron* deference

At least one study cited for each statistic in scholarly journals



Discussion / Questions



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