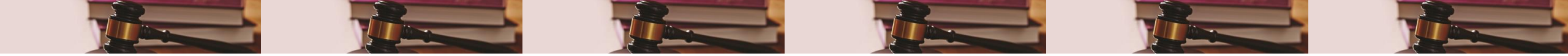

An Assist for Litigants Challenging Governmental Actions: Implications of the Supreme Court's Decision on Agency Deference

Charles Biro, Trial Attorney, Consumer Protection Branch, US Department of Justice

Daniel Jarcho, Partner, Alston & Bird LLP

Moderated by **James N. Czaban**, Partner, DLA Piper LLP

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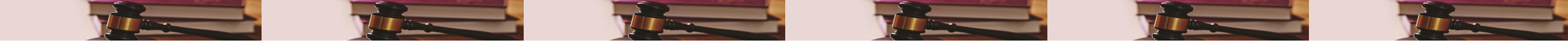

Kisor v. Wilkie:

A More Level Playing Field in Litigation Challenging FDA Actions?

Daniel G. Jarcho

Litigation Partner, Alston & Bird LLP

daniel.jarcho@alston.com

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DEFERENCE IS A ***BIG*** ISSUE IN LITIGATION AGAINST FDA

- Deference: the weight that a court will give to the agency's legal interpretation in resolving a case
  - The court can disagree with the agency's interpretation but rule in its favor anyway
  - Deference can and often does determine the outcome of a case
  - The playing field is (by design) skewed in the agency's favor

- The Court must decide how much weight to give the agency's interpretation

- *Auer v. Robbins* deference: the set of rules governing deference to the agency's interpretation of its own regulations (which the agency has drafted and is responsible for administering)

    - Under *Auer*, the court gives the agency's interpretation of its own regulation "controlling" weight unless the interpretation is "plainly erroneous" or "inconsistent with the regulation"

    - *Kisor v. Wilkie*: whether *Auer* deference should be eliminated

- *Chevron* deference (a separate subject): the set of rules governing deference to the agency's interpretation of the statute it is charged with administering

Kisor v. Wilkie

- The scope of the plaintiff's veterans disability benefits turned on the Veterans Administration's interpretation of an agency rule
- *Auer* deference determined the outcome of the case
- The plaintiff lost when the lower court deferred to the agency, relying entirely on the *Auer* deference doctrine
- The question presented to the Supreme Court was whether the *Auer* doctrine should be overruled
- In a 5-4 decision, the Supreme Court did not overrule the *Auer* deference doctrine
- **However, *Kisor* did address limits to *Auer* deference in a fashion not previously articulated by the Supreme Court
    - Some announced for the first time
    - Others drawn from different prior opinions and integrated for the first time, giving lower courts a roadmap to limit deference if appropriate

LIMIT #1: THE DEGREE OF DEFERENCE

- Previously most courts had considered *Auer* deference to be a kind of "super" deference
  - Agency's interpretation of its own regulations (under *Auer*) had greater weight than agency's interpretation of its own statute (under *Chevron*)
  - *Auer* standard: (assuming prerequisites apply) defer unless agency interpretation is "plainly erroneous" or "inconsistent with the regulation"
  - *Chevron* standard: (assuming prerequisites apply) defer unless agency interpretation is "unreasonable."
- *Kisor*: Because of the "plainly erroneous" formulation some courts have thought that "agency constructions of rules receive greater deference than agency constructions of statutes . . . . But that is not so."

LIMIT #2: OBJECTIVE FACTORS FOR DETERMINING WHETHER A REGULATION IS AMBIGUOUS

- *Auer* deference has always been limited to interpretations of regulations that are "ambiguous"

- Courts and commentators have criticized *Auer* deference on the ground that ambiguity is in the eye of the beholder

    - Critique: an inherently malleable standard in which the judge can determine the case's outcome by determining whether the regulation is ambiguous (because *Auer* was seen as "super" deference)

- *Kisor* articulates a number of objective factors to determine whether a regulation is ambiguous
    - Court must use "standard rules of interpretation" to construe the regulation:
        - Text
        - Structure
        - History
        - Purpose

- The regulation is not ambiguous simply because it seems "impenetrable on the first read" or because the judge's "eyes glaze over"

- There must be "genuine" ambiguity:

  - Choice between or among more than one reasonable reading

  - Careless drafting

  - Problem not foreseen by the drafters

  - Inherent limitations of language to describe specific situations

LIMIT #3: THE COURT DETERMINES THE OUTER BOUNDS OF PERMISSIBLE INTERPRETATIONS

- The Court will defer under *Auer* if the agency has a reasonable interpretation of an ambiguous regulation, yet some interpretations are not reasonable.

- The Court polices the outer bounds of what is reasonable

  - "It does not matter whether the word 'yellow' is ambiguous when the agency has interpreted it to mean 'purple.'"

Opinion of Justice Antonin Scalia in *United States v. Home Concrete & Supply, LLC*

LIMIT #4: THE COURT DOES NOT DEFER, EVEN TO A REASONABLE INTERPRETATION, IF IT IS NOT THE "OFFICIAL POSITION" OF THE AGENCY

- Must be the official position of the agency (though it need not be from the agency head)
- Informal statements and memos by low-level officials are typically not enough

LIMIT #5: THE COURT DOES NOT DEFER, EVEN TO A REASONABLE INTERPRETATION, IF IT DOES NOT IMPLICATE THE AGENCY'S SUBSTANTIVE EXPERTISE

- One justification for deference is the expertise of the agency and long-term familiarity with the subject at hand
- Typically no deference if the interpretation is outside of the agency's ordinary duties or developed in a regulatory regime in which enforcement is shared with another agency

LIMIT #6: THE COURT DOES NOT DEFER, EVEN TO A REASONABLE INTERPRETATION, IF IT IS NOT THE AGENCY'S "FAIR AND CONSIDERED JUDGMENT"

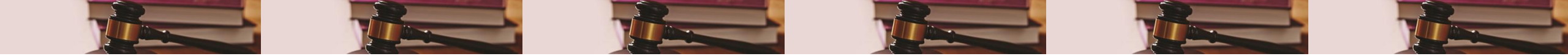
- Fair and considered judgment justifies the extra weight given through deference
- "Convenient litigating positions" and "post-hoc rationalizations" are typically not enough

LIMIT #7: THE COURT DOES NOT DEFER, EVEN TO A REASONABLE INTERPRETATION, IF IT CAUSES UNFAIR SURPRISE

- Unfair surprise justifies making the playing field more level
- Typically no deference when a new agency interpretation conflicts with a prior one
- Typically no deference when new regulatory action disrupts reliance expectations by addressing longstanding conduct not previously regulated

IN SUM:

- *Auer* deference is here to stay
- Courts have a new toolbox to use when addressing the applicability and scope of *Auer* deference.
- *Kisor* will force courts to be more careful and deliberate before deciding to defer to FDA's interpretation of its own regulations



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DOJ Consumer Protection Branch

- **Main Justice component of 65 prosecutors**
- **Leads DOJ efforts to enforce criminal and civil laws that protect Americans' health, safety, economic security, and identity integrity**
  - **Titles 18 and 21 Offenses**
  - **Primary DOJ authority over FDCA and FTCA**
- **Defends consumer protection agencies in litigation**

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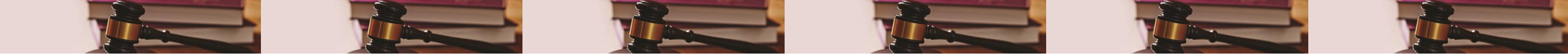
Post-*Kisor* Cases

- *Braeburn v. FDA*, 389 F.Supp.3d 1 (D.D.C. 2019)
  - Only FDCA case citing *Kisor*
- *Romero v. Barr*, 937 F.3d 282 (4th Cir. 2019)
- *Belt v P.F. Chang's China Bistro, Inc.*, 401 F.Supp.3d 512 (E.D. Penn. 2019)
- *Genus Medical Technologies, LLC v. FDA*, Civ. No. 19-544 (D. D.C. Dec. 6, 2019)
- Pending cases:
  - *Regenxbio v. FDA*, No. 19cv03373 (D.D.C.)
  - *Vanda v. FDA*, No. 19cv00301 (D.D.C.)

Other Recent Cases

- *Amgen v. Azar*, 290 F.Supp.3d 65 (D.D.C. 2018)
  - *Amgen v. Hargan*, 285 F.Supp.3d 397 (D.D.C. 2017) (ruling on "administrative record")
- *Teva v. Azar*, 369 F.Supp.3d 183 (D.D.C. 2019)
- *Eagle Pharm., Inc. v. Azar*, No. CV 16-790, 2018 WL 3838265 (D.D.C. June 8, 2018)
- *Athenex Inc. v. Azar*, 397 F.Supp.3d 56 (D.D.C. 2019)



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