

# Judicial Winds of Change: Healthcare Policy Implications of the Chevron Doctrine Overturn

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**DEVELOPMENTS  
IN PHARMACY LAW  
SEMINAR DPL XXXV**



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# Conflict of Interest Disclosure

- Jennifer Cyr:
  - I declare that neither I nor any immediate family member have a current affiliation or financial arrangement with any potential sponsor and/or organization(s) that may have a direct interest in the subject matter of this presentation.
- Jangus Whitner:
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# Learning Objectives

At the completion of this activity, the participant will be able to:

1. Analyze the potential impact of the *Chevron* doctrine overturn on the functioning of federal agencies and the role of courts
2. Apply understanding of the *Chevron* doctrine overturn's impact on active and future potential legal challenges



# Assessment Question

In the *Loper Bright Enterprises* decision, the U.S. Supreme Court invalidated prior cases that relied on *Chevron* to deem specific agency actions as lawful.

True or False



# Acronyms used throughout

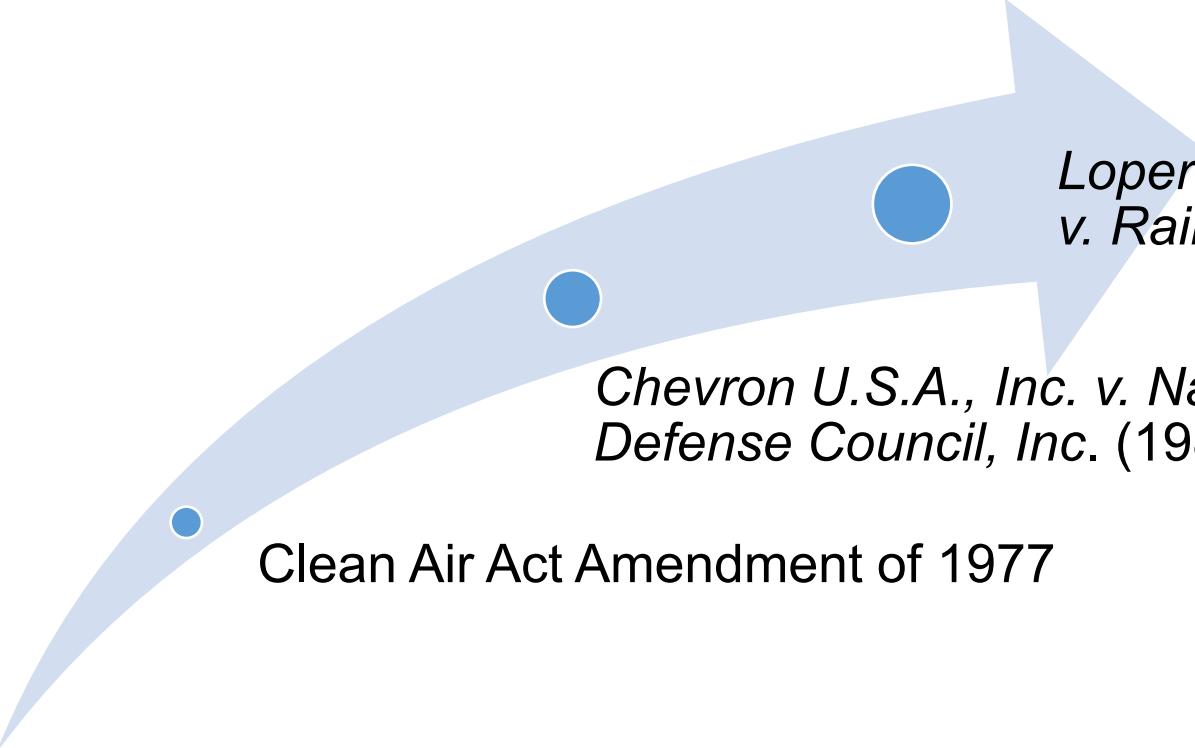
<b>3PL</b>	Third-Party Logistics Provider	<b>EPA</b>	Environmental Protection Agency
<b>ACA</b>	Affordable Care Act	<b>FDA</b>	U.S. Food & Drug Administration
<b>ACIP</b>	Advisory Committee on Immunization Practices	<b>HHS</b>	U.S. Department of Health & Human Services
<b>APA</b>	Administrative Procedure Act	<b>HRSA</b>	Health Resources & Services Administration
<b>CAA</b>	Clean Air Act	<b>IRA</b>	Inflation Reduction Act
<b>CMP</b>	Civil Monetary Penalty	<b>MSA</b>	Magnuson-Stevens Act
<b>CMS</b>	Centers for Medicare & Medicaid Services	<b>NAAQS</b>	National Ambient Air Quality Standards
<b>DSCSA</b>	Drug Supply Chain Security Act	<b>NOAA</b>	National Oceanic & Atmospheric Administration
<b>DSH</b>	Disproportionate Share Hospital	<b>SEC</b>	U.S. Securities & Exchange Commission
		<b>USPSTF</b>	U.S. Preventive Services Task Force



# History & Precedent



# How We Got Here



Clean Air Act Amendment of 1977

*Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc. (1984)*

*Loper Bright Enterprises v. Raimondo (2024)*



# Administrative Procedures Act (1946)

- Mandates courts to exercise their judgment in interpreting statutes that are ambiguous or silent on key issues.
- Set the statute of limitations to 6 years for civil suits against the government
  - Requires a person to have suffered a legal wrong or been harmed by an agency action.

(APA, 1946; Congressional Research Service, 2024)



# Clean Air Act Amendments of 1977

- **1970 CAA**
  - Outlines the EPA's duty to protect and enhance the U.S. "air quality and the stratospheric ozone layer"
- **1977 CAA Amendment**
  - Set standards for the prevention of significant air quality deterioration per the NAAQS and requirements for States that have not attained those standards
  - Created permit programs regulating new or modified 'stationary sources' of air pollution
    - Examples: factories, refineries, boilers, power plants
- **1981 EPA Regulation**
  - Implemented the permit requirements to allow for a plantwide definition for 'stationary source', known as the "Bubble" Concept

(EPA, 2024a-c; EPA, 1979; EPA, 1984)



# Chevron USA, Inc. v. Natural Resources Defense Council, Inc. (1984)

- In the amended CAA, Congress did not explicitly define “stationary source” (re: permits)
  - Question at hand: Does a court have the authority to derive a definition when Congress had not done so?
- In its decision, the U.S. Supreme Court
  - Deferred to *Morton v. Ruiz* (1974)
    - “If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency”
    - If the legislative delegation to an agency is implicit rather than explicit... “a court may not substitute its own” definition in place of “a reasonable interpretation made by” an agency
  - Held that if a statute is silent or ambiguous on a particular question,
    - The court must decide if the agency's interpretation is “based on a permissible construction of the statute.”
    - As long as the agency's interpretation is not unreasonable, a court should defer to the agency

*(Chevron USA Inc v. Natural Resources Defense Council, 1984; Morton v. Ruiz, 1974)*



# Loper Bright Enterprises v. Raimondo (2024)

- Magnuson-Stevens Act (MSA)
  - Law governing the management of fisheries in federal waters
  - Gives NOAA authority to require monitors on commercial fishing boats and require certain classes of boats to purchase their monitors
- Agency inconsistency
  - Herring boats not listed; NOAA agreed to pay for those monitors
  - When the government ran out of funds, NOAA reversed its decision and started requiring herring boats to pay
- Challenged in court
  - Lower courts ruled in favor of the NOAA, deferring to the *Chevron Doctrine*
  - Loper Bright Enterprises filed a petition for a writ of certiorari to the U.S. Supreme Court



# The Chevron Overturn



# The Court Case that Overruled Chevron

Who	<i>Loper Bright Enterprises v. Raimondo.</i> [+ <i>Relentless, Inc. v. Dept of Commerce</i> ]
Where	U.S. Supreme Court
When	June 28, 2024
What	<p>6-2 [6-3] Decision Held:</p> <ul style="list-style-type: none"><li>• The APA requires <b>courts</b> to “exercise their <b>independent judgment</b> in deciding” whether an agency’s actions are within its statutory authority.</li><li>• <b>“Courts may not defer</b> to an agency’s interpretation of the law simply because a statute is ambiguous; <i>Chevron</i> is overruled.” [emphasis added]</li></ul>

(*Loper Bright Enterprises v. Raimondo, 2024*)



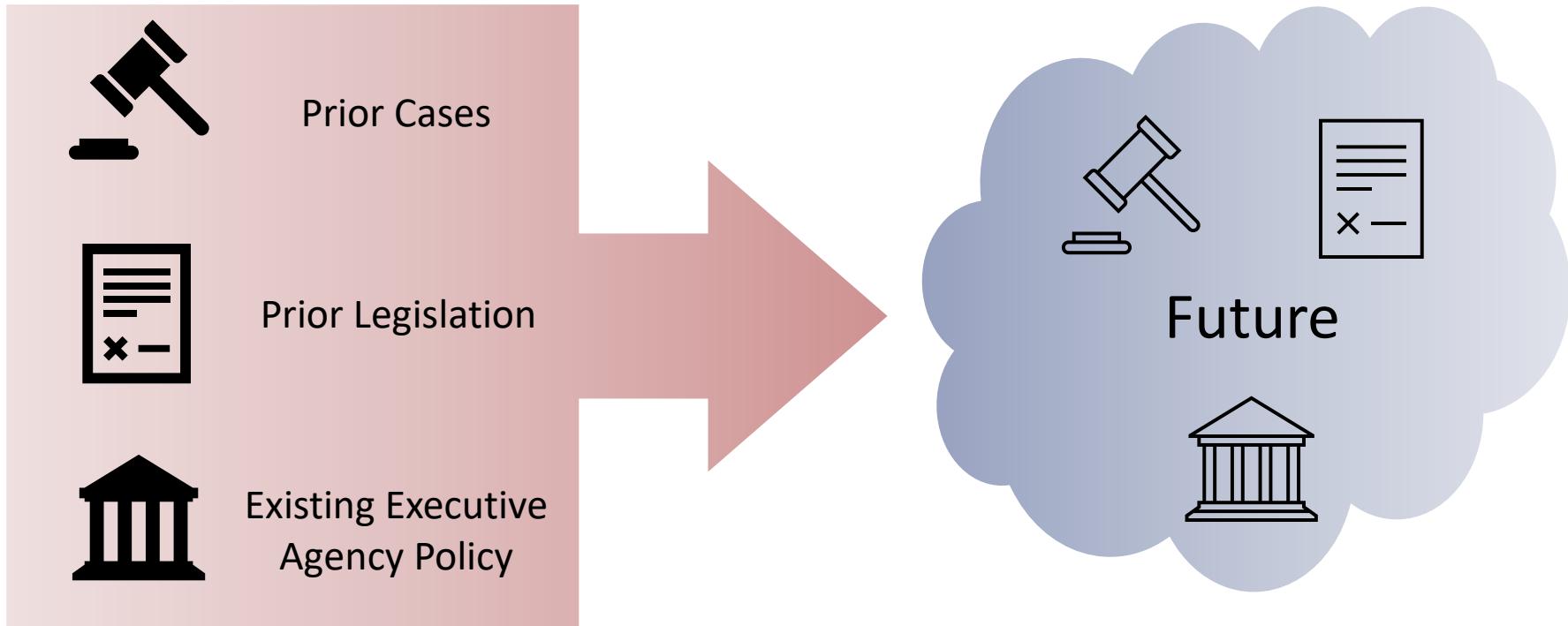
# The Why – Justice Opinions

Majority	Chief Justice Roberts	<ul style="list-style-type: none"><li><i>Chevron</i> deference conflicts with APA and judicial responsibility</li><li>“resolution of statutory ambiguities involves legal interpretation”</li><li>“task does not suddenly become policymaking just because a court has an ‘agency to fall back on.’”</li></ul>
Concurring	Justices Thomas & Gorsuch	<p><i>Chevron</i> deference:</p> <ul style="list-style-type: none"><li>was inconsistent with APA and constitutional separation of powers</li><li>lent itself to systemic bias in the government’s favor</li></ul>
Dissenting	Justices Kagan, Sotomayor, & Jackson*	<ul style="list-style-type: none"><li>This ruling expands the courts’ power over regulatory matters at the expense of the executive agencies (who have the specialized subject-matter expertise)</li><li>The ruling enables judges “to play a commanding role” in all future policy decisions - a role that Congress has not given to the courts</li></ul>

(*Loper Bright Enterprises v. Raimondo*, 2024)



# Where do we go from here?



(Chilakamarri et al., 2024; London & Azimpoor, 2024;  
*Loper Bright Enterprises v. Raimondo*, 2024)



# Post-Chevron Healthcare Implications



# Affordable Care Act: Preventive Services

- *Braidwood Management et al v. Becerra et al* (2022)
  - Plaintiff's claim: Preventive services at zero cost-share is unconstitutional
  - Appointments Clause:
    - Mandates significant government functions are required to be conducted by "Officers of the United States", who have been appointed by the President
    - USPSTF is run by officials not appropriately appointed
- District Court:
  - USPSTF unconstitutional
  - HRSA and ACIP constitutional
- Appeals Court:
  - USPSTF is unconstitutional, however, only applies to the plaintiffs
  - Remanded case back to district court regarding HRSA and ACIP

(*Braidwood Management Inc et al v. Becerra*, 2022; CRS, 2023)



# Inflation Reduction Act (2022)

- Drug Price Negotiation Program
- Granted the HHS Secretary authority to negotiate drug costs under Medicare with manufacturers
- Potential for future challenges:
  - Congress did not state a definition for what qualifies a drug to be eligible for negotiation in addition to the process of negotiations
- *Dayton Area Chamber of Commerce, et al. v. Becerra* (2023)

(Office of the Assistant Secretary for Planning and Evaluation, HHS, 2023; Wenneh, 2024)



# Recent Lawsuits Filed Challenging the IRA and Drug Price Negotiation Program

- *Novo Nordisk Inc, et al. v. HHS et al.* (2024)
- *Boehringer Ingelheim Pharmaceuticals, Inc. v. HHS* (2024)
- *Janssen Pharmaceuticals, Inc. v. Becerra et al.* (2024)
- *Bristol Myers Squibb Co. v. Becerra et al.* (2024)
- *AstraZeneca Pharmaceuticals LP et al. v. Becerra et al.* (2024)
- *National Infusion Center Association et al. v. Becerra et al.* (2024)



# CMS Interpretation of Medicare Statute

- *HMH Hospitals Corporation v. Becerra* (filed 6/28/24)
  - Medicare Part A reimbursement dispute
    - Inpatient Prospective Payment System (IPPS): standard reimbursement subject to various adjustments (e.g., DSH)
  - Disproportion patient percentage (DPP)
    - Common way to qualify for DSH adjustment to IPPS
    - Defined by Medicaid fraction + Medicare (SSI) fraction
      - CMS applies an interpretation of “entitled to” both Part A and SSI benefits
- Chevron-related argument:
  - CMS’ inappropriate interpretation of “entitled to [SSI] benefits” affects DPP calculations and the accuracy of Medicare IPPS payments
  - CMS interpretation carries different meaning than in Medicare statute

(*HMH Hospitals Corporation v. Becerra*, 2024)



# FDA Implementation of DSCSA

- Guidance Documents:
  - The bulk of FDA's DSCSA action
  - Recommendations that are not legally enforceable
- One Proposed Rule:
  - “National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers” (2/4/2022)
  - Immediate vs. long-term impact?

(FDA, 2024; Smith, 2024)



# Assessment Question

In the *Loper Bright Enterprises* ruling, the U.S. Supreme Court invalidated prior cases that relied on *Chevron* to deem specific agency actions as lawful.

True or False



# Assessment Question

In the *Loper Bright Enterprises* ruling, the U.S Supreme Court invalidated prior cases that relied on *Chevron* to deem specific agency actions as lawful.

**False. The court did NOT invalidate those prior cases.**



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# Questions?

