

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

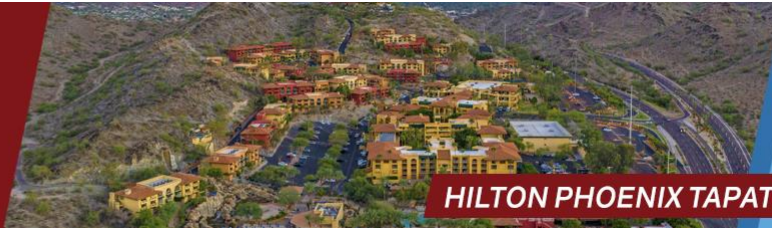
Jennifer Cyr, PharmD, MBAC  
Pharmacy Director  
Community Health Options

Jangus Whitner, PharmD, MHA  
Director, 340B Policy & Compliance  
Apexus



American  
Society for  
Pharmacy  
Law

**DEVELOPMENTS  
IN PHARMACY LAW  
SEMINAR DPL XXXV**



**NOVEMBER  
07-10**

**HILTON PHOENIX TAPATIO CLIFFS RESORT 2024**

# 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:
  - 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.



# 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>ACA</b>	Affordable Care Act
<b>ACIP</b>	Advisory Committee on Immunization Practices
<b>APA</b>	Administrative Procedure Act
<b>CAA</b>	Clean Air Act
<b>CMP</b>	Civil Monetary Penalty
<b>CMS</b>	Centers for Medicare & Medicaid Services
<b>DSCSA</b>	Drug Supply Chain Security Act
<b>DSH</b>	Disproportionate Share Hospital

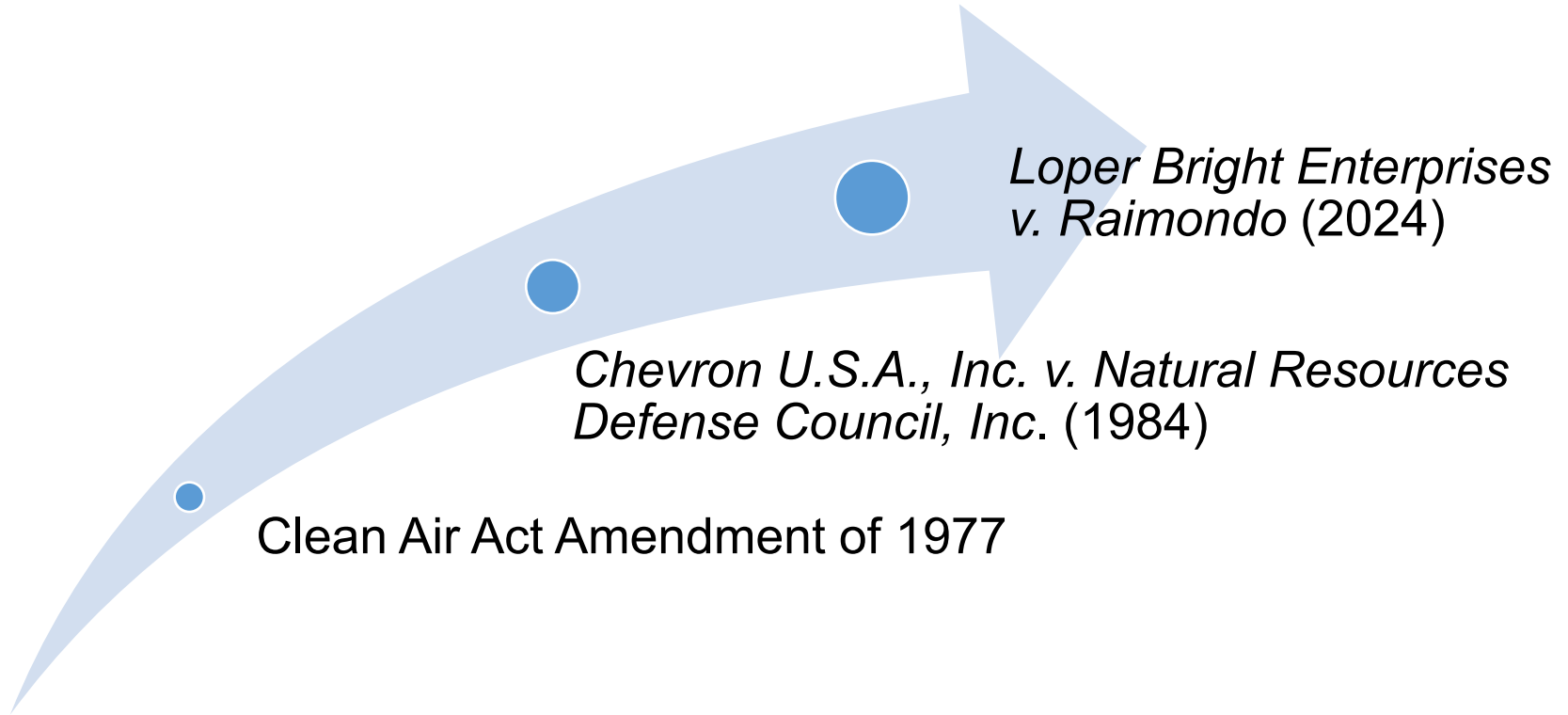
<b>EPA</b>	Environmental Protection Agency
<b>FDA</b>	U.S. Food & Drug Administration
<b>HHS</b>	U.S. Department of Health & Human Services
<b>HRSA</b>	Health Resources & Services Administration
<b>IRA</b>	Inflation Reduction Act
<b>MSA</b>	Magnuson-Stevens Act
<b>NAAQS</b>	National Ambient Air Quality Standards
<b>NOAA</b>	National Oceanic & Atmospheric Administration
<b>SEC</b>	U.S. Securities & Exchange Commission
<b>USPSTF</b>	U.S. Preventive Services Task Force



# History & Precedent



# How We Got Here



# 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

(Loper Bright Enterprises v. Raimondo, 2024)



# 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)



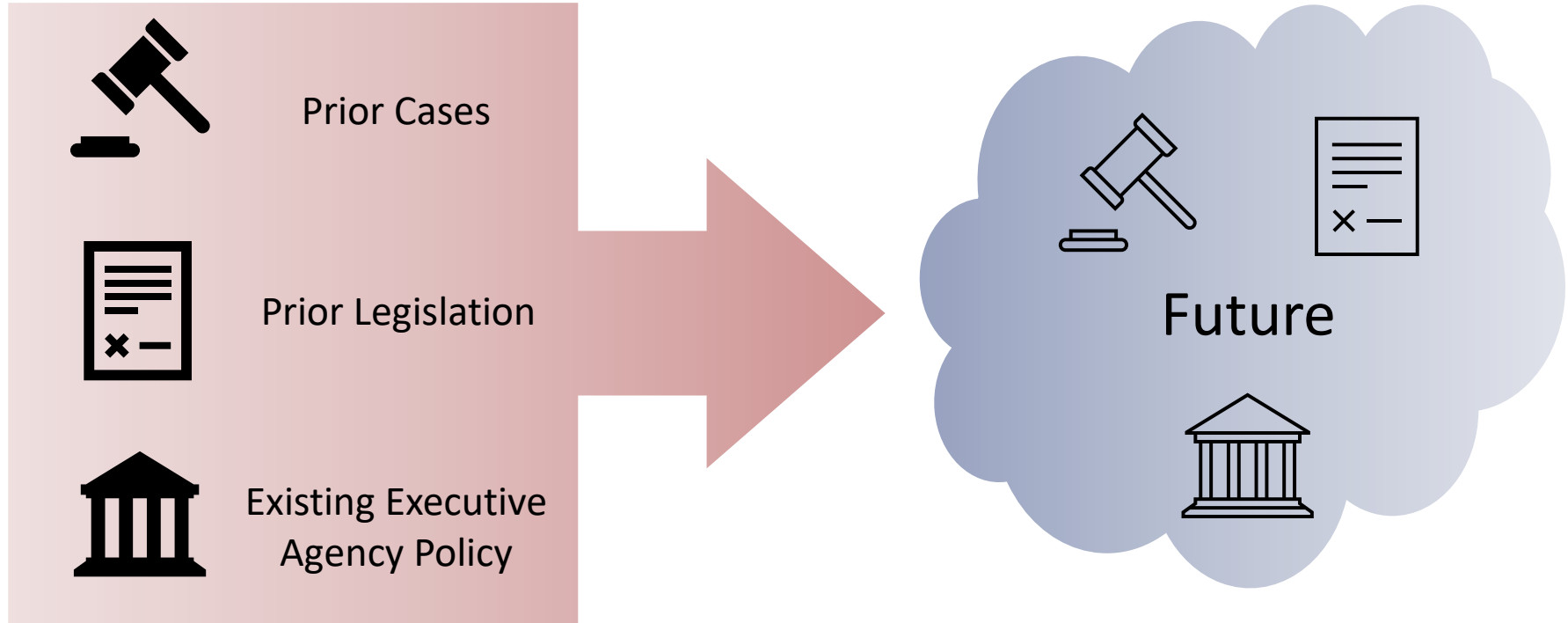
# The Why – Justice Opinions

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.**



# References

- Administrative Procedures Act, 5 USC §551 et seq. (1946). <https://www.justice.gov/sites/default/files/jmd/legacy/2014/05/01/act-pl79-404.pdf>
- Braidwood Management et al v. Becerra et al.* (2022). <https://cases.justia.com/federal/appellate-courts/ca5/23-10326/23-10326-2024-06-21.pdf>
- Chevron USA Inc v. Natural Resources Defense Council*, 467 US 837 (1984)
- Chilakamari, V., Ruge, M., Fine, D. R., Holloway, T. A., & Muscante, F. A. (2024, June 28). The End of Chevron Deference: What the Supreme Court's Ruling in *Loper Bright* means for the Regulated Community. *K&L Gates- U.S. Public Policy and Law Alert*. <https://www.klgates.com/The-End-of-Chevron-Deference-What-the-Supreme-Courts-Ruling-in-Loper-Bright-Means-for-the-Regulated-Community-6-28-2024>
- Congress.gov. (n.d.). Overview of the Seventh Amendment, Civil Trial Rights. [https://constitution.congress.gov/browse/essay/amdt7-1/ALDE\\_00000263/](https://constitution.congress.gov/browse/essay/amdt7-1/ALDE_00000263/)
- Congressional Research Service. (2023, Sep 12). Preventive Services Access on the Docket in *Braidwood v. Becerra*. <https://crsreports.congress.gov/product/pdf/LSB/LSB11040>
- Congressional Research Service. (2024, Sep 16). Judicial Review Under the Administrative Procedure Act (APA). <https://crsreports.congress.gov/product/pdf/LSB/LSB10558>
- Corner Post, Inc. v. Board of Governors of the Federal Reserve System*. (2024). U.S. Supreme Court. <https://www.scotusblog.com/case-files/cases/corner-post-inc-v-board-of-governors-of-the-federal-reserve-system/>
- Dayton Area Chamber of Commerce, et al. v. Becerra* (2023). [https://litigationtracker.law.georgetown.edu/wp-content/uploads/2023/06/Chamber\\_2024.08.08\\_ORDER.pdf](https://litigationtracker.law.georgetown.edu/wp-content/uploads/2023/06/Chamber_2024.08.08_ORDER.pdf)
- EPA. (2024a, April 16). Clean Air Act. <https://www.epa.gov/clean-air-act-overview/clean-air-act-text>
- EPA. (2024b, August 12). Stationary Sources of Air Pollution. <https://www.epa.gov/stationary-sources-air-pollution>
- EPA. (2024c, November 21). Evolution of the Clean Air Act. <https://www.epa.gov/clean-air-act-overview/evolution-clean-air-act>
- EPA. (1979, December 3). 'Bubble' Policy Added to EPA's Cleanup Strategy. <https://www.epa.gov/archive/epa/aboutepa/bubble-policy-added-epas-cleanup-strategy.html>
- EPA. (1984, June 26). Statement on the U.S. Supreme Court's Ruling of June 25th on EPA's "Bubble" Policy to Control Air Pollution. <https://www.epa.gov/archive/epa/aboutepa/statement-us-supreme-courts-ruling-june-25th-epas-bubble-policy-control-air-pollution.html>
- FDA. (2024). Implementation of Drug Supply Chain Security Act (DSCSA) Requirements. <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/fdas-implementation-drug-supply-chain-security-act-dscsa-requirements>
- HMH Hospitals Corporation v. Becerra*, 1:24-cv-01901. (D.C. 2024). <https://dockets.justia.com/docket/district-of-columbia/dcdce/1:2024cv01901/270139>
- London, A.M., & Azimpoor K. (2024, June). *Loper Bright's Potential Impact on the U.S. Department of Health and Human Services*. *Bloomberg Law*. <https://www.bloomberglaw.com/external/document/X3EH5278000000/litigation-professional-perspective-loper-bright-s-potential-imp>
- Loper Bright Enterprises v. Raimondo*. (2024). [https://www.supremecourt.gov/opinions/23pdf/22-451\\_7m58.pdf](https://www.supremecourt.gov/opinions/23pdf/22-451_7m58.pdf) & <https://www.scotusblog.com/case-files/cases/loper-bright-enterprises-v-raimondo/>
- Morton v. Ruiz*. (1974). 415 U.S. 199. <https://supreme.justia.com/cases/federal/us/415/199/>
- Office of the Assistant Secretary for Planning and Evaluation, HHS (2023, December 14). Inflation Reduction Act Research Series: Medicare Drug Price Negotiation Program: Understanding Development and Trends in Utilization and Spending for the Selected Drugs. (Research Report) <https://aspe.hhs.gov/sites/default/files/documents/4bf549a55308c3aad74b34abcb7a1d1/ira-drug-negotiation-report.pdf>
- SEC v. Jarkesy et al.* (2024). [https://www.supremecourt.gov/opinions/23pdf/22-859\\_1924.pdf](https://www.supremecourt.gov/opinions/23pdf/22-859_1924.pdf)
- Smith, C. (2024, August 15). Recent Supreme Court Decisions and the DSCSA. *The National Law Review*. <https://natlawreview.com/article/recent-supreme-court-decisions-and-dscsa>
- Wenneh, G. (2024, July 1). Overturn of Chevron Offers Major Assist to Drug Makers' IRA Battle. *Inside Health Policy*. <https://insidehealthpolicy.com/inside-drug-pricing-debates/news/overturn-chevron-offers-major-assist-drug-makers-ira-battle>



# Questions?

