

Medicare Drug Pricing Negotiations: Assessing Constitutional Structural Limits

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Abstract: A series of structural constitutional arguments lodged in multiple cases against Centers for Medicare and Medicaid Services' (CMS) authorities to negotiate prescription drug prices via the 2022 Inflation Reduction Act threaten the legitimacy of CMS program and federal agency powers.

Following decades of congressional resistance and inaction, the Inflation Reduction Act (IRA) of 2022¹ explicitly authorized — for the first time — the Centers for Medicare and Medicaid Services to negotiate prices directly with pharmaceutical companies for drugs provided via Medicare – Part D.² CMS' resulting Drug Price Negotiation Program (DPNP) seeks to increase consumer access to life-saving prescription medications through lower CMS expenditures and beneficiaries' out-of-pocket expenses³ that spur many Medicare beneficiaries to skip, delay, or ration their prescriptions.⁴ CMS' announcement in August 2023 of its list of 10 drugs slated for initial price negotiations⁵ are projected to collectively save taxpayers \$25 billion by 2031.⁶

Improving access to expensive prescription drugs through price reductions over time promotes communal

health. Pharmaceutical manufacturers, however, have challenged the IRA and CMS' authorities to regulate through manifold lawsuits.⁷ They raise a bevy of “rights-based” constitutional infringements under the First, Fifth, and Eighth Amendments. These specific arguments may seem imposing but are weakly based on federal agency limits to contract with private sector companies. Constitutional rights do not generally restrict agencies like the Department of Veterans Affairs from negotiating prices they pay for private sector services or goods, including drugs. Why should CMS be treated any differently?

Distinct substantive considerations arise from drug manufacturers' “structural-based” constitutional claims grounded largely in separation of powers principles and framed on a simple premise: that either Congress or CMS exceeded its constitutionally-allocated authorities in crafting the IRA or resulting DPNP provisions. Similar arguments centered on amorphous separation of powers concepts including the non-delegation doctrine, *Chevron* deference, and the major questions doctrine (MQD) have captured the attention of the U.S. Supreme Court and lower courts. Arguments on the scope of the IRA and CMS' drug pricing provisions promise to do the same. Ultimately, the fate of lower Medicare drug prices over time may rest with the Supreme Court which has shown a penchant for curbing administrative agency authorities notwithstanding clear public health benefits.

About This Column

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IRA Foundations and Purposes

Medicare as originally conceived in 1965 did not cover self-administered prescription drugs. This coverage gap may seem incredulous, but prescription drugs were a much smaller portion of Medicare recipients' health care expenses at that time. Escalating drug prices over decades led to calls for significant reforms. In 2003, Congress' passage of the Medicare Modernization Act created Part D to cover

ance documents,¹³ CMS selected ten drugs with the highest expenditures for the first round of price negotiations on August 29, 2023.¹⁴ These initial drugs treat chronic conditions including diabetes, heart disease, and cancers impacting tens of millions of Americans.¹⁵ The first negotiated prices are slated to take effect in early 2026,¹⁶ with other drugs following similar processes in ensuing years.¹⁷

for initial price reductions has opted out of negotiations.

What they have done is sued CMS through a bevy of initial cases scattered across U.S. federal courts. Multifarious claims suggest the creation and administration of the DPNP violate core individual rights.²¹ First Amendment claims allege requirements to accept CMS' rates as "fair" amount to compelled speech. Fifth Amendment arguments hinge on

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prescription drugs.⁸ Price controls were off the table at that time on the false premise that lower drug prices for consumers would flow from free market principles. U.S. drug prices have increased tenfold between 1980 and 2018, as have CMS' costs to provide them for Medicare beneficiaries.⁹

Democratic presidential nominee John Kerry campaigned in 2004 to lower drug costs via a Medicare overhaul.¹⁰ President Barack Obama bandied about the idea in deliberations over the Affordable Care Act (ACA) in 2010. Not until the passage of the IRA in 2022, however, was CMS given unprecedented authority¹¹ to identify and select eligible drugs, negotiate with manufacturers to determine fair prices, and implement price reductions over multiple years.¹² Foregoing formal notice-and-comment rulemaking in favor of agency-issued guid-

Emerging Litigation

Following decades of successfully evading price controls, Pharmaceutical Research and Manufacturers of America (PhRMA) did not accept CMS' DPNP quietly. Yet, drug manufacturers seem to have few options. They must either participate in CMS drug negotiations or face two major consequences: (1) an excise tax up to 95% of a selected drug's entire U.S. sales; or (2) withdrawal entirely from selling their drugs to CMS for Medicare or Medicaid programs.¹⁸ Both are considered untenable by manufacturers. High excise taxes would essentially erode all profits from specific drugs. And, with CMS expenditures comprising roughly 40% of the U.S. prescription drug market in 2019,¹⁹ company walk-aways from CMS' negotiation table are financially non-viable.²⁰ To date, none of the existing drug manufacturers slated

government "takings" of patented intellectual property without just compensation as well as procedural regulatory protections. Excise taxes based on national revenue inspire Eighth Amendment excessive fine arguments. Many legal observers consider these rights-based arguments meritless; to date, no court has ruled favorably on the same.

Structural Constitutional Arguments

The future of the IRA and CMS' DPNP may not depend on the Bill of Rights as much as structural constitutional principles reflecting legal strategies endorsed by the probusiness,²² regulatory-adverse²³ U.S. Supreme Court. In recent years, three congruent tenets premised on separation of powers — the nondelegation doctrine, *Chevron* deference,²⁴ and MQD — provide a means to dismiss

agency interventions that the Court views as overstepping statutory powers or reflecting impermissible congressional delegation of legislative authority. Resulting judicial opinions negate presidential initiatives and threaten agency powers.

Drug manufacturers directly allege that IRA provisions and CMS' execution run afoul of separation of powers principles.²⁵ IRA permissions for CMS to negotiate price reductions are, they argue, assimilate legislating. What is historically known as the nondelegation doctrine holds that Congress cannot broadly delegate

and MQD. In two cases, *Loper Bright Enterprises v. Raimondo*²⁸ and *Relentless v. Department of Commerce*,²⁹ the Court seeks to clarify or overrule *Chevron* in its 2023-24 term. Under *Chevron* deference, when a federal statute is ambiguous, courts may defer to reasonable agency interpretations of key provisions, thus enabling agencies to fulfill congressional directives.³⁰ Given explicit IRA authorizations for CMS to address drug access and health goals, the federal government may invariably raise *Chevron* deference concerning CMS' choices. The cur-

ity³⁷ when asked to expand statutes past largely-accepted underlying justifications³⁸ or when companies spend "millions of dollars per year" to comply with regulations.³⁹ Under these standards, CMS' DPNP provisions impacting the massive U.S. pharmaceutical industry seem ripe for MQD applications favoring business, industry, and property rights. Drug manufacturers may allege that Congress must more explicitly authorize a program that significantly limits their revenues and corresponding drug innovations to survive constitutional scrutiny.

Just as agencies look to legislative history and public health purposes before carrying out their statutes, courts must consider context and designated federal funds in upholding Congress' responses to health threats facing Americans today. Reviewing statutes outside their broader context, especially related to clear health priorities sustaining the IRA and DPNP, is the true infringement on separation of powers.

constitutional legislative powers to the other two branches. The doctrine had not been relied on since the New Deal era — that is until a 2019 Supreme Court decision, *Gundy v. United States*. In *Gundy*, multiple Justices expressed interest in reviving the doctrine to restrict Congress from allowing agencies to "prescribe rules" related to mandatory registration requirements via the federal Sex Offender Registration and Notification Act.²⁶ Since *Gundy*, opponents of administrative agencies have routinely argued nondelegation violations.²⁷ Appellate courts have largely rejected these arguments to date provided Congress sets "intelligible principles" for agencies to follow but application of these claims to CMS' DPNP may soon arrive before a more receptive Supreme Court.

Similar constitutional themes emerge under *Chevron* deference

rent political environment, however, suggests *Chevron* has fallen out of favor. SCOTUS has not cited *Chevron* to uphold agency decision-making since 2016.³¹ *Chevron's* demise almost seems inevitable.³²

Distinct from *Chevron* deference is MQD which challenges diverse agency regulations of "economic and political significance." Simply put, Congress must speak clearly for federal agencies to achieve "significant" national impacts. Since 2022, the Court has relied on MQD to condemn what it perceives as overbroad agency regulations targeting carbon emissions³³ and addressing student loan debt burdens.³⁴ Similar strategies in prior years denied agencies' authorities to set COVID-19 economic protections³⁵ and implement safety measures.³⁶ With Supreme Court backing, lower courts have warmed to evoking MQD to deny agency author-

A Cohesive, Structural Approach
SCOTUS' review of CMS' DPNP may be months away, but extant litigation in multiple federal circuits may result in disparate applications of anti-agency litigation strategies, mirroring trends in gun restrictions,⁴⁰ climate change responses,⁴¹ and labor reforms.⁴² Divisive appellate decisions may stymie or stall CMS' DPNP execution. To survive judicial scrutiny, IRA and DPNP must be considered in light of discrete public health threats of high prescription drug costs, elevating CMS' purposes of improving health outcomes.⁴³ To the extent that courts ignore congressional and agency directives, they usurp the roles of policy-makers in violation of separation of powers.

The nondelegation doctrine, *Chevron* deference, and MQD are triumvirate parts of a litigation strategy to avoid government regulation entirely. Some federal courts are highly skeptical. The nondelegation doctrine, for example, has been called a "Hail Mary" claim;⁴⁴ most appellate courts generally recognize that even the vaguest statutory directives are sufficient to circumvent it. Still, mixed appellate interpretations of when to defer to agencies under *Chevron* and what to label as a "major question" obfuscate agency authorities, limiting or scaling back specific interventions despite congressional or presidential appeals for agency action.⁴⁵

A more promising constitutional path ahead to sustain the IRA and DPNP arises from a parallel trend in judicial review of administrative

agency action tied to improving health outcomes. Public health justifications supporting holistic statutory interpretations based on legislative history and other contexts have dissuaded attempts to overrule provisions broadly and allow agencies to follow congressional directives. Courts have favorably interpreted statutes such as the Federal Coal Mine Health and Safety Act,⁴⁶ the Veterans Health Care Act,⁴⁷ or the Family and Medical Leave Act⁴⁸ which all address specific public health concerns. Many of these cases cite the Supreme Court's ACA decision in *Sebelius*⁴⁹ where it declined logical interpretations of specific terms, removed from context, to elevate comprehensive regulatory schemes carefully designed to extensively expand health care access. Other courts tend to uphold agency action following "logical extensions"⁵⁰ of accepted congressional charges including protecting the public's health.⁵¹

Even the Supreme Court's recent opinions severely restricting administrative powers recognize the primacy of established public health charges. SCOTUS' disparate MQD applications — rejecting broad COVID-19 vaccination mandates for industry⁵² but accepting identical requirements for facilities accepting federal funds under CMS requirements⁵³ — underscore how separation of powers arguments fall away when courts accept underlying public health justifications behind statutes and federal funding support. Other recent decisions considering CMS rulemaking declined to overrule *Chevron* or meaningfully strip it of broad discretion.⁵⁴ Just as agencies look to legislative history and public health purposes before carrying out their statutes, courts must consider context and designated federal funds in upholding Congress' responses to health threats facing Americans today. Reviewing statutes outside their broader context, especially related to clear health priorities sustaining the IRA and DPNP, is the true infringement on separation of powers.

Note

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References

1. Inflation Reduction Act of 2022, P.L. 117-169, Sec. 1191 et seq. (2022). Accessed Sept. 6, 2023, *available at* <<https://www.congress.gov/117/plaws/publ169/PLAW-117publ169.pdf>> (last visited Dec. 15, 2023).
2. L. Gostin, J. Hodge, and A. Twina-matsiko, "Medicare's Historic Prescription Drug Price Negotiations," *JAMA* 330, no. 17 (2023), doi:10.1001/jama.2023.19506.
3. Centers for Medicare and Medicaid Services, "Fact Sheet: Biden-Harris Administration Announces First Ten Drugs Selected for Medicare Price Negotiation," The White House, Aug. 29, 2023, *available at* <<https://www.whitehouse.gov/briefing-room/statements-releases/2023/08/29/fact-sheet-biden-harris-administration-announces-first-ten-drugs-selected-for-medicare-price-negotiation/>> (last visited Dec. 15, 2023).
4. S. Dusetzina, R. Besaw, C. Whitmore, et al., "Cost-Related Medication Non-adherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022," *JAMA Network Open* 6, no. 5 (2023), e231421, doi:10.1001/jamanetworkopen.2023.14211.
5. United States Department of Health and Human Services, "HHS Selects the First Drugs for Medicare Drug Price Negotiation," *available at* <<https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html>> (last visited Sept. 6, 2023).
6. L. Gostin, J. Hodge, and A. Twina-matsiko, *supra* note 2.
7. J. Hodge, E. White, and M. Saxon, "Table — Litigation Regarding CMS Drug Pricing Negotiation Authority," Sept. 7, 2023, *available at* <https://law.asu.edu/sites/default/files/2023-08/ASU_CPHLP_Table_CMS_Drug_Pricing_Litigation.pdf> (last visited January 17, 2024).
8. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173 (2003), *available at* <<https://www.govinfo.gov/content/pkg/PLAW-108publ173/pdf/PLAW-108publ173.pdf>> (last visited October 5, 2023).
9. Congressional Budget Office, *Prescription Drugs: Spending, Use, and Prices*, Jan. 2022, *available at* <<https://www.cbo.gov/system/files/2022-01/57050-Rx-Spending.pdf>> (last visited Dec. 18, 2023).
10. D. Lowe, "John Kerry on Drug Prices. Science Commentary," July 30, 2004, *available at* <<https://www.science.org/content/blog-post/john-kerry-drug-prices>> (last visited Oct. 6, 2023).
11. Inflation Reduction Act of 2022, P.L. 117-169, Sec. 1191 et seq. (2022), *available at* <<https://www.congress.gov/117/plaws/publ169/PLAW-117publ169.pdf>> (last visited Dec. 18, 2023).
12. Centers for Medicare and Medicaid Services, "Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026," *available at* <<https://www.cms.gov/files/document/revise-medicare-drug-price-negotiation-program-guidance-june-2023.pdf>> (last visited Sept. 25, 2023).
13. *Id.*
14. Centers for Medicare and Medicaid Services, "Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026," Aug. 2023, *available at* <<https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf>> (last visited Dec. 18, 2023).
15. Centers for Medicare and Medicaid Services, "Fact Sheet: Key Information on the Process for the First Round of Negotiations for the Medicare Drug Price Negotiation Program," Sept. 2023, *available at* <<https://www.cms.gov/files/document/fact-sheet-negotiation-process-flow.pdf>> (last visited Dec. 18, 2023).
16. Centers for Medicare and Medicaid Services, "Drug Price Negotiation Timeline for 2026," *available at* <<https://www.cms.gov/files/document/drug-price-negotiation-timeline-2026.pdf>> (last visited Sept. 25, 2023).
17. Centers for Medicare and Medicaid Services, *supra* note 12.
18. Centers for Medicare and Medicaid Services, *supra* note 16.
19. U.S. Health and Human Services Office of the Inspector General, "Drug Spending. Updated Oct. 2, 2023," *available at* <<https://oig.hhs.gov/reports-and-publications/featured-topics/drug-spending/>> (last visited Dec. 18, 2023).
20. J. Cubanski, T. Neuman, and M. Freed, "Explaining the Prescription Drug Provisions in the Inflation Reduction Act," Jan. 24, 2023, *available at* <<https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/>> (last visited Dec. 18, 2023); J. Cubanski, M. Rae, K. Young, et al., "How Does Prescription Drug Spending and Use Compare Across Large Employer Plans, Medicare Part D, and Medicaid?" May 20, 2019, *available at* <<https://www.kff.org/medicare/issue-brief/how-does-prescription-drug-spending-and-use-compare-across-large-employer-plans-medicare-part-d-and-medicaid/>> (last visited Dec. 18, 2023).

21. Gostin, *supra* note 2.
22. L. Epstein and M. Gulati, "A Century of Business in the Supreme Court, 1920-2020," *Minnesota Law Review Headnote* 107 (2022).
23. G. Metzger, "1930s Redux: The Administrative State Under Siege," *Harvard Law Review* 131 (2017).
24. *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984).
25. Gostin, *supra* note 2.
26. *Gundy v. United States*, 139 S. Ct. 2116 (2019).
27. D. Walters, "Decoding Nondelegation after Gundy: What the Experience in State Courts Tells Us about what to Expect When We're Expecting," *Emory Law Journal* 71 (2022).
28. *Loper Bright Enterprises v. Raimondo*, 143 S. Ct. 2429 (2023).
29. *Relentless, Inc. et al. v. Dep't of Commerce et al.*, No. 22-1219, 2023 WL 6780370 (U.S. Oct. 13, 2023).
30. *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984).
31. *Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131, 214244 (2016).
32. T. Berenson, "How Neil Gorsuch Could Dramatically Reshape U.S. Government," *Time*, March 19, 2017, available at <https://time.com/4701114/neil-gorsuch-confirmation-hearing-chevron-doctrine/> (last visited Oct. 10, 2023). C. Coglianese, "The Ambiguity in Judge Kavanaugh's Chevron Critique," *The Regulatory Review*, Sept. 6, 2018, available at <https://www.theregreview.org/2018/09/06/coglianese-ambiguity-kavanaughs-chevron-critique/> (last visited Oct. 10, 2023).
33. *West Virginia v. EPA*, 142 S. Ct. 2587 (2022).
34. *Biden v. Nebraska*, 143 S. Ct. 2355 (2023).
35. *Alabama Association of Realtors, et al. v. Dep't Health & Human Services*, 141 S. Ct. 2485 (2021).
36. *Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., Occupational Safety & Health Admin.*, 595 U.S. 109 (2022).
37. E. White, "Overcoming the Major Questions Doctrine with Federal Public Health Authorities," *Harvard Law & Policy Review* (forthcoming 2023).
38. *Id.* at *12.
39. *Chamber of Com. v. Consumer Financial Prot. Bureau*, 2023 WL 5835951 (E.D. Tex. Sept. 8, 2023).
40. *Cargill v. Garland*, 57 F.4th 447 (5th Cir. 2023).
41. J. Hijazi, "Biden Tailpipe Emission Rules Face 'Major Questions' Legal Wave," *Bloomberg Law*, April 14, 2023, available at <https://www.bloomberglaw.com/bloomberglawnews/environment-and-energy/XEJJHHVC000000?bna_news_filter=environment-and-energy#cite> (last visited Oct. 6, 2023).
42. M. Lao, "The Major Questions Doctrine, FTC Rulemaking, and Rulemaking on Non-Compete Clauses," *Journal of Antitrust Enforcement* 11 (2023).
43. *See American Hospital Ass'n v. Becerra*, 142 S. Ct. 1896 (2022); *Biden v. Becerra*, 595 U.S. 87 (2022).
44. *See Andy Warhol Found. Visual Arts, Inc. v. Goldsmith*, 143 S. Ct. 1258, 1282 n.17 (2023); *Saddozai v. Davis*, 35 F.4th 705, 709 (9th Cir. 2022).
45. J.L. Lineberry and J. Silliman, "New EPA and Corps 'Waters of the United States' Rule Conforms to Sackett v. EPA, Leaves Ambiguities," *JD Supra*, Sept. 13, 2023, available at <https://www.jdsupra.com/legalnews/new-epa-and-corps-waters-of-the-united-7018377/> (last visited Dec. 18, 2023).
46. *Sec'y of Lab. v. KC Transport*, 77 F.4th 1022 (D.C. Cir. 2023).
47. *Sanofi-Aventis U.S. & Novo Nordisk Inc. v. Dep't of Health and Human Serv.*, 3:21-CV-00806-FLW-LHG (Nov. 5, 2021).
48. *Restaurant Law Center v. Dep't of Lab.*, 2023 WL 4375518 (W.D. Tex., July 6, 2023).
49. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519 (2012).
50. *Dylan Campbell v. Universal City Development Partners, Ltd.*, 2023 WL 6196537 (Sept. 22, 2023).
51. *GMS Mine Repair v. Federal Mine Safety & Health Review Commission*, 72 F.4th 131 (D.C. Cir. 2023).
52. *Nat'l Fed'n of Indep. Bus. v. Occupational Safety & Health Commission*, 595 U.S. ____ (2022).
53. *Biden v. Missouri*, 595 U.S. 87 (2022).
54. *American Hospital Ass'n v. Becerra*, 596 U.S. 142 S. Ct. (2022).