Health Care
Affordability Lab
at Yale

VIA ELECTRONIC SUBMISSION

August 14, 2026

Senator Ron Wyden
Ranking Member
Senate Committee on Finance
Washington, D.C. 20510

Re: Response to Request for Information, "Commonsense Policy Options to Lower Drug Prices for Patients"

Dear Ranking Member Wyden:

The Health Care Affordability Lab at Yale University welcomes the opportunity to respond to your recent Request for Information (RFI), *Commonsense Policy Options to Lower Drug Prices for Patients*, released on June 16, 2026.

The Health Care Affordability Lab ("the Lab") at Yale is dedicated to producing research and evidence that can help policymakers and other stakeholders with efforts to lower health care costs without sacrificing quality. The Lab also prioritizes identifying practical, evidence-based solutions to inefficiencies in U.S. health care markets that can better ensure the system delivers greater value for patients and taxpayers alike.

The following comments are informed by the Lab's broader body of work, including two flagship initiatives: **1% Steps for Health Care Reform**, which highlights findings of fellow health economists and their targeted policy recommendations to reduce spending without sacrificing quality; and the **Just the Facts** memo series, which synthesizes the most robust research on pressing health policy matters for policymakers and the public. Specifically, these comments respond to matters raised in Sections I and II of the RFI, drawing on evidence concerning the incentives under the Orphan Drug Act; Medicare Part B billing for biologics and biosimilars; patient cost-sharing for insulin; vertical integration among insurers, PBMs, and pharmacies; and prescription drug copay coupons. The authors of respective research on these areas are cited throughout, and the Lab would be happy to connect you or your team with them if interested.

Section I: Lowering Drug Prices

Reforming the Orphan Drug Act

Strong academic evidence supports better tailoring the incentives under the Orphan Drug Act (ODA), as research suggests the law has directed support to prescription drugs that would likely have been developed without it.[1] Below we draw from a 1% Steps brief authored by Amitabh Chandra at Harvard University.[2]

Congress passed the ODA in 1983 to encourage investment in treatments for rare diseases, whose patient populations are often too small to reliably justify development costs. The law offers two primary incentives to encourage manufacturers to develop orphan pharmaceutical products: (1) research and development (R&D) tax credits (the Orphan Drug Credit under I.R.C. §45C, distinct from the general research credit under §41), and (2) seven years of market exclusivity. However, the market has since changed in three ways that make these incentives less well-targeted:

- **Some orphan drugs now generate substantial revenue.** Among the highest-selling drugs, the median orphan drug's annual price per patient is approximately seven times that of the median non-orphan drug.[3] Six of the ten top-selling drugs have an additional orphan drug designation, despite primarily treating non-orphan conditions.[4]
- **A large share of orphan drugs benefit from FDA programs designed to expedite development or review.** Approximately 71% of orphan-drug approvals from 2008 through 2017 benefited from at least one of four programs: accelerated approval, breakthrough therapy designation, fast track designation, and priority review.[5] By shortening development or review timelines, these programs reduce the cost and risk of bringing a drug to market.
- **Some ODA benefits go to drugs already marketed for other indications.** From 2008 through 2017, 38.5% of orphan-drug approvals were new indications for previously approved drugs, including drugs previously approved for rare or non-rare diseases.[6] Humira, for example, received five orphan-indication approvals between 2008 and 2016—each carrying its own seven-year exclusivity—even though most of its use and spending has historically been associated with non-orphan indications.[7]

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[1] Amitabh Chandra, "Reforming the Orphan Drug Act," 1% Steps for Health Care Reform, February 2021, https://onepercentsteps.com/policy-briefs/reforming-the-orphan-drug-act/
[2] Chandra, "Reforming the Orphan Drug Act."
[3] Karen Pomeranz, "Orphan Drug Report 2019," EvaluatePharma, April 2019, https://ptacts.uspto.gov/ptacts/public-informations/petitions/1524082/download-documents?artifactId=VrY9ZPcwnkZPOFJ6EZZoeykbaPo3hWFRChlmvROXgPXuSs3KuE4Fw-s
[4] "Medicine Spending and Affordability in the United States," IQVIA Institute for Human Data Science, August 2020, https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us; "Search Orphan Drug Designations and Approvals," U.S. Food and Drug Administration, https://www.accessdata.fda.gov/scripts/opdlisting/oopd/.
[5] "Orphan Drugs: FDA Could Improve Designation Review Consistency; Rare Disease Drug Development Challenges Continue," United States Government Accountability Office, GAO-19-83, November 2018, https://www.gao.gov/products/gao-19-83.
[6] GAO, "Orphan Drugs," GAO-19-83.
[7] Chandra, "Reforming the Orphan Drug Act."

Congress could consider three updates to the ODA:

First, make R&D tax credits the sole incentive and eliminate the ODA's seven-year orphan drug exclusivity. The two approaches differ in who bears the cost. Market exclusivity limits competition and allows manufacturers to charge higher prices. Because rare disease patient populations are small, manufacturers often rely on high per-patient prices to recoup their investment.[8] Patients who use these drugs bear part of the cost directly through higher cost sharing. Insurers and public programs pay the remainder, which leads to higher insurance premiums overall. Tax credits, by contrast, spread the cost across taxpayers and tie public support more directly to development spending.

Second, add a clawback provision to the R&D tax credits. Some drugs generate sufficiently high sales to suggest that the public subsidy was ultimately larger than necessary. A clawback could require manufacturers to repay credits after sales exceed a specified threshold. Japan operates a related system in which recipients of orphan-drug development subsidies begin repaying them once annual sales exceed a set amount.[9]

Third, condition the R&D tax credits on manufacturers agreeing to some form of price regulation after patent expiration if no generic or biosimilar competition emerges. Some orphan markets may remain too small to attract generic or biosimilar entry, leaving branded products with little competitive pressure even after their protections lapse. One approach to price regulation could be to require rates that generate a prespecified margin above the production costs of the orphan drug.

The potential savings are substantial. Based on 2019 sales data, a 10% price reduction on the six orphan-designated drugs among the ten highest-revenue drugs in the United States would reduce health spending by an estimated $5.24 billion, approximately 1.5% of total drug spending.[10]

Promoting Biosimilar Competition

To amplify biologic and biosimilar competition and incentivize providers to prescribe lower-cost biosimilars, **academic evidence supports modifying the design of Medicare J-codes so that a reference biologic and all of its biosimilars are reimbursed under a single, shared J-code.**[11] Physicians would then be paid a fixed amount for administering any product within the J-code group.

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[8] Helen Mooney, Aaron S. Kesselheim, and Benjamin N. Rome, "US Spending on High-Revenue Rare Disease Drugs in 2022," *The American Journal of Managed Care* 31, no. 11 (2025), https://www.ajmc.com/view/us-spending-on-high-revenue-rare-disease-drugs-in-2022.

[9] Nicholas Bagley, Benjamin Berger, Amitabh Chandra, Craig Garthwaite, and Ariel D. Stern, "The Orphan Drug Act at 35: Observations and an Outlook for the Twenty-First Century," *Innovation Policy and the Economy* 19 (2019): 97–137, https://doi.org/10.1086/699934.

[10] Chandra, "Reforming the Orphan Drug Act."

[11] Fiona Scott Morton and Zack Cooper, "Paying for Biologic PADs in Medicare Part B," 1% Steps for Health Care Reform, https://onepercentsteps.com/policy-briefs/paying-for-biologic-pads-in-medicare-part-b/

Physician-administered drugs, such as injections and infusions, are covered under Medicare Part B. The physician selects either the biologic or biosimilar to purchase, stores it in inventory, and administers it to the patient. Medicare then reimburses the physician based on the drug's average sales price (ASP), the volume-weighted average of the manufacturer's sales to all purchasers, plus a 6% markup.[12] Under current Medicare policy, a reference biologic and each of its biosimilars has a separate billing code, or J-code. This structure can raise spending in three ways:

- **Manufacturers face no price competition.** With one manufacturer per code, the J-code functions as a cost-plus contract. Reimbursement is based on the drug's average sales price, which the manufacturer largely controls.
- **Providers have no incentive to choose lower-priced alternatives such as biosimilars.** Reimbursement follows the acquisition cost of whichever product the physician administers, so a physician who selects a lower-priced biosimilar is simply reimbursed less.
- **Current payment rules leave a substantial share of the potential savings from biosimilar competition unrealized.** ASPE finds that in 2023, four reference biologics were priced at more than double their biosimilars, while still retaining between 20% and 38% of their market.[13]

A 1% Steps brief authored by Fiona Scott Morton and Zack Cooper of Yale University offers two changes: (1) assign a single J-code to each molecule, covering the reference biologic and all of its biosimilars, and (2) pay physicians a fixed amount for administering any product in the group—set at the price of the least costly alternative plus 5%, or $500, whichever is smaller.[14]

These changes would push manufacturers to compete on price, since physicians would then increase their margins by buying the least expensive product in the J-code. Because biosimilars are clinically comparable to their reference product, aligning payment this way lets competition lower prices without compromising the physician's clinical choice. Although other countries use different payment systems, their experience shows that biosimilar competition can put downward pressure on prices. One study of Europe and Australia estimated that average market prices declined by about 3.5 percentage points per year after biosimilar entry.[15] In a 2015

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[12] A Data Book: Health Care Spending and the Medicare Program," Medicare Payment Advisory Commission, July 17, 2025, https://www.medpac.gov/document/july-2025-data-book-health-care-spending-and-the-medicare-program/; The Inflation Reduction Act temporarily raised the markup for qualifying biosimilars (i.e., those whose ASP is no higher than the reference product's) to 8% of the reference product's ASP for a five-year window. For qualifying biosimilars for which CMS paid using ASP as of September 30, 2022, the applicable five-year period began on October 1, 2022. For qualifying biosimilars for which CMS first paid using ASP between October 1, 2022 and December 31, 2027, the applicable five-year period began the first day of that first calendar quarter. https://www.cms.gov/medicare/payment/part-b-drugs/asp-reporting

[13] Micah Johnson, Nguyen X. Nguyen, and Steven H. Sheingold, "Medicare Part B Enrollee Use and Spending on Biosimilars, 2018–2023," Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, January 15, 2025, https://aspe.hhs.gov/reports/biosimilars-medicare-part-b

[14] Scott Morton and Cooper, "Paying for Biologic PADs in Medicare Part B."

[15] Fiona Scott Morton, Ariel Dora Stern, and Scott Stern, "The Impact of the Entry of Biosimilars: Evidence from Europe," *Review of Industrial Organization* 53, no. 1 (2018): 173–210, https://link.springer.com/article/10.1007/s11151-018-9630-3

Norwegian national tender, the biosimilar Remsima was offered at a price approximately 69% below the reference product's tender price.[16]

Under conservative assumptions—including a roughly 30% reduction in biologic spending based on the European experience—this policy would save $2 billion per year.[17] It might save as much as $7.5 billion per year, which is approximately 1% of Medicare spending (in 2018 dollars), assuming steeper spending decreases.[18]

Section II: Enhancing Prescription Drug Affordability

Eliminating Cost-Sharing for Insulin

Strong academic evidence supports eliminating cost sharing for insulin, including for people with Medicare or private health coverage. For drugs like insulin, patient cost sharing does not steer patients toward cheaper, more cost-effective care. Rather, it drives patients to take less of a medication they need—with measurable consequences for their health.[19]

Our Lab has ongoing work examining the effect of eliminating cost sharing for insulin on insulin use and glycemic control. We use a rigorous study design to compare outcomes between patients with diabetes enrolled in employer-sponsored insurance plans that eliminated insulin cost sharing and patients enrolled in plans that did not. Early evidence suggests there are health benefits of eliminating cost sharing (including eliminating cost sharing for individuals in states that already cap out-of-pocket costs at fixed amounts per month). We look forward to sharing our published findings with the Committee as soon as we are able.

Other research shows that cost sharing for chronic medications can reduce adherence and health outcomes. Christopher Hollrah studies low-income Medicare beneficiaries who lose the Low-Income Subsidy, which had limited their drug costs to a few dollars per fill—drawing on claims data that predate the monthly $35 insulin cap enacted in the *Inflation Reduction Act*.[20] When these beneficiaries lose the subsidy and their costs rise, they fill 35% fewer insulin prescriptions—more than double the 16% reduction they make across their prescriptions overall, despite insulin's clear clinical value. Rather than switch to lower-cost generics, they fill fewer prescriptions. Hollrah's central result is that a drug's out-of-pocket price, not its clinical value, predicts how much patients cut back when costs rise. Chandra, Flack, and Obermeyer (2024) find the same pattern across a broader set of medications: when Medicare beneficiaries

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[16] Asbjørn Mack, "Norway, Biosimilars in Different Funding Systems. What Works?" *Generics and Biosimilars Initiative Journal* 4, no. 2 (2015): 90–92, https://gabi-journal.net/norway-biosimilars-in-different-funding-systems-what-works.html

[17] Scott Morton and Cooper, "Paying for Biologic PADs in Medicare Part B."

[18] Scott Morton and Cooper, "Paying for Biologic PADs in Medicare Part B."

[19] Amitabh Chandra, Evan Flack, and Ziad Obermeyer, "The Health Costs of Cost Sharing," *The Quarterly Journal of Economics*, Volume 139, Issue 4, November 2024, Pages 2037–2082, https://doi.org/10.1093/qje/qjae015; Christopher Hollrah, "Prioritizing Benefit? How Low-Income Patients Respond to Prescription Cost-Sharing," *American Economic Journal: Economic Policy*, forthcoming.

[20] Christopher Hollrah, "Prioritizing Benefit? How Low-Income Patients Respond to Prescription Cost-Sharing."

face abrupt out-of-pocket increases, they cut back on cardiovascular, diabetes, and respiratory drugs alike, and die at higher rates.[21]

These findings are relevant to the Committee's question about which additional chronic care drugs merit cost sharing caps. Patients should not be expected to reliably distinguish low-value from lifesaving treatment when responding to cost sharing. These findings suggest that eliminating cost sharing could most benefit patients taking prescription drugs with high out-of-pocket costs, chronic use, no lower-cost substitute, and documented sensitivity of adherence to price.

Banning the Use of Prescription Drug Copay Coupons

Strong academic evidence supports banning the use of prescription drug copay coupons on branded drugs that have generic substitutes for people with private insurance.[22] These coupons, offered by branded drug manufacturers and distributed to patients, lower out-of-pocket costs but raise total health spending for privately insured patients. Copay coupons are already banned in California[23], Massachusetts[24], and in the Medicare and Medicaid programs.

We draw on a 1% Steps brief authored by Leemore Dafny, Christopher Ody, and Matthew Schmitt.[25] These researchers have found that copay coupons increase the share of prescriptions filled by a branded drug versus its generic equivalent by over 60% and raise total annual prescription drug spending among the privately insured by approximately 1%.[26] Branded drugs can cost more than five times as much as their generic equivalents.[27] Therefore, a copay coupon that can pay some or all of the patient's cost sharing for a particular branded drug obscures the price gap between the generic and branded drugs.[28] This can steer patients toward more costly brand-name drugs.

The 1% Steps brief suggests eliminating prescription drug copay coupons would create incentives that:

- **Enable insurers to negotiate lower drug prices**. Without copay coupons, insurers could threaten to place higher-priced branded drugs on lower benefit tiers with high cost sharing, discouraging patients from opting for them due to higher out-of-pocket cost.[29]

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[21] Chandra et al. "The Health Costs of Cost Sharing."
[22] Leemore Dafny, Christopher Ody, and Matthew Schmitt, "Eliminating Prescription Drug Copay Coupons," 1% Steps for Health Care Reform, February 2021. https://onepercentsteps.com/policy-briefs/eliminating-prescription-drug-copay-coupons/
[23] California Legislature. 2017. *Prescription Drugs: Prohibition on Price Discount*, A.B. 265, 2017–2018 Reg. Sess.
[24] Commonwealth of Massachusetts. "Solicitation, improper inducement to use goods, facilities, services, or products covered by insurance." Mass. General Laws c.175H § 3
[25] Dafny et al., "Eliminating Prescription Drug Copay Coupons."
[26] Leemore Dafny, Christopher Ody, and Matthew Schmitt, 2017, "When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization," *American Economic Journal: Economic Policy* 9, no. 2(2017): 91–123.
[27] Food and Drug Administration. "Generic Drug Facts." Available at https://www.fda.gov/drugs/generic-drugs/generic-drug-facts. Accessed August 10, 2026.
[28] Dafny et al., "Eliminating Prescription Drug Copay Coupons."
[29] Dafny et al., "Eliminating Prescription Drug Copay Coupons."

- **Promote greater use of lower-cost generic drugs.** When generics enter the market, Medicare beneficiaries and patients in states that prohibit copay coupons fill fewer prescriptions for therapeutically equivalent brand-name drugs than patients in states that allow coupons. A study comparing Massachusetts, where coupons were prohibited, with New Hampshire, where they were permitted, found that coupon availability increased brand-name drug utilization by more than 60% in New Hampshire relative to Massachusetts.[30]
- **Slow drug price growth.** Copay coupons are associated with faster branded-drug price growth: roughly 12% annually for drugs with coupons versus 7–8% for those without coupons.[31]

Eliminating copay coupons could yield potential annual savings of $1.155 billion, representing approximately 0.9% of prescription drug spending among commercially insured patients.[32] Given these potential savings and that copay coupons are already restricted in California[33], Massachusetts[34], and in the Medicare and Medicaid programs, Congress should consider banning copay coupons for branded drugs with generic substitutes in the commercial market.

Vertical Integration Among Insurers, PBMs, and Pharmacies

Academic evidence supports reevaluating the MLR requirement for vertically integrated insurers. Researchers have found that vertical integration among insurers and pharmacies may allow integrated insurers to tunnel profits in order to circumvent the Medical Loss Ratio (MLR) rule, with the side effect of raising prescription drug prices for enrollees. Insurer-PBM integration can weaken competition among PBMs, raising premiums for enrollees in non-integrated plans.

The minimum medical loss ratio (MLR) requires health plans to spend a minimum share of premiums on medical costs, such as clinical services and quality improvement, rather than on administrative costs and profit. Introduced under the Affordable Care Act, the minimum MLR is 80% for individual and small-group plans and 85% for large-group plans, with a separate 85% minimum applying to Medicare Advantage and Part D plans since 2014. Vertical integration between insurers and providers can enable plans to circumvent this requirement. Because MLR rules apply only to the health plan itself, not to its broader corporate structure, integrated insurers may tunnel profits to affiliated providers by making inflated "medical cost" payments, which count toward MLR compliance without a corresponding increase in patient care. For instance, insurers can raise the reimbursement prices paid to their own integrated pharmacies for filling prescriptions. Because that spending counts toward the MLR minimum, the insurer satisfies the requirement on paper while the resulting profit stays inside the corporate family, at the pharmacy rather than the insurer. A 2026 study found that, in the three

[30] Dafny et al., “When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization.”
[31] Dafny et al., “When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization.”
[32] Dafny et al., “Eliminating Prescription Drug Copay Coupons.”
[33] California Legislature. 2017. *Prescription Drugs: Prohibition on Price Discount*, A.B. 265, 2017–2018 Reg. Sess.
[34] Commonwealth of Massachusetts. “Solicitation, improper inducement to use goods, facilities, services, or products covered by insurance.” Mass. General Laws c.175H § 3

years after MLR implementation, prices paid by insurers to their affiliated pharmacies increased by 9.5% relative to non-integrated pharmacies. Furthermore, this price increase was concentrated among insurers most at risk of MLR noncompliance: price increases from insurers whose MLR was below 90% were six times greater than those from insurers with MLR above 90%.[35]

Since Medicare Part D's cost-sharing and subsidy formulas are calculated as a share of the reimbursement prices, increasing payments to integrated pharmacies also raises costs for patients and the federal government. Moreover, vertical integration could grant insurers greater control over pharmacy choice, letting them steer enrollees toward integrated pharmacies and away from lower-cost alternatives. This process reduces patient volume at competing, non-integrated pharmacies, and places higher costs directly onto enrollees through cost-sharing.

Researchers estimated that if vertically integrated insurers divested their affiliated pharmacies, average Medicare drug prices would fall by 7.3%, annual consumer surplus in Medicare Part D would rise by 8.1%, and annual government spending on Medicare Part D subsidies and reinsurance would decrease by $5.3 billion— with the largest gains for rural consumers, who have fewer non-integrated pharmacy options.[36] However, divestiture would also raise premiums since integrated insurers currently use profits from inflated pharmacy prices to subsidize lower premiums[37] These price and consumer-surplus gains outweigh the resulting premium increase, leaving consumers better off overall.

Insurers are also becoming vertically integrated with PBMs. By integrating with PBMs, insurers can leave competitors with fewer alternatives for PBM services, which raises their costs and, in turn, their premiums. One 2015 merger between UnitedHealth and Catamaran, a PBM, caused non-integrated plans to raise their premiums by 42% relative to integrated plans. UnitedHealth's own enrollees, meanwhile, saw no decrease in their premiums, implying that the non-integrated premium increase may have arisen from the merger.[38]

[35] Kakani et al., "Profit Regulation and Strategic Transfer Pricing by Vertically Integrated Firms: Evidence from Health Care." Working Paper 35043, National Bureau of Economic Research, Cambridge, MA, 2026. https://www.nber.org/system/files/working_papers/w35043/w35043.pdf
[36] Yde, "Vertical Integration and Regulated Profits in Pharmacy Benefits Markets," job market paper, University of Virginia, Charlottesville, VA, 2025, https://www.ydeeric.com/
[37] Yde, "Vertical Integration."
[38] Gray et al., "Disadvantaging Rivals: Vertical Integration in the Pharmaceutical Market," *American Economic Journal: Applied Economics* 18, no. 1 (2026): pp. 286–304, https://doi.org/10.1257/app.20240011

Thank you for the opportunity to provide ideas and feedback on potential policy options to reduce prescription drug prices and lower patients' out-of-pocket costs. If you have questions about the information in this letter, please reach out to Andrea Harris, Managing Director of the Health Care Affordability Lab at Yale, at andrea.harris@yale.edu.

Sincerely,

Zack Cooper, PhD

Director, Health Care Affordability Lab at Yale
Associate Professor of Public Health and of Economics, Yale University
Director of Health Policy, Tobin Center for Economic Policy

CC:

Senator Catherine Cortez Masto
Senator Peter Welch
Senator Ruben Gallego
Senator Mark Kelly
Senator Tammy Baldwin
Senator Maggie Hassan
Senator Jeff Merkley
Senator Chris Van Hollen
Senator Tammy Duckworth
Senator Richard Blumenthal