Center on
Health Policy
at BROOKINGS

August 17, 2026

Senator Ron Wyden
United States Senate
Committee on Finance, Minority Staff

Re: Request for Information on prescription drug pricing

Dear Ranking Member Wyden,

Thank you for the opportunity to provide comments on the Senate Finance Committee Minority Staff Request for Information (RFI) regarding prescription drug pricing.[1] We write to provide comments on several areas of the potential policy options detailed in the RFI and identify ways in which these policies may be strengthened or modified to enable them to achieve their goals most effectively. We would be happy to supplement the below comments with additional sources and analysis, if desired.

As an initial matter, it may be helpful to explain the lenses through which we approached our analysis. First, we think it is important to keep in mind the *interactions* between the different sets of policies presented in the RFI. There are often tradeoffs involved in individual drug pricing policies, and it may be important to pursue policies as a package rather than individually. For example, pairing policies from Section I that would lower drug prices with those from Section II that would enhance patient affordability by increasing the generosity of a particular insurance benefit could result in a legislative package, which is overall cost-saving and would accomplish multiple policy goals simultaneously.

Second, we considered *operational* and *practical* aspects of the listed policies. All things being equal, we think it is important to prioritize policies which could be developed and implemented relatively quickly. We considered the complexity of each policy and the additional career civil servants who may be needed to implement it successfully. As another example, of the policies regarding patient affordability, we believe it is important to prioritize policies which would likely be experienced by patients directly.

Third and finally, although we are not political experts, we considered the potential *stakeholders* who may be supportive of or opposed to any particular policy. As one example, political staff may

[1] Senate Finance Committee Minority Staff, Request for Information: Commonsense Policy Options to Lower Drug Prices for Patients [hereinafter RFI] (June 16, 2026), https://www.finance.senate.gov/imo/media/doc/061626_sfc_drug_pricing_rfi.pdf.

decide that it is politically too difficult, given congressional makeup, to amend the portion of the Inflation Reduction Act (IRA) establishing the Medicare Drug Price Negotiation Program (MDPNP). However, there are ways to strengthen the impact of the MDPNP that lie outside the IRA itself, relying on the interaction of the MDPNP with other key federal programs. Reforms to the Medicare Part B payment structure or reforms that increase biosimilar uptake may bolster the impact of the MDPNP without requiring amendments to the law.

Section I: Lowering drug prices

In general, we are supportive of the broad goals of this Section, "continuing to lower the prices manufacturers charge for prescription drugs."[2] In our view, the vast majority of the proposals identified in this section are capable of contributing to that goal. Yet as noted in the introductory material above, we are mindful of the operational challenges raised by the staff's various proposals. Importantly, as the staff recognizes (based on Section III of the RFI), policies must also ensure that scientists and pharmaceutical companies are able to continue engaging in innovative research and development activities that advance the health of the public through the creation of new pharmaceutical technologies. One way to accomplish these dual goals includes not only providing predictable reimbursement to manufacturers but also rewarding manufacturers based on the clinical value their products provide to patients. The IRA's MDPNP already contains many elements consistent with this principle. They include requiring Medicare to consider, among other factors, "the extent to which such drug represents a therapeutic advance as compared to existing therapeutic alternatives," "comparative effectiveness of such drug and therapeutic alternatives to such drug," and "the extent to which such drug and therapeutic alternatives to such drug address unmet medical needs."[3]

International Reference Pricing (IRP)

Jointly with colleagues, we have co-authored a general policy brief on the topic of IRP,[4] which may be helpful to committee staff. We have also, with another colleague, submitted public comments regarding the Trump administration's GLOBE and GUARD proposed models and link them here for reference.[5] In our policy brief and public comments, we raise a number of important design choices that would need to be made by both Congress and Medicare staff in implementing any of the approaches to incorporating IRP into the negotiation process, including the choice of countries to include in the market basket, how, where possible, to gather otherwise confidential net price information, and how to compare international prices to U.S.-based ones. We note the significant operational and legal complexity involved in these design choices and the time it would take to develop relevant policy and implement the use of IRP as part of the MDPNP.

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[2] *Id.* at 2.
[3] 42 U.S.C. § 1320f-3(e)(2).
[4] Christen Linke Young, Richard G. Frank, & Rachel Sachs, *International Reference Pricing for Prescription Drugs: Recent History and Next Steps*, The Brookings Institution (July 9, 2025), https://www.brookings.edu/articles/international-reference-pricing-for-prescription-drugs/.
[5] Richard G. Frank, Kristi Martin, & Rachel Sachs, *Comments on GLOBE and GUARD Drug Pricing Models*, The Brookings Institution (March 2, 2026), https://www.brookings.edu/articles/comments-on-globe-and-guard-drug-pricing-models/.

As our policy brief (and the RFI) notes, there are also multiple options for how to incorporate IRP into the negotiation process, including as a factor in negotiations or as a component of the MDPNP ceiling price. In our view, if an IRP approach is pursued, using it as an additional section 1194(e)(1) factor in negotiations is preferable to incorporating it into the ceiling. Using international pricing as submitted by the manufacturer as part of the section 1194(e)(1) factors rather than as a ceiling price component provides the Centers for Medicare and Medicaid Services (CMS) with greater flexibility in how strongly to weigh the international pricing. Incorporating the international price into the ceiling would limit CMS' flexibility to make an offer above the international price, where CMS believed it was merited. An application of IRP that reduced prices too far would run the risk of reducing prices to such an extent that it would dampen the incentive to invest in the therapeutic areas affected by the large price reductions.

Negotiating lower prices on more drugs; Delivering lower negotiated prices to patients faster

We support the proposal to increase the number of drugs that are eligible to be selected for negotiation for the first time in any given year. We defer to current and former Medicare staff on the personnel needs that may be appropriate to enable the team to negotiate substantially larger numbers of drugs each year. We note, however, that at some point increasing the number of drugs that can be negotiated each year may result in Medicare "running out of" drugs that can be selected. The result would be that Medicare would select a smaller number (than the statutory number) of drugs for negotiation in a particular year.

To strengthen the MDPNP, therefore, it might be ideal to pair the ability to negotiate the prices of more drugs in any given year with the ability to negotiate at least some prices sooner than under current law. As an initial matter, we therefore agree with the committee staff that Congress should not pursue legislation to extend the time period before which small-molecule drugs may be selected. Recent evidence suggests that the small-molecule pipeline is healthy and getting more so. In 2025, 30 of 46, or 65%, of novel drug approvals by the Food and Drug Administration (FDA) were for small molecules.[6] The more distant part of the pipeline is also dominated by small-molecule products, as an estimated 62% of drugs being tested in Phase 1 trials are small-molecule products.[7] Finally, 42 of 72 mergers and acquisitions (58.3%) involving manufacturers of prescription drug products that took place in 2025 were for small-molecule producers.[8] In contrast to industry concerns, the evidence demonstrates that the development of small-molecule products continues to be dynamic.

If industry is taking the position that the cost, risk, time, and revenue lifecycles of small-molecule and biological products are sufficiently similar such that the same Negotiation Program exemptions should apply to both types of products, it is not at all clear why increasing small-molecule drugs' exclusion to match biological products' would be the right policy solution. Establishing parity between the exclusion for biological products and small-molecule products at nine years would also be a potential policy solution to consider. This policy change could be paired

[6] Bethany Halford, *FDA's New Drug Approvals Dipped in 2025*, C&EN (January 5, 2026), https://cen.acs.org/pharmaceuticals/FDAs-new-drug-approvals-dipped/104/web/2026/01.
[7] IQVIA, *Global R&D Trends 2026* (March 25, 2026), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-r-and-d-trends-2026.
[8] Data on mergers and acquisitions for calendar year 2025 obtained from Pitchbook on July 6, 2026.

with an increase in the minimum Medicare spend biological products must meet to be selected at nine years, decreasing to its current value as the 13-year threshold approaches. These policy proposals have the advantages of being feasible to operationalize and implement on a shorter timeframe.

Providing a stable investment framework for biosimilars

We share the committee staff's goal of ensuring stable incentives to develop biosimilars as a means of enabling lower-priced biosimilars to compete with their branded reference products. Where competition can be introduced as a mechanism for enabling lower prices over time, we are in general supportive of efforts to improve such competition. As one of us has recently argued,[9] it is not enough to implement policies that promote the development and licensure of biosimilars. Policymakers must also focus on incentives to actually prescribe or administer the biosimilars once they are licensed, and to date biosimilar penetration has lagged far behind generic drug penetration. As a preliminary note, some of our preferred policy levers for addressing this issue, including deeming all biosimilars to be "interchangeable" under FDA's processes[10] and promoting state laws focusing on substitution for biosimilars dispensed through pharmacies, lie outside the jurisdiction of this committee. At the same time, there may be opportunities for members to weigh in and support such policies, such as in the coming 2027 FDA user fee reauthorization cycle.

We do think the committee should explore ways to encourage biosimilar uptake within Medicare Parts B and D. Within Part B, we agree that prompt issuance of biosimilar J-codes would likely have a modest impact in encouraging biosimilar uptake. But Part B is not structured at present to encourage administration of lower-priced products, including biosimilars, and in our view the committee should consider broader reforms (as discussed further in Section II), including grouping licensed biosimilars with their reference biological products for reimbursement purposes and also blended reimbursement codes among branded products.

Within Part D, the RFI suggests exploring formulary placement policies that incentivize favorable coverage for comparatively low list price biosimilars. We think such policies would be in keeping with the existing Part D statute, which already requires Part D plans to "have in place . . . [a] cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate . . . ."[11] We would encourage the committee to consider whether some of the pharmacy benefit manager (PBM) reforms enacted as part of the Consolidated Appropriations Act in February 2026[12] could generate information that may be useful to Medicare in implementing any such changes. We also highlight a note of caution if the committee pursues an approach of *requiring* plans to cover biosimilars. The literature regarding the Medicare Part D protected classes offers important lessons showing that unless carefully designed, a policy that requires plans to cover certain products on their formularies can undermine the bargaining power of health plans

[9] Rachel E. Sachs, *A New Framework for Drug Pricing Law and Policy*, 101 Indiana Law Journal 389 (2026). Material in this comment regarding biosimilar uptake may be drawn in part from this article.
[10] FDA itself has requested that Congress make this change, U.S. Food & Drug Administration, *FY 25 Legislative Proposals* 2 (2024), https://www.fda.gov/media/176924/download, and at least one bill pending in Congress (the bipartisan Biosimilar Red Tape Elimination Act) would have this effect.
[11] 42 U.S.C. § 1395w-104(c)(1)(A).
[12] Pub. L. No. 119-75 (Feb. 3, 2026).

with manufacturers, resulting in smaller discounts and likely weakened price competition among the relevant products.[13] Nevertheless, we agree that some form of required or preferred coverage serves to expand the market for these products, which may be important to ensuring robust competition going forward. It may be helpful to consider approaches that would accomplish the goals of this policy while minimizing the potential for unintended consequences, such as monitoring to ensure preferred formulary placement for a lower net cost product.

Eliminating blockbuster bailouts

We agree with the committee regarding repeal of the expansion of the orphan drug exclusion in H.R. 1 and would not oppose framing such a policy change around an increase in the spending threshold for eligibility of orphan-only drugs into the program. That proposal would be simpler to operationalize than others based, for example, on the number of Medicare beneficiaries who have been prescribed the medication.

Enhancing manufacturer accountability for price gouging

We support the committee staff's proposals here. Re-basing the inflation rebates and extending them to Medicare Advantage units will be important for strengthening the inflation rebate program within Medicare. We also support the staff's suggestion to extend the inflation rebates to the commercial market.

Potential new payment models for prescription drugs

We support the committee's goals of affordability and access and are not opposed to the committee staff's suggestion regarding such new payment models, including for GLP-1s. However, we are unsure what problem is being solved by this proposal. We agree that the state budgetary contexts within which Medicaid programs operate make applying a subscription model to payments for new innovative Hepatitis C prescription drugs an ideal use of this approach. In that case, the subscription model made it easier for financially constrained Medicaid programs to predict their budget flows, allowing states to stay within a balanced budget when faced with a one-time treatment that was curative. Relatedly, the Center for Medicare and Medicaid Innovation's Cell and Gene Therapy Access Model, which began in 2024,[14] aims to centralize a complicated process of developing and administering an outcomes-based agreement for a different one-time therapy, benefiting state Medicaid programs. But neither of those features is present here as it relates to Medicare and GLP-1s.

Launch prices

We believe that the committee is correct in aiming to find a way to respond to manufacturers setting increasingly high launch prices. There are many ways to approach this issue, each of which centers on different policy goals and each of which would face different operational and implementation

[13] Pragya Kakani et al., *Medicare Part D Protected-Class Policy Is Associated with Lower Drug Rebates*, 43 Health Affairs 1420, 1426 (2024).
[14] Centers for Medicare & Medicaid Services, *CGT (Cell and Gene Therapy Access) Model* (last visited July 15, 2026), https://www.cms.gov/priorities/innovation/innovation-models/cgt.

challenges. In our view, an effort to determine whether launch prices are "excessively high"[15] should incorporate principles of true innovation as expressed in the IRA. That is, manufacturers who can demonstrate that their newly approved products provide clinical benefits over existing therapies, meet unmet medical needs, represent a first-in-class product, etc. ought to be rewarded either financially (through reimbursement) or from a regulatory perspective for developing such an innovative product. If not, one method might be to consider adopting a reference pricing approach, where new entering drugs that cannot show such increased clinical value would be reimbursed based on the existing products within the class, while those that can demonstrate increased clinical value can be priced in the same way new drugs are priced today. A related approach based on these principles is used in Germany to negotiate the prices for new prescription drug products.[16]

Another source of potentially significant pricing and spending reductions is requiring purchases of drugs on behalf of dual-eligible or low-income subsidy (LIS) beneficiaries to be paid for based on the lower of Medicaid prices or Part D prices. Previous analyses of this proposal have shown that it would result in significant savings. Specifically, the proposal would be for prescription drug manufacturers to provide "Medicaid-like" rebates for drugs purchased on behalf of duals and Part D LIS beneficiaries. The Congressional Budget Office (CBO) has repeatedly scored such proposals since 2013. Most recently, the 2018 and 2020 analyses estimated 10-year savings to the federal government of $148 billion to $154 billion.[17] While the IRA and H.R. 1 have led to changes in the populations served and the pricing of prescription drugs, the savings are likely to remain significant if not the same.

Section II: Enhancing prescription drug affordability

In general, we are supportive of the broad goals of this Section, to "lower out-of-pocket costs for patients."[18] In our view, the vast majority of the proposals identified in this section are capable of accomplishing that goal for patients who are prescribed high-cost drugs. At the same time, some of them could have the effect of increasing premiums for all beneficiaries or increasing overall system costs. As noted in our introduction, the committee staff should consider pairing these proposals with those articulated in Section I, taking inspiration from the IRA's pairing of cost-saving approaches (including the MDPNP and inflation rebates) with approaches that increase the generosity of the Part D insurance benefit. We note that the proposals targeted directly at patient cost-sharing (out-of-pocket caps, eligibility for Part D Low-Income Subsidies) would also avoid creating significant new operational burdens and could be implemented relatively quickly. Other

[15] RFI, *supra* note 1, at 17.
[16] James C. Robinson, Dimitra Panteli, & Patricia Ex, *Reference Pricing in Germany: Implications for U.S. Pharmaceutical Purchasing, Commonwealth Fund Issue Brief* (February 2019), https://www.commonwealthfund.org/sites/default/files/2019-02/Robinson_reference_pricing_germany_ib.pdf.
[17] Congressional Budget Office, *Require Manufacturers to Pay a Minimum Rebate on Drugs Covered Under Part D of Medicare for Low-Income Beneficiaries* (December 9, 2020), https://www.cbo.gov/budget-options/56833; Congressional Budget Office, *Require Manufacturers to Pay a Minimum Rebate on Drugs Covered Under Part D of Medicare for Low-Income Beneficiaries* (December 13, 2018), https://www.cbo.gov/budget-options/54735/.
[18] RFI, *supra* note 1, at 3.

proposals, such as responses to vertical integration, are important to pursue but might require a longer timeframe.

Specialty generics

In Medicare Part D/Medicare Advantage Prescription Drug (MA-PD) plans, prices for specialty generics are relatively high. But there is an important nuance: the strongest evidence is not that vertical integration raises *all* generic prices; it is that insurer/PBM-affiliated specialty pharmacies can be reimbursed at very high prices for specialty generics, and integrated firms can steer volume to those pharmacies.[19] The effect on total plan net costs is more mixed and depends on rebates, fees, transfer pricing, and benefit design. The evidence suggests that out-of-pocket costs for specialty generics are elevated too, but the evidence is stronger at the plan/sponsor level than specifically at the affiliated specialty-pharmacy transaction level. Some recent evidence shows higher list and net prices for Part D drugs sold through vertically integrated arrangements, especially specialty pharmacies.[20] One promising avenue for addressing this aspect of the affordability problem is to regulate transfer prices. For MA-PDs, the strongest version might combine affiliated-pharmacy reimbursement caps, cost-sharing based on the capped/benchmark price, net-price transparency, and anti-steering protections.

PBM private label drugs

We support the committee staff's focus on this issue, recognizing that there are situations in which PBMs' use of private label drugs—particularly when combined with the types of vertically integrated steering behavior described above—may inflate prices and harm competition. However, this committee may wish to investigate for which products this behavior exists in the Medicare program, and for which products it is concentrated among commercial payers. For example, although the RFI notes the ways in which each of the largest PBMs has not only developed but also listed on its commercial formularies its own private label products, a recent study focusing on ustekinumab biosimilars showed that Part D plans that are vertically integrated with both PBMs and their private labelers "rarely covered their affiliated biosimilar, despite covering nonaffiliated biosimilars."[21] The committee may wish to gather information on formulary differentials across markets before considering the most helpful course of action in this space.

Addressing price-linked compensation

In our view, this is a particularly important policy proposal to pursue that would accomplish the goals set out in both Sections I and II. As the RFI notes, a range of actors across the prescription

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[19] See, e.g., Federal Trade Commission, *Second Interim Staff Report: Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers* (January 2025), https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf; Pragya Kakani et al., *Use of and Steering to Pharmacies Owned by Insurers and Pharmacy Benefit Managers in Medicare*, 6 JAMA Health Forum e244874 (January 10, 2025).

[20] Pragya Kakani et al., *Profit Regulation and Strategic Transfer Pricing by Vertically Integrated Firms: Evidence from Health Care*, NBER Working Paper 35043 (April 2026).

[21] Grace Castle et al., *Cost and Coverage of Originator and Biosimilar Ustekinumab Products in Medicare Part D*, 9 JAMA Network Open e2631556 (August 17, 2026). https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2852899.

drug supply chain are compensated at least partially on the basis of a figure that is linked to the price of a particular drug. By removing incentives for supply chain actors, including PBMs and clinicians, to prefer higher-priced products to lower-priced ones, and possibly even by *adding* incentives for them to prefer *lower-priced* ones, this reform could both lower patients' out-of-pocket costs and lower overall drug pricing and system spending.

First, we support efforts to "delink" provider compensation from drug prices under Medicare Part B. The Medicare Payment Advisory Commission (MedPAC) has written that "[t]here is no consensus on the original intent" of the 6% add-on, but that potential explanations include those listed in the RFI, including an intent to "cover drug storage and handling costs," "to maintain access to drugs for smaller practices," or "to cover factors that may create a gap" between reported Average Sales Price (ASP) and average purchase price.[22] We agree with the committee staff that in serving these goals, it is not clear "why the add-on payment should be linked to the price of the underlying drug."[23] We support the types of policy proposals listed on page 31 as strategies to reduce or eliminate financial incentives to prescribe more expensive products where less expensive ones might be available.

Second, we support efforts that take the additional step of encouraging the administration and prescribing of lower-priced products within Medicare Part B, rather than simply removing incentives to prescribe higher-priced products. Some of these proposals would have the effect of increasing competition between related branded products. For example, MedPAC has articulated a proposal under which "Medicare should establish a single ASP-based payment rate for groups of drugs and biologics with similar health effects"[24]—a form of yardstick competition related to payment systems, like the Inpatient Prospective Payment System in Medicare. Assigning each branded product to its own billing code, as is done currently, "does not spur competition among therapeutically similar single-source drugs and biologics . . . ."[25] Grouping such products together would over time give manufacturers "incentive to lower their prices relative to competitors to make their products more attractive to providers . . . ."[26]

Other such proposals would have the effect of increasing biosimilar uptake, related to the policy proposals set forth in Section I, by grouping biosimilars with their reference biologic for payment purposes, as Part B already does for generic drugs and their reference small-molecule branded drug.[27] Like the above-described reforms proposed by MedPAC regarding brand-brand competition, the goal of such grouping would be to encourage administration of lower-priced biosimilars in the consolidated class of products, leading to increased biosimilar uptake within classes of physician-administered drugs.

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[22] Medicare Payment Advisory Commission, Report to the Congress: Medicare and the Health Care Delivery System 68 (2015).
[23] RFI, *supra* note 1, at 30.
[24] Medicare Payment Advisory Commission, Report to the Congress: Medicare and the Health Care Delivery System 34 (2023).
[25] *Id.* at 35.
[26] *Id.* at 33; *see also id*. at 35–37 (describing relevant implementation issues).
[27] *Id.* at 31.

Section III: Bolstering biopharmaceutical innovation in the United States

As with the previous sections, we are supportive of the broad goals of this Section, to "enhanc[e] research and development (R&D) investments and incentives in areas of unmet need, bolster[] domestic clinical trials, and recruit[] and maintain[] scientific talent in the United States."[28] Innovation in the next generation of therapies is the first step to ensuring future access to these products. In our view, a key determinant of the strength of American biomedical research is the stability of the National Institutes of Health (NIH) and FDA. Relatedly, nearly all newly approved drugs have been supported by NIH funding.[29] We recognize that reforms focusing on the NIH and FDA lie outside of this committee's jurisdiction. However, we encourage the committee to partner with others, where relevant, to reverse the destructive actions being taken by the Trump administration regarding the NIH and FDA and to support these agencies where possible.

Focusing on approaches within the committee's jurisdiction, one approach to promoting increased innovation in the biopharmaceutical sector would target the most fragile and productive segment of the industry. Smaller, younger biotechnology firms originate the vast majority of first-in-class novel drugs, while large traditional pharmaceutical manufacturers typically focus on scaling and more incremental innovations.[30] Recent data reported by IQVIA show that in recent years smaller and emerging biotechnology firms originated 56% to 67% of new active substances.[31] Smaller, younger biotechnology firms are fragile because they often have long periods of time during which they collect no revenues. Therefore, their survival is threatened by cash flow challenges. Smaller, younger biotechnology firms are also vulnerable to private capital shortage for that segment of the industry. A refundable tax credit can partially offset that constraint.

One promising approach to targeting this segment of the industry would consist of targeted tax incentives in combination with a targeted grant program related to the NIH Small Business Innovation Research (SBIR) program. A targeted refundable tax credit or closely related mechanism would offer pre-revenue innovative firms funds to sustain their operations, thereby supporting firms likely to generate important new innovative products. There are important design features that require consideration if Congress were to pursue legislation in this area. First, if the relevant executive branch actors express reluctance regarding having the Treasury write substantial checks to private enterprises, an alternative would be to make the credit transferable rather than refundable. That is less direct but does not require the Treasury to write checks to early-stage biotechnology firms. A second design issue is identification of firms to be targeted. Some likely

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[28] RFI, *supra* note 1, at 3.

[29] Ekaterina Galkina Cleary et al., *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019*, 4 JAMA Health Forum e230511 (2023) (finding that NIH funding was contributed to 99.4% of drugs approved from 2010 to 2019).

[30] Kate H. Kennedy, Krisstel Gomez, Natalie J. Thovmasian, & Dennis C. Chang, *Small Biotechs Versus Large Pharma: Who Drives First-in-Class Innovation in Oncology?*, 28 Drug Discovery Today 1 (2023); Emily H. Jung, Alfred Engelberg, & Aaron S. Kesselheim, *Do Large Pharma Companies Provide Drug Development Innovation? Our Analysis Says No*, STAT (December 10, 2019), https://www.statnews.com/2019/12/10/large-pharma-companies-provide-little-new-drug-development-innovation/.

[31] IQVIA, *supra* note 7.

targeting criteria include value of assets, size as measured by number of employees and age of firm.

While the cash from a refundable tax credit would be useful to early-stage biotechnology firms, it also raises risks related to fraud, complex compliance risks (as described in the Internal Revenue Service's pharmaceutical-specific research credit audit guidance),[32] and the subsidization of research that would have occurred anyway. Considering these risks, a policy design might include clear qualifying-cost rules, project-level documentation, caps per firm, enhanced scrutiny for amended/refund claims, registration of advisers or preparers, risk-based audits, and fast-track refunds for lower-risk firms with strong track records. Here, the committee may seek to learn from several OECD countries that have implemented refundable tax credits for biopharmaceutical R&D. Australia, Canada, and Norway report the most positive experiences with refundable tax credits for R&D.[33] Evidence from across the OECD shows that refundable tax credits have the greatest impact for small and emerging biotechnology firms.[34] Yet these programs have had to address challenges related to complexity that can dilute the impact of the credit.

A simultaneous expansion of a targeted NIH/SBIR grant program would be designed to complement the refundable-transferable tax credit. The goal of these grants would be to fill gaps not covered by the tax credit. The grants would target the earliest, highest-risk science. They would focus on proof-of-concept activities, target validation studies, platform feasibility analyses, and first-in-class work that might be pursued before a firm has enough payroll or qualified expenses to benefit from a refundable tax credit. There would need to be coordination between the NIH/SBIR program and the administration of the tax credit to avoid "double dipping." The grants should be milestone-based, where funds are distributed after key milestones are reached (e.g., reproducible data are produced, validated assays, clinical readiness indicators). Grants should prioritize firms pursuing projects with high potential public health value. The expanded NIH/SBIR grant program should permit "bridge grants" to ease the transition for commercial investors. It would be important for the administrator of such bridge grants to be allowed to develop a carefully designed compliance infrastructure.

The track record for existing activities of the NIH/SBIR program is strong. The National Academies assessed the overall program in a recent report,[35] finding that more than 12% of drugs approved between 1996 and 2020 were associated with NIH/SBIR-funded firms and 16% of priority review drugs were tied to NIH/SBIR funded firms. The report also noted that the grants

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[32] Internal Revenue Service, *Pharmaceutical Industry Research Credit Audit Technique Guide* (April 2024), https://www.irs.gov/pub/irs-pdf/p5931.pdf.

[33] Ajay Agrawal, Carlos Rosell, & Timothy Simcoe, *Tax Credits and Small Firm R&D Spending*, 12 American Economic Journal: Economic Policy 1 (2020); OECD, *SKATTEFUNN R&D Tax Credit 2024*, https://stip.oecd.org/innotax/incentives/NOR1.; Bill Ferris, Alan Finkel, & John Fraser, *Review of the R&D Tax Incentive*, Department of Industry, Science and Resources, Australian Government (April 2016). https://www.industry.gov.au/sites/default/files/May%202018/document/pdf/research-and-development-tax-incentive-review-report.pdf.

[34] The OECD has compiled a variety of reviews and evaluations of R&D tax policy. They are available at: https://www.oecd.org/en/topics/r%26d-tax-incentives.html.

[35] National Academies of Sciences, Engineering, and Medicine, *Assessment of the SBIR and STTR Programs at the National Institutes of Health* (2022).

from NIH/SBIR were especially valuable where private financing opportunities were limited. However, there are notable cases where multiple grants yielded no commercialization, and there are risks to commercial financing crowd-out.

Sincerely,

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