FAMILIESUSA
THE VOICE FOR HEALTH CARE CONSUMERS

August 17, 2026

Honorable Ron Wyden
Ranking Member
Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510-6200

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

Dear Ranking Member Wyden and fellow Senate Democrats,
As the longtime national, nonpartisan health care consumer advocacy organization, Families USA appreciates the opportunity to comment on the *Request for Information: Commonsense Policy Options to Lower Drug Prices for Patients* (i.e., the RFI). For more than 40 years, Families USA has committed to guaranteeing that every family and individual throughout the nation has access to high-quality and affordable health care that improves overall health. Central to realizing that vision is addressing and reducing the burden of prescription drug prices on America's families.

The high and rising cost of prescription drugs in the United States is a profound health problem and a significant financial strain on our nation's families. Large drug corporations often seek to maximize profits by raising the prices of both existing and new prescription drugs to obscene, price gouging levels. U.S. drug prices remain nearly twice as high as prices in comparable countries, even after rebates.[1] As a result, more than 40% of adults reported not taking their medications as prescribed in the past year, rationing their medications, skipping doses, or never filling their prescriptions at all due to the high cost.[2]

Families USA applauds lawmakers for taking important steps to systemically bring down drug prices and rein in the rate of skyrocketing price increases. The Inflation Reduction Act of 2022 (IRA) is landmark legislation that includes several key provisions to address the underlying prices of certain medications and control the rate of price increases for drugs in Medicare. Most notably, the IRA gave the Centers for Medicare & Medicaid Services (CMS) the ability to negotiate drug prices in Medicare for the first time in our nation's history, among other key reforms. Now, lawmakers must build on the foundation laid by the IRA by

advancing key reforms to promote healthy competition in prescription drug markets and further rein in high and irrational costs to make prescription drugs truly accessible and affordable for everyone.

Families USA offers comments on five specific requests for feedback in the RFI that we believe are particularly important to ensuring our nation's families have access to affordable and high-quality prescription drugs.

- Section I: Lowering Drug Prices;
    - I: Bolstering Medicare's Ability to Negotiate Lower Drug Prices;
        1. Factoring International Pricing Into Negotiation: *We invite feedback on how best to incorporate international pricing into the Medicare drug price negotiation framework*.
        2. Negotiating Lower Prices on More Drugs: *We request expert and stakeholder feedback on this concept and other approaches to allowing the Secretary to negotiate more drugs annually.*
        3. Delivering Lower Negotiated Drug Prices to Patients Faster: *Senate Democrats invite experts and stakeholders to submit policy ideas that would help boost the biosimilar market*.
    - II. Enhancing Manufacturer Accountability for Price Gouging;
        4. *Senate Democrats request feedback on… [extending the Part B and Part D inflation rebates to the commercial market]*.
    - III. Potential New Payment Models for Prescription Drugs
        5. *Senate Democrats request feedback on how and whether Congress could hold pharmaceutical manufacturers more accountable for excessively high launch prices and bring more transparency to manufacturer launch price decisions*.

<u>Section I: Lowering Drug Prices; I: Bolstering Medicare's Ability to Negotiate Lower Drug Prices</u>

- Factoring International Pricing Into Negotiation: *We invite feedback on how best to incorporate international pricing into the Medicare drug price negotiation framework*.

While we appreciate lawmaker efforts to strengthen the Medicare Drug Price Negotiation Program and its ability to deliver more affordable medications to Medicare beneficiaries, **Families USA urges lawmakers to exercise caution when considering international**

reference-based pricing (IRP), such as most favored nation (MFN), for setting health care payments, including incorporating such approaches into the Medicare Drug Price Negotiation Program's price negotiation framework. IRP is a method of benchmarking drug prices to the prices paid by other countries for the same or similar set of drugs.[3] While IRP shows some promise in lowering U.S. drug prices overall – given excessive U.S. drug prices relative to comparable countries[4] – Families USA is concerned relying on IRP would fail to achieve the *optimal* price or valuation for prescription drugs that would maximize benefits to American patients.

Fundamentally, drug prices should not only be affordable but reflect the drug's relative value and clinical quality, and importantly, the extent to which the drug meets the unique health and health care needs of U.S. patients. Aligning the economic incentives in drug pricing in this way is critical to incentivizing (and financially rewarding) drug manufacturers to develop the high value and innovative medications that meet the health and health care needs of our nation's families. **Yet, the ability for IRP to aid in achieving rational U.S. drug pricing is undermined by two major sets of constraints and operational challenges**:

1. First, by adopting international reference pricing, U.S. lawmakers would delegate important payment decisions to other countries, and with limited input or accountability from the American public. Countries' approaches to setting drug prices vary widely and reflect different patient populations, clinical practices, and health care policy priorities or social preferences.[5] For instance, the United Kingdom's approach to setting drug pricing – including through its National Institute for Health and Care Excellence – values drugs that extend a patient's quality of life relatively higher than those that extend life expectancy, whereas U.S. lawmakers, advocates and most importantly, health care consumers, may value the development of medications that maximize extending patient life expectancy relatively higher.[6] As a result, referencing such prices could risk misaligning U.S. drug pricing and their valuation away from the unique health and health care needs and preferences of our nation's families. Moreover, many comparable countries whose reference prices may be used in an IRP based approach often use certain pricing methodologies, such as QALYs, that run afoul of our nation's existing protections for certain marginalized populations, including individuals with disabilities.[7]
2. Second, publicly available data on international reference prices from nearly all countries whose prices would be appropriate to cite in an IRP-based approach are limited to list prices, which may undermine the ability of IRP to put downward

pressure on U.S. drug prices in the first place.[8] Because many countries put in place confidentiality agreements that keep the underlying negotiated prices (that is, net drug prices) hidden from public view, an IRP-based approach would need to reference *list* prices.[9] List prices are unilaterally set by drug manufacturers and are inflated – they do not reflect the final negotiated price between drug manufacturers and health care purchasers, whether that be private or public payers.[10] By relying on other countries' list prices, an IRP approach risks aligning U.S. prices to inflated list prices that are largely set by drug manufacturers and, in some cases, even exceed current U.S. list prices.[11] Moreover, by relying on list prices, multinational drug manufactures and other national governments could more easily game U.S. implementation of the IRF by inflating public list prices while expanding rebates and other concessions to ultimately maintain private net prices.[12] IRP approaches such as most-favored-nation are particularly suspectable to this sort of gaming since the pricing benchmark is based (and impacted) by one country's price (e.g., the lowest national drug price among OECD countries).[13]

As such, **Families USA is concerned that incorporating IRP into the Medicare Drug Price Negotiation Program may generate drug prices that continue to be inflated and misaligned with the specific health and health care needs and priorities of the U.S. population, undermining efforts to put in place strong financial incentives for drug manufacturers to focus on true therapeutic innovations that drive population health and well-being for our nation's families.**

Instead, **Families USA urges lawmakers to focus on strengthening our nation's capacity to *independently* set and achieve rational drug pricing**. Specifically, lawmakers should work with CMS to strengthen the Medicare Drug Price Negotiation Program's method for setting maximum fair prices to ensure CMS' initial pricing offers (and ultimately the final negotiated prices) align with the drug's therapeutic value.

For example, Families USA remains concerned with CMS' negotiation approach that uses Part D net prices as the basis for setting initial negotiation pricing offers to drug manufacturers. Substantial evidence shows that the drug prices paid by Medicare Part D are significantly inflated compared to the prices paid by other public payers within the United States, as well as prices paid by other comparable countries. [14,15,16] For instance, according to the Government Accountability Office (GAO), Part D net prices were at least two to four times higher than publicly available prices in comparable countries in 2020.[17] Part D net prices do not reflect the true value of these medications and relying on them as a fundamental starting point for price negotiations undermines the Medicare Drug Price

Negotiation Program's ability to achieve meaningful cost savings for consumers and families and drive value-based pricing in prescription drug markets. Indeed, research confirms that final negotiated prices associated with the 15 drugs subject to the Medicare Drug Price Negotiation Program in 2027 were often found to be somewhat irrational – that is, not aligned with the drug's relative therapeutic value – where, for example, four drugs were priced too high relative to a value-based benchmark.[18]

As such, we encourage lawmakers to work with CMS to employ a cost-effectiveness approach to develop a preliminary price range, which could then be adjusted to arrive at a maximum fair price. Specifically, we recommend CMS establish non-biased cost-effectiveness targets or thresholds that serve as an initial price range for each selected drug, and which could then be adjusted based on comparative effectiveness research, the prices of therapeutic alternatives, and other manufacturer specific data to arrive at a maximum fair price. To calculate these targets, CMS should, in consultation with the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE), determine an upper and lower bound cost or price per unit of health gained (as well as cost per condition-specific measure of clinical benefit) that it deems appropriate and reflective of the opportunity cost of the treatment in relation to the treatment's added net benefits for Medicare patients over time.[19]

We believe the cost effectiveness approach outlined above guarantees that the maximum fair price calculated by CMS truly reflects the therapeutic value of the drug subject to negotiation and, importantly, avoids relying on prices, such as Part D net prices, that are all too often the result of widespread market failures and pharmaceutical industry gaming.[20] Further, this approach has the added benefit of providing the strongest financial incentives for drug manufacturers to focus on true therapeutic innovations.

- Negotiating Lower Prices on More Drugs: *We request expert and stakeholder feedback on this concept and other approaches to allowing the Secretary to negotiate more drugs annually.*

Families USA strongly supports expanding the number of drugs eligible for negotiation under the Medicare Drug Price Negotiation Program. At the same time, Families USA urges lawmakers to go further and allow commercial insurers to voluntarily adopt the negotiated prices. The IRA limits the number of drugs that are subject to government negotiation each year, and the negotiated prices are not automatically available to consumers with private health insurance.[21] This leaves millions of consumers with private coverage, including employee-sponsored insurance, vulnerable to continued high and

irrational prescription drug prices. Lawmakers should advance legislation that requires the secretary of the U.S. Department of Health and Human Services (HHS) to expand the number of drugs subject to negotiation and to extend all negotiated prices to private sector health insurance, should insurance plans want to adopt the Medicare-negotiated price.

- Delivering Lower Negotiated Drug Prices to Patients Faster: *Senate Democrats invite experts and stakeholders to submit policy ideas that would help boost the biosimilar market*

Families USA applauds lawmakers for exploring ways to boost the biosimilar market, as promoting healthy generic competition between biologics and biosimilars is critically needed to promote more affordable and high-quality biologic medications to the benefit of health care consumers.

Biologic drugs – otherwise known as large molecule drugs – are a class of drugs derived from living organisms and used to treat conditions such as cancer and autoimmune diseases.[22] Importantly, compared to traditional small molecule drugs, like penicillin or aspirin, biologic drugs are more complex and tend to be expensive to develop and produce.[23] As a result, biologic drug prices are particularly high and inflated, especially as drug corporations continue to abuse the patent system to charge monopolistic prices, among other reasons outlined below. During the past 10 years, the cost of biologic drugs increased dramatically; between 2013 and 2021, annual spending on biologics increased from $100 billion to $260 billion, a 160 percent increase.[24] Today, certain biologic drug prices are as high as $500,000 per year, putting patient access for these lifesaving medications at serious risk.[25]

In 2010, policymakers passed the Biologics Price Competition and Innovation Act (BPCIA) which created a formal FDA pathway for the approval of generic versions of biologics with the hopes of promoting generic competition among biologics and in biologic markets - as was similarly facilitated for small molecule drugs through the passage of the Hatch-Waxman Act in 1984.[26] These biologic generics are known as biosimilars. Yet, due to key payment distortions, conflicts of interest, and market failures across the prescription drug supply chain, biologics continue to face very limited generic competition, especially as compared to small molecule drugs.[27] Key examples of challenges that disproportionately and negatively impact biosimilars competition include:

- Lack of transparency on patents associated with brand name biologic medications, undermining the ability of would-be biosimilar competitors to determine when

brand name patents expired or may warrant a legal challenge, and ultimately to pursue generic market entry.[28] Currently, there is no federal database or related reporting requirements for the collection and disclosure of biologic drug patents, respectively.[29]

- Biologic drug manufacturers' unchecked patent abuses, which put up legal barriers to undermine generic development and approval, such as patent thickets, product hopping, and pay-for-delay schemes.[30]
- Onerous and unnecessarily strict FDA clinical trial requirements that raise the barrier to entry for would-be biosimilar companies to pursue biosimilar development and approval, including achieving FDA's "interchangeable" designation that would allow such biosimilars to be substituted for high-cost brand name biologics by pharmacists under state substitution laws.[31]
- Conflicts of interest among pharmacy benefit managers (PBMs) that disincentivize coverage of low-cost biosimilars through formulary placement and coverage decisions. Because PBMs generate revenue based on rebates and a drug's list price, PBMs are financially driven to steer patients toward pricier brand name biologics and provide such biologics more favorable coverage over cheaper generic alternatives.[32]
- Misaligned incentives in Medicare physician payments that encourage providers to prescribe expensive brand name medications over affordable biosimilars.[33] Currently, Medicare Part B reimburses for physician administered drugs based on the average sales price (ASP) plus 6 percent of the medication; tying physicians' payment to a percent of a drug's ASP creates incentives for physicians to prescribe higher cost brand name biologics in order to maximize their revenue at the cost of prescribing competing biosimilars.[34]

Due to many of these challenges, only 17 distinct biologic drugs have faced biosimilar competition out of the more than 200 biologic drugs approved by the FDA, since the passage of the BPCIA in 2010.[35] Making matters worse, the limited set of biosimilars that are approved do not achieve the market share required to put competitive and downward pressure on brand name biologic prices - because health insurers/PBMs fail to adequately cover them and clinicians tend to underprescribe them.[36] As a result, brand name biologics with biosimilar competition retain the vast majority of their market power (as much as 75 percent of their market share) and can maintain their inflated prices (only decreasing their prices on average by 4 to 10 percent).[37] This stands in stark contrast to the small molecule drug market, where brand name small molecule drugs facing generic competition lose significant portions of their market power (retaining only 23 percent of their market share) and as a result must decrease their prices on average by 39 to 79 percent.[38]

As such, Families USA recommends lawmakers enact a full range of commonsense reforms that address the key payment distortions, conflicts of interest, and market failures across the prescription drug supply chain that limit biosimilar development, approval, and prescription. To promote biosimilar competition in biologic drug markets and achieve more affordable, high-value drug pricing, lawmakers should:

- **Enhance regulatory oversight of health insurer/PBM formularies and utilization management practices to guarantee robust coverage and utilization of the relatively highest value drugs (e.g., biosimilars).** Specifically, enhance CMS' annual formulary review process by requiring CMS to add a key "step" in its formulary review process to ensure Part D sponsors provide broad access to generics, biosimilars, and other lower cost drugs.[39]
- **Address distortions baked into Medicare physician payment to encourage clinicians to prescribe higher value and more affordable biosimilar and other generic drugs.** Specifically, reform Part B payment for physician administered drugs to remove incentives for physicians to prescribe high-cost drugs, by aligning Part B payment rates to the price of the least costly alternative (LCA) drug.[40]

Families USA also encourages Senate Finance members to work with their colleagues in Senate HELP and Senate Judiciary, respectively, to advance the following reforms to further promote biosimilar competition and consumer access to affordable medications:

- **Reclassify all biosimilars as "interchangeable" for the purposes of FDA approval to further improve the prescription and substitution of biosimilars**, such as included in the Biosimilar Red Tape Elimination Act (S. 1954 in the 119th Congress).[41]
- **Require biologic drug manufacturers to report all patents and patent information applicable to their covered biologic drugs to FDA and require the FDA to publicize such information via the "Purple Book,"** in the same manner as is done for small molecule manufacturers, upon applying and receiving FDA approval and thereafter.[42]
- **Close legal loopholes that allow drug corporations to artificially extend their drug monopolies and market power by reining in key patent/exclusivity abuses, such as patent thickets, product hopping, and pay-for-delay practices**, such as included in the ETHIC Act (S. 2276 in the 119th Congress).[43]

Ultimately, accelerating the introduction of biosimilars into the market is critical for promoting more affordable prescription drugs for our nation's families, potentially saving consumers at least $237 billion over the next 5 years and generating up to $5,500 in savings for the average patient who takes biologic drugs.[44]

Section I: Lowering Drug Prices; II: Enhancing Manufacturer Accountability for Price Gouging

- *Senate Democrats request feedback on…[extending the Part B and Part D inflation rebates to the commercial market].*

Families USA strongly supports extending the Medicare Part B and Part D inflationary rebates to the commercial market. The IRA requires that drug manufacturers pay a rebate when they increase prices faster than the rate of inflation for some drugs covered under Medicare Part B and almost all covered drugs under Medicare Part D. These rebates are called inflationary rebates. Drug manufacturers that do not pay the rebate will face a significant monetary penalty. Congress should extend the inflationary rebates to include drugs covered in the commercial market to better protect individuals in employer-sponsored plans and other private plans from drug manufacturers' high prices and exorbitant yearly increases. This would also protect those in the commercial market from potential cost-shifting by drug companies who might attempt to seek more from other payers when their drug prices drop in Medicare.[45]

Section I: Lowering Drug Prices; III: Potential New Payment Models for Prescription Drugs

- *Senate Democrats request feedback on how and whether Congress could hold pharmaceutical manufacturers more accountable for excessively high launch prices and bring more transparency to manufacturer launch price decisions.*

Families USA strongly supports holding drug manufacturers accountable for excessively high launch prices. Median launch prices of new drugs have increased significantly over the past two decades – from $2,115 per year in 2008 to $180,007 per year in 2021 – driven by drug companies' abuse of their market power and anti-competitive practices that serve to keep prices high to maximize drug company profits at the expense of consumers and taxpayers.[46] What makes these inflated prices particularly egregious is they are largely irrational and not associated with higher quality or more innovative medications.[47]

The most important and foundational step lawmakers should take to holding drug manufactures accountable for high and irrational prices is to enforce existing federal law that requires public disclosure of negotiated drug prices and historical net prices across the commercial market in order to empower consumers, researchers, policymakers, and other health care purchasers with critical information to rein in drug prices.

Currently, for the vast majority of Americans with health insurance, drug prices are established in closed-door negotiations between drug manufacturers and various health care purchasers, including health insurers and pharmacy benefit managers, as well as other health care entities across the prescription drug supply chain including wholesalers, group purchasing organizations, and pharmacies.[48] One of the most important pieces of drug pricing information is the net drug price – that is, the actual price after accounting for any manufacturer rebates, concessions, or other discounts that are negotiated between drug manufacturers and health insurers and PBMs. These negotiated net prices – not list prices or wholesale acquisition prices – are most directly impact health insurance premiums and, increasingly, patients' cost sharing obligations in the commercial market, yet they remain largely hidden from public view or oversight.[49] This lack of transparency is alarming, particularly given that high and rising drug prices are a major driver of our nation's health care affordability crisis.[50]

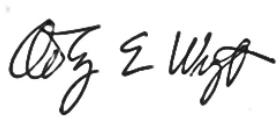
In 2020, CMS released the Transparency in Coverage (TiC) rule, requiring commercial insurers to publicly disclose health care payment rates, including negotiated drug prices.[51] This rule marked a significant step in driving higher value care in the U.S. health care system by beginning to unveil the actual prices of health care services, including prescription drugs, for the first time. Yet, before the rule could take effect in 2022, HHS deferred enforcement of key requirements that health insurers publicize negotiated drug prices due to industry pushback and pressure.[52] **Families USA recommends that the Senate Finance work closely with Senate HELP to direct HHS to enforce existing law that requires disclosure of negotiated drug prices and historical net prices for prescription drugs across the commercial market, including the prescription drug disclosure requirements in the TiC rule.**

Conclusion

Thank you for the opportunity to respond to this RFI and for your time in considering these comments. We strongly support this renewed effort to comprehensively lower the cost of

prescription drugs for consumers and the health system alike, and we stand ready to assist you in this endeavor. Please contact Aaron Plotke, Associate Director of Healthcare Financing & Pricing at Families USA at aplotke@familiesusa.org, with any questions.

Sincerely,



Anthony Wright

Executive Director

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