

Fulfilling the Promise of Congress's Commitment to Lowering Drug Prices



On June 22nd, Senate Finance Committee Chairman Ron Wyden (D-OR) released “[Principles for Drug Pricing Reform](#).” Families USA welcomed the release of this document, as did other advocacy organizations who are working to reduce the burden of prescription drug prices on consumers. These principles come at a critical time: on July 13th, Congressional Democrats laid out their plan for an FY2022 Budget Resolution that among other key investments, promises to lower the price of prescription drugs.

KEY POINTS

- » Congress is on the precipice of making historic reforms to lower the price of prescription drugs this year
- » For consumers and families to have meaningful relief from unaffordable drugs, Congress must adopt the key elements described in this paper.

Now leaders in the Senate and House of Representatives must agree on specific policies that can meaningfully achieve that goal. House leadership has put forward their plan by way of reintroducing H.R. 3, [H.R. 3, Elijah E. Cummings Lower Drug Costs Now Act](#), which includes a variety of legislative details that can meet the promise of this moment. As an immediate next step, the Senate Finance Committee must develop legislative language that puts its principles into practice, ensuring consumers and families across our nation have meaningful relief from the high and out-of-reach costs of prescription medications. If they are to fulfill the promise of the Wyden principles, they must include the key elements described below.

1. Ensuring True Medicare Price Negotiation

What the Wyden Principles Say

“Medicare must have the authority to negotiate with pharmaceutical companies, especially when competition and market practices are not keeping prices in check....In a negotiation policy, Congress must establish clear criteria for market failure and for which

drugs to negotiate price [and] define what constitutes a fair price in these circumstances... Allowing the Secretary of HHS to negotiate the price Medicare will pay creates a much needed mechanism to achieve fairer prices when the market has failed to do so.”

Putting These Principles into Practice

Other high-income countries regulate drug prices so that pharmaceutical companies cannot charge consumers unrestricted, excessive prices and raise those prices on consumers whenever they want.

Senator Wyden has made a straightforward commitment to change the way Medicare pays for drugs. To make his principle a reality, the Secretary of HHS will need sufficient authority and scope to negotiate drug prices in the best interest of Americans. In order for the negotiation process to work, there needs to be:

» **A focus on drugs that are priced unreasonably based on clinical data, public benefit and the costs to commercialize the product.**

The principles call for broad new authority for Medicare to negotiate drug prices, with a higher priority placed on reducing the price of drugs with little competition and/or inappropriate profit margins relative to manufacturing costs. The Wyden prioritization principles importantly focus on evidence of market failure as demonstrated in excessive prices. Although single-source brand-name drugs are the major drivers of increased prescription drug spending, manufacturers of drugs with multiple actual or potential competitors (such as the notorious case of Daraprim) and manufacturers of generic or biosimilar drugs (such as the notorious case of insulin) can and do still unjustifiably raise prices, putting these drugs out of reach for many consumers. Market failures are pervasive in prescription drugs, and *legislation needs to give HHS the flexibility to identify drugs for negotiation based on their burden to Medicare and to consumers, rather than on overly narrow, theory-based definitions of market failure.*

» **A transparent and clear upper limit established from which to negotiate.** The principles state clearly that the federal government needs a benchmark that establishes a fair price with which to begin the negotiation process. There are a limited number of benchmarks that can be used in estimating a fair drug price, and the options are well-known.¹

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Any one of these options, or a hybrid approach, could be a sound basis for Medicare negotiation.

- » **A strong enough incentive to bring manufacturers to the table.** Any effective price negotiation mechanism must include strong measures to bring pharmaceutical companies to the table and prevent sabotage or withdrawal from a negotiation process. Pharmaceutical manufacturers may well take an approach of trying to discredit the new framework early on by withholding one or more high profile drugs from Medicare unless the federal government has powerful tools to prevent that tactic.

2. Applying Negotiation to the Initial “Launch” Prices of New Drugs

What the Wyden Principles Say

“For some drugs, prices may be justified based on the remarkable clinical benefits they offer. But many, like recently approved Alzheimer’s drug, Aduhelm, launch at prices far beyond any reasonable justification of the clinical value to patients, caregivers or society. Medicare does not currently have the requisite tools to ensure a fair price for such a drug.”

Putting This Principle into Practice

The basic structure for negotiating launch prices is similar to that for other drug price negotiation, as described above: It will require a focus on drugs that are priced unreasonably, a transparent and clear upper limit established from which to negotiate and a strong enough incentive to bring manufacturers to the table. But it is notable that H.R. 3, the important drug bill that passed the House in the previous Congress, included criteria for targeting launch prices of new drugs that would have exempted Aduhelm from negotiation. As Senator Wyden has shown, criteria for negotiating launch prices likely need to be broader than those in H.R.3 to effectively identify drugs that are priced unreasonably based on clinical data, public benefit and manufacturer cost.

3. Addressing Abusive Price Increases for Existing Drugs

What the Wyden Principles Say

“Prices of drugs that increase faster than inflation will not be subsidized by patients and by taxpayers.... Requiring rebates on price hikes above inflation will rein in companies that gouge the millions of patients who take older drugs.”

Putting This Principle into Practice

Senator Wyden committed to controlling price increases on already approved and priced drugs. Under existing policy, prices on drugs that have already been approved are often and outrageously increased by several multiples the rate of general inflation.² There is no policy justification for these increases given that the launch price was ostensibly set to offset development and manufacturing costs — it is pure monopolistic gouging. Manufacturers should be prohibited from increasing prices at a rate higher than inflation, with airtight penalties to offset any such increases. Senators Wyden and Grassley wrote [legislation](#) in 2019 that among other provisions, would have negated price increases within Medicare that cannot be justified by broader inflation rates. The Wyden principles go even further than this 2019 legislation, which focused on Medicare price increases. These principles ensure that neither patients nor taxpayers writ large will have to subsidize price increases that are faster than inflation. This commitment is further underlined by the Wyden language highlighted in the next section.

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4. Applying Medicare Drug Pricing Reforms to Other Payers

What the Wyden Principles Say

“Drug pricing reforms that keep prices and patient costs in check should extend beyond Medicare to all Americans, including those covered by employer and commercial health plans.”

Putting This Principle into Practice

More than 60% of all adults report that they have difficulty affording their prescription drugs, with people ages 50 to 64— those who are not yet eligible for Medicare— reporting the most difficulty affording high-cost drugs.³ Drug pricing reform must include protections to prohibit drug companies from shifting costs from Medicare patients to everyone else. As Senator Wyden has stated, all Americans should be protected.

5. Incentivizing True Innovation Rather than Patent Abuses

What the Wyden Principles Say

“Drug pricing should reward scientific innovation, not gaming of the patent system.”

Putting This Principle into Practice

Both pricing reforms and reforms to patent and competition law are needed to change industry behavior and thereby incentivize the development of more innovative drugs. Drug manufacturers should be able to reap profits from their drugs, but only if they are truly innovative. Similarly, manufacturers should be afforded patent protection and marketing exclusivities, but only for a limited period after a drug comes on the market. When drug companies can extend patents for decades by gaming the system or by paying off potential competitors, it increases everyone’s costs and creates terrible incentives for the pharmaceutical industry.

Congress must shut down abuses of patents and marketing exclusivities, building off elements of legislation passed by the Senate [HELP Committee](#) in 2019. At the same time, Congress should enact policies that provide a pathway for drug manufacturers to adequately price — and incentivize — truly innovative drugs, competitive generics and biosimilars while not incentivizing drugs with marginal benefit.

Conclusion

House and Senate Budget Committees have accounted for significant investments in drug pricing reform in their FY22 Budget Resolution. Chairman Wyden has set forth his vision in his “Principles for Drug Pricing Reform.” The House has reintroduced H.R. 3. Taking these developments together, it is undeniable that Congress is on the precipice of making historic reforms to lower the price of prescription drugs this year. The American people have named drug pricing reform as their number one health care priority. Now is the time for Congress to take action to ensure that no one in America has to skip dosages or not fill a prescription due to cost.

Endnotes

¹ See Sean Dickson and Timothy Lash, “Pricing Remdesivir: A Domestic Reference Price Approach,” *Health Affairs* Blog, June 23, 2020, June 2020; Ollendorf et al., “External Reference Pricing: The Drug-Pricing Reform America Needs?”, Commonwealth Fund 2021, <https://www.commonwealthfund.org/publications/issue-briefs/2021/may/external-reference-pricing-drug-pricing-reform-america-needs>; ICER, “Value Assessment Framework,” <https://icer.org/our-approach/methods-process/value-assessment-framework/>; Andrea Sheldon and Kevin Pierce, “NADAC-plus: An emerging paradigm in pharmacy pricing?”, Milliman, 2018.

² Stephen W. Schondelmeyer and Leigh Purvis, RX Price Watch: Brand Name Drug Prices Increase More than Twice as Fast as Inflation in 2018 (AARP Public Policy Institute, November 2019), <https://www.aarp.org/content/dam/aarp/ppi/2019/11/brand-name-drug-prices-increase-more-than-twice-as-fast-as-inflation.doi.10.26419-2Fppi.00073.005.pdf>

³ Ashley Kirzinger, Lunna Lopes, Bryan Wu, and Mollyann Brodie, “KFF Health Tracking Poll – February 2019: Prescription Drugs,” March 1, 2019, <https://www.kff.org/%20health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>.

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