

COMMITTEE ON FINANCE

CHAIRMAN RON WYDEN

Principles for Drug Pricing Reform

Goals

The United States is the largest market for biopharmaceuticals, yet prices in our country for many prescription drugs are the highest in the world. Americans often tell their elected officials they worry that being prescribed an expensive drug therapy will ruin them financially. This is unacceptable. The root causes of high drug prices are numerous, and we urgently need reforms that provide real solutions.

This paper lays out a series of principles that demonstrate that making prescription drugs more affordable while encouraging innovation and scientific breakthroughs are not mutually exclusive. Pricing reform across the supply chain can support the future of American innovation by creating the right incentives to develop new, truly valuable treatments, while also ensuring American families can afford them.

Overwhelming majorities of Americans agree it's time for Congress to act. As Chairman of the Senate Finance Committee, I intend to propose solutions that build on bipartisan proposals to reduce pharmaceutical prices already passed by the Committee. Our legislation will continue to be developed with input from members of the Committee and other Senators, a process that has already begun. The focus of this effort is to produce a consensus proposal that can pass both chambers of Congress.

Principles

- 1. Medicare must have the authority to negotiate with pharmaceutical companies, especially when competition and market practices are not keeping prices in check.**

Many older drugs command high prices because they face no competition from generics, biosimilars, or branded alternatives, despite outliving their original patent. Meanwhile, new drugs are also entering the market at unprecedented prices. For some drugs, prices may be justified based on the remarkable clinical benefits they offer. But many, like the 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. 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.

In a negotiation policy, Congress must:

- Establish clear criteria for market failure and for which drugs to negotiate the price;
 - Define what constitutes a fair price in these circumstances;
 - Give the Secretary both tools and guidelines to negotiate a fair price; and
 - Create the right incentives to ensure that pharmaceutical companies participate in the negotiation process.
- 2. American consumers must pay less at the pharmacy counter.** The Medicare Part D benefit structure leaves millions of patients exposed to extreme out-of-pocket spending, while failing to create the proper incentives to direct patients towards drugs that cost less. The legislation will include and build upon existing bipartisan proposals to restructure the Part D benefit in order to realign these incentives and reduce high patient out-of-pocket spending to affordable monthly limits.

Many drugs today compete with generics, biosimilars, and branded alternatives, but that competition can be distorted by middlemen. For example, formularies are often set by health insurers and pharmacy benefit managers in a manner that encourages pharmaceutical companies to compete on the difference between list and net prices. Meanwhile, consumers lose out when they pay for medicine based on higher list prices at the pharmacy counter. The "Rebate Rule" proposed under the previous Administration does not properly address this problem and should be blocked. The legislation will also include targeted policies to ensure that patients see savings on specific types of critical drugs, such as insulin, for which the rebate dynamics are extreme and inhibiting access. The legislation will discontinue certain rebate practices

that limit competition and patient access to affordable drugs, and seek greater transparency in the supply chain.

- 3. Prices of drugs that increase faster than inflation will not be subsidized by patients and taxpayers.** Americans are paying more than ever for the same drugs they've been using for years, because pharmaceutical companies have been allowed to raise prices at will while patients and taxpayers foot the bill. Requiring rebates on price hikes above inflation will rein in companies that gouge the millions of patients who take older drugs. At the Senate Finance Committee markup of the Prescription Drug Price Reduction Act of 2019, Congressional Budget Office Director Phil Swagel noted, "The inflation rebate provides an incentive and is a factor that will affect prices, but it will not control prices."

Americans often look to insulin, a lifeline drug that millions of Americans count on, as Exhibit A for runaway price gouging. Since the 1990s, insulin prices have increased more than 1,200 percent while the fundamental nature of the drug has not changed.

- 4. 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.** While the Senate Finance Committee has jurisdiction over Medicare and Medicaid, prescription drug affordability and access is a challenge for all Americans. I will work within the Finance Committee and with other committees of jurisdiction to ensure these reforms apply to as many Americans as possible. Policies that target both exorbitant prices of drugs and reduce out-of-pocket spending for patients must extend beyond Medicare.
- 5. Drug pricing should reward scientific innovation, not gaming of the patent system.** Recent years have seen the introduction of many groundbreaking new treatments for diseases like hepatitis C, cancers, and genetic diseases, including gene therapies. The research that led to these medical advances can largely be traced back to small biotechnology companies that take on a disproportionate share of the risk of R&D. To protect their ability to innovate, policies developed in the Finance Committee can be tailored to the scale of these companies, as well as other factors that affect their access to capital. Government funding for R&D should continue to receive strong support, while also protecting taxpayers, who shouldn't be paying twice for the research when a drug comes to market with high prices.