

POLICY *focus*

RECIPES FOR RATIONAL GOVERNMENT

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Why Are Pharmaceutical Drugs So Expensive?

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Introduction

About six in ten Americans say that lowering the cost of prescription drugs should be a priority for the President and Congress. For years, public opinion polls have found that the cost of drugs is Americans' number one health concern. Over half (55 percent) of all Americans report taking prescription drugs.

To identify policies to make drugs more affordable, the public first should understand why drugs are often expensive.

Many factors contribute to the cost of pharmaceutical drugs: Drug makers invest incredible resources in costly research, development and drug trials. And many of the drugs they research never make it to market. Intellectual property policies (patents and exclusivity periods) rightly limit market competition when a new drug is brought to market so that companies can recoup the costs associated with research and development. Our complex and opaque healthcare payment structure makes it difficult for patients to make informed decisions based on price. And even policies of foreign countries can increase the costs of drugs here within the United States.

There are two potential paths for America today: We can expand the role of government in setting drug prices, or we can foster greater individual choice and market competition to hold prices down. The former path would inevitably have unintended consequences, like drug shortages and reduced innovation. The latter would make drugs more affordable and accessible, while also encouraging and rewarding innovation. We all want to see ever more advances in drugs that heal sickness, reduce suffering, and prolong life, so it's important we choose the right path.

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Why You Should Care

Here's what's at stake in our debate about how to lower drug prices:

- **A Key Component of Health Care:** Americans depend on pharmaceutical drugs to manage many chronic conditions, prevent disease, and reduce pain. Affordable, accessible drugs can reduce costs to other parts of our health sector by keeping patients healthy and out of the hospital.
- **Individual Choice:** Choice is critical in health care; not everyone responds the same way to the same drug. A strong drug policy allows for maximum information and choice. We should work to reduce the role of any third-party payers that might restrict patient choice.
- **Abundant Access:** We should resist any policy that would lead to rationing or shortages, including price controls. It doesn't matter how low the price of a drug if the pharmacy shelf is empty.
- **The Next Generation of Cures:** America leads the world in drug innovation. Today, sadly, many patients and families suffer from diseases for which there is no cure—yet. Innovative (profit-driven) companies are working to change that. The wrong policies could jeopardize American drug innovation.

The best public policy would find the right balance between ensuring affordability, choice, and access for consumers without limiting incentives for drug innovators.

Bringing a New Drug to Market

Bringing a drug to market costs a lot. There are “out-of-pocket costs” as drug developers employ teams of researchers and purchase materials, and there are “time costs” (as investors wait for returns—often for more than a decade).

Then there are trial costs when a new drug must undergo rigorous safety testing, including human trials during the third and final (and the most costly and critical) phase of pre-approval testing at the Food and Drug Administration. After approval, the FDA requires yet more tests to determine how a drug should be labeled and dosed, and how it compares to other drugs in terms of effectiveness.

Sadly, the overwhelming majority of new drugs fail to ever reach approval, meaning drug companies often incur enormous expenses for drugs that will never reach the market or be sold. Medscape estimates that the ratio of researched drugs to approved drugs is between **5,000 to 1 and 10,000 to 1**.

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WAYS TO DECREASE GOVERNMENT TRIAL COSTS:

Speed up the
time for the
trial period

Streamline trial
regulations
and processes

Some of these expenses are inevitable—they are the result of Thomas-Edison-like dedication to the slimmest chance of success even when facing overwhelming odds. But there may be some ways to decrease the costs of government trials, including speeding them up (which would reduce time costs) and streamlining regulations and processes. Lawmakers should consider every reasonable recommendation to do so without hindering patient safety.

Intellectual Property Protections

Given the extremely high cost of developing new drug formulas, our legal system allows drug companies to secure patents and market exclusivity that protect them from competition from other producers of the new drug for a set amount of time. The idea, of course, is to allow drug companies to recoup their investment in research and development without being undercut by competitors who didn't make a similar investment in developing the therapy or drug.

Current patent law gives drug companies 20 years before generic competitors can compete with a new drug. This window starts as soon as human trials of a drug begin, meaning drug companies don't really have a full 20 years; they have the balance of time after human trials result in the approval of their new drug, which often takes years.

Exclusivity is **different from a patent**. Patents and exclusivity periods are governed by different statutes and apply to different drugs in different ways. Exclusivity periods are intended to be an additional incentive for drug makers to develop certain types of drugs such as “orphan” drugs for rare diseases.

While IP protections for drugs are necessary to attract investment, they also limit market competition for drug production, which ensures that the prices for new drugs will remain high for an initial period. When competition is ultimately introduced, drugs face a steep decline in price. This area of law seeks to strike a balance between affordability for patients and rewards for innovative and risk-taking drug makers and their investors.

Market Distortions

The market for health care of all kinds—services, screenings, drugs—is extremely distorted in the United States due to government intervention at both the federal and state level.

Private Insurance

Americans typically use health insurance to pay for most of the care they consume, including drugs. Because of a tax exclusion for employer-sponsored insurance plans, most privately-insured Americans accept the insurance plan they get through work (rather than shopping for a plan based on their individual preferences).



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This means that most privately-insured Americans simply accept the drug formulary (the list of covered drugs) associated with their employer’s plan. Even for those without employer coverage, a wealth of state- and federal-level regulations govern what must be covered by private insurance and in some cases, restrict cost-sharing. This limits competition and innovation in our payment structures.

Increasingly, insurance plans work with entities called Pharmacy Benefit Managers or PBMs. These companies administer insurers’ drug benefits and oversee prescription drug use for the insured, always looking for efficiencies, offering rebates, and producing savings. Some **criticize PBMs** for not passing savings on to consumers and call for greater transparency, demanding that PBMs disclose their financials.

While the call for greater transparency is good, transparency need not be mandated. Instead, lawmakers should address the distortions in our health payment pipeline that favors third-party payers, or middlemen, in transactions where they are not needed. When patients consume more healthcare services and products directly, price transparency and price competition are an inevitable result.



INSURED

**By Medicare:
55 million
seniors**

**By Medicaid:
70 million low-
income people**

Medicare and Medicaid

Most Americans over 65 are on Medicare, which has a prescription drug program called “Part D,” and low-income Americans can get Medicaid, which comes with a drug formulary that varies by state. In an attempt to combat high drug prices, some policymakers have suggested allowing these government programs to “negotiate” prices with drug companies.

Sadly, this would do more harm than good. While “negotiation” sounds like a fair and innocuous practice, the problem lies with the size and market influence of behemoth government programs. Medicare insures more than 55 million seniors (who consume a disproportionately high share of the nation’s drugs), and Medicaid insures more than 70 million low-income people (with about 9 million people in both program as

“dual eligible.”) This means that the federal government could act as a monopoly—or in this case a monopsony or single buyer—in strong-armed “negotiations” over price. Drug companies couldn’t reasonably walk away from doing business with Medicare and Medicaid, creating a steep imbalance of power.

Foreign Price Controls and Reimportation

Many foreign countries have attempted to combat high drug costs with price controls (policies that limit how much consumers can pay for certain drugs). While this policy seems to benefit consumers, sadly, it creates its own problems. Countries with price controls on drugs often experience drug shortages, a disservice to the very patients that these policies intended to help. Price controls also threaten to bring new innovations to a halt.

But price controls can make the prices of drugs appear attractively lower than what U.S. customers pay. This is especially true when international drug companies raise prices on American consumers in an attempt to offset the losses associated with foreign price controls.

For this reason, some Americans advocate for “drug reimportation” as a means to introduce foreign competition to domestic drug markets. The hope of such a policy would be to force drug sellers in the U.S. to lower prices to match foreign prices. (Indeed, some U.S. consumers already order some drugs online internationally.)

There is a safety concern with such a practice: The U.S. government cannot ensure that drugs from other places have been manufactured, stored, or transported in ways that meet U.S. safety regulations. Obviously some, but not all, consumers are willing to take that risk.

But the more important concern with drug reimportation is the idea that Americans would be “importing foreign price controls.” Put another way, if foreign price controls lowered prices within the United States, the same problem would result here as is the case overseas: Drug makers would see a diminished return, decreasing their incentive to produce drugs in high demand, resulting ultimately in shortages and the end of continued research and innovation.

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Free trade is valuable: It allows various countries to specialize and exchange goods and services to mutual benefit. But price controls, even in foreign nations, introduce a distortion into the global market that Americans should not have to face. Some advocates of free trade suggest that allowing drug reimportation could be a first step to dismantling foreign price controls, but Americans ultimately have no control over the domestic policies of foreign governments, over drugs or any other area. This strategy would come with critical short-term costs, as well as great risk.

Medicare Part D—A Model for Future Reforms

Medicare Part D is an innovative program that allows seniors and people with disabilities to choose among approved private plans for prescription drug coverage. It is exceedingly rare for a government program to cost less than initially projected, but Medicare Part D premiums are today about \$32 per month, or about half of initial projections.

Why has Medicare Part D been such a success? Competition and choice are key to keeping prices low. And the government is currently exploring ways to ensure that manufacturer-negotiated discounts get shared with Part D patients at the pharmacy counter, saving seniors even more.

Because seniors have some “skin in the game” in Medicare Part D, they too care about keeping drug costs low. This is a positive aspect of Part D that should be replicated in other programs, including Medicaid. Medicaid beneficiaries are capable of making informed choices about what drug coverage (or other health care) is right for them, and according to the experience of Part D, the results would be reduced overall drug costs as well as higher patient satisfaction.

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What You Can Do

Get Informed

Learn more about lowering the cost of pharmaceutical drugs. Visit:

- [Independent Women's Forum](#)
- [American Action Forum](#)
- [Galen Institute](#)

Talk to Your Friends

Help your friends and family understand these important issues. Tell them about what's going on and encourage them to join you in getting involved.

Become a Leader in the Community

Get a group together each month to talk about a political/policy issue (it will be fun!). Write a letter to the editor. Show up at local government meetings and make your opinions known. Go to rallies. Better yet, organize rallies! A few motivated people can change the world.

Remain Engaged Politically

Too many good citizens see election time as the only time they need to pay attention to politics. We need everyone to pay attention and hold elected officials accountable. Let your Representatives know your opinions. After all, they are supposed to work for you!

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ABOUT INDEPENDENT WOMEN'S FORUM

Independent Women's Forum (IWF) is dedicated to building support for free markets, limited government, and individual responsibility.

IWF, a non-partisan, 501(c)(3) research and educational institution, seeks to combat the too-common presumption that women want and benefit from big government, and build awareness of the ways that women are better served by greater economic freedom. By aggressively seeking earned media, providing easy-to-read, timely publications and commentary, and reaching out to the public, we seek to cultivate support for these important principles and encourage women to join us in working to return the country to limited, Constitutional government.

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of people
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information and
consider making a
donation to IWF.