
ISSUE ♦ BRIEF

National Taxpayers Union

Prescription Drug Costs: Better Ways to Help Patients and Taxpayers

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Government clampdowns or price controls on prescription drugs can produce adverse effects that ultimately harm patients and taxpayers. Fortunately, policymakers have better alternatives. Here are just a few ideas from National Taxpayers Union:

1) Negotiate and Promulgate Trade Policies that Prioritize Savings. Smart trade policies, in the form of new agreements, enforcing existing agreements, and utilizing dispute forums can be key to ensuring that the intellectual property backing up U.S.-manufactured drugs of all types is protected rather than exploited.

For [several decades](#), India has pursued a controversial policy of allowing its drug industry to copy patented U.S. drugs in controversial ways. Today, while India produces huge volumes of drugs for export, it is facing [new questions](#) about fake drugs and its appropriation of others' discoveries. In the late 2000s and early 2010s, the "promise doctrine" in Canada's courts effectively sanctioned the invalidation of some two dozen patents on innovator drugs being sold within that country's borders. This approach was taken by lower courts to rule on patents' "utility" (validity) based on judgments of whether or how well a patent fulfilled its "promises." It wasn't until 2017 that the Supreme Court of Canada [ruled](#) that this approach was "unsound." In 2015, the Information Technology and Innovation Foundation's [annual report](#) on the world's worst "innovation mercantilist policies" cited Russia for its "subsidies, price preferences, procurement restrictions, and other policies as part of an explicit import substitution goal" with pharmaceuticals. These and other countries' behavior essentially raise the prices that patients and governments elsewhere must pay to finance the R&D of blockbuster drugs. More U.S. diplomatic and economic pressure can be helpful in mitigating such behavior.

Three years ago, Congress passed the Bipartisan Congressional Trade Priorities and Accountability Act. The new law specifically directed the Executive Branch to pursue trade deals that will:

- Ensure "that the provisions of any trade agreement governing intellectual property rights that is entered into by the United States reflect a standard of protection similar to that found in United States law";
- "[A]chieve the elimination of government measures such as price controls and reference pricing which deny full market access for United States products"; and
- "[E]nsure that government regulatory reimbursement regimes are transparent, provide procedural fairness, are nondiscriminatory, and provide full market access for United States products.

The current U.S. Canada Mexico Agreement on trade is one key test of whether such principles will be fairly and evenly applied, as well as whether it will reflect the balanced U.S. policy toward patented drugs and generics that has tended provide taxpayers with both long-term and intermediate savings on pharmaceuticals dispensed through government programs. This and future trade agreements must pay particular attention to the Trade Priorities and Accountability Act's guidance. Congress will be debating renewal of this law next year.

2) Reduce Barriers within the FDA drug approval process. The Food and Drug Administration's (FDA) drug approval process was established to ensure only the safest of products enter the market. However, the FDA's current approach is outdated and fails to meet the needs of a modern and increasingly complex health care system. Lengthy and costly regulations can cause delays to innovative breakthroughs that would enhance public health. It can take over a decade and hundreds of millions of dollars to approve a new drug, with much of that cost stemming from FDA clinical trials. As the clinical trials become a longer process, good drugs become delayed and it is more expensive to produce new drugs. The result is fewer drugs coming to market and that are costlier for consumers to purchase.

Congress and the administration should engage in a comprehensive overhaul of the FDA to streamline efficiencies and cut down on red tape. Faster approval of safe drugs can increase innovation, and by approving drugs more quickly, it can decrease costs associated with research and development. This will allow research companies to put more resources into developing new life saving medications and restrain drug costs on consumers.

Some progress has already been made, especially in the area of generic approvals. FDA Commissioner Scott Gottlieb's policy of clearing away the agency's backlog of work has led to record numbers of generic drug approvals in Fiscal Year 2017 (at 936). In October 2018, [Gottlieb announced](#) that record had been shattered again, rising to 971 for the end of the just-concluded fiscal year. These approvals translate directly into savings for the health care system: [roughly \\$26 billion](#) over the last 20 months, according to the Council of Economic Advisers.

More can be done. In September 2017 NTU joined with a [diverse coalition](#) of organizations asking CMS to clarify its Medicare reimbursement policies so as to clear up a disincentive against utilizing biosimilar drugs, which can offer substantial savings to taxpayers.

3) Repeal Taxes and Unnecessary Regulations that Raise Medication Costs. Misguided taxes on pharmaceutical producers raise the cost of medication for patients across the system. As these taxes increase costs, it becomes more difficult for middle class families to meet their health care and prescription drug needs. Since enactment of the Affordable Care Act (ACA) in 2010, health care costs [have not slowed](#) to the degree originally promised. While supporters of such taxes believe these added costs will only be paid for by corporations, in reality, these costs will be passed on through consumers in the form of higher prices.

To reduce the cost of prescription drugs, lawmakers should repeal all ACA taxes. Repealing the Branded Prescription Drug Fee, just one of the numerous new taxes included in the ACA would mark important progress. As the Tax Foundation described in a [2015 analysis](#), this tax "is targeted at pharmaceutical companies that sell branded prescription drugs. Unlike most taxes, the Branded Prescription Drug Fee is calculated not as a percentage of pharmaceutical company's total sales, but in proportion to its share of the branded prescription drugs market." The problem is that this levy can quickly add up as a major burden. According to the study:

There is significant reason, in theory, to believe that an excise tax such as the Branded Prescription Drug Fee would lead to rising pharmaceutical prices. According to a [study](#) from RAND, demand for prescription pharmaceuticals is highly inelastic: sales typically fall by only 0.05-0.08% for each 1% increase in cost. This means that a tax on branded prescription drugs would probably not lead to a large fall in drug sales, but would mostly translate into an increase in drug prices. Because the branded prescription drug industry is about [\\$268 billion](#) in size, a tax of \$3 billion on the industry is equivalent to roughly 1% of sales – which would lead to a significant portion of the observed rise in prices.

Public officials must pay greater attention to the artificial -- but palpable -- pressure their revenue-raising policies can exert on consumer-based markets. Indeed, by cutting into the prosperity of our health care sector through short-sighted taxes, they may be adversely impacting the long-term revenue picture for government treasuries, which might otherwise have benefited from healthy corporate profit, property, and other tax receipts.

4) Have the Private Market Take the Lead to Reduce Drug Costs. As we've experienced since the enactment of the ACA, additional government involvement in the health care market has not performed as promised. In order for costs to go down, the government needs to take a back seat to foster private sector competition.

Value-based health care has more potential than any other model for delivering what free-market public policy advocates have long sought: stronger patient-provider relationships, consumers empowered with decision-making over how to deploy resources, limited government interference in the evolution of services, and nimble programs capable of embracing evidence-based results. Ultimately, this approach boils down to paying for individualized drug therapies whose effectiveness is based on measurable outcomes -- prevention of costlier problems and treatments down the line. This will foster an organic fiscal responsibility that is far more durable than complex rules, price controls, or rationing.

One illustration of such a trend is the recent merger between health insurer Cigna and the Pharmacy Benefit Manager (PBM) Express Scripts. Cigna CEO David Cordani has set an ambitious goal for his company to achieve across its programs “CPI [consumer price index]-level medical cost inflation by 2021,” with value-based care as a central driver.

[Calculations show](#) that if this goal were applied to Medicare and Medicaid:

Official [federal estimates](#) project that Medicare and Medicaid combined will grow from \$1.18 trillion in 2021 to \$1.74 trillion in 2026. If, instead, those programs grew only as fast as the [government's forecasted rate](#) of general CPI for the same period, outlays would be \$1.33 trillion — a much more manageable scenario.

The principles behind value-based care can also be commendable adapted to individual products. Bayer has developed a Commitment Program for its recently approved cancer therapy drug Vitrakvi, whereby the company will [refund the cost](#) of the drug to “payers, patients and third-party organizations paying on behalf of patients, in the event eligible patients do not experience clinical benefit within 90 days of treatment initiation.” This revolutionary approach could incrementally but powerfully change the way pharmaceuticals compete.

5) Reform Government Health Programs that Needlessly Raise Prices Across the System. One of the major debates sure to arise in the upcoming Congress will relate to the size and role of government in America's health care system. Some continue to push for expanded federal involvement far beyond

the ACA, but such proposals are misguided and will not get to the root of the problem. Before Congress should move forward with a government takeover of the private insurance market, policymakers should explore reforms to the many problems already plaguing government-run programs that are meant to subsidize consumer drug costs. In many cases, these programs are well intended but fail at achieving their goal, and leave taxpayers footing the bill for their shortcomings.

The 340B program is an instance of well-intended policy that instead appears to be exacerbating higher drug costs. Established in 1992, it requires pharmaceutical manufacturers participating in Medicaid to provide discounted drugs to certain healthcare providers that serve uninsured and low-income patients. Because 340B enables hospitals to purchase outpatient drugs below market value, many hospitals have an incentive to increase their profit by prescribing more expensive drugs without passing along the savings to the safety-net patients. As a result of these lucrative incentives, hospital enrollment in the 340B program has exploded -- up from 7,806 entities in 2013 to 21,554 in 2017, a 176 percent increase. Earlier this year a [joint communication](#) to Congress from NTU and Council for Citizens Against Government Waste observed:

Non-hospital entities, such as federally-qualified health centers, Ryan White HIV/AIDs program grantees, and specialized clinics must operate within the rules of their federal grants and programs, so there is more of a guarantee they will utilize their 340B drug savings required by the law. On the other hand, 340B hospitals have no such restriction and can utilize the funds for anything they choose, such as constructing new buildings and other overhead and investment activities. Congress should institute an audit or tracking system for how 340B hospitals utilize their pharmaceutical savings and make sure it is in line with the law's intent.

In addition, NTU [has endorsed](#) a bipartisan bill to declare a "time-out" on new enrollees to the program while new managerial controls are developed.

Another example of needed program reform is in the area of "compounding" -- pharmacies that specialize in customized formulations of drugs. While useful for many patients, such pharmacies have also been involved in safety scandals as well as accused of [promoting unnecessary medications](#). Medicare's Inspector General noted that between 2006 and 2015 Part D experienced a rate of expenditure increase on compounded drugs that was about four times faster than for other medications in the program. Between 2010 and 2015 the Pentagon's Tricare program had to clamp down on reimbursements for compounded drugs after payments for these items rose from \$23 million for an entire year to \$550 million in *one month*.

6) Enhance Oversight Measures of Government Health Care Programs. If taxpayers are forced to pay for billions of dollars in programs that are meant to reduce the cost of prescription drugs, they deserve to have that money spent in an efficient and cost effective manner. Far too often do we hear stories of agency mismanagement of funds, beneficiaries abusing their position, and individuals trying to game the system.

Congress should work to achieve real solutions to not only recover misspent money on prescriptions after the fact, but also to detect and prevent such problems before they happen. One place to start is by introducing smart card technology into the government health care system. Utilizing identity and information management techniques developed in the private sector, smart cards can not only reduce fraudulent transactions, they can assist with other costly health problems such as prescription abuse. Twelve citizen groups [have endorsed](#) legislation for a smart card pilot program in Medicare. Writing in support of the bill (HR 6690, the Fighting Fraud to Protect Care for Seniors Act), the groups observed:

Federal health care programs have long been plagued by improper payments, one component of which is attributable to fraudulent activities such as identity theft, billing for services never rendered, or falsifying patient records to obtain prescription drugs illicitly. A [2012 study](#) led by former Director of the Centers for Medicare and Medicaid Services Donald Berwick pegged the fraud rate alone (as opposed to other types of improper payments) in Medicare and Medicaid at between 3 percent and 10 percent of all dollars spent. In 2016 GAO [estimated](#) that smart cards could have impacted roughly one in five of health care fraud cases it examined from 2010 on the federal level. Companies that have experience with developing smart cards provide much higher estimates of this salutary effect.

Even accepting Berwick's or GAO's lower-end calculations, however, it is clear that the federal government could realize reduced fraud costs of several billion dollars annually with an aggressive smart card initiative for Medicare and other federal health programs such as Medicaid and the Children's Health Insurance Program. Instituting a pilot project for this technology, is an appropriate and proper place to begin this transformation.

HR 6690 passed the House in the 115th Congress, and awaits Senate action in 2018.

Payment review processes could likewise save taxpayers billions in Medicare and Medicaid if applied more aggressively. Such implementation could occur in several ways through executive or legislative branch action, as NTU and CCAGW recently explained in a [November 2018 letter](#) to the Senate Finance Committee:

In September 2012, CMS launched a prepayment review demonstration project in 11 states with high incidences of improper payments and fraud, as well as four states with high numbers of short hospital stays. Despite being hamstrung by CMS rules that proscribed the RACs from freely pursuing areas of vulnerability in Medicare claims and the fact that it was abruptly truncated one year short of its statutory three-year duration, the RACs' prepayment demonstration project still recovered a net of \$192 million on behalf of Medicare beneficiaries. ... Taxpayers and Medicare beneficiaries have waited patiently for decades for CMS to move away once and for all from the wasteful and inefficient "pay and chase" program integrity model. Adding a significant prepayment review program, coupled with the current post-payment review program, is exactly the kind of private-sector best practice CMS is seeking to help prevent tens of billions in losses each year to protect Medicare now and in the future.

These two recommendations only scratch the surface of steps government can take to more effectively steward the resources it already has for health care and prescription drugs.

7) Recognize the Balance between Intermediate and Long-Term Cost Savings for Taxpayers.

In issuing an Advance Notice of Proposed Rulemaking on certain reimbursements for Medicare Part B physician-administered drugs -- which included linking payments for those drugs to an international pricing index -- the Department of Health and Human Services established a five-year savings target of more than \$17 billion for the program. In pursuing such a goal, it is important to remember that short-term savings (assuming they materialize) must be weighed against offsetting costs to taxpayers.

Price controls have some appeal because in the near future, they appear to deliver lower costs to consumers. Unfortunately, they come with consequences. According to a 2008 Rand Institute [study](#) of drug price controls: “In general, price controls reduced life expectancy over time. The price control scenario simulated the effect of a 20-percent reduction in manufacturer revenue while holding consumers' out-of-pocket prices constant. Price controls would have small negative effects on life expectancy for current cohorts, but more significant negative effects in the future ... The results illustrate that imposing price controls would offer a modest benefit to the current generation but pose substantial risks and potentially high costs for later ones.”

One reason that prescription drug spending historically accounts for a share of total national health expenditures hovering slightly above or below 10 percent annually is because costly innovator pharmaceuticals combine with less expensive generics to keep the overall trend somewhat stable. From 2010 to 2014, branded and unbranded generic drugs grew from 77.2 percent to 87.5 percent of all prescriptions dispensed nationwide. That proportion has since risen to 90 percent, for a savings to the total health care system of more than \$250 billion annually. Taxpayer-funded programs share in these benefits.

At the same time, innovative patented medications have a crucial place of their own in a balanced system that delivers longer-run gains for taxpayers. Even high-priced pharmaceuticals tend to be a better long-run bargain because they replace hospital stays, surgeries, recovery therapies, and other costly activities that would have to occur in their place. A National Bureau of Economic Research [study concluded](#) that every dollar spent on prescription drugs led to a \$2.06 reduction in overall Medicare expenditures.

Furthermore, encouraging the utilization of prescription drugs in government programs could, according to the Congressional Budget Office, yield palpable fiscal gains for taxpayers. [CBO concluded](#) that for every 1 percent increase in prescriptions filled for Medicare participants, spending on medical services within the program falls by 0.2 percent. Even higher payoffs may be possible for those with chronic conditions.

Fact-based, up-to-date research is needed to inform public policy on a consistent basis of how important the uniquely balanced U.S. system for prescription drugs can be for patients and taxpayers. CBO has an especially vital role to play in researching the fiscal benefits of a free market for all types of pharmaceuticals, as well as accurate appraisals of proposals such as price controls and importation. Without these, public officials could make serious mistakes that will endanger America's health, economic prosperity, and fiscal stability.

About the Author

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