
Report on 100 Days of Action on the American Patient First Blueprint

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The Beginning of a Sea Change

For years, American patients have suffered under a drug-pricing system that provides generous incentives for innovation, while too often failing to deliver important medications at an affordable cost. The flaws in America's drug markets have been a topic of discussion in healthcare policy circles for years, but no comprehensive approach to reform has ever been undertaken.

On May 11, President Trump and Health and Human Services (HHS) Secretary Alex Azar released the American Patients First blueprint, a comprehensive plan to bring down prescription drug prices and out-of-pocket costs.

The extensive number of proposals in the blueprint reflect the scale of the task: restructuring and reforming a fundamentally flawed drug-pricing system that governs a more than \$400 billion sector of our economy. Reforms of significant parts of the healthcare market on a similar scale, such as Medicare Part D, have generally taken several years to implement, and several years after that to effect changes across the entire drug market.

“The President’s blueprint for lower drug prices is working, drug prices are coming down, and American patients are going to see the savings in their pocketbook.”

— SECRETARY ALEX AZAR

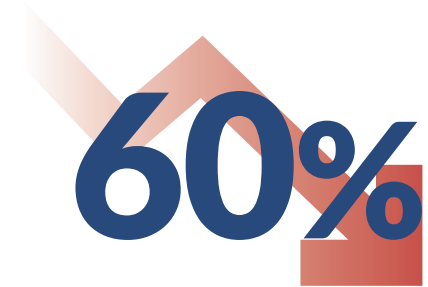
In the 100 days since May 11, HHS has taken dozens of actions on the four strategies contemplated in the blueprint: increased competition, better negotiation, incentives for lower list prices, and reducing out-of-pocket costs. Together, these actions have helped bring into focus a vision for a more competitive pharmaceutical marketplace. Pharmaceutical manufacturers, pharmacy benefit managers, and other actors in the market have indicated that they recognize the scale of disruption this would involve.

At the time of the release of the blueprint, few observers believed that, within months, drug manufacturers would begin to change their annual ritual of significant price hikes. Yet that is what happened in the months following.

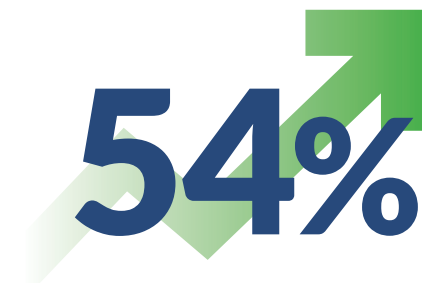
Within these first 100 days, 15 drug companies have reduced list prices, rolled back planned price increases, or committed to price freezes for the rest of 2018. Cutting list prices and rolling back proposed increases in particular are an unprecedented recognition of the fundamental changes going on in drug markets.

In this report, for the first time, we are publishing data from HHS's Assistant Secretary for Planning and Evaluation that finds clear evidence that drug company behavior has changed dramatically since the release of the blueprint's proposals.

Two shifts in drug pricing behavior following the release of the blueprint are notable:



fewer brand-drug **price increases** than the same period in 2017



more generic and brand-drug **price decreases** than the same period in 2017

*Period from May 11, 2018 through August 15, 2018

These shifts in pricing are just the beginning of a sea change in drug markets, as manufacturers respond to new incentives and comprehend the more dramatic changes to come. Administrative action and presidential leadership have driven the beginnings of this change, but legislative changes to the laws that govern drug markets will play a role as well. This report will highlight many of the administrative changes that have occurred and lay out some areas of future action.

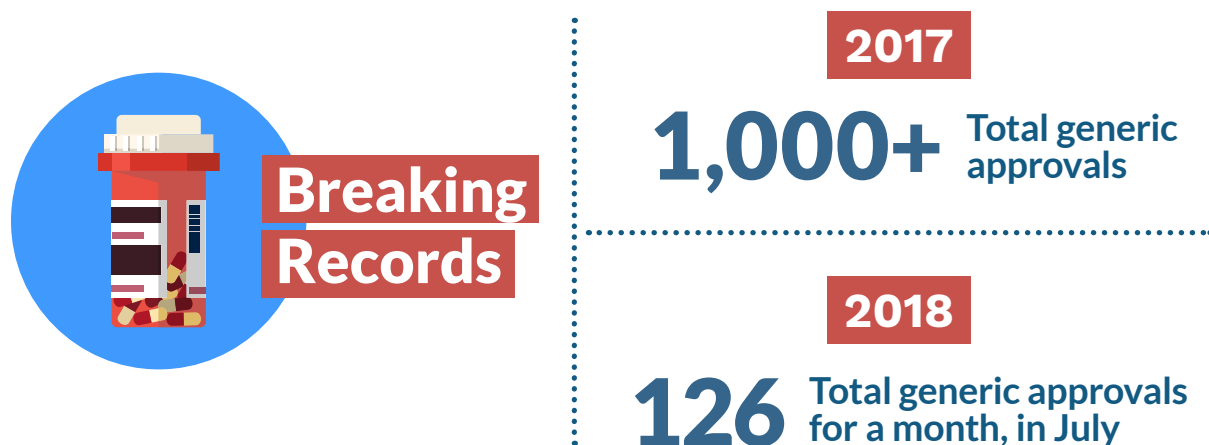
Increased Competition

Under President Trump, before the launch of the drug pricing blueprint, the Food and Drug Administration had already made it a priority to speed approval of generic drugs, resulting in a record number of generic approvals in 2017.

Since the blueprint, this has accelerated: In July, FDA approved more generic drugs than in any single month in its history.

In the past 100 days, FDA also approved the first generic drug under a pathway designed to expedite the development and review of generic drugs for products that lack competition, approved the first generic version of the EpiPen, and approved a new biosimilar competitor for an expensive drug that fights infection in cancer patients (just the 10th biosimilar ever approved). FDA's success reflects actions taken under President Trump, by Commissioner Scott Gottlieb, to support efficient and streamlined reviews of generic drug applications as part of a Drug Competition Action Plan and encourage biosimilar development as part of a Biosimilar Action Plan.

HHS has launched an unprecedented working group to examine how the safe importation of drugs could address price spikes by manufacturers in the United States of sole-source drugs that do not have blocking patents or exclusivities. FDA has also laid out fundamental reforms to stoke more competition down the road, including the July launch of the Biosimilar Action Plan and significant measures to prevent drug companies from gaming safety programs to block generic competition.



Better Negotiation

Inevitably, in some parts of the drug market, there is not yet enough competition to drive down prices. That is why President Trump made tougher negotiation by Medicare and Medicaid a key piece of his vision for lowering drug prices, and HHS has been able to deliver negotiation tools even faster than many thought possible.

In a historic step, the Centers for Medicare & Medicaid Services has given Medicare Advantage new tools to negotiate lower prices for expensive Part B drugs, a \$12 billion drug market. The savings from these lower prices could be passed on to the 20 million seniors enrolled in Medicare Advantage plans as soon as next year.

The administration has also provided new guidance to help insurers and drug companies share information earlier to reach better deals for patients, solicited comment on ways to use private-sector competitive acquisition for Medicare Part B drugs, and approved a first-of-its-kind waiver for a state to negotiate value-based contracts with drug makers. These steps are part of overall efforts to give government programs negotiation tools successfully used by the private sector. Driving down prices through negotiation, however, is only one element of greater affordability.

Incentives for List Prices

Patients don't just suffer when they or their employer or insurer fails to receive a discount on a medication. They can also face high out-of-pocket expenses even if a large rebate has been paid, because their cost sharing is generally calculated as a share of list price. Unfortunately, the incentives in America's drug pricing system continue to drive list prices higher, which increases patients' coinsurance and copays. Higher list prices reward all actors in the system – even pharmacy benefit managers that are supposed to be keeping costs down for patients.

Eliminating these perverse incentives and instead putting in place incentives that restrain list-price growth is a key piece of the President's blueprint. This will involve examining the avenues by which market actors are paid as a share of list price and considering alternative methods of compensation. Numbers released since the launch of the blueprint by two of the largest pharmacy benefit managers indicate that their business models could be modified to work in a new system with fixed-price compensation, rather than one based on share of list prices.

One brake on rising list prices is the Medicaid Drug Rebate Program's inflation penalty, which charges drug companies larger rebates when prices increase faster than inflation. The Affordable Care Act, however, put a cap on the rebates that could be paid, allowing runaway price increases without penalty. HHS transmitted language to Congress on undoing this giveaway to drug manufacturers, and Rep. Michael Burgess, Chairman of the House Energy and Commerce Health Subcommittee, has now introduced language to that effect.

Within weeks after the blueprint's release, CMS made significant changes to its Drug Pricing Dashboard, highlighting the individual drugs with the highest price increases in Medicaid, Medicare Part B, and Medicare Part D, and, for the first time, the manufacturers responsible. This complements an internal tracking project that keeps President Trump, Secretary Azar, and CMS Administrator Seema Verma apprised of all drug price increases. As reflected in the data outlined earlier in the report, there have already been significant reductions in the rate of these price increases.

Lower Out-of-Pocket Costs

Bigger discounts and lower list prices will help drive down out-of-pocket costs for American patients. But the administration is also taking more direct action to empower patients to pay less in out-of-pocket costs. Within two weeks of the blueprint's release, CMS put health insurers on notice that it is unacceptable to impose "gag clauses," which can cause seniors to pay more for drugs by prohibiting pharmacists from discussing cheaper options.

Two proposed changes to Medicare will also lower seniors' out-of-pocket drug costs and make sure the program's payment amounts reflect actual drug costs: reducing the payments made for certain new drugs in Medicare, and lowering payments for drugs under the 340B discount program, which expands on reforms already implemented by the Trump administration that are estimated to be saving patients \$320 million a year.

Looking Ahead: Administrative and Legislative Action

Together, these four strategies will work to build a new drug pricing system characterized by real competition, lower prices, and healthy incentives for innovation. Despite the progress made, the most significant parts of the President's blueprint are largely still in the works. A few particular areas are worth highlighting here.

The blueprint raised the possibility of requiring the display of list prices in direct-to-consumer television advertisements, as part of the fair-value information consumers can expect to receive. Upon the blueprint's release, at Secretary Azar's direction, HHS began examining this issue.

Another significant area for action is stronger negotiation within the Medicare Part D program, for which new regulations are typically released on an annual basis. Significant steps to improve negotiation by prescription drug plans in this program are in the works, and laid out at length in the blueprint.

The blueprint also proposed examining restrictions on the use of rebates, which can be done through revisiting the interpretation of the Anti-Kickback Statute. As outlined in the negotiation section of this report above, the Trump administration is strongly supportive of measures to negotiate large discounts on drugs. But the current rebate system, where all actors make profits as a share of list price, can be a driver of higher list prices. Rebates calculated as a share of list price and paid by drug companies to payers are not necessary to drive a strong negotiating ecosystem. This system could be replaced with a model that benefits patients every time a negotiation happens.

Imagine a world where manufacturers drop their list price to their current net value and PBMs leverage their negotiating skills in lowering those prices further with upfront fixed-price discounts, based on the same tools they use today. Patients would find themselves paying less every time one of these negotiations occurs.

These further reforms can be accomplished through administrative action, but there is a great deal of room for legislation as well. HHS has transmitted language to Congress on a number of areas, including gag clauses and the Affordable Care Act cap on Medicaid inflation penalties. Legislation to ban gag clauses in private insurance, sponsored by Sen. Susan Collins, has already passed out of committee.

Modernizing the benefit structure of the Medicare Part D program to better protect seniors with high drug costs will also require legislative action, laid out in the President's 2019 Budget. Many actions to improve negotiation in Medicare are possible without legislation, but more sweeping actions, such as creating a unified drug benefit from Part B and Part D, will also require Congress to act.

These are just several highlights of future actions contemplated in the President's American Patients First blueprint. HHS has plans in the works to deliver on every aspect of the blueprint, and market actors who have responded to actions so far can expect reforms that aim toward a new, patient-friendly system to continue.