



1600 20 Street, NW • Washington, DC 20009 • 202/588-1000 • [www.citizen.org](http://www.citizen.org)

## Actions the Trump Administration Should Take to Lower Prescription Drug Prices

Americans support strong action to reduce medicine prices and end the monopoly abuses of prescription drug corporations by wide margins and across party lines. During the campaign and early months of his presidency, Donald Trump supported a call to action to lower prescription drug prices. [Reports](#) indicate that the Administration has assembled a “Drug Pricing and Innovation Working Group” and is compiling an upcoming executive order ostensibly intended to lower prescription drug prices. Reports also suggest that policies included in the pending executive order will be friendly to prescription drug corporations, and represent a radical departure from the Donald Trump of the campaign trail who promised that he would take bold action to ease Americans’ pain and make medicines affordable. Below are Public Citizen’s recommended actions for the Trump Administration to take to bring down medicine prices.

- **End monopolies. Allow competition.** Prescription drug corporations take advantage of government-granted monopolies to charge as much as we will pay to care for our loved ones – and sometimes more. We should take away monopoly privileges when corporations charge unreasonable prices. We should authorize generic competition with high-price patented drugs as a means to reduce costs for public programs.
  - NIH and other sponsors of government-funded research should adopt licensing guidelines administratively. When U.S. government programs and consumers are charged more than other wealthy countries for medicines developed with U.S. government funds, we should allow competition on said product through March-In or other remedies that would challenge the infringing corporation’s monopoly. The NIH and other agencies should include such guidelines in future licensing agreements as well as adopt administrative guidelines that limit government-granted monopolies on existing medicines under similar conditions.
    - Other triggers for licensing may include:
      - Anticompetitive, [abusive or unfair practices \(e.g. unlawful off-label marketing\)](#). The [Improving Access to Affordable Prescription Drugs Act](#) (S.771, H.R.1776), introduced by Sen. Al Franken and 15 other senators, includes language that would rescind FDA-granted exclusivities on a product when said product was involved in a finding or admittance of fraud or other wrongdoing, this may serve as a model for criteria (see Sec. 304).
      - Excessive cumulative revenues from the sale of the product that exceed the amount that would justify a temporary monopoly to provide incentive for drug development. Once a company has achieved a large enough return on its research and development investment, remaining exclusivity periods should be curbed to prevent windfall profits at the expense of consumers and taxpayers.
      - Refusals to license technologies, when such refusals present barriers to follow-on innovation.
      - Risk to public health through supply issues (e.g. stock-out problems) rooted in the monopoly.
      - Enabling the government to obtain low-cost versions of the products for the purpose of stockpiling products for emergencies.
      - Other situations where non-voluntary authorization is otherwise in the public interest.
  - Federal agencies should adopt similar criteria for authorizing the government use of patented medical technologies under [28 USC § 1498](#) when prescription drug corporations abuse their

monopoly positions. Under § 1498, officers of the federal government may make use of patented inventions for public purposes at any time in exchange for financial compensation to patent holders. As distinguished from March-in, federal funding of the invention is not required under § 1498, which means § 1498 is applicable to a much broader universe of technologies: any patented invention. Application of the use, however, is limited to uses by and for the federal government. See a [recent law review](#) detailing the use of § 1498 to reduce drug prices.

- [In early May](#), the Louisiana department of Health Services proposed using this federal statute to license generic firms for the production of key, high priced Hepatitis C treatments distributed under Medicaid. The secretary of Health and Human Services should immediately move to approve this action. This would see immediate cost savings and set the tone for lower drug prices in the U.S. It would also open this strategy for use in other states.
  - The Department of Justice should revise its guidelines regarding antitrust and intellectual property issues to include pricing standards for the abuse of monopoly power and more robust standards against product tying (damaging medical innovation and access through anticompetitive controls on a technology essential for new combination products).
- **No backroom deals to keep prices high.** Today, prescription drug corporations pay each other millions of dollars to delay price-cutting competition and maintain monopoly prices. Through mergers and acquisitions they reduce competition and dodge paying their fair share in taxes. Our government should prohibit backroom deals that keep prices high and hurt Americans.
    - While putting an end to anticompetitive reverse-payment agreements would require legislation, the FTC should continue to litigate aggressively to prevent, stop and recoup ill-gotten gains of [pay-for-delay deals](#) between brand-name and generics firms that block competition and cost consumers and taxpayers \$3.5 billion every year.
    - Additionally, the FTC should crack down on abusive, anti-competitive and unfair practices such as off-label marketing.
    - FTC must prevent anti-competitive mergers and acquisitions in the pharmaceutical industry that short-circuit and inhibit price-lowering competition. In our view, the increasing trend in generics industry consolidation is an important part of the story of why we're seeing incredibly large overnight increases in prices offered by generics firms for certain products.
- **Crack down on pharma fraud.** Many prescription drug corporations routinely break our laws, overcharge the states, bribe healthcare providers, manipulate safety data and illegally market their drugs. Federal agencies must crack down on corporate crime and demand that drug corporations are as accountable as the rest of us.
    - Legislation that stiffens civil penalties, under the federal False Claims Act, against prescription drug corporations engaging in these kinds of unlawful practices is needed. Until such legislation is passed, the Department of Justice should seek to maximize criminal penalties imposed on these companies as well as their executives, including, when appropriate, incarceration.
    - So-called Corporate Integrity Agreements (CIAs), into which companies enter with the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) as parts of civil settlements, should be strengthened to allow more rigorous federal monitoring of pharmaceutical companies in order to identify, and ultimately prevent, systematic fraud that has long been the norm. Annual compliance reports submitted to the OIG pursuant to CIAs should be made public and companies should be significantly punished for violating the terms of CIAs.
    - Rather than following PhRMA's [suggestion](#) to weaken anti-kickback laws, OIG should crack down on enforcement against illegal rebates, kickbacks and bribes to prevent fraud and abuse. The Department of Justice should be instructed to pursue these cases vigorously.