



## President Sends Drugs for America Act to Congress

By Norman M. Goldfarb

In an unusual Sunday press conference at the White House, on April 1, 2018, Donald J. Trump, President of the United States, announced new legislation, "The Drugs for America Act," to speed the availability of new drugs for patients in need.

At the press conference, President Trump said, "This is America's moment. And there is not a moment to lose — not a moment — for the good American citizens who have the worst diseases. Believe me, millions of sick people are dying while drug companies, and believe me, we have the best drug companies, complete all the bureaucratic red tape that burdens these fine American companies. I call upon members of Congress from both sides of the aisle to send me a bill to sign by the end of this month. Affordable healthcare is a joke if we don't have the drugs to cure diseases like cancer and heart attacks."

"We need to build on the Affordable Prescription Drugs Act we passed last year," said President Trump. That legislation redirected \$5 billion in NIH funding to companies developing unaffordable, high-priority drugs ("UPDs"), and amended the Prescription Drug User Fee Act (PDUFA) to accept equity shares instead of cash fees from companies developing UPDs.

The President said his administration will work closely with Congress to pass the Drugs for America Act. The Act includes five main provisions:

- A compassionate "right to try" program will expedite the process whereby sick patients obtain unapproved drugs. The program will use an online "postcard" that patients can submit to a new FDA Office of American Drugs. The FDA will build a national stockpile of these drugs, financed by the payroll taxes paid by illegal immigrant workers.
- First-in-class UPDs will no longer require pivotal ("Phase 3") testing before marketing. However, manufacturers will have to collect and report real-world safety data for at least one year before they can apply to FDA for permanent approval of a UPD drug.
- Deportation will be deferred for illegal immigrants enrolled in Phase 1 studies of first-in-class UPDs.

Scott Gottlieb, FDA commissioner, said, "The Drugs for America Act will move the U.S. a big step closer to the day when our good citizens can obtain the drugs they need, when they need them. That's *real* compassion."

Senate Minority Leader Chuck Schumer, who was present at the press conference, told reporters, "Democrats have been demanding these changes for years. I congratulate my good friend, the President, for meeting us halfway on this bipartisan legislation that Democrats should get most of the credit for. Since it is April 1<sup>st</sup> today, I just hope President Trump is serious about this legislation and it's not just another one of his elaborate practical jokes."

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