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Executive Order: Affordable Prescription Drugs for America

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In an unusual weekend signing ceremony at the White House, on Saturday, April 1, 2017, Donald J. Trump, President of the United States, issued an executive order, "Affordable Prescription Drugs for America," to address the growing problem of unaffordable prescription drugs.

In a prepared statement, President Trump said, "Given the current state of 'government' in Washington, we need to focus on goals that everyone can agree on. We can all agree that prescription drugs are less and less affordable for hard-working Americans, the wonderful companies that employ them, and the government programs that protect the health of our veterans, our aging neighbors, and the disadvantaged. Starting today, April 1, 2017, I will make prescription drugs affordable again for Americans."

President Trump ordered the following measures to take effect immediately:

- The Centers for Medicare & Medicaid Services (CMS) will, by April 30, 2017, determine detailed criteria for identifying "Affordable Prescription Drugs" (APDs) vs. "Unaffordable Prescription Drugs" (UPDs). These criteria will consider absolute price, relative price, price history, and value. By June 30, 2017, CMS will classify current drugs accordingly.
- The Food & Drug Administration (FDA) will establish a new Office of Drug Affordability (ODA) to expedite the review of New Drug Applications (NDAs) of APDs with a 20% reallocation of medical and scientific personnel. To be eligible, manufacturers must guarantee that their new drugs will meet APD criteria.
- The FDA will remove the Phase 3 "pivotal trial" requirement for APDs, provided drug manufacturers assume the liability and obtain insurance to cover serious side effects for three years post-approval. By April 30, 2107, the National Office of Health Insurance (NOHI) will specify the liability and insurance requirements.
- The National Institutes of Health (NIH) will exercise the federal government's option, under the Bayh-Doyle Act of 1980, to impose its "march-in rights" to impose 10% royalties on UPDs based on research funded by the Federal government. These funds will be used to offset the cost of UPDs to the Department of Veterans Affairs (VA).
- U.S. Customs and Border Protections (CBP) will impose a 30% affordability tariff on imported UPDs, to be used to fund clinical research by American companies in the U.S. on generic and bioequivalent drugs.
- The Commerce Department will require employer certification that company group health plans limit coverage of UPDs to employees who are citizens or legal residents of the United States.

The President will work closely with Congress to pass legislation, the Affordable Drug Act, to implement measures that cannot be implemented through administrative action:

- Require manufacturers to give CMS wholesale, most-favored-nation pricing for UPDs, based on the lowest prices in Canada and six Western European countries.
- Limit pharmacy benefits managers (PBMs) to 5% margins on UPDs.
- Amend the 21st Century Cures Act to redirect $5 billion in NIH funding to companies developing high-priority APDs, as determined by CMS.

- Amend the Prescription Drug User Fee Act (PDUFA) to accept equity shares instead of cash fees from companies developing high-priority APDs.

At the signing ceremony, Tom Price, Secretary of the Department of Health & Human Services (HHS), said, "April 1st marks a new day for those who believe in this country. We will build a wall around America to protect our citizens from importing unaffordable drugs and a highway to bring affordable drugs to every legal American. It may be April Fool's Day today, but we are not fooling around with America's health."

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