Trump plans rollback of drug industry regulations

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Trump met last week with pharmaceutical industry lobbyists and executives at the White House where he announced his plans to drastically reduce the regulatory power of the Food and Drug Administration (FDA) while slashing taxes on the pharmaceutical industry.

Participants at Tuesday's meeting included Stephen Ubl, head of the drug industry trade group PhRMA, and the CEOs of Novartis, Merck, Eli Lilly, and Johnson & Johnson.

Trump has demagogically postured as a critic of the pharmaceutical industry, including calling for rule changes to allow the federal government to use the bulk purchasing power of Medicare to negotiate drug prices with pharmaceutical companies.

"Pharma has a lot of lobbies, a lot of lobbyists and a lot of power," Trump said at his first press conference as president-elect on January 11. He said that it was necessary to "create new bidding procedures for the drug industry, because they're getting away with murder."

Trump has now abandoned any pretense of opposition.

"We're going to be changing a lot of the rules," Trump proclaimed prior to the meeting.

"I'll oppose anything that makes it harder for smaller, younger companies to take the risk of bringing their product to a vibrantly competitive market. That includes price-fixing by the biggest dog in the market, Medicare, which is what's happening," Trump told reporters after the meeting, reversing his previous position on allowing Medicare to negotiate prices and falsely stating that the program currently does so.

"We're going to be lowering taxes, we're going to be getting rid of regulations that are unnecessary," said Trump. He said that he wants to get rid of 75 or 80 percent of FDA regulations.

Biotech and Pharmaceutical stock shares rallied following the meeting, and Trump's plan was met with approval by the industry lobbyists and CEOs gathered at the meeting.

"Tax, deregulation—those are things that could really help us expand operations," commented Eli Lilly CEO Dave Ricks, according to Reuters.

"These changes are going to be great for the country," Celgene Chairman Robert Hugin told the *Washington Post*.

The deregulation of the FDA and the streamlining of the drug approval process will result in less knowledge about the safety and efficacy of the drugs approved by the FDA.

"Streamlining drug approvals sounds good, but the agency has already weakened approval standards and patients are paying the price—hugely expensive drugs that don't even work," Diana Zuckerman, president of the National Center for Health Research, told the *New York Times.*

Dr. Michael Carome, the director of Public Citizen's health research group, noted in a statement that Trump's proposal would "destroy the ability of the agency to protect patients and consumers from unsafe or ineffective medications and medical devices, hazardous foods and dietary supplements, and dangerous tobacco products."

"The end result would be countless preventable deaths, injuries and illnesses across the US," he said.

These risks have already been heightened by the bipartisan legislation passed late last year, the 21st Century Cures Act. The Act significantly rolls back the regulatory authority of the FDA, lowers the standards that must be met before a drug is approved, and expands expedited approvals.

The FDA will be further hindered by Trump's executive orders instituting a hiring freeze and the rule that two regulations must be removed for every new one.

"That will cripple the FDA's ability to do anything other than regulate by non-binding guidance documents," David Vladeck, a professor at Georgetown University Law Center, told the *Washington Post.*

"To hollow out the agency's authority by forbidding it from dealing with emerging issues through new regulations, and perhaps even giving guidance will jeopardize consumers and threaten the reputation of the agency around the world," Vladeck said.

Trump tied his criticism of high drug prices to his "America First" rhetoric of economic nationalism, attacking "global freeloading" through "foreign price controls."

"Our trade policy will prioritize that foreign countries pay their fair share for U.S.-manufactured drug, so our drug companies have greater financial resources to accelerate development of new cures, and I think that's so important," Trump said.

Instead of allowing Medicare to negotiate drug prices, which Trump referred to as "price fixing," he claimed that

competition spurred by deregulation and tax cuts would bring down drug prices.

This approach will do nothing to address skyrocketing drug prices in the United States, which have doubled since 2011 and are up to ten times higher in the US than in other countries.

The pharmaceutical industry, which continues to consolidate through mergers and acquisitions, is notorious for dodging competition when it threatens the bottom line. For example, drug companies will often raise prices almost simultaneously with their competitors, a practice known as "shadow pricing." When a drug is about to go off patent, companies will often pay potential generic competitors to hold off on introducing generic versions in "pay-for-delay" deals.

Moreover, there is little evidence that high drug prices are due to the costs associated with researching and developing drugs. According to an article published in August of last year in the *Journal of the American Medical Association*, large pharmaceutical companies invest only 10 to 20 percent of their revenue in R&D. The authors cite an analysis that looked at 26 products or product classes over the past 25 years and found that more than half originated in publicly funded research centers.

The authors of the article conclude that "there is little evidence of an association between research and development costs and drug prices; rather, prescription drugs are priced in the United States primarily on the basis of what the market will bear."

In response to Trump's meeting, Democrats continued to perpetuate illusions in the president's demagogic attacks on the pharmaceutical industry, with Senator Bernie Sanders and Maryland representative Elijah Cummings issuing a joint statement saying they "hope" Trump "really" takes on the industry.

"I look forward to working with President Trump on this issue if he is serious about standing up to the pharmaceutical industry and reducing drug prices," Sanders said after Trump's meeting.

The Trump administration has not yet named its nominee for FDA commissioner, who would be charged with "streamlining" the agency. Four possible nominees have been mentioned, all of whom favor weakening FDA regulations.

Jim O'Neill, an associate of Trump transition adviser and Silicon Valley billionaire Peter Thiel, is a managing director at Thiel's Mithril Capital Management. He has called for changing FDA regulations to allow pharmaceutical companies to begin marketing drugs before they have been shown to be effective.

"We should reform FDA so it is approving drugs after their sponsors have demonstrated safety, and let people start using them at their own risk, but not much risk, of safety," O'Neill said in a 2014 speech.

Balaji Srinivasan, another Thiel associate, is the CEO and co-founder of 21 Inc., which develops software and hardware for bitcoin micropayments, and was a co-founder and chief technical officer at Counsyl, a company that developed a prenatal genetic test for chromosome-related birth defects.

"Drug development shows that modern regimen is not necessary for safe innovation," Srinivasan said in a tweet in December.

Scott Gottlieb is a former FDA deputy commissioner and venture capitalist who has worked with numerous drug companies. He is currently a resident fellow at the conservative American Enterprise Institute.

Finally, the Trump transition team has spoken with Dr. Joseph Gulfo about possibly heading the FDA. Gulfo, a former CEO of drug and medical device companies, has criticized the FDA for delaying approvals by requiring clinical trials demonstrating that a drug is effective, and has called on the FDA to rely more on "biomarkers" rather than actual clinical outcomes. He says that any attempts to impose price controls on drugs would be "punishing" the pharmaceutical industry.

The positions of the potential nominees are at odds with a report released by the FDA last month showing that reducing drug approval standards would pose greater financial and health risks for patients.

The report highlighted 22 case studies of drugs, vaccines and medical devices tested since 1999 where promising data from smaller and shorter phase 2 clinical trials, which often rely on biomarkers instead of clinical outcomes, diverged from the larger phase 3 randomized controlled trials. The phase 3 studies failed to confirm phase 2 findings on effectiveness (14 cases), safety (1 case), or both (7 cases).

"As a result of the Phase III studies discussed in this paper, patients outside of clinical trials were not subjected to drugs that would not benefit them or to the risk of unnecessary serious toxicities, and did not suffer unnecessary financial expenditures. Where effective alternative therapies existed, they were not diverted from proven treatments; where an implanted medical device was at issue, patients were spared unnecessary surgical procedures," the report concludes.