Trump Vows to Ease Rules for Drug Makers, but Again Zeros In on Prices

By KATIE THOMASJAN. 31, 2017

Vows to Get Rid of Drug Regulation

"We're going to be cutting regulations at a level nobody's ever seen before," President Trump said Tuesday in a meeting with pharmaceutical executives.

President Trump promised some of the nation's top drug company executives in a meeting at the White House on Tuesday that he would slash regulations at the Food and Drug Administration and make it easier for them to manufacture products in the United States.

He also described as "fantastic" the person he planned to nominate for commissioner of the Food and Drug Administration, someone he said would streamline the agency and get drug approval decisions faster.

"You can't get approval for the plant, and you can't get approval for the drug; other than that, you're doing fantastic," Mr. Trump said at the meeting, to laughter from top executives of companies like Merck, Johnson & Johnson, Eli Lilly and Novartis.

But even as he struck a cordial tone with them, he said that lowering drug costs would remain a focus and that he would discuss the issue further during the nonpublic portion of the meeting, away from the news media. "The U.S. drug companies have produced extraordinary results for our country, but the pricing has been astronomical," Mr. Trump said. "We have to get prices down for a lot of reasons."

Battered by public outrage over the rising costs of drugs in recent years, the drug industry has.regarded.Mr.Trump warily in recent weeks. Pharmaceutical and biotechnology stocks rallied after his election as investors bet that Mr. Trump would reduce corporate taxes and adopt more industry-friendly policies than his Democratic opponent, Hillary Clinton, who had made reducing drug prices a campaign issue.

But that optimism gave way to unease after Mr. Trump pledged to tackle the drug pricing issue himself, <u>including raising the possibility</u> of allowing <u>Medicare</u> to negotiate the prices of drugs directly, something the industry has long opposed.

Just a few weeks ago, Mr. Trump singled out the pharmaceutical industry for its high prices, accusing it of "getting away with murder."

At the meeting Tuesday, Mr. Trump again referred to Medicare's role, saying he would oppose anything that prevented competition, including "price fixing by the biggest dog in the market, Medicare, which is what's happening."

A White House spokesman later clarified that his remarks meant that the president "supports increasing bidding and competition for all drugs in Medicare."

But the president also tried to persuade the executives that he would provide them with assistance, saying: "We can save tens of billions of dollars, and you people are going to do great. You're going to do great."

In comments after the meeting, the drug industry leaders said it had been productive and said they welcomed the president's pledges on cutting regulations and speeding approvals.

But drug safety advocates criticized his comments, saying that eliminating agency regulations would mean rolling back consumer protections on products as diverse as drugs, cosmetics, food and dietary supplements.

"Trump's horrifying proposal reflects utter ignorance about the F.D.A.'s essential role in protecting public health and once again demonstrates his commitment to placing corporate profits above protecting the safety of the American people," said Dr. Michael Carome, director of Public Citizen's health research group.

Dr. Carome said many of the regulations had been set up by Congress so they could not easily be removed. "Most of these regulations, to do away with them would require new statutes and new laws to be passed," he said.

Others said the agency had already loosened the approval process for new drugs in recent years, with questionable benefit.

"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," said Diana Zuckerman, president of the National Center for Health Research, a Washington research group that advocates strong safety and efficacy standards. She recently studied expensive new cancer drugs and found that many did not help patients feel better or live longer.

During the meeting, Mr. Trump also told the executives that he was close to naming a candidate to lead the F.D.A.

"You're going to get your products — either approved or not approved — but it's going to be a quick process," he said. "It's not going to take 15 years," apparently a reference not to the length of time it takes the agency to approve drugs but to how long it takes a to develop a drug.

He also appeared to express frustration at what he said were unnecessary delays by the agency, especially for drugs that treat patients who are close to death. The agency justifies the delay by saying it needs to evaluate whether the drug is safe, and whether it works, Mr. Trump said: "We can't approve the drug because we don't want to hurt the patient," he said, "but the patient is not going to live more than four weeks."

The Trump administration has not said who the finalists for the position are, but two widely circulated candidates are Dr. Scott Gottlieb, a former F.D.A. official with longstanding ties to the pharmaceutical industry, and Jim O'Neill, an associate of the billionaire Silicon Valley investor Peter Thiel, who has said he favored allowing drugs to be approved even if their efficacy had not been proved.

At the meeting, many of the drug industry leaders were eager to emphasize their long histories in the United States as well as their American manufacturing plants, even though the pharmaceutical industry — like many others — has increasingly moved its production overseas. More than half of the finished drug products that are sold in the United States are made here, according to a recent report in The Wall Street Journal, but the majority of the raw ingredients used to make those products are manufactured in countries like China and India.

Even Joseph Jimenez, the chief executive of the Swiss pharmaceutical giant Novartis, emphasized the company's American ties, pointing out the billions of dollars it spends on research and development and saying, "Our global headquarters is near Boston." Eric Althoff, a spokesman for Novartis, which is based in Basel, Switzerland, said Mr. Jimenez was referring to the company's research and development headquarters.

Mr. Jimenez and others supported Mr. Trump's pledge to cut taxes and regulations. "One of the things that can help us is a lower tax rate," Mr. Jimenez said.

"Yep, we'll get it," Mr. Trump replied.