Nominee for US Food and Drug Administration commissioner has deep ties to drug industry

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The Trump administration announced on Friday that it intends to nominate Scott Gottlieb as the new Food and Drug Administration (FDA) commissioner. Gottlieb has close ties to the drug industry and, if confirmed, will work to roll back regulations at the FDA.

President Trump had already made clear his wishes to eliminate most regulations at the FDA. After a meeting with drug industry executives on January 31, Trump announced that he wanted to get rid of 75 or 80 percent of FDA regulations, along with cutting taxes on pharmaceutical companies.

"Our slow and burdensome approval process at the Food and Drug Administration keeps too many advances…from reaching those in need," Trump said in his first address to Congress.

Gottlieb is a physician and resident fellow at the conservative American Enterprise Institute. He is a regular contributor to news outlets such as *Forbes* and the *Wall Street Journal*. Unlike many of Trump's nominees, he has some experience with the agency he has been nominated to oversee.

He worked at the FDA under George W. Bush from 2003 to 2004 as a senior adviser to the FDA commissioner and director of medical policy development, before moving to the Centers for Medicare and Medicaid Services (CMS) where he helped implement the Medicare Part D drug benefit. He returned to the FDA as deputy commissioner for medical and scientific affairs from 2005 to 2007.

He also has close ties to the industry he will be charged with regulating. Since 2007, he has been a venture partner at the world's largest venture capital firm, New Enterprise Associates (NEA), helping the firm manage its health care investments. He is also a managing director at the merchant and investment bank T.R. Winston & Company, and previously served as a senior adviser for health policy at Arcoda Capital Management.

He has served on the boards of a number of pharmaceutical and medical device companies, including GlaxoSmithKline, Glytech and Tolero Pharmaceuticals. According to STAT News, he currently serves as an adviser to GlaxoSmithKline, Cell Biotherapy and Bristol-Myers Squibb.

Between 2013 and 2015, Gottlieb received more than $400,000 in consulting and speaking fees from pharmaceutical companies, including Vertex, GlaxoSmithKline, Daiichi Sankyo, Pfizer, and Novo Nordisk, according to CMS's open payments data web site.

Michael Carome, director of Public Citizen's Health Research Group, was quoted by Chemical & Engineering News saying that Trump's pick "is entangled in an unprecedented web of Big Pharma ties. He has spent most of his career dedicated to promoting the financial interests of the pharmaceutical industry."

"Gottlieb's appointment would accelerate a decades-long trend in which agency leadership too often makes decisions that are aligned more with the interests of industry than those of patients," he said.

Diana Zuckerman, president of the National Center for Health Research, a research advocacy group, said she was troubled by the potential for conflicts of interest. "He'd clearly need to divest his own stock and resign from the boards," she told STAT News, "and unless he swore on a stack of Bibles that he wouldn't return to boards, investments, etc., it would be a good example of the 'swamp' that Donald Trump promised to drain."

"If [Gottlieb] is confirmed, he would be the most interest-conflicted commissioner in American history, by far," Daniel Carpenter, a professor of government at Harvard and author of a history of the FDA, told Vox.

Of the four individuals under consideration for the position, Gottlieb was the preferred candidate of the biotech and pharmaceutical industries, with 72 percent of biopharma executives favoring the pick, according to a survey of 53 drug firms by Mizuho Securities. Pharmaceutical executives had raised concerns that if drug approval regulations were rolled back too drastically—as proposed by some of the other candidates—it would become difficult to gain insurance coverage for costly medications.

"It could have been worse," Gregg Gonsalves, co-director of Yale's Global Health Justice Partnership, told Vox. "Unlike many of Trump nominees, he's actually highly qualified to destroy the agency he's meant to lead."

"We could have had a saber-toothed tiger guarding the henhouse like Jim O'Neil, and instead we [may get] a garden-variety fox at the helm," he said.

The claim that bureaucratic inefficiencies at the FDA are responsible for delaying the approval of life-saving drugs, "where a culture of control strangles innovation," as a recent *Wall Street Journal* editorial puts it, has little basis in reality.

FDA drug approval times have accelerated dramatically in recent decades. The median review time for new drug approvals has dropped from 27 months in 1993 to 10 months in 2016, according

to data from the FDA. The majority of new drugs take advantage of at least one of the different expedited approval pathways offered by the agency.

Gottlieb's extensive writings on health care and drug regulation provide clues as to the priorities he will pursue at the agency.

He wishes to streamline the approval process for generics, which he argues has been hampered by unnecessary regulation, in order to increase competition and drive down drug prices.

While there exists a backlog of applications for generics, since the passage of the 2012 Generic Drug User Fee Agreement (GDUFA) the median time for approval of generic applications, known as abbreviated new drug applications (ANDAs), has fallen from 24 months in 2013 to 15 months in 2015. In 2016, more than 700 ANDAs were approved.

According to an article published by the Regulatory Affairs Professional Society (RAPS) this past November, which drew from an analysis by RBC Capital Markets, while there were 23 innovator drugs with ANDAs awaiting a reply from the FDA, another 125 innovator drugs, which had gone off patent and had no approved generics, had no ANDAs submitted whatsoever.

"RBC data shows that the issue of a lack of generic competition isn't so much of an issue of FDA's speed in bringing this competition to market, but in industry submitting applications that would create this competition," said the RAPS article.

Last July, Gottlieb penned an article for the Massachusetts newspaper *South Coast Today* in which he praised the 21st Century Cures Act, which passed in December, for allowing the wider use of "surrogate" measures and "adaptive" clinical trials in which parameters are modified based on observations of biomarkers and require smaller patient populations.

In a 2012 article for *Health Affairs*, Gottlieb decried the FDA's "increasingly unreasonable hunger for statistical certainty" and "hunger for extreme certainty about how drugs work."

He criticized the agency's "culture of mistrust," which is "devoted to averting risks and protecting the public," for leading drug reviewers to "believe it is appropriate to prioritize safety over speed."

"In so heavily prioritizing one of its obligations—the protection of consumers—the FDA has sometimes subordinated and neglected its other key obligation, which is to guide new medical innovations to market," he wrote.

He also took the FDA to task for what he sees as "a profound lack of confidence in the ability of doctors to make careful judgments."

"Reviewers believe that if the FDA does not use its approval process to coerce reluctant sponsors into constructing exhaustive studies—studies that extract every single kernel of potentially relevant clinical information—then no one will ever adequately mine these data. And because physicians cannot be fully trusted to do their jobs without this information, and companies can't be trusted to market drugs responsibly, the FDA believes the delays caused by collecting such extensive data in prolonged trials are worthwhile," he wrote.

He argued that since junior staff at the FDA are less willing to "embrace uncertainty," approval decisions should be made by a central committee of senior scientists who would, for example, be less concerned with how doctors prescribe medications.

At a 2013 debate sponsored by Intelligence Squared U.S., Gottlieb argued that the "FDA's caution is, at times, hazardous," because of the agency's "growing resolve to make sure the trials supporting drug approval meet an arduous but increasingly outdated standard for proving efficacy."

"Americans deserve a less cautious FDA and an FDA that actively embraces advances in science," he said.

Gottlieb's calls for easing the standards for clinical trials and ignoring physician prescribing practices raise a number of concerns.

First, doctors rely on the FDA to review the clinical trial data—data that is often never made available to the public—to determine that a drug is safe and effective for specific indications.

Second, doctors are allowed to prescribe medications for uses not indicated on the FDA-approved label. In certain settings, this practice can improve the standard of care and lead to innovations in medicine. Around one fifth of all drug prescriptions are for such "off-label" uses. However, a number of studies have found that doctors often prescribe drugs for off-label uses that have little scientific support.

For example, according to a 2006 article in the *Archives of Internal Medicine*, 73 percent of off-label drug mentions by physicians to patients had little or no scientific support.

A 2009 survey of 1,200 primary care physicians and psychiatrists, published in the journal *Pharmacoepidemology and Drug Safety*, found that 41 percent of the physicians mistakenly believed that at least one drug-indication, with uncertain or no supporting evidence, had been approved by the FDA.

"These results indicate an urgent need for effective methods of disseminating information to physicians about the level of evidence supporting off-label drug uses, with special attention to common off-label uses known to be ineffective or to carry unacceptable risk of harm," the authors conclude.

A 2016 article published in *JAMA Internal Medicine*, based on data from Canada, found that off-label prescribing, especially for indications with little supporting evidence, was associated with higher rates of adverse drug events.

One of the tasks faced by the next FDA commissioner will be to provide guidance on the off-label promotion of drugs. The recently passed 21st Century Cures Act eases restrictions on the pharmaceutical industry promoting drugs for off-label uses, allowing companies to avoid funding expensive clinical trials for new indications. With Gottlieb at the helm, it is likely that the FDA will codify this practice.