President Donald Trump's pick to head the FDA is spurring concerns about drug approvals and off-label promotion.

Trump March 10 nominated Scott Gottlieb to be the commissioner of the Food and Drug Administration. The nomination was widely praised by drug and device industry groups, but a consumer group and other stakeholders told Bloomberg BNA they are concerned that Gottlieb, who is a resident fellow at the American Enterprise Institute and previously worked at the agency as a deputy commissioner, has advocated for quicker drug approvals with less evidence and wants to loosen restrictions on off-label promotion of drugs and medical devices. Critics of the nomination also are concerned that Gottlieb is too closely tied to industry.

The next step in the confirmation process is for the Senate Health, Education, Labor and Pensions Committee to hold a hearing on Gottlieb. A date for the hearing hasn't been set yet. Sen. Lamar Alexander (R-Tenn.), chairman of the committee, March 10 said in a statement, "It's critical to have the right person in charge of the FDA, an agency that affects virtually every American and regulates about a quarter of all consumer spending in the United States."

"I look forward to meeting with Dr. Gottlieb and scheduling a hearing to discuss his plans to implement 21st Century Cures and work with Congress to bring safe and effective drugs and medical devices to patients more quickly and to protect the nation's food supply," Alexander said. The 21st Century Cures Act is a 2016 law to speed new drugs and devices to market.

**Drug Approval, Off-Label Promotion**

Gottlieb has advocated for faster drug approvals and "having the FDA tolerate more uncertainty about whether drugs are safe and effective for their proposed uses," Michael Carome, director of Public Citizen's Health Research Group, told Bloomberg BNA March 13.

"Tolerating more uncertainty means basically approving everything faster with less evidence" and "that's a major concern," Carome said.

Carome said that since the 1990s, "the pendulum has already swung too far towards favoring speed of approvals over the level of evidence" and "we think [Gottlieb] is someone who will continue that trend in the wrong direction."

Also, Gottlieb "has advocated for loosening restrictions on communications from drug and medical device manufacturers on off-label uses of their products," Carome said.

**Gottlieb favors allowing more communications on off-label drug, device uses.**

Michael Carome, Public Citizen

Off-label communication has been a big issue lately. In November 2016, the FDA held a public meeting on off-label communications at which pharmaceutical and medical device industry groups called on the FDA to revamp its policies ([14 PLIR 1550, 11/18/16](https://www.bna.com/14plir1550111816/)).

Gottlieb favors allowing more communication on off-label uses and "we think the agency already allows too much" communication, Carome said. "The sole goal of those communications is to encourage off-label prescribing and we think the rules should be tightened and not loosened."

University of Wisconsin bioethicist R. Alta Charo told Bloomberg BNA in an email she is very concerned about Gottlieb's position on off-label promotion.

Gottlieb "has a history of comments suggesting that physicians' expertise is a sufficient safeguard against the effects of promoting off-label use (to physicians and directly to patients) through marketing schemes," Alta Charo said. "But physicians are already allowed to use their own good judgment to prescribe off-label, and his views simply support a policy of allowing companies to make even more money by promoting unproven uses above and beyond what physicians might do on their own."

Mark Mansour, an attorney with Mayer Brown in Washington, told Bloomberg BNA, "I think [Gottlieb] will push for a change in the regime of off-label promotions. I think the policy that FDA has had in place is going to be refined quite a bit."
Ties to Industry

There is also a concern that Gottlieb is too closely tied to the drug industry.

Gottlieb "is someone who is entangled in an incredible, unprecedented web of ties to industry spanning his professional career," Public Citizen's Carome told Bloomberg BNA.

Carome said Gottlieb has been both a venture capitalist and sat on the boards of several drug companies. Gottlieb also "accepted large amounts of money for the period 2012 to 2015, at least $400,000, in speaking fees and consulting fees from several companies and we think it's just impossible for him to really fully disengage from those ties to industry," Carome said.

"Like many of President Trump's other nominees, Scott Gottlieb has extensive financial ties to the industries he'd be in charge of regulating."

Diana Zuckerman, National Center for Health Research

"If he becomes Commissioner, I hope Dr. Gottlieb will enforce the law and focus on fulfilling the FDA's essential public health mission," Zuckerman said. "I expect that industry will strongly support Dr. Gottlieb's nomination but divesting could potentially be complicated and therefore could delay his confirmation."

Bloomberg Intelligence analyst Brian Rye told Bloomberg BNA that he expects Democrats will "make a big deal about [Gottlieb's] ties to industry, but they have so far been unable to block nominees who enjoy strong Republican support, so unless there are unexpected problems on the GOP side, he's likely to be confirmed."

Immediate Challenges

If confirmed, Gottlieb will face several challenges as he starts his new job.

Gottlieb's "immediate challenges are to navigate the user fee legislation through Congress, to address the hiring challenges at FDA, and to secure adequate funding for the agency in upcoming budgets," Wayne L. Pines, president of health care at APCO Worldwide, told Bloomberg BNA March 13. APCO Worldwide is a global public affairs and strategic communications consultancy. Pines also served 10 years in senior positions at the FDA.

Congress is preparing to consider legislation to reauthorize the laws governing industry-paid user fees, which help fund the FDA. All of the FDA's user fee programs expire Sept. 30. New legislation will be needed to reauthorize the programs for fiscal years 2018 through 2022. The agency has separate fee programs for prescription drugs, generic drugs, biosimilars and medical devices.

On March 21, the Senate HELP Committee will hold its first hearing on the reauthorization of the user fees. At the hearing, FDA witnesses will testify about how these agreements benefit patients and how the FDA can continue to improve its performance.

Praise for Gottlieb

Michael Reilly, executive director of the Alliance for Safe Biologic Medicines, told Bloomberg BNA Gottlieb "is a great choice" and "his resume speaks for itself."

Gottlieb "wants to speed up the approval process, but without in any way undermining the role of the agency, which is to make sure safety is their focus," Reilly said.

Reilly said Gottlieb "wants to get things that have been backlogged moving forward, whether it's orphan drugs" or generic drugs.

Daniel A. Kracov, who is the co-chairman of the life sciences and health regulation practice at Arnold & Porter Kaye Scholer LLP in Washington, told Bloomberg BNA he thinks Gottlieb "is an excellent choice."

"He's got high level experience at FDA. He's got both a medical background and understands the legal and policy framework at the FDA," Kracov said. "He's someone who didn't just spend his time at FDA checking the box, but he's someone who really thought creatively about how the agency could be improved."

Kracov said "even with his experience, he'll have somewhat of a learning curve in areas outside of the therapeutic products. But he's a very smart guy and I think he'll be quite good."

Gottlieb's "keen interest in medical innovation and new technologies makes him an excellent choice to help FDA keep pace with the exciting developments in 21st Century medicine."

Deborah M. Shelton, a partner in the FDA Practice Group of McCarter & English in Washington, told Bloomberg BNA in an email Gottlieb's "keen interest in medical innovation and new technologies makes him an excellent choice to help FDA keep pace with the exciting developments in 21st Century medicine."

Shelton said she anticipates that Gottlieb "will strike the appropriate balance between the need to ensure appropriate [the] risk/benefit [profile] for approved medicines while accelerating the approval of innovative therapies...
Carol Pratt, an FDA regulatory attorney with Lee & Hayes in Vancouver, Wash., told Bloomberg BNA in an email Gottlieb is a good choice primarily “because much of what he has said the FDA needs to do is consistent with the goals of the 21st Century Cures Act. Hopefully the nomination of Gottlieb to head the FDA is a signal that the Trump administration intends to support implementation of the Cures Act, which includes the need for increased staff and funding.”

Kracov, Shelton and Pratt are Bloomberg BNA health-care advisory board members.

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