

Scott Gottlieb sworn in to head the FDA

Scott Gottlieb becomes commissioner of the FDA, as the agency's role is threatened by an administration adverse to regulation. Susan Jaffe, *The Lancet's* Washington correspondent, reports.

Only 6 months ago, Scott Gottlieb was still a resident fellow at the American Enterprise Institute, a conservative thinktank, when he presented testimony to a US Senate committee investigating prescription drug prices. Before he began, he volunteered that he was “a reformed government bureaucrat, having worked at FDA [US Food and Drug Administration] for a number of years”. He blamed astonishing price hikes—500% in the case of Mylan’s EpiPen—on “regulatory failures stemming from FDA policy, and I think that policy can be fixed”.

On May 11, Gottlieb was sworn in as the 23rd commissioner of the FDA after being approved earlier this month by the US Senate, over the strong objections of most Democrats. Now Gottlieb will have a chance to fix a daunting array of policies.

Gottlieb was nominated to the post by President Donald Trump, who has promised to eliminate unnecessary regulations and bureaucratic red tape to boost business and create jobs. To that end, Trump has ordered federal agencies to propose ways to reorganise and streamline their operations, in anticipation of a less generous government budget. Trump’s detailed budget proposal was released as this article went to press.

Americans rely on the FDA’s roughly 16 770 employees to regulate the safety of 20% of the products they buy, including goods that appear to have little in common, such as dietary supplements, gene therapy, artificial knees, surgical tools, prescription drugs for people and animals, nanotechnology products, blood and biologics, tobacco, and cosmetics—not to mention fruits and vegetables. Because many of these products are manufactured or harvested around the world, the FDA has staff

stationed in China, Europe, India, and Latin America.

“If you look at the enormity of the portion of the economy overseen by FDA, it really isn’t a surprise that its work gets more complicated each year”, said Steven Grossman, deputy executive director of the Alliance for a Stronger FDA, an advocacy group.

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Job credentials

“I think Scott Gottlieb’s the right man for the job”, said Janet Marchibroda, director of health innovation at the Bipartisan Policy Center, a Washington, DC, thinktank founded by former Democrat and Republican Senate majority leaders. “He’s got many perspectives he brings to the challenges at hand.”

Gottlieb, 44, a physician trained in internal medicine, is returning to the FDA for the third time. From 2003 to 2004, he was senior adviser to the FDA commissioner on medical technology and deputy commissioner for Medical and Scientific Affairs from 2005 to 2007. More recently, he was a partner in a venture capital firm investing in various health-care companies, in addition to serving as a medical industry consultant and a resident fellow at the American Enterprise Institute.

Gottlieb is “no stranger” to Congress, said Lamar Alexander, a Republican senator from Tennessee and chairman of the Senate’s Health, Education, Labor and Pensions committee, having testified on Capitol Hill 18 times. Alexander also noted during Gottlieb’s nomination hearing in April that he is

a cancer survivor and knows “firsthand how medical treatments affect patients and their families.”

But reviewing Gottlieb’s credentials and meeting with him has made the committee’s senior Democrat Washington state senator Patty Murray, “increasingly concerned about whether he can lead the FDA in an unbiased way given his unprecedented industry ties”. She was not reassured by his promise to recuse himself for 1 year from decisions affecting some of the companies in which he has investments. She said those companies have more than 120 drugs in development that could come before the FDA for approval. “He has not convinced me that he can withstand political pressure from this administration or that he will be truly committed to putting our families’ health first”, said Murray before joining the minority of 42 senators who voted against his nomination on May 9.

Alexander had the opposite reaction, praising Gottlieb’s industry connections and previous government roles as a plus. “That’s not so unusual for someone who is going to be head of the FDA”, Alexander said during the nomination hearing. “And in my view, it helps to have somebody who knows something about a subject.”

This type of experience is essential, said Marchibroda. “If you’re not working with industry and you’re not part of the fabric of drug development in this country, then you’re probably not qualified to do the job.”

A full agenda

Gottlieb arrives at FDA as the agency is charged with implementing the groundbreaking 21st Century Cures Act, which became law in the final days of the Obama Administration with unusual bipartisan support that has not appeared to diminish



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under the new administration. It would accelerate drug development, assessment and delivery of new drugs, and provide funding to implement the law, including new staff at a time when the FDA has an estimated 1000 vacancies and a backlog of hundreds of generic drug applications.

The FDA approved or tentatively approved 835 generic drug applications in the fiscal year ending Sept 30, 2016—more than any other year. But as of April 1, the agency had 2640 applications under review, including slightly more than half awaiting industry action.

“They’re coming in as fast—or probably even a little faster—as they’re getting approved and going out the door”, said David Gaugh, senior vice president for sciences and regulatory affairs at the Association for Accessible Medicines (formerly the Generic Pharmaceutical Association).

Although the FDA does not have any direct responsibility for controlling drug prices, Gottlieb has said that access to inexpensive generic drugs is necessary for lowering drug prices. “There are literally billions of dollars worth of drugs each year that are sold as branded drugs at high prices, but should be subject to generic competition”, he said at his Senate nomination hearing.

Gottlieb returns to the FDA as new 5-year user fee agreements make their way through Congress. 2 weeks ago, a Senate committee approved new user

fees that would replace agreements that expire in September. Drug, medical device, and tobacco product manufacturers pay these fees to cover cost of the FDA-approval process. This year’s user fees make up about 40% of the agency’s US\$4.655 billion budget.

But when Gottlieb addressed the FDA staff for the first time on May 15, he told them his top priority is yet another issue. “Unquestionably, our greatest immediate challenge is the problem of opioid abuse”, he said. “This is a public health crisis of staggering human and economic proportion.” He said the FDA cannot solve it alone, but can help by “giving health-care providers the tools to reduce exposure to opioids to only clearly appropriate patients, so we can also help reduce the new cases of addiction”.

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Other issues will also require Gottlieb’s attention. The food industry is seeking at least a 3-year delay in updating the nutrition facts labels that appear on most packaged foods, said Michael Jacobson, president of the Center for Science in the Public Interest. There is also a guidance urging reductions in salt in prepared foods that has yet to be finalised. And earlier this month, the FDA announced it would give restaurants another year to comply with requirements that menus disclose calorie information.

White House orders

Complicating these challenges is an executive order Trump issued shortly after taking office, declaring a hiring freeze across the federal agencies. That directive appears to have been modified by another order, asking agencies to plan for reorganisation and staff reductions that will be needed to adjust to the president’s anticipated budget cuts. “The easiest way to

paralyse the agency is to cut the staff”, said Jacobson.

Some members of Congress working on the new budget did not appreciate this anticipation, ahead of Congress’ approval of the budget. Earlier this month, a congressional committee contradicted those instructions with a brief civics lesson on the role of Congress and a special warning in its 2017 budget report: “FDA and USDA [US Department of Agriculture] should be mindful of congressional authority to determine and set final funding levels for fiscal year 2018. Therefore, the agencies should not presuppose program funding outcomes and prematurely initiate action to redirect staffing prior to knowing final outcomes on fiscal year 2018 program funding.”

Another Trump executive order is also creating some bewilderment. In late January, the president directed federal agencies to eliminate two regulations for each new one they issue. Since the FDA regulates so many kinds of products the public relies on, finding current rules that could be scrapped might not be easy. Halting new regulations may not be an option since numerous federal laws—including 21st Century Cures—require the agency to issue regulations to tell affected industries, health-care providers, and others how to follow those laws. After 4 months, the FDA is still working with the administration to implement the directive.

In his address to the FDA staff, Gottlieb tempered his enthusiasm for the agency’s mission with a Trump-like belief in the value of limited government. “We need to make sure we’re getting the most public health bang for our efforts and the resources that we’re entrusted with”, he said. “I know we only have limited resources to do these hard tasks. And I also know, from my prior work at FDA, how much we accomplish with the limited tools and resources we have available to us.”

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