# Why Scott Gottlieb is the one Trump official everybody seems to like

## The FDA chief is making real progress tackling the most serious health issues in America.

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Less than a year into the job, Scott Gottlieb has won over critics. *AP Photo/J. Scott Applewhite*

When Scott Gottlieb was appointed commissioner of the Food and Drug Administration last May, some were concerned he'd be a shill for the pharmaceutical industry.

A major sticking point at his confirmation was what Sen. Patty Murray (D-WA) called "unprecedented financial entanglements" — including previous posts on five pharmaceutical company boards.

A doctor and former FDA deputy commissioner under George W. Bush, Gottlieb knew medicine and the agency better than Trump's other potential candidates to FDA — including Silicon Valley insiders with no background in health. But he also came to the job with controversial ideas about how to speed up the already fast drug approvals at the agency.

Nearly a year into the job, Gottlieb has won over critics and allayed many fears of the public health community. He is getting away with things like cracking down on tobacco and salt in food — moves that would have been dubbed "nanny state" in the Obama era. He's also surprised many with a slate of evidence-based policies and policy directions, on everything from drug pricing to opioids, that both respect science and address the most pressing public health issues today.

What's more, Gottlieb's FDA hasn't been beset by the scandals and ethical concerns that have plagued other agencies, including the Environmental Protection Agency and the Centers for Disease Control and Prevention. Instead, the FDA is now widely seen as a place of stability, evidence-based decision-making, and progress.

“I think that he’s done a lot for FDA’s morale at a time like this,” said Joshua Sharfstein, an associate dean at the Johns Hopkins School of Public Health and former FDA deputy commissioner.

And Gottlieb has managed all this when many of his counterparts in other agencies are tearing down regulations, following President Trump’s orders. He’s even won praise from the commander in chief. “Scott Gottlieb, as you know, is a star,” Trump said at the World Economic Forum in Davos, Switzerland.

It’s still early days, however. It’ll take time to see whether Gottlieb delivers on many of the promises he’s made. Here’s a rundown of some of his most significant moves, and what to look out for next.

## 1) He’s made unprecedented moves against big tobacco

In a speech last summer, Gottlieb said the agency would work to offer less risky products for smokers who want or need nicotine. In that context, he pushed back the compliance deadline for FDA regulation of e-cigarette products. *Justin Sullivan/Getty Images*

One of the pet peeves in public health is that the things that actually affect many people (the food environment, traffic accidents, tobacco) don’t often enough make it to the top of policymakers’ agendas.

But from the start of his tenure, Gottlieb has vowed to focus on those oft-ignored issues. For starters, he’s promised to tackle what is still the greatest cause of preventable death in the US: tobacco.

In March 2018, Gottlieb announced that the FDA would move to put in a place a regulation that will set a maximum amount of nicotine in cigarettes. That means America could become the first country in the world to force tobacco companies to reengineer their products so they’re less addictive.

The approach is supposed to work in two ways. We know longtime smokers in the US typically initiate the habit in their youth, so making cigarettes less addictive could help keep young people from getting hooked on the products in the first place.

The policy would also attempt to help established smokers who are already addicted to nicotine take up safer alternatives like e-cigarettes, which are widely believed to be less deadly than conventional cigarettes. And Gottlieb has a plan for that: In a speech last summer, he said the agency would work to offer less risky products for smokers who want or need nicotine. In that context, he pushed back the compliance deadline for FDA regulation of e-cigarette products, which was seen as a win for the e-cigarette industry.

The moves were viewed as historic and were mostly heralded by the public health community.

But the two prongs of Gottlieb's tobacco strategy need to work together to make an impact on public health, making cigarettes less appealing while at the same time creating a tightly regulated marketplace for safer alternatives (such as e-cigarettes) that ex-smokers can turn to. If Gottlieb only delivers on one part of his tobacco promise but not the other (for example, failing to crack down on regular cigarettes while helping the e-cigarette marketplace flourish, especially among youth), the strategy — however avant-garde and unprecedented — will fail.

Right now the tobacco industry is expected to push hard against the nicotine regulations, which could take as long as a decade to implement. Meanwhile, e-cigarettes are going unregulated and there's evidence that more and more young people are taking them up. So it's a long road ahead before the FDA can deliver on Gottlieb's vision.

## 2) He's strengthening nutrition regulations

In keeping with his evidence-based regulatory approach, Gottlieb has also promised to tackle another of America's greatest public health challenges: chronic diseases like obesity and diabetes. He's repeatedly championed nutrition policy as a key priority for the FDA, promising to move ahead with Obama-era efforts to help Americans make healthier food choices.

To date, he's taken several steps on this front. After nearly a decade of delays — including one that happened just before he was sworn into office — Gottlieb has said the FDA will finally implement regulations requiring restaurants and other food outlets with 20 or more locations to post calorie counts beginning in May of this year. That means any big chain — from grocery stores to movie theaters, amusement parks to vending machines to restaurants — will have to show how many calories come with their sandwiches, popcorn, cocktails, and french fries. Upfront. Right on the menus.

Then-first lady Michelle Obama in 2014, when more transparent food labels were first proposed. Gottlieb has vowed to get them enacted. *AP Photo/Carolyn Kaster*

In a recent speech at the National Food Policy Conference, he vowed to move ahead with modernizing the nutrition facts panels on food packages, so consumers can make more informed choices about what they're eating. And he talked about the impact that cutting sodium in the food supply could have. "There remains no single more effective public health action related to nutrition than the reduction of sodium in the diet," he said.

While in the speech, he said he's committed to advancing voluntary sodium reduction targets for the food industry, and the new nutrition facts panels, the FDA hasn't made any official announcements about coming changes. And voluntary reductions may not be enough in the long run, since the vast majority of the salt Americans consume comes from processed foods.

And whether he can follow through with other promises remains to be seen. But his tough stances have come as a pleasant surprise to the public health community.

"The Obama admin was really active in this area — through legislation and executive action," said Jason Block, a physician and researcher at Harvard Medical School who has been studying calorie labeling.

"I think the general perception about how the FDA would be operating under the Trump administration is that those things would would grind to a halt." Instead, the commissioner has indicated that he intends to move ahead with all these initiatives. "He's not ignoring the food side of FDA, and I think that's really good news," Block added.

## 3) Gottlieb is getting kudos for his work on drug prices

Gottlieb is also one of the frontmen for Trump's high-profile promise to bring down prescription drug prices. The president was unorthodox for a Republican during his campaign, pressing for more active government intervention on an issue that Americans routinely cite as their most pressing health care concern.

But given his close ties to the industry, Gottlieb's appointment was greeted by much skepticism from drug pricing hawks.

Nearly a year into his tenure, however, even some experts who would criticize Trump broadly for more or less abandoning his promise to address drug costs have had kind words to say about Gottlieb.

"Gottlieb is committed to improv[ing] competition in generic drugs, making it easier for generics and biosimilars to come to market," said Rachel Sachs, a law professor at Washington University in St. Louis, earlier this year. The White House, meanwhile, has done "absolutely nothing on this issue."

In particular, Gottlieb has been praised for leading the charge to get 1,000 generics approved in 2017. He has more recently taken aim at pharmacy benefits managers, the middlemen between health insurers and drugmakers who are subject to increasing scrutiny from DC policymakers —

though it's not yet clear what he can or will do, besides use his bully pulpit to press for changes to drug rebates and other administrative quirks that he said keep drug costs high for patients.

"Patients shouldn't face exorbitant out-of-pocket costs, and pay money where the primary purpose is to help subsidize rebates paid to a long list of supply chain intermediaries," Gottlieb said at a meeting of top health insurance lobbyists last month. "Sick people aren't supposed to be subsidizing the healthy."

Generics and PBMs are areas where drugmakers have said they are willing to compromise. They prefer to make it easier for cheaper generic drugs to come to the market than to have more direct government intervention. They have also mounted a concerted public relations campaign to direct more of the attention to PBMs and health insurers.

That has left experts with a sense that while Gottlieb is doing what he can as head of the FDA, the administration overall is not taking an aggressive approach to an issue that Trump made a central campaign issue.

"[Gottlieb] is quite sincere and doing what he can on the generic competition," Len Nichols, a George Mason University health policy professor, said in January. But, he added: "That's pretty much nice little window dressing around the edges."

Gottlieb has also said he wants to do more to promote biosimilars — the generic analogue for so-called biologics, medications that use living cells and more complex molecules to treat diseases. They hold great promise for treating heretofore untreatable diseases and are growing rapidly as a result — but they also often come with five-figure price tags.

## 4) Gottlieb has become a leader in the Trump administration on the opioid crisis

Gottlieb has also become an unexpected champion of addressing the opioid crisis — leading even harsh critics of the Trump administration to hope he sticks around. "Gottlieb has been shockingly good so far," Keith Humphreys, a drug policy expert at Stanford, said. "I hope he doesn't get fired," he quipped — a reference to the many people who have left or been pushed out of the Trump administration.

The key seems to be in how Gottlieb, who has called the drug epidemic the "biggest crisis facing the FDA," has so far navigated what are essentially the two major elements of the issue.

First, remember that this crisis began as a prescription painkiller problem, with the drugs proliferating across the US throughout the late 1990s to the late 2000s, leading to misuse, addiction, and overdoses. Over time, more and more overdose deaths have been tied to illicit opioids such as heroin and fentanyl — as some have initiated their opioid use with illicit drugs, but also as others, losing access to painkillers but still addicted to opioids, transitioned to illegal drugs instead.

As a result, the opioid crisis is now the deadliest drug overdose epidemic in US history, with opioids causing at least two-thirds of the nearly 64,000 overdose deaths in 2016. While that was an all-time high, preliminary federal data suggests 2017 was even worse.

Experts say that to fully deal with the crisis, officials will need to address two big problems: Access to painkillers needs to be cut to prevent more people from starting on opioids. And access to treatment — especially medications like buprenorphine and methadone, which are linked to reductions in mortality among opioid addiction patients of 50 percent or more — needs to improve as well. (Read more on the full solutions experts recommend for the crisis.)

The FDA can't do all this by itself. But as the country's regulator of medicines, it can play a big role. And some of this work involves what's essentially a bit of repentance — the FDA carries a bit of the blame for the crisis, experts say, because it didn't do enough to get dangerous opioid painkillers that it regulates under control early on in the epidemic.

Gottlieb, for now, has sent all the right signals. His first major move at the FDA was to get the drugmaker Endo to withdraw Opana ER, an opioid painkiller, from the market after it was repeatedly linked to misuse (including a particularly nasty outbreak that caused a rise in HIV/AIDS cases in Indiana). He has also said that in the future, his agency will be "very aggressive" in warning consumers about opioid products and, if necessary, getting them off the market.

At the same time, Gottlieb has also issued guidance to encourage further development of anti-addiction medications and reduce the stigma that can be attached to these kinds of treatments. He's admonished health insurers for not covering all of the currently available medications. And under him, the FDA approved a new formulation of buprenorphine that will only need to be administered once a month (though this likely would have gotten the okay even without Gottlieb in charge).

We are still in the early days of the administration. Will the FDA ultimately do more to regulate opioids and consider their public health risks before allowing them on the market — or yank future products if necessary? Will it try to further loosen regulations on anti-addiction medications such as buprenorphine? Will it aggressively pursue more medications to combat addiction? These are open questions.

But at least so far, experts and activists are happy with what they're seeing.

"I was among the more skeptical of this appointment," said Daniel Carpenter, a Harvard professor who has long studied the FDA. "Yet he has embraced a science-based regulatory role for the agency in opioids, in homeopathic regulation, in digital therapeutics and other areas.

"For now, and I emphasize it's early, I think Gottlieb has done a good job."