FDA Chief Goes Against the Administration Stereotype

Dr. Scott Gottlieb isn't rolling back his agency's mission., although he is straddling the interests of the drug and health industries along with public health

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By Sheila Kaplan and Katie Thomas

WASHINGTON — Scott Gottlieb, the commissioner of the Food and Drug Administration, came to the job with a résumé straight out of the Trump administration's playbook.

A millionaire with a libertarian bent, he made his money working for the industry he now regulates, and had investments in 20 health care companies whose products could come before the agency for approval. Pharmaceutical and medical device executives enthusiastically supported his nomination, while consumer and public health groups sounded the requisite alarms.

"Unprecedented financial entanglements," complained Senator Patty Murray, Democrat of Washington, during his confirmation hearing.

Now, more than nine months after he was confirmed, Dr. Gottlieb has achieved something unusual among President Trump's appointees: He has quieted some skeptics, while also managing to keep industry supporters content and the president on his side. He has done so by making moves to protect public health while also offering rewards to industry — double plays that have some willing to give him a second look.

"He doesn't want to blow up the agency," said Mark I. Schwartz, a Washington lawyer who worked at the F.D.A. in Republican and Democratic administrations.

Dr. Gottlieb has briefed Mr. Trump several times on agency issues, like opioids and generic drugs. During a dinner at the World Economic Forum in Davos, Switzerland, last month, President Trump told a group of European business executives, including a few from the pharmaceutical industry, that "Scott Gottlieb, as you know, is a star."

So far, the commissioner has displayed a collaborative management style, seeming to allay the concerns of some career employees who had balked at his industry ties and were dismayed by articles he had written criticizing the F.D.A. He has overcome some divisions by promoting several agency veterans, but he has also hired a few industry insiders for top positions. He is described by staff as energetic and intense, while holding town hall-style meetings before making decisions.

"He's being thoughtful; he's being deliberative," said William Hubbard, who retired from the F.D.A. after 30 years, including work as a consultant to a former commissioner, Dr. Margaret A. Hamburg, until she stepped down in 2015. "He seems to be putting aside some of his more extreme rhetoric from when he was outside, and working through the issues with a public-health orientation."

Although Dr. Gottlieb declined to be interviewed for this article, he is quite chatty online. He issues lengthy statements after nearly every major decision, and banters on Twitter, chiding reporters for eating unsafe Thanksgiving leftovers or laughing along at jokes about his skinny jeans, or his prized backyard chickens.

“I thought he was a bad pick,” said Andrew Kolodny, a co-director of opioid policy research at Brandeis University. “But I may have been wrong.”

Dr. Kolodny singled out the agency’s success last summer in getting Endo Pharmaceuticals to stop selling an extended-release opioid, Opana ER, citing its concerns that the drug’s benefits no longer outweighed the risk of abuse.

Critical decisions ahead

Even as Dr. Gottlieb makes some progress, there are major unsettled regulatory matters before the agency. They include the extent to which drug companies can market their products for off-label uses as well as how much oversight is needed for the laboratory-developed tests that hospitals and doctors often use to detect conditions ranging from heart disease to ovarian cancer — a booming business.

Among the most far-reaching decisions will be the efforts taken to reduce the time for drug companies to develop new drugs.

“That is where anxiety lies,” said Mr. Hubbard, who added that the key will be ensuring that, in moving new products to market more quickly, public health is not compromised. “The test will be whether he can do that safely, and we won’t know the results of that for quite some time.”

Some early decisions have drawn criticism, like postponing requirements for food companies to note sugar and other nutritional information on package labels. Another sparked an outcry when Dr. Gottlieb partly reversed his own position, deciding against disclosing the reasons the agency gives drug companies when it turns down products.

Dr. Jean Rinaldi, left, showing Dr. Gottlieb the cardiac devices laboratory of the F.D.A.’s Center for Devices and Radiological Health in Silver Spring, Md.CreditMichael J. Ermarth/United States Food and Drug Administration

He has taken steps to speed drug and device approvals, and has promised to do more.

Dr. Michael Carome, director of the consumer group Public Citizen's health research arm and a former health department official, opposed Dr. Gottlieb for the job, and has not seen anything to change his mind.

"The bottom line is this: He's pursuing a pro-industry deregulatory agenda that ultimately is going to put patients at risk," Dr. Carome said. "The F.D.A. now views industry as their customers, and they need to keep them happy."

A government past

Dr. Gottlieb's Republican credentials made him a strong candidate for the agency's top post from the beginning. He had previously worked for both the Department of Health and Human Services and the F.D.A. during the administration of President George W. Bush.

But his chances were not clear early last year, after President Trump vowed to slash drug regulations and, in an address to Congress, described the F.D.A.'s approval process as "slow and burdensome." Other names surfaced, like Jim O'Neill, an associate of the Silicon Valley billionaire Peter Thiel. Mr. O'Neill had suggested that drugs could be approved without first proving they worked and supported the creation of colonies at sea that would be beyond government reach.

Those views made Dr. Gottlieb look mainstream by comparison. So after a hearing that focused on his ties to the drug and device industry, he was confirmed by the Senate, 57 to 42, on May 9.

Critics pointed to Dr. Gottlieb's stints on advisory boards for pharmaceutical companies, among them GlaxoSmithKline and Daiichi Sankyo, and his consultant work for others, including Vertex Pharmaceuticals and Bristol-Myers Squibb.

His investments through New Enterprise Associates, a venture capital firm, and T.R. Winston & Company, an investment bank, were also called into question. Earlier in Dr. Gottlieb's career, before attending the Mount Sinai School of Medicine, he worked as a health care investment banking analyst for Alex. Brown & Sons.

That experience, Dr. Gottlieb has said, benefits the F.D.A. because it helps him understand the industry. He has recused himself for two years from matters concerning about 20 companies with which he was associated — in accordance with the White House ethics pledge. The day he was sworn in, he sold all of his health-related stock, including investments in Tolero Pharmaceuticals, Collective Health and U.S. Renal Care, according to a financial report filed with the Office of Government Ethics. He purchased government bond funds.

Like most of Mr. Trump's appointees, Dr. Gottlieb has also hired industry lawyers and lobbyists whose former clients often have business before the agency. Among them are Jack Kalavritinos, an associate commissioner who had lobbied for the device maker Covidien, now owned by Medtronic, for seven years; Nina Devlin, a senior communications adviser who was the head of global communications at Mylan, makers of the EpiPen; and Rebecca K. Wood, who was a partner in the law firm Sidley Austin and is now the agency's top lawyer.

According to her financial disclosure forms, Ms. Wood did legal work for many of the drug industry's largest companies and trade groups, including AbbVie, Bayer, St. Jude Medical and the Medical Information Working Group, which favors the expansion of off-label uses for drugs. She also worked for New Enterprise Associates, in which Dr. Gottlieb was a venture partner. An agency spokeswoman said that Ms. Wood has had to recuse herself already from several matters, but declined to detail the issues involved.

A balancing act

By taking a more conventional approach to the job, Dr. Gottlieb stands out among other presidential appointees, some of whom have aggressively rolled back regulations or are curtailing the scope of their agencies' powers, as at the Environmental Protection Agency and the Department of Energy.

He has already disagreed with an administration position, objecting to a plan to move an international food-safety division to the trade office, saying it would hurt the country's reputation as a food watchdog.

The administration backed down on the trade matter, but Dr. Gottlieb has been forced to compromise on other issues. Last October, he questioned proposals backed by Vice President Mike Pence and others that would give terminally ill patients greater access to experimental treatments. He did make a concession — promising that the F.D.A. would find a way to make it easier for patients to get some of those treatments, although he noted that the agency already approves 99 percent of such requests. Mr. Trump also recently told Republican lawmakers that Dr. Gottlieb was leading the effort to get legislation passed by Congress.

That balancing act has also been on display in Dr. Gottlieb's approach to regulating tobacco. Last July, he sent tobacco stocks into a dive after he vowed to take aggressive steps to render cigarettes nonaddictive by forcing manufacturers to cut nicotine levels.

But even as he railed against big tobacco, Dr. Gottlieb softened the blow by delaying for several years the deadline for companies to comply with tough new rules on e-cigarettes, cigars and other products.

At the time, he said smokers needed better and more substitutes to get them off nicotine.

But whether he can maintain that balance remains to be seen: Last month, an F.D.A. advisory committee rejected a major alternative tobacco product to be considered under the new regulations, saying its manufacturer, Philip Morris International, could not claim it was safer than cigarettes. The product under review was the IQOS, a heated tobacco stick device that the company wanted to market as a healthier alternative to cigarettes.

If the industry can't overcome such hurdles for approval or finds the process too cumbersome and expensive — Philip Morris is spending billions of dollars developing smoking alternatives that would need agency approval — Dr. Gottlieb's efforts to straddle the division between public health and commerce could be hobbled.

Despite the panel's rejection — the experts questioned the science behind the product — agency officials were quick to say they would continue reviewing Philip Morris's studies and would ask for more information.

Kenneth Warner, a tobacco control expert and dean emeritus of the University of Michigan School of Public Health, said he found it surprising that the F.D.A. was taking such strong steps to rein in the tobacco industry. "It's somewhat ironic to me that it takes a Republican administration to think about a new regulation like that, that would have a benefit for public health," he said.

Congressional Democrats, though, are still smarting from Dr. Gottlieb's decision to extend the deadline for compliance with new e-cigarette rules, which took effect in 2016. The rules called for companies with products already on the market to disclose their contents and to prove their positive impact on public health in order to gain approval.

Before becoming commissioner, Dr. Gottlieb served on the board of directors of Kure, a retailer that sells e-cigarette products in lounge-like settings. He has since sold his stake in Kure and said he would recuse himself from any decisions involving the company for two years.

Tackling anger over drug prices

High drug prices — and what to do about them — were a frequent topic of the last election, and the Trump administration seems poised to offer some new proposals in its budget.

Here, Dr. Gottlieb has shifted the agency's position. F.D.A. officials have traditionally said that regulating prices is beyond the agency's purview. But Dr. Gottlieb has taken steps to encourage more competition for products that have lost patent protection, including shortening an agency backlog for approvals of new generic drugs and publishing a list of off-patent drugs for which there is no alternative.

He surprised critics by holding up for ridicule brand-name drug companies that had refused to supply would-be rivals with samples of their drugs to deter generic competition.

"End the shenanigans," Dr. Gottlieb said at a Federal Trade Commission meeting in November.

The commissioner's actions so far are likely to do little to substantially lower prices for most Americans, and they notably do not address the towering prices that brand-name drugmakers set for their products.

Still, Chester Davis Jr., president and chief executive of the Association for Accessible Medicines, which represents generic drug companies, was effusive. "The commissioner has been very effective in using his bully pulpit to shine a very bright light on anti-competitive practices," Mr. Davis said.

Another closely watched decision will be Dr. Gottlieb's response to the charged question of how broadly drug companies can market products for unapproved uses. The pharmaceutical industry

has won some court cases by arguing that companies have a First Amendment right to promote products for conditions that have not been sanctioned by the agency.

Before becoming commissioner, Dr. Gottlieb supported so-called "off label" promotion. He has not yet moved to issue final guidelines, first proposed under the Obama administration, that will let drugmakers discuss unapproved uses with entities like insurance companies. He has also issued few warning letters to drug companies for deceptive advertising.

Any decision the agency makes worries people like Dr. Joshua M. Sharfstein, who was at the F.D.A. in the Obama administration. "If the F.D.A. surrenders on First Amendment issues, there could be very serious consequences for the agency's ability to do its job," he said.

Senator Murray is still concerned about Dr. Gottlieb's leadership, saying the agency wasn't doing enough on nutrition or to keep children away from tobacco products. She added that "the F.D.A. is too often focused on doing what's best for massive corporations, rather than patients and families."

Senator Elizabeth Warren, Democrat of Massachusetts, was also an early critic, but she has grown more supportive. "Dr. Gottlieb is willing to tackle tough problems," Senator Warren said. "I let him know when I think he's got it wrong, and when he's got it right."

Jennifer Miller, an assistant professor and clinical trials transparency expert at New York University School of Medicine, said a pilot program started by Dr. Gottlieb, in which pharmaceutical firms voluntarily release information about their clinical studies for approved drugs, was a step in the right direction.

"The industry is already trending toward releasing them," Dr. Miller said. "It's a safe time to roll out a pilot. I think he'll likely be successful and learn what works and what didn't."