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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Grading Gottlieb: How Attys View FDA Chief's First 6 Months

By **Jeff Overley**

Law360, New York (November 9, 2017, 10:18 PM EST) -- In Scott Gottlieb's first six months as U.S. Food and Drug Administration chief, he has moved rapidly to streamline approvals and has become something of a rock-star regulator who tweets energetically about everything from gene therapy to skinny jeans.

Gottlieb, who was sworn in as FDA commissioner on May 11, has prioritized quicker approvals of prescription drugs and medical devices, including direct-to-consumer DNA tests and digital health software. In doing so, he has adopted a relatively freewheeling public posture — including an enthusiastic embrace of social media — that has lent a subtle aura of coolness to the wonky world of FDA policymaking.

Here, attorneys dish on Gottlieb's early impact and his likely next moves.

Embracing the Spotlight

The FDA has long been led by dynamic commissioners who devote long hours to the agency's vast mission of public health. But Gottlieb has nonetheless wowed observers with a seemingly inexhaustible stamina. He's marshaled that vim and vigor to deliver a nearly nonstop stream of speeches, tweets, blog posts and news releases — to say nothing of his many new guidances and policy moves.

"One of the things that has struck me over the past six months is that Commissioner Gottlieb seems to be interested in communicating frequently and directly with industry," Axinn Veltrop & Harkrider LLP counsel Suchira Ghosh said. "He's certainly making a lot of formal statements frequently, and he's publishing on FDA's Voice blog pretty frequently as well. And I think that's a positive thing."

Scott Gottlieb, commissioner of the Food and Drug Administration, answers a question during a Senate Committee on Health, Education, Labor and Pensions meeting on the federal response to the opioid addiction crisis, at the Capitol in Washington. (AP)

According to FDA records, Gottlieb has given 15 public speeches during his first six months as commissioner. The two previous FDA commissioners, Margaret Hamburg and Robert Califf, each delivered five speeches during the comparable periods.

Like his predecessors, Gottlieb has also held numerous private meetings with stakeholders. But he has interacted more frequently and intimately with corporate groups than Hamburg and Califf did.

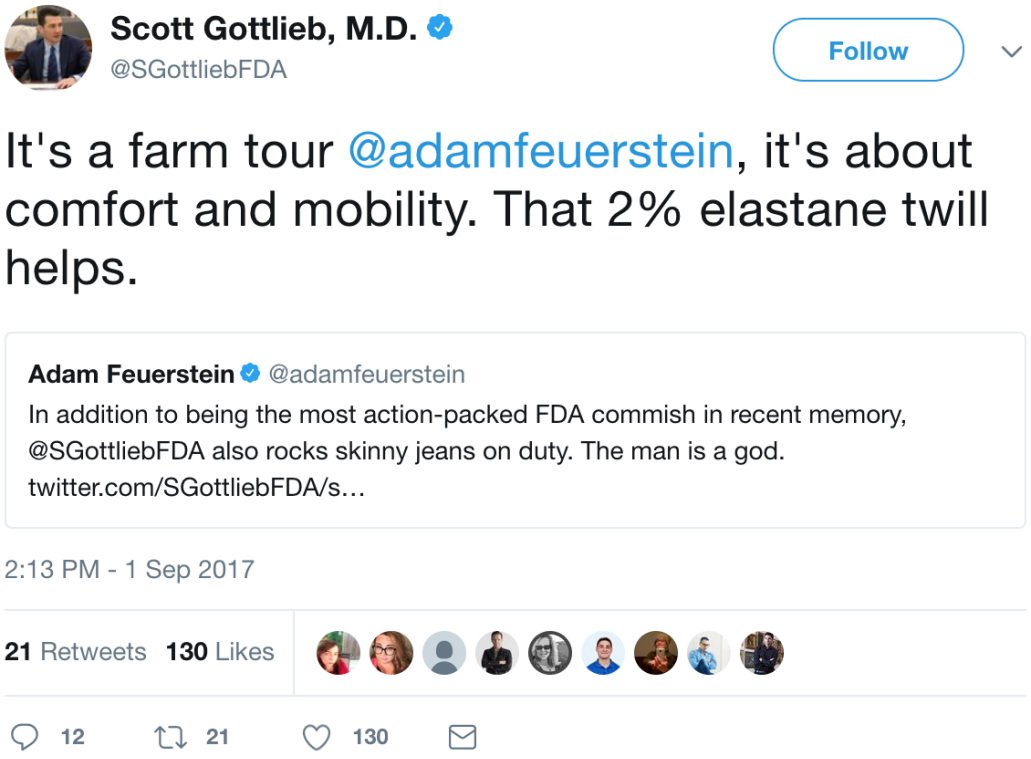
For example, Gottlieb has attended the board meetings of Pharmaceutical Research and Manufacturers of America, the Biotechnology Innovation Organization, the Medical Device Manufacturers Association and the American Clinical Laboratory Association, according to public calendars of his meetings.

Hamburg, the last FDA commissioner to take office at the start of a new administration, met with representatives of PhRMA and BIO early in her tenure. But she also met with dozens of patient and consumer groups soon after taking office, whereas Gottlieb has met so far with just a few such groups, the calendars show.

Gottlieb previously worked at venture capital firm New Enterprise Associates and health care merchant bank T.R. Winston. Sammy Almashat, a research associate at consumer group Public Citizen, said Gottlieb's tendency to meet with industry insiders is unsurprising because "he's sympathetic to their views."

“It’s a little bit irrelevant,” Almashat added, “because essentially the industry already wields a lot influence over the [FDA’s] new-drug division.”

Gottlieb’s most visible public statements take place on Twitter, where he has posted more than 1,100 tweets since taking office, an average of roughly six per day. The commissioner’s tweets betray few signs of hesitance or scripting, and have often been playful, as when he trumpeted the functionality of slim-fit denim.



Early Steps on Easier Approvals

Gottlieb’s nomination was met with relief in some left-leaning circles, given that President Donald Trump reportedly considered picking a Silicon Valley businessman with libertarian-leaning views, such as approving drugs without proof of effectiveness. But there were still lingering concerns to address, as evidenced by remarks that Gottlieb delivered at an all-hands meeting to FDA staff within days of taking office.

“Patient and consumer protection are at the heart of what we do,” Gottlieb said, according to a transcript. “And I believe deeply in that fundamental mission of this agency.”

Christopher Mikson, a Mayer Brown LLP partner, said Gottlieb’s performance thus far has tamped down concerns about radical changes and the potential “tearing down of the agency.”

“It’s not that he’s not striving for significant change,” Mikson said. “But I think it’s not the type of change that people had been raising significant controversy over.”

So far, Gottlieb has stressed his desire to carefully balance business interests and consumer safety. But

some observers say seeds are being planted for potentially major shifts in how the FDA approaches product approvals.

For example, the FDA last year refused to consider a proposed rare-disease drug called migalastat from Amicus Therapeutics, saying more research was required. But in July, the agency reversed course and told Amicus it would accept the drug application after all.

In addition, the FDA in June approved Portola Pharmaceuticals Inc.'s blood clot drug Bevyxxa, even though its clinical trial fell short of an effectiveness target.

"There have been, in our view, some worrisome signs that the agency under his leadership increasingly is making decisions that are placing industry above public health," said Michael Carome, director of Public Citizen's Health Research Group.

In September, Gottlieb endorsed greater use of "seamless" clinical trials that don't use the traditional three-phase approach. That would set the stage for quicker drug approvals in the long run — possibly benefiting consumers if drugs can be developed at less expense, but also requiring safeguards to ensure trials are still rigorous.

"Six months is way too short a time period to actually accomplish that type of goal," Mikson said of faster approvals. "I do think, though, that even though it's only been six months, he's taken pretty telling steps in that direction on a number of fronts."

Off-Label Openness

One of the biggest unanswered questions for Gottlieb's tenure centers on off-label promotion of drugs and devices. A key regulation involving off-label promotion — which was finalized by the Obama administration and then delayed by the Trump administration before Gottlieb's confirmation — is under FDA review, and action is possible by March.

Gottlieb has made many favorable statements about letting drugmakers promote unapproved uses so long the promotion is truthful. In a 2006 speech as deputy FDA commissioner, Gottlieb declared that "off-label use of medicines provide important opportunities for patients to get access to the latest clinical practice," according to a transcript.

In 2012 as a fellow at the American Enterprise Institute, Gottlieb urged Big Pharma to sue the FDA over off-label limits, writing that "the drug industry needs to be willing to take the prerogative to challenge the facts in some of these cases and have that day in court."

And in 2015, Gottlieb was paid $600 per hour for work supporting Amarin Pharma Inc. in its landmark defeat of FDA restrictions on promotion of omega-3 drug Vascepa. As part of that work, Gottlieb filed a

declaration in New York federal court criticizing the FDA's "near-total ban on off-label promotion."

Although changing the FDA's stance would likely face obstacles — including potential resistance from anti-fraud lawyers at the U.S. Department of Justice —it is possible that Gottlieb's passion for the subject could make a difference.

"Given his track record of moving quickly and devoting resources to things that he feels are a priority, I feel like even in this space, which is kind of notoriously intractable, he might be able to [move] forward an agenda in the not-so-distant future," said Backfield PLLC founder Katlin Backfield, a former FDA lawyer who left the agency last year.

'Earnest Progress' on Device Policies

Gottlieb's first six months have also seen notable updates to medical device policies, some of which were drafted during the Obama administration. For example, the FDA has finalized guidances on how device approvals can be supported by real-world evidence and how companies can use specialized methods known as medical device development tools.

In addition, the FDA in late September launched a pilot project in which specific companies — including Apple Inc., Fitbit Inc. and Johnson & Johnson — are being "precertified" as high-quality manufacturers of digital health products. The agency's stated goal is to "revolutionize digital health regulation" by identifying reliable companies and allowing them to submit less information when seeking approval for individual products.

Bradley Merrill Thompson, an Epstein Becker Green member, noted that Gottlieb hasn't yet taken action on many thorny topics, such as how laboratory-developed tests should be regulated. But he called Gottlieb's work so far a significant down payment on the device industry's sought-after policy changes and clarifications.

"I really do feel as though the Gottlieb-led FDA has been making earnest progress," Thompson said. "There is certainly a huge amount of work yet to be done — indeed most of the actual work — but I certainly didn't expect all of that to be completed in the first six months."

Strong Actions on Generics, Opioids

One of the most widely covered aspects of Gottlieb's tenure has been his relatively aggressive campaign to bring down drug prices, something the FDA has historically viewed as peripheral to its core mission.

Key initiatives include spotlighting 250 brand-name drugs that lack generic competition and fast-tracking approvals of generics that copy them. In addition, Gottlieb on Wednesday made waves by accusing

brand-name drugmakers of “shenanigans” aimed at stifling generics.

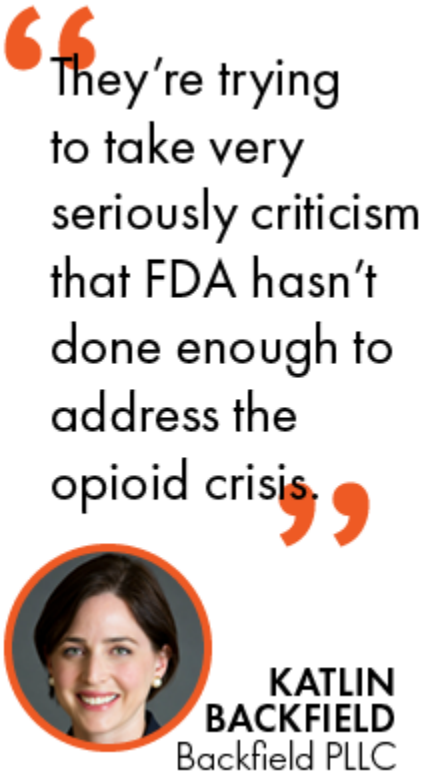
Ghosh called this an exciting time for generic-drug makers and said that “there is definite FDA interest in and intent on making some concrete changes in this space.”

Significant attention has also focused on the FDA’s role in tackling the nation’s opioid epidemic, which claimed an estimated 53,000 lives last year, or an average of about 145 a day.

Among several steps, the FDA has explored mandatory prescriber training, taken unprecedented action to remove an opioid painkiller from the market, and scheduled a two-day public workshop for December on how “innovation in packaging, storage and disposal” of opioids could curb abuse.

For years, the FDA has come under fire for being too passive about opioid abuse, which is rooted in painkillers that the agency has approved. Last month, Gottlieb vowed tougher action, saying that agency officials are committed to “using all facets of our regulatory authority to change the trajectory of this epidemic.”

Backfield noted that the FDA is “only one piece of the puzzle” when it comes to solving the problem, while also saying the agency now seems to recognize it can do more.



“From what they’ve done, it seems like they’re trying to take very seriously criticism that FDA hasn’t done enough to address the opioid crisis,” Backfield said. Gottlieb, she added, is “not leaving any stone unturned in figuring what can the agency do to address this crisis at this moment.”

--Editing by Brian Baresch and Bruce Goldman.