PINK SHEET
CITELINE REGULATORY

26 May 2017 | **News**

Gottlieb Unlikely To Make Major Changes Right Away, Former Official Says

by Mark W. Sherman

New US FDA commissioners have a lot of housekeeping to do before they can get to the fun stuff, according to former associate commissioner Wayne Pines.

US FDA Commissioner Scott Gottlieb has used his first weeks in office to signal that the agency will be taking significant steps on *drug pricing* and the use of *opioids*. But even as he aims for bold policy changes, at least for a while Gottlieb will be consumed by more prosaic tasks, according to Wayne Pines, health care president at APCO Worldwide and former associate commissioner for public affairs.

“Admittedly, this administration is somewhat more chaotic and somewhat less directive than previous administrations – actually, by far – but nevertheless, things just don’t happen that way in Washington,” he said May 16 at a meeting of the Coalition for Healthcare Communication. “[Gottlieb] knows as well as anybody that the first thing that the commissioner really, really does on a day to day basis is not to approve new drugs, is not to change major policies, it’s to do administrative things.”

For example, he said, Gottlieb has to fill a large number of vacancies, most of them at CDER. (Also see "*A Hiring Freeze By A Different Name: OMB Wants Agency 'Workforce Reduction' Plans*" - Pink Sheet, 12 Apr, 2017.)

FDA's staffing challenges are complicated by two Trump administration initiatives: a general hiring freeze, which Gottlieb just announced has been lifted for FDA, and a belt-tightening budget proposal, which Gottlieb has been distancing himself from. (Also see "*Gottlieb Distances Himself From Trump's User-Fee Heavy Budget*" - Pink Sheet, 25 May, 2017.)

Even beyond those pressures, FDA also faces more routine bureaucratic hurdles. “I’ve met with every recent commissioner … trying to help them solve that problem, and it has to do with the

PINK SHEET
CITELINE REGULATORY

federal hiring practices," Pines said. "If I offer you a job today and say, 'I'm really going to expedite this, but, you know, we'll see you in December,' it just doesn't work. So Scott's going to have to deal with a lot of those purely administrative issues, which nobody will see."

Gottlieb, however, has a head start on these and other administrative problems by virtue of his prior stints at the agency, according to Peter Pitts, president of the Center for Medicine in the Public Interest and former associate commissioner for external affairs.

"He has worked at the agency twice ... so his learning curve from the administration perspective is much less severe than previous people in that position," he said.

In addition, Pitts said, Gottlieb knows he has to win the confidence of the career employees, which describes all but a handful of FDA staff, all of them in the commissioner's office. (*See box for political staff who have recently joined the agency.*)

"What Scott understands is, the way that a commissioner succeeds is to get buy-in from senior staff, and that's a lesson that either goes unlearned or gets learned late in the game," he said. "Scott understands that from Day One."

New Faces At FDA

At least two people have joined FDA's senior leadership team under President Trump. Anna Abram is deputy commissioner for policy, planning, legislation and analysis, building on her experience as an aide to Sen. Richard Burr, R-N.C., on the Health, Education, Labor and Pensions Committee. On the panel, Abram helped craft the Food and Drug Administration Safety and Innovation Act (FDASIA) as well as the 21st Century Cures Act.

Jack Kalavritinos, associate commissioner for external affairs, has experience in both the public and private sectors. In the administration of President George W. Bush, Kalavritinos was director of intergovernmental affairs at HHS, where he helped with the rollout of the Medicare Part D prescription drug benefit. Afterwards, he worked for seven years in government affairs at the device firm Covidien.

Being Visible

In addition to filling staff vacancies, Pines said, Gottlieb needs Congress to give him a budget and renew the Prescription Drug User Fee Act. (Also see "*User Fee Add-Ons: Senate Bill Tweaks Orphans, Opioids, Patient Data*" - Pink Sheet, 8 May, 2017.)

All told, Pines said, there's not much room for drama and, in some ways, not much need for it, especially when it comes to drug approvals.

“I know with the other candidates, they were talking about blowing up the efficacy standard, but I don’t sense a whole lot of dramatic change,” he said in reference to proposals to limit FDA’s role to ensuring safety (Also see "*Trump Meets With Two US FDA Commissioner Candidates; Third Still Lurking*" - Pink Sheet, 12 Jan, 2017.).

However, he continued, “the industry is happy with the way that the process is working, the patient community is increasingly involved, [and] drugs are getting through, especially in the oncology area, [and so] I don’t think anybody wants to change it dramatically and I know that Scott doesn’t want to change it dramatically, so you’re not going to see any big changes.”

Even on opioids, there is only so much FDA can do, Pines said, even though it has to be seen as doing something. (Also see "*Opioid Policy At US FDA To Become 'More Forceful,' Gottlieb Says*" - Pink Sheet, 23 May, 2017.)

“FDA has really a limited role in opioids – they do approve the products, but the products are going to be out there, they’re very useful for pain,” he said. “The problem is at the medical level, with prescribing. It’s the people who are deliberately misusing the products, the people who are getting addicted to them, and there’s very, very limited stuff that FDA can do. Nevertheless, the agency is going to be held accountable for that, and that’s going to be a tricky type of policy thing.”

Staying The Course

What can be said, Pines added, is that changes that have been occurring at the agency will continue to occur, as part of a natural, intrinsic process.

For example, he said, it has become less rigid about clinical trial criteria – a trend he credits to CDER Director Janet Woodcock, now also acting head of the Office of New Drugs.

“One of the things that [Woodcock] has been able to do is to bring a new sense of flexibility to the agency in terms of the nature and the size of the clinical trials that are, and the number of clinical trials that are required for drug approval, and that will continue,” he said. “I don’t think that’s new, I think it’s part of an existing trend.”

In addition, he said, FDA will continue to reach out to patient groups, a practice he also attributes to Woodcock.

“I’ve organized a number of times when patients have gone in to brief the agency about their disease – not about a drug, but about their disease,” he said, “and increasingly you’re going to see patient-reported outcomes that have some scientific basis, that are going to be used to help be the supporting evidence for new drug approval.”

PINK SHEET
CITELINE REGULATORY

All in all, Pines said, there is a flywheel effect at work, where initiatives that have been in place will continue to develop, regardless of who's at the helm.

"No matter who the commissioner was, no matter who the president was, we would have seen that continuation because it's being driven at the operating level of the agency," he said. "And there is surprisingly, buy-in from practically all of the FDA review divisions, and that's hard to come by at the FDA, where you've got a dozen different divisions agreeing on an approach."