

## FDA Focus: What Covington's Practice Chair Is Watching

By Jeff Overley

*Law360 (May 31, 2019, 6:59 PM EDT)* -- The U.S. Food and Drug Administration's new leader may calm the nerves of stressed-out drug and device makers by eschewing his predecessor's assertive style and letting his lieutenants hold the microphone on many agency announcements, the co-chair of Covington & Burling's FDA practice tells Law360.

Denise Esposito, a D.C.-based partner who's been with Covington since 2015, has a life sciences resume that stretches back to 1992 and cuts across BigLaw, Big Pharma and the FDA itself.

After earning her juris doctorate at the University of Michigan Law School, Esposito practiced at WilmerHale and one of its precursor firms, Wilmer Cutler & Pickering. She moved on in 2004 and served as general counsel at Emergent BioSolutions Inc., which focuses on biological and chemical threats. In 2010, Esposito began a five-year stint at the FDA, where she eventually became chief of staff to then-Commissioner Margaret Hamburg.



Denise Esposito

In a recent conversation, Esposito told Law360 about hot topics involving over-the-counter medicines, drug prices and next-generation products that blur the line between biologics and medical devices. She also predicted that new FDA Commissioner Ned Sharpless might revert to allowing directors of the agency's centers, such as the Center for Drug Evaluation and Research, or other agency experts take the lead on announcing new policies and actions.

This interview has been edited for length and clarity.

### What have you found noteworthy so far from Commissioner Sharpless?

He is committed to staying on course with former Commissioner Scott Gottlieb's priorities. When Gottlieb came in, he was quite clear about setting his agenda and his priorities at the outset. Dr. Sharpless has said he's committed to staying the course, so I would expect that on the big issues — opioid misuse and abuse, drug pricing, modernizing medical review, balancing innovation and competition — we'll see him continue those initiatives. I suspect, as others do, that he would show a

particular interest in oncology and real world evidence, given his background [as director of the National Cancer Institute].

In terms of differences, I think we'll see a very different style than Scott Gottlieb. Scott had a very unique style — he was very media savvy, business savvy, he sort of gets it. He also hit the ground running, knowing how to navigate the agency. I think we'll see Dr. Sharpless play a little bit more of a behind-the-scenes role. We're already seeing fewer media statements and announcements from the commissioner, and the public face being delegated to the center directors or the subject matter experts in the commissioner's office, as opposed to the commissioner himself. So maybe he'll carry on the legacy, but in a lower-key fashion.

### **Would that lower-key style have any practical significance?**

One of the things that it means for our clients is that the spokesperson for the agency is more likely to be somebody that they've dealt with directly — so, a center director with deep knowledge of their space, or somebody in the Office of Regulatory Affairs who understands ORA deeply and whom the clients have engaged with.

I think there was a fair amount of industry stress involved with Commissioner Gottlieb's statements coming out but no real way to engage with the commissioner. Because very early on, Gottlieb made very clear that he wasn't going to take company-specific meetings, and he really held to that as far as I know. And so I think there was some agita among pharma and device companies about, "What's the commissioner going to say next that we haven't really had an opportunity to engage on?" There was a fair amount of tension in the industry about that. So maybe now that communications are being moved down, we'll see some of that dissipate. Only time will tell.

### **Is the idea that you just never knew what you were going to wake up to in terms of an announcement from Commissioner Gottlieb?**

The concern was that communications were coming out of the commissioner's office on matters that historically would have come out of a center, and the regulated company would have engaged with the center and had a sense of where the center was going to come down. Because they engaged directly with the centers that regulate them, there was a little bit more predictability and sometimes more collaboration with the agency. When the communications were coming from on high without a lot of opportunity to discuss the science behind it with the center director in advance, it was much more of an unknown.

### **So are you expecting more predictability going forward?**

I don't know. I'm suspecting that we might go back to having a little more transparency — transparency about what the FDA's needs are, and what they want the company to do, as opposed to a very public announcement without a lot of opportunity to engage with the agency.

I'm personally hoping for a little bit more traditional engagement at the center level, rather than situations where the commissioner's office decides that a statement needs to be made, basically making policy by either taking enforcement action or making a very public statement thematically about a big issue, which normally would have evolved at the center level.

### **When you were at the agency, you worked on promotional issues — what are you watching there?**

[On the First Amendment], I think watching the agency settle on a balanced middle ground of communication has been really interesting. FDA is probably watching to ensure that the industry doesn't drive a huge truck through the exceptions that the agency has created. I think they're looking for balance.

So I've definitely been watching not only the court cases but also how FDA is reacting to specific examples of companies doing more off-label communications.

### **What other FDA issues is your practice especially focused on these days?**

The concept of either using a 3D printer or a very high-tech biological process to literally grow replacement organs. If I needed a kidney replaced, instead of having to approach a friend or family member, it could be grown for me. FDA's doing a lot in the regenerative medicine space.

There are some interesting questions around whether something is a biological product or a device — does it get regulated by the Center for Biologics Evaluation and Research or the Center for Devices and Radiological Health? So for example, when something is grown with human cells or even animal cells, but then functions like a device, how is FDA going to regulate it? We've seen a fair amount of activity in the space of replacement veins and arteries — if they're grown biologically, the questions are whether they are biological products or devices, and what the standards for approval are.

### **What policymaking are you keeping an eye on?**

Over-the-counter drug review reform. There are folks in our group who have been heavily involved in the policy discussions and legislative efforts. Those products are regulated largely by this antiquated OTC monograph system. And I think FDA is looking for a streamlined approach, and industry is looking for ways to innovate OTC products without having to go through the whole monograph rulemaking process.

There's legislation that's being negotiated that balances those competing interests. And there's been a lot of talk about what the exclusivity regime would look like if companies do human clinical studies, which in the OTC drug world, unless you've filed a new drug application, there wasn't a lot of opportunity for exclusivity incentives. So those are some of the key issues there.

### **What's an FDA issue that hasn't received as much attention as it deserves?**

Before the 21st Century Cures Act, and even more so since Cures, the agency has been working really hard to hire young scientists — there was funding in Cures for this, and FDA had its eye on how to replenish the staff with scientists who are relatively recent vintage to keep the FDA current on technology.

It's critical that FDA have reviewers who understand the new technology, and in order to do that FDA really has to bring in specialists to keep up with the rapid pace of change in medical technology. There's been criticism of the agency over the years for not doing that, and the agency felt hamstrung because of limitations in hiring authority and compensation ability, and also because people stayed for a very long time. And we're seeing more turnover — we're seeing a lot of retirements, we're seeing people come out into industry as various groups in FDA are being restructured around new technology.

**If you could wave a magic wand and change or clarify one FDA policy, what would it be?**

When Gottlieb became the commissioner, he obviously stepped much more into drug pricing and reimbursement than any commissioner in modern history. And it would be helpful for FDA to engage, particularly with the drug industry, on the agency's current thinking about how to appropriately balance innovation and competition.

I come to this from the perspective of representing mostly innovators, not only the original innovators but also follow-on innovators who might do an innovative combination product or an innovative formulation. And because of the real pressures around drug pricing, we saw the FDA under Gottlieb's leadership sort of rein in the statutory exclusivity grants.

Gottlieb spoke very openly about believing that innovators are engaging in gamesmanship to evergreen their exclusivity and keep prices high, and I think the industry has heard him and has responded in certain ways. From where I sit, I would love to see where the agency envisions landing, so that the pendulum doesn't swing so far in the direction of fast generic approvals that we see unintended consequences — for example, drug safety issues, or disincentivizing the innovators, which could undermine congressional intent.

--Editing by Emily Kokoll.

*This is part of a series of interviews with FDA practice leaders.*