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FDA Focus: What Ropes & Gray's Practice Chair is Watching

By Jeff Overley

January 21, 2020 -- In Law360's latest installment of FDA Focus, Ropes & Gray's life sciences practice chair shares his thoughts on "woefully outdated" regulatory policies that need a soup-to-nuts overhaul, urgent issues confronting the new U.S. Food and Drug Administration commissioner and swirling uncertainty in the booming field of digital health.

Greg Levine

Greg Levine, a Washington, D.C.-based partner and BigLaw lifer, has been with Ropes & Gray LLP since 2008, when he joined after 12 years at Arnold & Porter. Levine earned his law degree from the Georgetown University Law Center in 1996 and now guides a practice with almost 30 lawyers in Washington, Boston and Chicago.

This interview has been edited for length and clarity.

What do you find rewarding about leading an FDA practice?

What I like about this area of law in general — not just leading the practice — is that while it seems narrow in the sense that you're always dealing with FDA-related issues, you get to practice a number of types of law. We do our regulatory counseling for clients, which is the bread and butter of our practice, but we also spend quite a bit of time on transactions and litigation and government investigations. And so you're practicing a very broad range of law within this substantive area of the FDA.

Also, FDA law is constantly changing. It's a lot of cutting-edge developments in technology and medicine, and so it's just very interesting and exciting substantively. It's things that affect people's lives very directly.

What's a key skill for an FDA lawyer, aside from scientific prowess, that isn't taught in law school?

We actually don't focus on whether people have a background in science. Having a background in science can be beneficial, but frankly, success as an FDA lawyer involves the same types of skills as success in any other aspect of law. You need good analytical skills. You have to be a good writer. You have to be able to communicate your analysis orally to clients.

We're looking for those same attributes, and then also looking for people who have some demonstrated

interest in the field or just show enthusiasm for this field of law. It's absolutely a niche type of field. It's not what your traditional law student is interested in pursuing. It's not corporate transactions or litigation work, which most students coming into law school would think that they would be pursuing.

If people aren't specialists in science, how do they typically wind up practicing FDA law?

A couple different ways. We find people who have an interest in medicine for different reasons — not necessarily science per se, not chemistry or biology — but just clinical medicine or the health care system.

And we find people who have an interest in administrative law or regulation. And this is one of the areas of regulation and administrative law that you find in the newspaper essentially every day. It affects your life in direct ways, whether it's food, cosmetics, drugs or medical devices. We're all dealing with FDA-regulated products probably multiple times per day.

What hints about the agency's direction have we heard from Commissioner Stephen Hahn during his first weeks on the job?

Not much yet. He was pretty careful in his statements that he made when his nomination was reviewed before the Senate. And the **one big policy announcement** so far has been in the area of vaping products, but I think that was really being driven from the White House.

As someone with **an oncology background**, I would think he'd be particularly interested in the standards for drug approval. There's been a lot of incredible progress made in oncology, and I'm sure fostering that and other aspects of drug development would be something of interest to him.

Are there any hot-button issues he'll have to tackle sooner rather than later?

The issue with laboratory-developed tests and **how those are going to be regulated**. At the end of the Obama administration, they **kind of gave up** and threw up their hands. The ball is now largely in Congress' court, but the FDA's been very active in dealing with congressional staff to shape what the eventual legislation might be with respect to LDTs.

My understanding is there's still an intention to advance legislation, but of course we have a lot of things going on in the world, and an election coming up, that create challenges to getting legislation through Congress. But I do think that's something that's going to have to be addressed in the future. In the meantime, the FDA is likely to have a light regulatory touch as long as you don't have some major crisis that explodes.

During this administration, Commissioner Scott Gottlieb was generally seen as a strong leader, but he left after less than two years, and then we had an interim commissioner for eight months. Has that leadership dynamic mattered?

I would say Commissioner Gottlieb was a strong commissioner in the sense that he was very visible publicly, a very avid user of social media. But if you look at what he did, by and large you really saw stability at the FDA. We didn't see some sea change from the Obama administration to the Trump administration in FDA policies.

And this was not the first time we had an interim FDA commissioner for a significant period of time. This happens periodically. Typically, what you see is the FDA just continues to go about its day-to-day business. And if there are big policy decisions that have to be made, they tend to get deferred until you have a new commissioner in place.

Personally, I haven't noticed a significant hindrance of the agency's ability to do its work or any kind of inconsistency in the way the agency acts as a result of having an interim commissioner.

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

The whole area of digital health is something that we're getting a lot of questions on. There's significant uncertainty with regard to what FDA regulation will look like in the future. That's an issue we deal with frequently — advising companies if they're developing an app, where it's a pharmaceutical company developing an app to support use of a drug or it's a company that's developing an algorithm to help diagnose a disease or condition.

And in particular, FDA has been working on this [Digital Health Software] Pre-Certification program, and a lot of people are very interested in where that's going and how that's going to play out.

Some members of Congress have had questions about the Pre-Cert program. What are we watching for specifically?

Whether it becomes reality. So far it's just a concept, and there's been a lot of attention paid to it, and a lot of work done on it, both by FDA and industry participants. But we're watching whether this is going to become formally the way that certain digital health technologies are regulated in the future.

The pilot program started with nine companies. Is the question whether FDA opens it up to any companies that prove they're reliable developers of these products?

Right. They've moved from a conceptual phase to a testing phase to evaluate whether they think it will have the effects that they want it to have, which is to have it be efficient but maintain the safety and effectiveness of these technologies. So they've gone into a testing phase, and ultimately if they decide it's successful and they want to implement it, then we get into some of these questions like, **do they have the authority to implement it** without legislation?

What pending litigation are you watching?

FDA law is an area of administrative law, and so we're always interested in key developments in administrative law litigation, such as [the U.S. Supreme Court's 2019 decision] Kisor v. Wilkie. That was a decision looking at **Auer deference** [the idea that courts should defer to an agency's reasonable interpretations of its own ambiguous regulations].

So we're interested in the effects of that decision, if any, in practice. When companies in the future challenge the FDA's interpretations of its own regulations, how is this recasting of the Auer deference doctrine under Kisor v. Wilkie going to affect the degree to which courts extend deference to the FDA?

This is an area of law that has had, and I expect will continue to have, very concrete effects on how FDA regulates companies and how companies think about FDA regulation with regard to their advertising and promotion.

How's Kisor playing out so far in your eyes?

There's always going to be an area of FDA regulation that's so squarely within the scientific and technical expertise of the agency that courts are not going to second-guess it. But there could be areas on the margins that are less squarely based on the FDA's scientific expertise, and are maybe more policy oriented, where FDA decisions might be more vulnerable to challenge.

Talk about one or more of the FDA's most significant moves during the Trump administration.

I'm a little reluctant to describe decisions the FDA has made in the last three years in the policy area as Trump administration policies. A lot of what FDA has been doing really has been continuing what FDA was already doing.

So, for example, the agency had a lot of actions that it was mandated to take under previous legislation. A

lot of those actions already were trending in a direction that philosophically you'd think would be consistent with a Republican administration — more expedited drug approvals, or allowing the use of real world data, or deregulation of mobile medical apps and other digital health technologies. We haven't seen a policy sea change; it's really been more stability in the transition between administrations.

The one thing where the Trump administration came in and did something that you might say was a change in direction really was more procedural, which was this action they took **to inhibit agencies from issuing regulations**.

The "two-for-one" policy requiring two regulations to be repealed when a new regulation is issued?

Exactly. And that has only further accelerated this trend of regulating by guidance rather than rules. And from a personal perspective, I don't think that's a beneficial change, but that is one change that we've seen.

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

This one goes back years, but for me, the promotional requirements for medical device manufacturers are woefully outdated. The regulations were written in the 1970s. They've never been updated.

These rules were written before the trend toward greater home use of medical devices, written before the internet existed. And they're not as complete as FDA's rules are with respect to drug promotion. And a lot of the enforcement in this area by FDA is loosely patterned on drug regulations, but it lacks clarity on a variety of questions that face medical device manufacturers that might not be the same as for drug companies.

What are the standards for comparative claims? We have different statutory standards for drugs and devices, and we have regulations in the drug area but not the device area with respect to that. That's an important one. This is one of my personal pet peeves, but I feel like the regulations for medical device promotion probably ought to be scrapped and we ought to start over from a blank piece of paper and replace them. They need to be modernized and clarified.

Why exactly is that important?

I think the practical impact is that because the rules are so unclear, device manufacturers interpret them in a widely divergent manner. And so relative to the drug industry, there's a lot more variation, for example, in how much risk information is disclosed.

With the drug industry, you have clearer rules with regard to fair balance and what has to be in an advertisement or promotion. You have more uniformity from company to company than you see in the device industry. And the consequence is that you can have some sense of unfairness, or a lack of a level playing field, from company to company.

So is the idea that some device makers are more cautious and disclose tons of stuff, while other device makers feel like they can disclose very little?

You have a great disparity in practices. Whether it's with regard to disclosure of risk information, or how you word various claims, or what scientific basis you have to support particular types of claims, or a comparative claim of device A vs. device B, there's just less clarity in the rules and less uniformity in what companies do relative to each other.