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FDA Focus: What Morgan Lewis' Practice Chair Is Watching

By **Jeff Overley**

Law360 (September 5, 2018, 2:28 PM EDT) -- Morgan Lewis & Bockius LLP's Kathleen Sanzo, leader of the firm's U.S. Food and Drug Administration practice, tells Law360 she's tracking food safety challenges, surging litigation against dietary supplement companies, new FDA policies on personalized-medicine devices and the agency's efforts to boost generic drugs.

Kathleen Sanzo

Sanzo, who is based in Washington, D.C., is a 32-year veteran of Morgan Lewis whose work spans pharmaceuticals, in vitro diagnostic devices, food safety and more. She counsels clients on regulatory strategies and legal compliance, among other things.

Sanzo earned her Juris Doctor from Emory University School of Law and her Master of Laws from The George Washington University Law School.

This interview has been edited for length and clarity.

What do you find most rewarding about leading an FDA practice?

Being able to help new lawyers learn about how law and science interact together. It's always interesting, especially because many of the lawyers that come into this area of practice are scientists in one way or another. It's very interesting and enlightening to see when they finally understand that there's a way that you can combine the two. And it's exciting because then they understand how they can take what for many has been their first calling and apply it in the legal context. That's just always so gratifying.

What's an important skill for an FDA lawyer — aside from a background in science — that they don't teach in law school?

The most important aspect you need in addition to science is really understanding the industry. Many of the companies that we advise are biotech and small companies that are raising funds, and so it's important to understand that the regulatory advice that you're giving really can affect the valuation of the company. So you really need to understand the dynamics of the industry at the time that you're trying to advise these companies on regulatory pathways for their products.

How might regulatory advice affect a company's valuation?

In terms of whether or not the FDA thinks that the clinical trial pathway of a company is practical, relevant, likely to be successful. Depending on FDA's view of that — and whether their view tends to be more enthusiastic or less enthusiastic — that can definitely impact the valuation of the company in terms of how quickly its product is going to be approved, how expensive the clinical trials are going to be, and really dictate whether that company is going to be able to raise funds.

What do you look for when hiring an FDA lawyer?

We do look for if they've had any relevant experience in science or in the pharmaceutical or medical device industries. We also look to see if they have an aptitude for regulatory issues, because I think being a regulatory lawyer takes a certain skill type. Reading regulations, understanding how they fit into the larger scheme of the regulatory framework, are all important things. You have to like to do it, first of all, and then you have to be good at it.

So, someone with a sharp eye who also sees the bigger picture?

Yes. And an understanding and appreciation of why administrative law is important. How the FDA is organized. How do they think about their frameworks? How do they carry regulatory concepts from one part of the pharma industry to the device industry, and vice versa? So, you have to be able to see patterns around regulation that are going to help you interpret what FDA is doing, whether it's through a regulation or a guidance document.

Could you give me an example of a pattern?

A very good example is FDA's entrance into [electronic cigarette] tobacco regulation. FDA was taking a lot of device concepts and applying them to tobacco regulation. So if you understand FDA's thinking around how devices are regulated, you're going to have a better understanding of what FDA is going to expect with regard to tobacco filings. It's that sort of analogous pattern of regulation that makes you a better adviser and counselor in terms of helping your clients understand, "OK, this is what FDA is going to be looking for."

The whole concept of the 510(k) device filing is very similar to the concepts — substantial equivalence, substantial similarity — that are in the tobacco regulatory framework. And so it's not the drug concept — it's the medical device concept that's being imposed on the tobacco arena.

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

On the food side, the Food Safety Modernization Act and foreign supplier verification issues are huge, and they're causing a lot of concern in the industry in terms of, "How do we police and control the global supply chain?" And that's a new concept in the food industry, relatively new. And it's going to be difficult because a lot of the suppliers in the supply chain are smaller, startup companies or small businesses. So that's an issue.

On the drug and device side, we're thinking about — and our clients are thinking about — the whole concept of personalization of therapeutic treatments and how that's going to play out. Is manufacturing of drugs going to become much more local? Are you going to have hospitals all of a sudden becoming

manufacturers? Are you going to have pharmacies becoming manufacturers, similar to what they're doing in the compounding space?

So as personalization becomes more of a reality, I think there are going to be new issues that FDA is going to have to think about and that our clients are beginning to think about. What do you do about 3D printers? The entrance of new technologies into traditional drug and device [fields] is something that most companies are thinking about.

I imagine that gives you plenty to advise about.

Yes, and it also means that you have to know the tech space in order to advise on all of these issues. And [when it comes to] the partnering that's going on with the tech industry, they're not really that educated about FDA regulatory issues. And so it's a whole learning process for the partnerships that are beginning to occur.

What litigation are you watching?

We have a lot of dietary supplement companies as clients. And there is more than enough litigation in the dietary supplement space around promotional claims, which causes a lot of consternation, because these are products that FDA has basically said are fine to market. And you have lots of litigation in which the claims are being challenged, and it makes it very difficult to do business, honestly.

Is that a long-standing concern?

It's been a long-standing concern, but the number of lawsuits that are now being filed against dietary supplement companies is just astronomical. And so it seems as though there ought to be a national policy on this, and there just isn't at this point, because each state has its own false advertising statutory framework. I don't know what the answer is, but it's making it difficult for the companies in this space to really do business.

What types of suits are you seeing?

A normal dietary supplement, under FDA's rules, you could say supports cardiovascular health. But then you have courts in California and other states saying, "Well, the scientific literature is not 100 percent consensus about that particular claim, so it's not substantiated." Meanwhile, FDA has said those are perfectly legitimate claims that you can carry on your product if you have adequate substantiation. It's this tension between what FDA has said is legally appropriate and what the courts within the states are saying under false advertising laws is inappropriate.

Why are we seeing more cases?

They're easy cases to file. And I think that's why we're seeing an uptick.

What policymaking are you tracking?

The FDA's approach to regulation of in vitro diagnostics. We have FDA issuing guidance suggesting that they're going to rely on this new framework for approval of IVDs. The guidance that said we're not going to require IVD makers to come in and get every single test approved. It's going to be almost like a base system of approval, and then you can add on various indications to that test.

It seemed like a plausible system, and it seemed like a system intended to try to move these products through the regulatory process. But I think we don't know yet how easy or difficult it's going to be.

Talk about one of the FDA's most notable moves during the Trump administration.

One of the issues I'm sure a lot of people are talking about is FDA Commissioner Scott Gottlieb's recent decision to identify pharma companies that are making it difficult to secure samples for testing by generic-drug companies. It's a new approach to trying to force parts of the industry to cooperate with other parts of the industry. I don't know whether or not that's going to be effective.

Commissioner Gottlieb mentioned at [the BIO 2018 conference in June] that he feels like he has a lot of tools at his disposal to make it easier for generic-drug companies to actually create the test results that they need to get their products to market. For example, he mentioned at BIO going to the [U.S. Department of Veterans Affairs] to have the VA secure samples of branded or innovator products, which generics companies could then use to do bioequivalence testing. These are really novel approaches that he's articulating.

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

Because I'm immersed in IVD issues, I think that would be the issue that a lot of people would like to know the answer to: To clarify how companies can get their products direct to consumer more easily.

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

--Editing by Rebecca Flanagan and Katherine Rautenberg.