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FDA Focus: What Latham's Practice Chair Is Watching

By **Jeff Overley**

Law360 (April 2, 2019, 2:22 PM EDT) -- The global co-chair of Latham & Watkins LLP's health and life sciences practice tells Law360 about the legacy left by the U.S. Food and Drug Administration's outgoing commissioner, when it makes sense for companies to sue the FDA, and his nostalgia for the good old days of informal interactions with regulators.

John R. Manthei

John R. Manthei, a D.C.-based partner, has been at Latham for 19 years. Before joining, he served from 1998 to 2000 as counsel on the House Energy and Commerce Committee advising lawmakers on FDA issues.

Manthei earned a bachelor's degree from Miami University in Ohio and his J.D. from the University of Wisconsin Law School.

This interview has been edited for length and clarity.

The big news right now is FDA Commissioner Scott Gottlieb's departure — what will his legacy be?

A big part of what he's tried to achieve is efficiency in the regulatory process. If you go back and look at the FDA's Critical Path Initiative that was launched in the early 2000s, it says, how do we build efficiency in the regulatory process? And how do we take the tools that are being used in medical device development and pharmaceutical development, and how do we build them in and make them appropriate for regulatory decision-making?

And I think one of Gottlieb's legacies is working to make the regulatory process more efficient. Not only with specific initiatives, but from a cultural perspective, that will be one of his important legacies. Making the process more efficient, less expensive, faster. Ultimately, that should have an impact on both pricing and access.

What's a trend your practice is especially focused on these days?

I'm hard-pressed to find an issue where multiple disciplines aren't being implicated. It's unusual any more for us to have an FDA issue that doesn't also immediately bring in [Medicare and Medicaid] coverage and reimbursement issues. And most of our clients are thinking not just domestically but also internationally.

It's being able to work with clients on all those different areas. What does it mean for FDA approval? What does it mean for approval outside of the United States — in Europe and Latin America and Asia?

What does it mean for how the product gets paid for? What are the intellectual property implications? What are the market exclusivity implications? I think clients are increasingly looking to be able to navigate multidiscipline issues. And we've seen a significant uptick in that over the last couple years.

How exactly has that changed in recent years?

The issues that the pharma and device industries face are incredibly complex, and companies are not just thinking domestically, they're thinking globally. And one of the things our clients have really pressed on us is to be able to work with them and grow with them as they develop business plans for their products on a global basis.

And we structured our practice really to be able to do that, whether it be intellectual property and related litigation, whether it be licensing, whether it be potential antitrust issues, whether there are corporate issues and the related disclosures that may take place. Getting FDA approval is just one step in the process.

What litigation are you watching?

We've actually been involved in two recent victories against the FDA — a drug exclusivity case on behalf of Eagle Pharmaceuticals, and a compounding case on behalf of Endo Pharmaceuticals. In both instances, we argued strict statutory construction, and we ultimately prevailed.

And the big takeaway is that the FDA has an authorizing statute, and it's important to view the agency's actions through what the statute actually authorizes them to do. If they deviate from the statute, there are times when they need to be held accountable for that. You want to work collaboratively with the agency — suing the agency, it's not something that you just do. But if you're right on the science and you're right on the law, you really shouldn't ever be afraid to defend yourself.

The other one we'd be watching is the next time the agency gets challenged on a First Amendment basis. Obviously the agency has had recent losses in Amarin, Caronia and Pacira. And I think the next time the agency is challenged, that's something we'll obviously be watching very closely. I think it's only a matter of time.

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

The leadership at FDA may not be getting as much credit as it deserves for working to make the regulatory process more efficient. The efforts that they've made to have collaborative interactions with the different stakeholders — I'm not sure they've gotten enough credit for that. It's been an enormous effort, and it absolutely has paid off. Those of us who live day-to-day in the trenches with the agency, we've seen it.

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

It would be helpful to kind of roll the clock back in some of the interactions with the agency. As a result of the different user-fee programs, there was a big push to provide more structure to the interactions, and to create an administrative record on specific guidance that you might receive from the agency.

I've been at this long enough where I remember when you used to be able to pick up the phone, either during the course of a review and in advance of a meeting, or following up on a meeting, and get really constructive feedback. A lot of the interactions now with the agency are all now centered around very strict guidelines, meetings and then meeting minutes.

One of the things that's been lost is that ability to have almost real-time feedback or informal interactions that can make the process go much more efficiently. So if I had a magic wand, I'd love to be able to have that level of interaction that we used to have at the beginning of my career. Almost by design the interactions now are much more structured. Those very structured settings are the only time you have meaningful feedback from the agency. That ability to have informal feedback has been lost. So if we could roll the clock back to permit those types of interactions, I think both FDA and industry would be better served.

--Editing by Brian Baresch.

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