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FDA Focus: What Mayer Brown's Practice Chair Is Watching

By **Jeff Overley**

Law360 (August 21, 2018, 3:01 PM EDT) -- Christopher Mikson, newly christened leader of the U.S. Food and Drug Administration practice at Mayer Brown LLP, tells Law360 he's watching for a "dramatic increase" in biosimilar applications, a crackdown on stem cell treatments and congressional action on brand-name drugmakers' anti-generic maneuvers.

Christopher Mikson

Mikson, who began leading the practice this year, is based in Washington, D.C., and has been at Mayer Brown since 2015. He came to the firm after a year-and-a-half stint at Jones Day and a 13-year run at Akin Gump Strauss Hauer & Feld LLP.

After earning his law degree at Rutgers Law School, Mikson picked up a doctorate in medicine at Jefferson Medical College in Philadelphia. He focuses on patent disputes, drug approvals and product marketing litigation, among other things.

This interview has been edited for length and clarity.

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

I'm brand new to the role; I've only been in it a couple of months now. I'm enjoying the leadership role. I'm still adjusting to it. The buck stops here is the way I look at it. With the clients, I'm the one who takes the lead — I'm the primary contact, I set the tone, I'm the one who makes and is responsible for most of the recommendations.

So it's a different role than being another member of a multiperson team with someone else leading it. I'm finding it very rewarding to apply my own thoughts and judgment. And it's enjoyable also to lead others, and to particularly work with people who are younger, who are up-and-coming and probably someday going to step into the role themselves. It's really enjoyable to teach the younger people and help bring them along and help develop them.

What do you look for when hiring an FDA lawyer?

First, the ability to dive down into the real nitty-gritty details. Some of these regulations and guidances and issues are very, very, very subtle. But then also a simultaneous ability to step back and look at

everything from the big-picture level.

And then second, I like to see someone who has done something else before they come into the FDA practice that has some connection or utility to the industries that we're working on. One of my colleagues had a background in advertising before actually being a lawyer, and we have found that background incredibly useful in both pitching business and servicing clients. The reason that's so important is because one of the subtle points of FDA regulation is that it's not so much what the drug or device does — it's what you say the drug or device does that controls how you're regulated by FDA.

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

Biosimilars. We had a key U.S. Supreme Court decision last year that **decided** one of the fundamental questions. And so now, I think this year we're going to see a dramatic increase in biosimilar applications and, as a result, a dramatic increase in the work to be done both in terms of assessing the regulatory and patent landscape for our clients, and then also handling the litigation that ensues. It's not unlike the Hatch-Waxman litigation for generic drugs. It's going to be an analogous type of litigation for the biosimilars.

I talk to people who were around in 1984 right when Hatch-Waxman came out, and I think a lot of us lose sight of this fact: All of the growing pains that we're going through with the relatively new biosimilars statute, they went through all those growing pains with Hatch-Waxman too. They had a number of years where they weren't sure what different things meant. In a way, history is sort of repeating itself.

What litigation are you watching?

One of the things I'm looking out for in the long term is Chevron deference. There **might be a shift** on the Supreme Court on that issue. And if there's a shift on the court on that issue — one of the major components of our FDA practice being Administrative Procedure Act litigation with the agency — it would significantly change the analysis of whether and when to bring that type of litigation against the agency, and if so, what kind of strategy to use.

Frankly, with a number of clients over the past few years, we've discussed the possibility of litigation. But one of the first things we always say is we have to be careful because the agency is going to get every benefit of every doubt and then some. And if that picture changes, that could be a significant development.

What policymaking are you watching?

For [FDA] Commissioner [Scott] Gottlieb, one of his themes is to increase the availability of, and lower the prices of, generic drugs and biosimilars. That's something we're keeping a close eye on. One of the things we're monitoring right now is the Creates [Creating and Restoring Equal Access to Equivalent Samples] Act, which would encourage generic competition by lowering the perceived barriers for generic applicants to obtain samples with which to conduct their studies.

Do you think the bill will pass?

It's hard to tell. I think a while ago the answer would have been "yes," and then more recently the answer would have been "maybe." Because it seems like people are doing things to water down the bill.

But it could very well emerge in the fall and be on the table for action.

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

The administration appointing Dr. Gottlieb is just a fundamental policy shift. His approach has been very, very proactive and very goal-oriented and very transparent. I think just the choice of the commissioner himself is a [notable] policy.

What specifically is notable about Gottlieb's policies?

I'm fascinated by his approach to clinical studies. He started saying our current clinical study system was an outdated paradigm. And he's made good on those initial statements. He's continuing to push for changes. I think of it as the evolution of the clinical trial process. Because with all the new technologies we have, we don't necessarily need to be wedded to the traditional phase I, phase II, phase III approach. He's talking about compressing them all together. And I think that alone is something that — if it's done appropriately and it's done with the appropriate margin of safety — could have a significant effect on the industry and increase the availability of all sorts of new, innovative drugs.

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

The area of regenerative medicine, and particularly the area of human cell and tissue products. It's a very interesting area, and it affects so many people, and I just don't see much press about it. There are any number of clinics around the country doing stem cell treatments in the orthopedic area. That has traditionally been an area of uncertainty for FDA regulation. Strictly speaking under the [Public Health Service Act], that type of therapy might need strict premarket approval as a biologic, but under another area of the statute, it might not.

What FDA finally decided last year is that this type of therapy is going to need a biologics license application. And they realized that that's going to be a paradigm shift for people in industry, so they're going to give 36 months of enforcement discretion. That was in November 2017. So that means in November 2020, the hammer may start coming down.

I almost feel like the whole issue has sort of been tabled, and then it could come, all of a sudden, out of the closet in 2020. It could be one of those sleeping dogs that just is going to suddenly wake up in a few years.

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

One of the areas would be DESI drugs. It's another one of those sleepers. The Federal Food, Drug and Cosmetic Act was amended in 1962 to require both safety and efficacy for new drug approval. Prior to that, you only needed to show safety. What FDA did after that change was they instituted a policy called the Drug Efficacy Study Implementation, meaning for those drugs that had been approved prior to 1962, they would start the process of requiring studies to show not only safety but efficacy.

I guess that sounded good on paper, but it really has been a very, very, very slow process. Even now, years after the DESI process was started, there are a whole number of drugs that are on the list, or not on the list, or people aren't quite sure where they are. If you had a magic wand, one of the clarifications would be a resolution of the status of the DESI drugs. The dispute is that technically they should be required to show both safety and efficacy, but they were approved before that requirement was in the

statute. So they're not illegal drugs because they met the standards applicable at the time.

But FDA is now trying to play catch-up and get these drugs through the process of showing efficacy as well as safety, and it's just proceeding at a snail's pace. I would clarify whether some still need to go through the process to show efficacy.

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

--Editing by Katherine Rautenberg and Aaron Pelc.