Portfolio Media. Inc. | 111 West 19th Street, 5th Floor | New York, NY 10011 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

FDA Focus: What Loeb & Loeb's Practice Chair Is Watching

By **Jeff Overley**

Law360 (October 23, 2018, 6:59 PM EDT) -- Scott Liebman, head of the U.S. Food and Drug Administration practice at Loeb & Loeb LLP, tells Law360 that he's watching drugmakers loosen up on social media, tracking a high-stakes patent case at the U.S. Supreme Court and wondering whether the opioid crisis will prompt fundamental changes to the FDA's drug approval process.

Scott S. Liebman

Liebman, who is based in New York and Washington, D.C., joined Loeb & Loeb in early 2014. He practiced at Porzio Bromberg & Newman PC from 2005 to 2014, specializing in compliance and commercialization for life sciences clients.

After attending Lehigh University in eastern Pennsylvania for his undergraduate studies, Liebman earned his law degree from the Seton Hall University School of Law.

This interview has been edited for length and clarity.

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

Pragmatism is critical: You need to provide practical advice. It's easy to say no. It's much harder to find a way to say yes while mitigating risk and protecting the company.

Sometimes clients have innovative ideas [and want to] communicate things in certain ways, use social media in certain ways. And we have a regulatory framework that is not necessarily set up for how consumers or patients use social media. So it's easy to tell someone, "No, you can't do that." But really thinking through what their business objective is, and how we get to yes while mitigating risk, is important.

What do you look for when hiring lawyers for your FDA practice?

It goes back to the client's business. I look for candidates who have diverse backgrounds, because that's what better serves our clients. My FDA practice is pretty diverse, and we counsel clients on things from clinical development through commercialization and distribution. If you don't have an understanding of

the industry, it's hard to help clients.

Obviously, if you're a younger associate, I'm looking for different skills. But if you're in that midlevel, I'm expecting you to know the business.

What's a good indication that an attorney understands the business?

A lot of the people on my team either worked for life sciences companies in-house or have been seconded. Early in my career, I was very fortunate to spend years seconded to a client, and almost every lawyer on my team at some point has been seconded to a client.

One of my junior associates just came back from a secondment, and his perspective entirely changed. He recognizes how valuable it was to sit in with the client and see how the business operates and see how the internal lawyer thinks outside of the vacuum of a law firm.

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

We're still pretty focused on off-label issues. Although we received **the much-anticipated guidance**, and it did come with some clarity, the industry still seeks greater guidance related to truthful, nonmisleading information that's off-label.

I was watching the [Brett] Kavanaugh hearings, and I was sitting there thinking, "The Roberts court legacy is solidifying. The Roberts court idea around First Amendment rights for corporations is going to be essentially solidified." So I think that we're less likely to get final clarity from the Supreme Court. I don't see the appeals going to the Supreme Court at this point. So our best bet is still from the FDA.

Why don't you think this will reach the Supreme Court?

I think the way the court's going to stack up with Kavanaugh is there are going to be greater rights for corporations. I think that the Department of Justice is going to be less likely to appeal. I hope that the FDA gives clarity on it.

Isn't it starting to feel like the FDA doesn't think it needs to give ground?

I agree. I feel the same way — that the FDA has taken that perspective — but I still get questions from clients on it. They think they have real, truthful, nonmisleading information that is not consistent with the label, and there are clients that want to have that information out.

What do you expect on off-label policymaking in the next few years?

I think that we are going to see more of the status quo for a variety of reasons. I think of the makeup of the [U.S. Supreme] Court. I think of the perspective or stance that the FDA has taken. Maybe even one of the factors is companies' unwillingness to challenge the FDA. So I think that all of the forces are just leaving us at a standstill.

What litigation are you watching?

Helsinn v. Teva at the Supreme Court. The case contemplates whether confidential clinical trial contracts meet the standard for the on-sale bar [which holds that patents can sometimes be invalidated

if inventions were sold before a patent filing]. So right now clients need to be careful and thoughtful in their contract negotiations and drafting.

Essentially there are questions on whether a confidential clinical trial agreement meets the standard for the on-sale bar, and as clients are negotiating contracts, they need to think about whether the elements of that contract are going to meet the standard.

What FDA policymaking are you watching?

For a variety of reasons we're watching the policymaking around the opioid crisis. You have to watch it because the FDA has made opioid addiction its quote-unquote highest priority. And as the agency's opioid policy steering committee confronts the issue, they're evaluating the drug approval process, packaging, distributing, dispensing and everything in between.

So policy or regulatory movement in any of those areas can affect clients regardless of whether they're a manufacturer or a distributor of an opioid. I think the opioid crisis may cause changes in the larger regulatory framework. The opioid crisis is an area that may have the agency re-evaluate some of the hallmarks of regulation.

What changes to regulatory hallmarks could we see?

I'm thinking about how opioids were approved and how you revise the approval process. And is it going to affect the communication of risk information? There are all of these areas that the steering committee is looking at that could affect the traditional framework.

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

The administration's effort to reduce the cost of drugs. It's one of the administration's top priorities. It's most notable, I think, because the FDA does not have direct control over how a manufacturer prices a drug.

I find it fascinating to watch the FDA, the Centers for Medicare & Medicaid Services, and the U.S. Department of Health and Human Services as a whole pull different levers, like the generic drug approval process, that they have control of to affect or influence the pricing of drugs.

One of those levers could be required disclosure of drug prices in advertisements — what do you think the impact of that might be?

Drug pricing is complicated, and if it's going to be disclosed to a patient or even a provider, I think we need to be very clear. The agency needs to really think through how it is communicated in an effective and meaningful way that a lay person understands.

Do you think there is a coherent policy they can adopt where everybody discloses in a clear and meaningful and consistent manner, or are you skeptical?

There would have to be more standardization for it to be meaningful to patients. There has to be education around it. There would have to be some uniformity or standardization.

The biggest concern would be there's disclosure of dollar amounts, but comparative claims are not comparing apples to apples. And it can get confusing. We'd want to make sure that if it's going to be disclosed to patients, there is an apples-to-apples comparison. This is where [FDA officials] have the least actual power. They're trying to pull levers of influence to affect manufacturers, but it's going to be difficult without legislation.

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

I think a lot about communication of risk information or health information more generally. The FDA has a three-year strategic plan for risk communication and health literacy with an implementation plan that has like 35 or 40 action items. The plan covers 2017-2019. We are right in the middle of that plan. But you don't really hear that much about it. It's not really covered that often in the press.

I think it's one of the most important things going on in the FDA right now. Patient behavior has changed dramatically. I think of my mom. If she has a diagnosis or a prescription from a doctor, the first thing she does is Google it. The days of the learned intermediary doctrine are vanishing. Knowledge is cheap and abundant, but truthful, nonmisleading information and good analysis is more important than ever.

The strategic plan mentions social media. Where are things with social media — are drug companies dipping their toes into the water any deeper?

Social media has changed American behavior in so many different ways, but for life sciences manufacturers, it's really hard for them to effectively communicate on social media under the regulatory framework.

But a recent citizen petition from Pfizer called attention to drugmaker activity on social media.

Right. And remember the whole Roseanne Barr scenario? Sanofi weighed in on Twitter and said there are known adverse events to our products but racism is not one of them. I would say that was one of the more progressive uses of social media that the industry has done. It was an effective use of social media for a life sciences manufacturer, which we have not really seen.

They are dipping their toes into it. The industry wants to use it. We just haven't figured out how because the framework doesn't work.

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

I'd like to see a little more clarity around cosmetics. With the rise of social media and influencers, cosmetics is a massive market, and the barrier to entry is relatively low, and we're seeing more and more products being sold.

Clarity on claim substantiation can be helpful to consumers. Does the consumer understand the difference between reducing the appearance of something and reducing the actual thing? Does the consumer care? I'm not sure they even care.

I actually think we'll see more enforcement in this area, and I'd love to see more clarity in it. Is the class action bar going to lead the enforcement against it? I don't know. I think there's a possibility for it.