

## FDA Focus: What BakerHostetler's Practice Chair Is Watching

By Jeff Overley

*Law360 (October 11, 2019, 5:57 PM EDT) –*

The co-leader of BakerHostetler's U.S. Food and Drug Administration practice tells Law360 he's alarmed by a surge of contaminated drugs, watching for possible legal challenges to government crackdowns on vaping and concerned that large drug compounders will shut down because of FDA restrictions.

Lee Rosebush, a Washington, D.C.-based partner, has been with BakerHostetler since 2013. He previously practiced at Morgan Lewis & Bockius LLP and Epstein Becker Green, and prior to those law firm stints, he worked as a pharmacist at Walgreens and the Cleveland Clinic.

Rosebush earned his law degree at the Case Western Reserve University School of Law and also holds graduate degrees in finance from Indiana University and pharmacy from Purdue University.

This interview has been edited for length and clarity.

### **What do you find rewarding about leading an FDA practice?**

Working with the cross-section between science and the law. Unlike many other industries served by big law firms, in the FDA world, we have a distinction of working with the legal side of the issues but also working with the science behind it. Helping shape policy, but also helping shape medical treatments, is an extremely rewarding issue for me.

### **What's an important skill, aside from scientific prowess, for an FDA lawyer that they don't teach in law school?**

The ability to translate between law and science. I honestly think that is the key element for an FDA attorney, the reason being that not every attorney speaks science and not every scientist speaks legal jargon. And so it does make a tremendous difference when you have an attorney who can speak both of them and sort of translate back and forth between the groups. It is something that can be learned, but I do think it's also an innate skill that separates FDA attorneys.



Lee Rosebush

### So if you're not endowed with it, how do you develop it?

You need to further your education — not necessarily to get full degrees, but to continue to take courses, or find the right mentor. I was blessed by the fact that I've been able to work with some of the best FDA attorneys in the industry. I worked with Brad Thompson on the medical device side at Epstein Becker, and I worked with Kathy Sanzo at Morgan Lewis. Both of them were able to show me the ropes before I took over here at BakerHostetler.

### It reminds me of the saying, 'If you can't explain it simply, you don't really understand it.' Is the idea something like that?

It's exactly like that. And I would say that's part of the key to legal and policy discussions with the FDA — if you can't understand the idea and the science behind it, it's tough to be able to get the agency to move in your direction.

### What do you look for in an FDA lawyer when making hiring decisions?

What's key to me is somebody who's got the drive behind them. I don't necessarily look at credentials, such as where they graduated from; I look at what they want to do going forward, and I look at their ability to communicate and their will to work hard. I've been lucky because I've been able to find associates and partners for our group who have got that drive to continue to push and make our group one of the best in the country.

### How do you gauge that enthusiasm?

I look at past experience, and we do reach out and talk to references. To me, references are key. Here in D.C., it's a small bar, and we have strong connections with many of those in the D.C. bar.

### What's an FDA issue your practice is especially focused on these days?

Our practice focuses extremely heavily on compounding and pharmacy-related issues. The **recent litigation** involving FDA and bulk compounding is something we're continuously monitoring on a daily basis.

### What's a big issue that's up in the air on compounding?

There's a major policy issue that the agency and the administration need to address. And that's the ability for compounding from bulk ingredients. That obviously makes a huge difference for drug shortages. The agency has not issued a formal bulks list to this day.

Currently, the agency has addressed two final substances — vasopressin and nicardipine. Other than that, we don't have a final determination from the agency on any other substance. They did release recently a notice on nine additional bulk substances; however, that hasn't been finalized, and I can tell you I'm aware of many, many comments that will be submitted on the nine substances.

### The law undergirding all of this passed about six years ago — are we just going to continue like this for the foreseeable future?

Yes, the agency has made clear that they're going to continue to use their enforcement discretion on the

bulks list. There are close to 200 substances that a 503B outsourcing facility — [the technical term for a large compounder] — can continue to compound from bulk ingredients with until the agency addresses those substances. And so we are just in a holding pattern from an enforcement discretion [perspective].

The major issue I've seen — I can tell you a lot of my clients have said this — is if the agency continues to [restrict] the ability to compound from bulk ingredients, you will see many of our 503B outsourcing facilities either become regular 503A compounding facilities or become repackagers, because if we continue down this pathway, I can tell you there won't be many 503Bs left.

### **What's an area of litigation you're keeping an eye on?**

I think what you're going to see is a strong review of First Amendment rights for advertising. I think it applies to tobacco — for example, in the Juul situation — as to what they can and cannot say.

You're seeing the prohibition of marketing of certain products. With some of the vaping products, you're seeing it related to flavors and use by minors. And obviously nobody wants to see kids smoke. But the question is, what can and can't you say related to tobacco products?

Pick a flavor, such as coffee. Would a coffee flavor be pointed toward teenagers? Or would a coffee flavor be pointed toward adults? I know a lot of people, including myself, who drink coffee. I would say that a coffee flavor could be promoted toward older individuals.

Now the question is, is advertising for a coffee-related flavor enough to say you can't do that anymore because the administration, as well as some of the states, have said they're not going to allow flavored vaping to continue? The question then becomes, is that a First Amendment right to be able to promote your product how you'd like to, or is the public health issue more important?

### **Is litigation expected?**

It wouldn't be a surprise. Obviously the vaping industry is quite large, and you're looking at not just those who distribute products but also the retailers that sell the products and are potentially impacted by the administration's action as well as state action going forward.

And the advertising issue goes beyond tobacco. Take, for example, CBD-based products and THC. As of right now, if you look at the administration's push toward CBD products, they allow [certain promotional claims] for topical and cosmetic-based products, but they haven't allowed it for oral-based products.

And the actions that they have taken in the oral world — the dietary supplement world — haven't necessarily been based on the distribution of the product by itself. It's really been based on the claims. Again, it's advertising, what you can and can't say about it, based on the claims associated with those CBD-based products. And so again it shows you that advertising, promotion and the First Amendment are going to come up in another hot area — in this case, CBD and THC.

### **Is there a recent court decision that's had a notable impact on your practice area?**

Obviously the case involving the FDA and Endo Pharmaceuticals had a huge impact. The question becomes what's going to happen now. The discussion around [what constitutes an] "essential copy" [of an FDA-approved drug] has potentially put all compounding under 503B at risk.

And so now we're stuck between a rock and a hard spot. Are you able to compound from bulk? Are you going to have the essential copy issue impact all compounded products? And if both are impacted, does that mean you really shouldn't be a 503B at all?

### **What's a significant FDA policy unveiled by the Trump administration?**

I would say drug importation, if we get it moving forward. The reason being its implications across so many different areas. The question of safety — we look at the NDMA impurity issue currently going on with active pharmaceutical ingredients, and do we want to trust our drug supply from other places? We can look at drug pricing in terms of having pricing mechanisms from imported products. We can look at its ability to resolve drug shortages. Importation to me is probably one of the most extremely important ideas in either direction that the administration goes.

### **Are we actually expecting them to open the door widely on importation?**

A lot of people don't realize it, but there was actually a statute that was passed during the Clinton administration and signed into law that allowed for importation of drugs. However, that statute required a secretary [of the U.S. Department of Health and Human Services] to sign off on importation. And so the question has always been, what's it going to take to allow importation?

And it's important to remember that the Hill in this situation doesn't necessarily have a say as to whether it is or isn't. All it would take is for a secretary to sign off if you had a push from the administration here — there isn't a requirement for a legal change.

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

I think the NDMA issue with both ranitidine and losartan-based drugs. Putting aside the FDA practice and my legal hat, as a pharmacist, that scares me. Because that's become a drug security and national security issue, where if you think of different ways that somebody who wanted to impact our country from outside the United States could do so, it could very easily show that it can be done.

And to me that is an extremely important national security issue that hasn't necessarily been addressed enough, because think of ranitidine being an over-the-counter product and how many people took that product.

### **But is there suspicion that the contamination was intentional?**

It wasn't necessarily intentional, but what would stop somebody from making it intentional?

### **What do you think of the idea that this contamination threatens consumer confidence in generic drugs?**

I agree. And it comes from more than just contamination. We've seen the issues related to data security and data integrity. You see the FDA's push now related to some of the generic manufacturers who've had issues in India and China related to generic-drug approvals. You've seen issues here in the states related to data integrity, and the agency's continued push toward strengthening of clinical data. You take that, along with this impurity issue, and it makes you wonder about some of our products.

## **If you had a magic wand and could clarify one FDA policy, what would it be?**

What I'd really like clarity on is what they're looking for on data integrity, whether that be for an application to get a drug approved, or for a bulk substance that we nominate for compounding, or for importation testing. What is it they are looking for to help them make the decision? Because it's no longer just a policy and legal issue, even though it's treated that way. It's really a science issue. Because it's hard to argue with the science.

So I wish the agency would come forward and be more clear and transparent on the specific science they're looking for on making these determinations going forward. Across the board, the agency in these situations needs to be more clear and transparent on the specific science they need to make a decision.

--Editing by Aaron Pelc.

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