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FDA Focus: What Sidley Austin's Practice Chair Is Watching

By **Jeff Overley**

Law360 (February 22, 2019, 5:38 PM EST) -- Becky Wood, co-chair of the U.S. Food and Drug Administration practice at Sidley Austin LLP and former chief counsel of the FDA, tells Law360 she's tracking U.S. Supreme Court action on drug and device safety, eyeing new approaches to product approvals and fretting about political impacts on FDA recruiting.

Becky Wood

Wood, a D.C.-based partner, has been at Sidley Austin for most of a two-decade career devoted to drug and device law. She stepped away in 2017 and 2018 for a high-profile stint as the FDA's top lawyer.

A graduate of Yale University and the New York University School of Law, Wood clerked for Eighth Circuit Judge Pasco Bowman before launching her career at Sidley Austin, which boasts more than 50 lawyers focused on regulation, compliance and enforcement involving foods, drugs and medical devices.

This interview has been edited for length and clarity.

How did you get your start in this area of law, and why did you stick with it?

As a new associate coming off a federal clerkship, I was very interested in having a D.C.-style practice, and very interested in the overlap of litigation and regulation. Very early in my career, I had the opportunity to get involved in litigation involving highly regulated FDA products. And I just fell in love with that area of law.

I thought it was absolutely fascinating. The subject matter, the importance of doing right by patients, the importance of understanding not only the litigation aspects but also the regulatory overlay — it was very, very interesting to me.

And so for those same reasons you've stuck with it?

I really did. And the firm has terrific colleagues, and I've always had opportunities to work on very cutting-edge litigation. The litigation that I worked on oftentimes included FDA-regulated products and oftentimes a constitutional overlay, so I found that very interesting.

When you mention a constitutional overlay, what are you referring to?

It could be First Amendment issues, [federal] preemption [of state law] issues, those sorts of things, where there's not only a very interesting and evolving legal framework, but also a very important need to understand the role that FDA plays in regulating.

Sidley Austin has worked extensively on First Amendment issues involving the FDA, particularly with drug promotion. Could you talk about how the issue has evolved over the years?

In my view, there has been a First Amendment revolution in the federal courts. When I started practicing, there was a lot of skepticism about so-called commercial speech, and whether it would be entitled to a significant degree of constitutional protection.

Following the Supreme Court's **decision in Sorrell**, the Second Circuit's **decision in Caronia**, the Amarin **decision** and other decisions that have really swelled up over the last five years or so, I think there's been a real renaissance in people's thinking about the importance of free speech in the setting of highly regulated life sciences products.

And so to me, there are endlessly fascinating questions about how you balance the First Amendment imperative from the courts with the way in which FDA does its job, and the way in which these products are regulated.

Do you expect this area of law to keep evolving?

I think so. To some extent it will be [influenced] by additional Supreme Court cases. I think also it will continue to have a significant impact on the way in which FDA does its work and calibrates how it's going to address speech that may be protected, and the kind of record it may need to develop to establish its view when it wants to limit the amount of speech that it feels is appropriate from a public health perspective.

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

Problem-solving. Many of us in law school learn to identify risk, and that of course is an essential part of the practice of law. But the most effective lawyers can calibrate how significant the risk is and think creatively about ways to mitigate the risk.

Clients no longer want 20-page academic memos from their lawyers. They really want to partner with lawyers who are very high up the learning curve, who have deep insight, and who really want to suggest to them some ways around the challenges they're facing. And so even new lawyers are getting an opportunity to think in that way, in a way that's very different from when many of us started practice, where the practice was perhaps a little more academic.

How do you become effective at problem-solving?

You have to learn the basics, and you also have to be curious. Curiosity is a really important trait in a successful lawyer.

Also, thinking about it from the client's perspective. From the client's perspective, they don't just want to know the legal standard. They want to know how it applies to their particular issue. And I think the more you see the senior lawyers around you solving problems, the more young lawyers get practice with that.

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

You obviously want somebody who has exceptional credentials, who is articulate, who is really going to dig in and be curious about the problem or opportunity that the client is facing — the ability to not just see the small question in front of you but also relate it to larger issues.

Clients think about a problem that they have, and it may have an FDA regulatory or enforcement element to it, but they might also have a privacy issue, a data breach issue, intellectual property issues or fraud and abuse issues. The ability to think about when you need to bring in colleagues with expertise in those issues is also important.

You recently served as the FDA's chief counsel. What did you take away from that experience?

It was a very exciting time to be at the agency, and it still is. What Commissioner [Scott] Gottlieb has talked about is a **21st Century Cures** mentality: enormous energy, an enormous sense of creativity, and really looking at new ways to promote innovation, competition and better tracking of safety issues. It's a very exciting time to be serving under Scott Gottlieb's leadership and with the leadership team there.

The Office of Chief Counsel is a very special place. I have incredible respect for the people who serve there, their expertise, their dedication to public service. The seriousness of purpose, and the expertise the agency brings, is really hard to match anywhere in government.

How does that experience benefit the clients you serve?

It gives you a deeper sense of the public health issues that the agency is balancing and how the agency sees things. And an ability to help clients navigate that in a more grounded way.

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

I'm very interested in **real-world evidence**. The 21st Century Cures Act really laid out **a new paradigm** to encourage the agency to have a mentality of more flexibility around harnessing the power of big data to make more-efficient decisions about getting products to market more quickly, potentially identifying postmarket safety issues more quickly, and responding to them more quickly.

A lot of the rules of the road are still being developed. I was very interested in the naming of Amy Abernethy, who really pioneered a lot of the real-world-evidence issues as a thought leader, as the new No. 2 person at the agency.

So I think it's going to be a big year of the agency setting up the infrastructure. We've already seen **recent guidance documents** giving additional guideposts about how to use real-world evidence, but there's a lot of unanswered questions. And I think that'll be a very exciting issue to watch in the coming year.

Separately, federal preemption remains a very important question, and the courts are continuing to

provide additional insight. The fundamental questions remain: When you have a product that is highly regulated by FDA, in what circumstances is there room for state tort law? And it's an exquisitely complex area of law that is very dependent on the particular product at issue.

The legal framework for medical devices may look very different than the legal framework for drugs. But [something that is] always a very important issue in that kind of litigation is, how do you tell the FDA's story, and to what extent does FDA's decision-making trump a particular question, like failure to warn or design defect? And in what circumstances is there an opportunity for state tort to proceed?

What pending litigation — involving an FDA-regulated industry but not necessarily the FDA itself — are you keeping an eye on?

The degree of deference owed to federal agencies under the Chevron and **Auer** frameworks. The amount of deference that the agency gets for its determinations is often very critical to the outcome of litigation. So that's one issue that is very crosscutting in administrative law that we're watching closely.

What's a recent court decision that's had a notable impact on your practice area?

The trio of Supreme Court preemption decisions. Riegel, which extended premarket approval preemption in certain circumstances. Wyeth vs. Levine, which set out the framework for applying implied preemption to biopharmaceutical drugs. And the Buckman line of cases, which discussed when state tort can second-guess the agency's determination about whether it had sufficient information from the regulated entity to make a decision and whether different information would have changed the agency's decision.

That trio of cases continues to be very important, and so any time the Supreme Court has an opportunity to further flesh out the issues that were left open in those cases, that can be very impactful.

The issue of preemption has come before the Supreme Court time and again going back many years. Is that topic going to take even more time to flesh out?

I think so, particularly because the legal framework is very different depending on what kind of product it is. So for medical devices, it's express preemption, and by and large for drugs, it's implied preemption.

So those are just very different legal structures, and the devil is always in the details of a preemption case, because it's very dependent on the specific record. So it's not surprising that you're seeing a number of iterations play out in the court.

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

Having a leadership team that is very innovative and dedicated to bringing the 21st Century Cures mentality to bear. If you're looking at innovation, safety, harnessing real-world evidence or improving competition, there's a real sense of momentum at the agency right now.

There's also been a real focus on attracting the most world-class talent and thought leaders. There's been a couple of recent announcements that are very exciting for the agency. Frank Yiannas has been very well received as a sort of food safety czar to help the agency continue to modernize techniques for tracking food safety issues.

As I said earlier, the announcement of Amy Abernethy and her deep knowledge on these incredibly cutting-edge real-world-evidence issues. There's a real sense at the agency of always trying to maintain world-class thought leadership to develop these very innovative policies.

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

There was a recent report from the Aspen Institute and a number of former FDA commissioners calling for the FDA to be an independent agency.

In many ways, the FDA already feels like an independent agency. It has such a broad and science-based mandate from Congress. It literally sits a little bit outside the Beltway. And this call by a bipartisan group of former commissioners that asks, "Would it be better to have the agency actually be independent? Does it make sense for the FDA to report into [the U.S. Department of Health and Human Services]? Would it make sense for FDA to have its own litigating authority?" That's a very important question of whether that would be a better model.

Separately, I think FDA is in a moment where it is very conscious of its need to keep world-class talent and attract it. I worry a little bit about what the [partial government] shutdown does to the attractiveness of government service for world-class scientists and others.

Keeping FDA in a position where it can continue to fulfill the 21st Century Cures mandate of rolling out more efficiencies in its hiring, being more attractive to world-class scientists — particularly in areas where there aren't very many people who have the expertise, if it's a rare disease or something — is very important.

What are they doing to make it more attractive?

I think the very fact of the mission that they have is inherently attractive in many ways.

So is it partly about making clear what you get to work on if you come there?

That may well be part of it. Certainly on the legal side, my experience was we were getting applications from incredibly talented people and attracting that talent. My worry is, when you see a shutdown where 40-percent-plus of the workforce is furloughed, is there a way to mitigate the potential harm it does to people wanting to pursue a very important career in public service?

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

In the area of regenerative medicine, FDA has in recent years stood up a suite of guidances to provide more direction about how to bring products to market and which products are regulated or not. That continues to be a place where you have a very new and emerging industry and a need for additional guidance on how to do it.

Also, the accelerated pathways are where you've seen FDA announce more clarity around when those are available. And certainly we've seen banner years from the agency in terms of novel therapies that are approved.

So I think continuing to provide clarity for folks about how to get into those pathways, and if they're not in those pathways, how they can continue to efficiently move their products through. My sense is that the agency has been very focused on those issues, and those are incredibly helpful to bringing particularly novel therapies to patients who don't have good alternatives right now.

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

--Editing by Kelly Duncan and Aaron Pelc.