TRANSCRIPT Episode 30 – Seth Olson

Jonathan Bench: Today I'm joined by Seth Olson, an FDA regulatory attorney in Kirton McConkie's International Section, where he advises clients across the life sciences industry on regulatory, compliance, and transactional matters involving the U.S. Food and Drug Administration and other federal health agencies. His work spans medical devices, pharmaceuticals, biotechnology, human cell and tissue products, food, dietary supplements, and cosmetics. Drawing on his experience as a former regulatory counsel at the FDA, Seth helps companies navigate complex and evolving regulatory requirements with practical, strategic guidance. Seth, welcome to the podcast.

Seth Olson: Hi, Jonathan. So nice to be with you.

Jonathan: It's been fun getting to know you as you join the firm. I want a little bit of your backstory here, though, for our listeners, because I always like the human element behind the professionalism. Give us a little of your personal background and how you landed where you are now, ultimately at Kirton, but also some of the key steps along the way.

Seth: Yeah, it's been a long process for me, and honestly not something I entirely planned. In a way, things just happened by chance, or opportunities arose that I was able to take advantage of at the right time, along with some personal risk-taking.

Let me start with when I first got exposed to regulatory law, which was before law school. I worked at two different dietary supplement and cosmetic companies in Utah. One was called Neways and the other MonaVie. Neither one is in existence anymore, but I got really good exposure to how regulatory agencies look at health products and cosmetics, and how that affects product quality, labeling, advertising, and ultimately a company's ability to market those products.

At those companies, I was largely working with international attorneys in Europe, the Middle East, Russia, and parts of Asia, but mostly Europe, to help get products cleared, approved, or notified for marketing in those countries. I also helped the companies develop new products they could sell into those markets.

After a while, I decided it would be really cool to become an attorney myself. So I went down the usual path and went to law school. After working for a few years, I moved to New Hampshire and did my first year of law school at the University of New Hampshire in Concord, formerly Franklin Pierce Law School. I had a wonderful experience there.

While I was there, I also took advantage of a dual JD/MBA program. I was very interested in business in addition to law, so instead of going straight into my second year of law school, I focused on a concentrated one-year MBA. It wasn't the same as doing a two-year MBA at a

top school, but we studied many of the same case problems, and it was a great experience. I'd call it an MBA-light experience.

At the end of the day, though, I wanted to be an attorney, so I went back to law school. During that time, I was also on law review at the University of New Hampshire. But I decided that I wanted to transfer to George Washington University in Washington, D.C.

One reason was that I had been thinking hard about the kind of law I wanted to practice. I originally thought I wanted to do patent law and IP law, but because of my earlier exposure to regulatory law, FDA work was very appealing to me. Since the FDA is a federal agency located in D.C., and most FDA attorneys are still there, it felt like a natural place to end up.

Another reason I chose GW was that my father is also a GW grad. It was meaningful for me, not just to become a second-generation lawyer, but also a second-generation alum. In some ways it felt like walking in the same footsteps my dad had walked in D.C. a long time ago.

While I was there, I was fortunate to get a job as a law clerk during my second and third years of law school at Morgan Lewis in their FDA practice group. I learned from and was mentored by some really great attorneys there. Kathy Sanzo, who headed the FDA practice at Morgan Lewis at the time, was a great mentor to me—really kind and an excellent FDA attorney whom I still look up to. Another was Gary Yingling, who I'd call an OG FDA attorney. He had worked at the FDA for a long time and was very influential there. Those people were instrumental in mentoring me and encouraging me to go work at the FDA right out of law school.

After graduating, I was fortunate to do exactly that. I applied to the FDA, and back then it was actually really difficult to get a job either in a center or in the Office of Chief Counsel. There are different types of attorney positions at FDA. The main one is in the Office of Chief Counsel, which works under an arm of HHS. Those attorneys are typically assigned to a product center—Drugs, Devices, Biologics, Tobacco, or Foods—and they advise on litigation, enforcement, and other legal risks those centers have to deal with.

I didn't work in that group. I worked specifically for the Center for Devices and Radiological Health, or CDRH, which oversees medical devices, radiological products, and electronic products like lasers and TVs. I always thought it was fascinating that FDA regulates televisions, light bulbs, and laser beams.

Jonathan: I haven't eaten a laser beam in a long time.

Seth: Who knew? But because they're radiation-emitting products, there are standards. If people are importing lasers that don't meet those standards, they may need a waiver.

I worked in the Office of In Vitro Diagnostics and Radiological Health. So I focused on in vitro diagnostics—think of lab tests like flu tests, strep tests, glucose tests, STD tests, and tests for other diseases. I also worked on radiology products like X-rays, CAT scans, and ultrasound.

While I was at FDA, I had a great experience learning from the people there and from the leadership in the office and throughout CDRH. One thing that really impressed me was how kind and collegial people were. I never really came across anybody with an ego or with something to prove. Everyone was just a great colleague to work with.

The mission that really appealed to me at FDA was the balance between protecting public health and supporting innovation. On the one hand, FDA enforces regulations, looks for bad actors, and tries to stop unsafe products from reaching the market. Enforcing quality regulations is a big part of that. On the other hand, what many people don't realize is how much FDA works with industry to encourage innovation—to help develop new treatments, cures, medicines, and therapies. So there's a lot of negotiation and working with science and regulations to try to find good outcomes for patients and public health.

After about a year and a half at FDA, I was approached by recruiters to see whether I'd be interested in working in big law. As you know, D.C. is expensive, and raising a family there on a government salary is challenging. I honestly wish I could have stayed at FDA a little longer, because I got a lot of great experience there, but I took an opportunity with Alston & Bird.

That was also a great experience because I worked with more really smart FDA attorneys. One was Mark Shnison, a former associate commissioner for legislation at FDA. Another was Kathy Burgess, who I would say is one of the foremost GMP and drug quality experts in the world. She has a massive India practice and helps many API manufacturers there navigate FDA issues, since so many active pharmaceutical ingredients used in the U.S. are manufactured in India.

After about two years at Alston & Bird, I decided I wanted to get more specialized device experience and go back to my roots from FDA. Hogan Lovells has one of the best device practices anywhere, and I was fortunate to be hired there. I learned from people like John Kahn, Randy Prebula, John Smith, and Mike Heil. They were excellent mentors and helped me deepen my understanding of premarket submission pathways such as 510(k)s and PMAs, as well as quality issues, 483s, warning letters, and other FDA enforcement matters.

I was at Hogan Lovells for about a year and a half, during COVID, which was an especially dynamic time to be in life sciences and medical device law. There was so much investment in health-related products. We worked on a lot of EUAs—Emergency Use Authorizations—

for COVID tests, PPE, and other products, and spent a lot of time tracking FDA policies during the pandemic.

One thing I realized there—and this is not a critique of Hogan, because I really enjoyed it—was that the practice was structured in a way that made you very specialized. I wasn't looking to become so narrow that I couldn't work on other things too. So when Latham & Watkins reached out, I went there and stayed about four and a half years before joining Kirton.

At Latham, it felt like the best of both worlds. I had this close, specialized device training, and then I could step back and apply those skills more broadly across the life sciences industry. I was able to take those regulatory skills and use them in transactions—whether that was M&A, regulatory diligence, or spotting where risk areas were and where things could go south quickly for a company.

That included looking at compliance history, warning letters, 483s, and the realistic amount of work it would take to come into compliance. I also got more experience working with litigation teams when clients were challenged by FDA in ways we disagreed with—appealing decisions, strategically escalating issues within FDA, and potentially going to court when necessary, all while maintaining a long-term working relationship with the agency. Learning how to do that professionally was an important skill.

Now, how did I get from D.C. to Salt Lake City after FDA and these big firms?

Jonathan: Yeah. How and why? That's a good question.

Seth: How and why—and why Kirton McConkie? There are other large firms in Salt Lake that do have FDA practice groups in D.C. I'd be disingenuous if I didn't mention faith. As a member of The Church of Jesus Christ of Latter-day Saints, and having grown up in Utah, that mattered to me.

Even though I lived on the East Coast for 15 years, I always had family here, and I grew up with the culture here. One thing Kirton McConkie offered me was the opportunity to interact more directly with the Church as a client. That has made the work more meaningful for me personally. Not that my other clients' work wasn't meaningful—many of them are developing products that save lives, and that's an incredible thing to be part of—but being able to work for an organization that is part of my faith adds another layer of meaning.

That's really why I chose Kirton McConkie. They also offered me the opportunity to build an FDA practice group in Salt Lake, which, to my knowledge, really doesn't exist here in the same way. I'm sure there are other attorneys in Salt Lake who dabble in FDA work, but there isn't a dedicated practice that I'm aware of.

One of the big parts of coming here and establishing a new practice is building relationships with stakeholders in Salt Lake, in Utah, and in the Mountain West. That means connecting with industry groups like BioUtah and BioHive, finding the groups that support the clientele I'm looking for, and building those relationships so they can become referral sources for me over time.

Jonathan: Seth, you hinted at this earlier: the FDA is much more complex than people think at first glance. A lot of people hear "Food and Drug Administration" and think they understand it, but you taught me after we started working together that it's much broader than that. Tell us a little bit about what people generally get wrong about how the FDA works and what it really does.

Seth: That's so true. In a way, FDA becomes the scapegoat for a lot of unpopular policies or decisions that may not be politically in vogue at the moment.

People need to step back and think about what FDA really is. It's a government agency governed by statutes, regulations, policies, and science. Underlying all of that is the need to balance the statutory framework, the agency's mission, and the science behind the products it regulates.

FDA regulates drugs, medical devices, biologics—which are basically drugs made from proteins, vaccines, or other larger molecules—along with tissue products, human cell products, food, dietary supplements, and more. One common misconception involves dietary supplements. Because labels say the product has not been evaluated by FDA, people assume supplements aren't regulated at all. That's not true. FDA does not require the same kind of premarket review for supplements that it does for certain drugs and devices, but supplements and food are absolutely regulated by FDA. In fact, food is one of the most heavily regulated product categories there is.

Another thing I learned from working there is how professional the people at FDA are. They deal with a lot of anger from the public and from industry, because many FDA decisions are unpopular. But those decisions are based on science, or sometimes on the lack of science.

So what is FDA supposed to do? Approve a drug just because people hope it works? Ignore major quality problems? Allow a dietary supplement company to make aggressive disease claims that could mislead patients into taking a supplement instead of pursuing treatments that actually work? There's a lot of misunderstanding about what the agency is there to do. I do think FDA has done a better job in recent years of being more transparent about its goals and what it's trying to accomplish.

Jonathan: A lot of FDA guidance isn't black and white. Can you talk a little about that, and about how you help clients make decisions when they're operating in those gray areas?

Seth: That's a great question. Like every legal question, it depends on the facts. What is the company doing? What is the product? What exactly is going on?

There isn't a law or rule for every scenario, so a lot of the time you have to take a strategic, risk-based approach. How risk-tolerant is the company? How aggressive do they want to be in a gray area?

One example is HCT/Ps and stem cells, where FDA policy has shifted over time and it's often been unclear exactly what FDA's position or authority is. Take amniotic fluid. For years, there was an industry built around collecting, processing, and selling amniotic fluid for wound healing. There appears to be science supporting its use, and there seem to be few or no major safety issues. But then FDA took the position in guidance that amniotic fluid is not a cell or tissue under the applicable framework, but a discrete fluid, meaning it didn't fall under the HCT/P definition. That meant it had to be regulated as a biologic under a BLA, which costs millions of dollars to develop. Overnight, that essentially shut down an entire product space that may have been beneficial and low-risk.

Another example is laboratory-developed tests, or LDTs. For decades, FDA maintained that it had some jurisdiction over these tests—tests developed and run within a single laboratory, like many diagnostic tests you might get through a lab service. Those labs are already regulated under CLIA, but FDA also claimed authority over the tests themselves.

More recently, FDA finalized regulations aimed at bringing certain high-risk LDTs through premarket pathways like PMA or De Novo review. That got challenged in court, and the court ruled that these were really lab services, not test kits in the way FDA had argued. That surprised a lot of the industry. Under the current administration, the decision was not appealed, so now the question is: where exactly are we? I don't think anyone has fully articulated the answer. One district court ruling doesn't necessarily settle the issue forever. FDA could revisit it under another administration, in another venue, with different arguments. So these gray areas remain very real.

Jonathan: We hear a lot about companies getting hit with a 483 or a warning letter, as you mentioned. What usually determines whether a company can bounce back quickly or whether it just makes things worse with the FDA?

Seth: That's a great question. Most companies that manufacture, sell, or distribute FDA-regulated products have to register with FDA. Once they do, they go into FDA's inspection system, and eventually the agency is going to inspect them.

For viewers, a 483 is simply FDA Form 483. It's the form inspectors use to document inspectional observations. When FDA inspects a facility, they compare what they see to the applicable quality system or good manufacturing practice regulations. They look at

whether required procedures are in place, whether complaints are being investigated, whether the company understands root causes, and whether the manufacturing process is actually under control.

If it isn't, FDA will cite the company for it, and rightly so. If I'm taking a drug, I want to know it's made consistently and safely every single time. If I'm on an operating table, I don't want the device my doctor is using to fail because of bad manufacturing controls. Quality procedures matter because they ensure products are made in a consistent and controlled way.

Where companies get into real trouble is, first, they're not honest with themselves. Second, they try to fix things on a shoestring budget. I understand not every company has the same access to capital, but quality is the one thing that can break your company or put you out of business faster than anything else.

If you're a foreign manufacturer, FDA can put you on import alert and stop your products from coming into the United States. I've seen that happen. If you manufacture domestically, FDA can issue a press release that puts hospitals, doctors, or consumers on notice that your products may not be safe. That can devastate a business.

So what makes the difference? Being honest with yourself. Getting outside quality audits and experienced consultants if needed. Taking advice from people who really know the space. And being transparent with FDA. Don't go radio silent. If you stop communicating with the agency, that raises red flags because it suggests you don't have control of the situation.

Keeping communication open shows FDA that you're making progress and committed to fixing the issues. It buys time before the next inspection and helps build credibility with the agency. Many large, sophisticated companies have had 483s, and many have received warning letters. The difference is how they respond. The successful ones are transparent, proactive, and serious about remediation. They don't hide things.

And absolutely, never lie to FDA. Never fabricate documents. That is the fastest way to turn a regulatory problem into a criminal one.

Jonathan: Well, Seth, we probably have time for just one more question, and this is one I didn't prep you for. If you were not an attorney today, and money were no object, what would you be doing with your time?

Seth: That's a great question. Honestly, if I weren't an attorney and money were no object, but I were in the same situation I am now, I think I would still become an attorney.

Jonathan: Go back to law school?

Seth: I would. I really enjoy what I do, Jonathan. I know our profession can be hard and that mental health can be a real challenge for a lot of lawyers, but I think I found an area of law that I genuinely enjoy, and that makes it interesting and rewarding for me.

That said, I would spend a lot of time with my wife and kids. This is a demanding profession, and it takes us away from home. I'd probably get a homestead—maybe 10 to 20 acres—and do a fun homesteading project where I could live more off the land and do some farming. Hard work, but rewarding work. There's something really satisfying about it.

Coming back to Utah, we bought a small property with a little orchard already on it. It also had grapevines, so now I'm learning what it means to have a vineyard and what I'm supposed to do with these grapes. I'll be honest—the first year was not great. I didn't do a good job bottling them, and they all went bad. Which maybe proves I should stick to being a quality attorney who knows what not to do.

But that's been a lot of fun, and mostly I'd just want to spend more time with my kids, learn what they're interested in, and encourage them in whatever they want to do.

Jonathan: Great. Seth, thanks for your time and your expertise. It's been fun to hear your perspective and your background, and I look forward to catching up with you in a future episode on some current FDA developments and what they mean for the broader manufacturing environment, especially for international companies trying to get a foothold here in the U.S.

Seth: Okay. Hey, Jonathan, great—and let's do it, because I do have some thoughts on that. I think we could take a deeper dive into specific issues international companies face and the challenges they have.

Jonathan: Great. Thanks, Seth. Talk to you next time.