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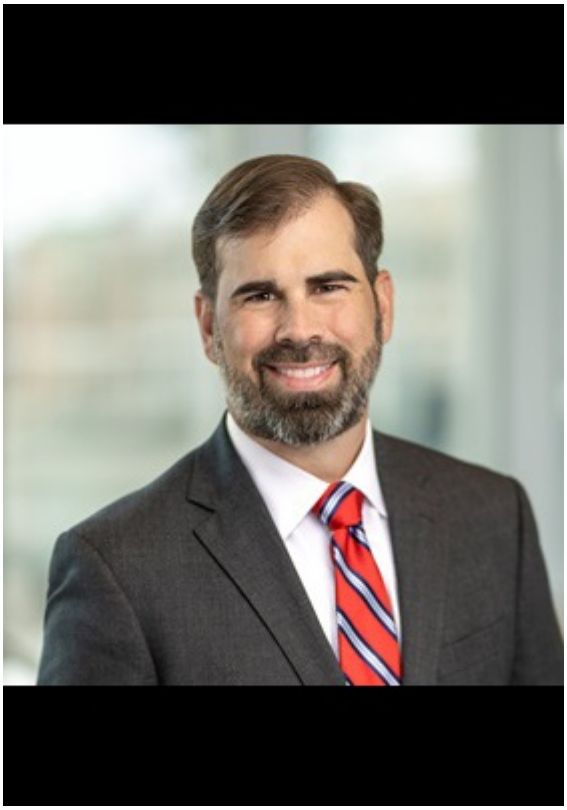
‘One Little Cog’: Former J&J Attorney Discusses Return To Private Practice

by Elizabeth Orr

In this wide-ranging interview, lawyer Philip Desjardins talks about regulatory issues from AI to LDTs – as well as the passion for patient health that keeps him in the medtech arena.

Attorney Philip Desjardins has worked on all sides of the medical technology industry. He launched his career at the US Food and Drug Administration, where he served as the device center’s associate director for policy, before moving into private practice. After that first stint at Arnold & Porter, he spent eight years at Johnson & Johnson as the vice president of global regulatory affairs. He’s now back as a partner in the life sciences and healthcare regulatory practice at Arnold & Porter.



Arnold & Porter

Medtech Insight recently caught up with Philip to discuss his top current priorities, where he thinks the device industry is headed, and his thoughts on a range of hot topics.

The interview has been edited lightly for clarity.

Q What are your priorities now that you're coming back to Arnold & Palmer and private practice?

A I think it's twofold. First, in the short term, it's reintroducing myself to the firm's partners and associates, getting people to remember who I am – connecting and establishing those old relationships and building new relationships.

Then on the client-facing side, it's developing those relationships. There are many clients that I worked with closely eight years ago that are still clients, and I want to reintroduce myself to them. But more important is building those existing and new relationships, establishing myself as a trusted partner, someone they can come to when issues are going on, and that we build those long-term relationships.

Q **Your background is in government work and private practice. How much of a transition was it for you to go to a device manufacturer?**

A I wouldn't say it was a huge transition, meaning it wasn't novel issues. But it was really eye-opening in terms of the complexities of an organization the size of Johnson & Johnson.

It's a little bit different than just going from private practice to a device manufacturer because the device industry runs the full spectrum, from companies with two employees to a J&J or Medtronic with hundreds of thousands of employees across the globe. But I would say, the version of the industry that I saw at J&J in their medtech business ... the intricacies that an organization like that is facing on a day-to-day basis is something I don't think I fully appreciated. I knew it was out there, but you get a different perspective from throwing yourself into the weeds and recognizing the amount of issues that they're facing when making any particular decision. How will this [decision] impact, first and foremost, patients? How will it impact regulatory status? How will it impact stakeholders and stockholders? The complexity of decision-making was one thing that I really learned during my time at Johnson and Johnson.

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Q **What keeps you interested in the device industry?**

A There's two things. The easy answer is the diversity of products that you see. You can be working on a relatively low-complexity product one day and then talking about a completely different type of product, different anatomy, different disease state, with the highest level of complexity, the next day. And I think that's the answer on a day-to-day basis.

But for me, I'm really grounded in why I'm doing this in the first place. I really do feel like I'm connected to patient health and to public health. I'm one little cog in the wheel of the health care ecosystem. The work that I do that enables new technologies to reach patients means I'm playing a role in patient access and patient health.

There was a draft guidance document that I was working out when I was at FDA about 15 years ago. One of my roles at the agency was to write regulations and guidance documents, but also to go through all the comments that come back from the public. Ninety-nine percent of those comments are going to be from trade associations, manufacturers or other impacted financial stakeholders. You can kind of anticipate what the feedback is going to be. You look for those tweaks that can make a policy better and more beneficial for all stakeholders. But every once in a while, you'll get a comment coming back in from a patient or a patient group. And there's one that jumped out at me.

The guidance document was talking about a very specific type of technology, and one

of the comments that came back was from a patient that was involved in a clinical trial for one of these types of products. They had to jump through hoops to get this technology. And their comment basically said, 'My life and my health benefited from this product, and I want future patients to also have access.'

The reason I bring it up is because for me, it was a real direct connection to the work that I was doing at the agency, the work that I still do in private practice, and how we enable access to those innovative technologies. There are technologies that are being studied today that I want to make sure that I have access to and that my kids have access to in the future. And if I can speed up the innovation timeline and get that product on the market six months faster, that's a handful of additional patients who are going to have access to it. That's what drives me and motivates me in this industry.

In medtech specifically, we're all going to need this type of technology at some point, and the more confidence that we have in the ecosystem, in the oversight and the safety and efficacy of these products, I think we all feel better.

Q **What are some of the bigger changes you've seen in the device industry and device regulation over the course of your career?**

A When I first joined FDA right out of law school, I thought of myself as working in the medical device space. Whenever people asked me what that meant, I would talk about the range of products from tongue depressors to artificial hearts and knee implants and things. But they were physically tangible products that were being used to make patients healthier.

But if asked right now what my industry focus is, I don't frame it as medical devices, I frame it as medical technology. That incorporates all the things that I used to talk about, but the technology aspect has really changed a lot since I entered the practice.

I was at FDA when the iPhone first launched. I remember having conversations with our digital health team around, 'All right, what does this mean for us?' Somebody on

my team had one of the first iPhones and they had to explain the app store to me.

There were some early versions of products that had things that probably right now would be considered medical devices. One of the first ones was a very basic heartbeat monitor. That itself didn't give me immediate concerns as a regulator, but we started to see where this might be going. And that was 2007-2008.

Now to look at how embedded technology is into the medical device and medical technology world – if I had a time machine to bring myself from 2008 to where we are now, I don't think I could have comprehended how integral the software piece would be in so many of the products that we're dealing with.

Q **Are we starting the same type of surge with AI?**

A I don't think of AI as a brand-new frontier, but I think it's a continuation. Further complexities are being added to how we're thinking about software. There's tremendous opportunities that AI can introduce, but it still makes basic errors.

Appropriate oversight in that space is going to be so critical because you can already see the potential horror stories of how this could play out if we move too quickly without the right level of oversight. That’s the new frontier for the medtech industry. I don't think we can even comprehend how integrated this will become in the future. I think that's what a lot of the medtech industry is looking at and expect to spend a lot of time on over the next couple of years.

Q **How do you think the shift towards decentralized clinical trials is affecting device manufacturers?**

A Across all medical products, this is, in some ways, an absolutely necessary evolution of the regulatory landscape. COVID really shined a light on the need for this level of regulatory flexibility. This idea that all trials would be centralized largely through hospitals and health care settings – we saw that there were products that were necessary for the pandemic that could only be studied out in a real-world

environment.

There's two ways that I think this is going to be beneficial for the medical device and medtech industry. First is better evidence generation. Fundamentally, the baseline assumption with decentralized clinical trials is that the regulations themselves aren't really changing: The FDA and all stakeholders still have the same expectations about the rigor of trials, the accuracy of data and the protection of information, but it's allowing flexibility on where you collect this information.

It's going to open up new populations to be better understood. Across industry, there's a recognition that we need to study all medical products on a more diverse set of stakeholders, of patients, of subjects. Historically, if you weren't located within 30 or 40 miles of a large academic medical institution, you probably didn't have access to these types of clinical trials. By expanding the network that we can reach out to for subjects and patients, that will add more diversity and a better foundation for understanding how these products will interact on patients.

Number two, from an innovation standpoint, I think decentralized trials could significantly decrease the cost of evidence generation. Historically, one of the big problems with evidence generation has been patient follow-up. When somebody comes in and they're having surgery, it's very easy to get that that day-one data, that week-four data, even that week-20 data. But if you're looking for a 10-year study, how do you track these patients geographically throughout the course of their lives?

If we start a remote study where we're tracking them by not just how they show up to our office, but their email addresses, their telehealth options, I think there's a lot more ability to track these patients and the cost of follow-up goes down significantly. Particularly for the medtech industry, as those costs drop on clinical and evidence generation, it opens up greater opportunities to study these products in more depth and to invest in evidence generation and clinical trials for maybe those small or mid-sized companies that historically found it cost-prohibitive from an evidence perspective.

Q **The other big topic right now is, of course, the FDA's proposed rule on lab-developed tests. What are your high-level thoughts on that?**

A I was part of the [Medical Device User Fees] negotiating committee, representing both Johnson & Johnson and Advamed, and LDT regulation was a very, very important piece that we wanted to focus on. We haven't seen [Congress pass] legislation since the FDA wrote the first regulatory framework in 2014, [but] I think everyone agrees that a legislative solution would probably be an easier fix. It doesn't mean it wouldn't be complex or controversial. But a legislative solution would give more confidence for all stakeholders that FDA has the right as the legislative authority to act in this particular space.

This is a controversial solution. I don't think there's any single set of stakeholders that think this is the perfect solution. I think everyone's thinking, 'All right, we've got to figure out a solution here,' and it looks like FDA is taking their best shot on it. The biggest takeaway for me is that I believe FDA is going to move quickly in this space. I think their goal is to get this finalized as quickly as possible to get ahead of any election pause. Anytime we go into an election cycle, we can't even get draft regulations out. And if there's an administration change, it might be back to the drawing board.

From a timing perspective, I absolutely think FDA is acting with a sense of urgency. The FDA's first draft guidance document was released after I left CDRH, but there had already been a lot of discussions about it. And it's taken us nine years to get from draft guidance document to proposed rule. My guess would be that going from proposed rule to final rule is going to happen in nine to 12 months.

Q **What else are you watching for from the FDA in 2024?**

A We've already touched on this, but not only is industry looking at AI, but the FDA continues to keep an eye on it. The FDA's proposed list of guidance documents for 2024 has both final guidance documents and some draft guidance documents on AI. This is going to be an area FDA, and CDRH in particular, continue to monitor closely.

> And as we see more technology integrate AI, I think FDA will have a better sense of how they want to apply their regulatory oversight, so I wouldn't be surprised if we see both more guidance documents on this as well as more comments and FDA speaking at the forums, at the summits where these technologies are being discussed. I will be keeping a close eye on what FDA says in this space.
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> I would also be paying attention to how FDA is going to continue to rely on real-world evidence and other flexible methods that industry can use to generate evidence to support the regulatory process and get a better understanding of how [products] are being used. And on-label promotion is absolutely something every manufacturer should be thinking about. The more they know about how physicians are prescribing their devices and how they're utilizing them, the more the manufacturers and FDA can learn about what's happening in the real world.
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> The third topic that I was interested to see [on the FDA's list of priorities] was some additional looks at the third-party review system. Third-party review has been around for, I think, close to 20 years. And it's gone through ebbs and flows of how much industry has relied upon it. But for most traditional medical devices, I don't think it is a well-utilized program. The concept is, rather than having FDA do the first review, go through a trusted third-party reviewer who has been accredited by FDA who will provide that first level of review. It doesn't mean FDA doesn't put eyes on it or that FDA isn't clearing the product. But it does a lot of heavy lifting to make sure the fundamental questions of safety, efficacy, and substantial equivalence have been looked at.
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> I think FDA has looked at it as a potential release valve, when huge volumes or boluses of information are coming into the agency; they've only got so many resources to look at products. And when they think about new programs – and I'm immediately thinking about LDTs – when they've got huge boluses of products that are coming through the agency, they're not going to be funded to bring on a thousand new reviewers. Even if they had the funding, I don't think they're going to have the resources just to onboard that level of resource. So my thinking is if they invest in a

third-party review system, they can leverage sophisticated organizations that already understand the FDA regulatory process.

Again, it doesn't mean FDA is not going to be actively involved. But if they anticipate hundreds or thousands of applications around the transition from the old LDT rubric to the new diagnostic expectations, the thicrd-party review program might be a good way to keep up with that demand.

Q **And finally, what advice about approaching the FDA would you give a startup company trying to get a device or technology to market?**

A The first thing would be that having a strong regulatory strategy early on is so critical. If you know what that strategy is, you can go into FDA, whether it's tomorrow or three years from now, and know what that process is going to look like. If people are looking to invest in you, they're going to want to know what your regulatory process will look like. Not just what you think it might look like through the most optimistic lens, but something that's been pressure-tested and reviewed by other people to make sure it's realistic – for example, that your product really will be eligible for de novo as opposed to PMA, or that you'll have enough evidence to support your indications.

A lot of companies, particularly pre-revenue, early-stage companies, are very optimistic in terms of how they look at regulatory timelines and regulatory expectations. One of the things that I think everybody knows is you are going to have to go to FDA before you start selling that product. My recommendation is getting as much information as early on as possible as to what that process is going to look like. There may be very, very minor tweaks to a product that might kick it from a class II to a class III product and a much higher level of regulatory oversight. Those are the types of things that are important to know, early on, hopefully on day one, to make sure that you're driving your business in the right direction.