The Legalization of Off-Label Promotion: Vascular Solutions Beat the FDA and What Their Victory Means for Medtech

For as long as I can remember, at every company meeting I've ever been to, the topic of off-label promotion is always covered. Whether it was new-hire orientation, a national sales meeting, or some other large commercial event, the dissemination of off-label information was always presented as not only a fireable offense, but something that could get you thrown in jail. C.R. Bard, Boston Scientific, Covidien, Medtronic. Everyone considers this to be extremely important. And rightfully so.

BUT, doctors use medical devices off-label all the time. If you go to any societal conference, physicians present off-label uses for medical devices on a regular basis. In fact, talk to any KOL, and they think it's almost humorous that medical device companies take off-label promotion so seriously.

Because I've spent the majority of my medical device career in a sales or marketing capacity, I've always found this to be an interesting dynamic. Our physician customers discuss **and** use our products off-label all the time. But we can't say anything? If a doctor asks a question about an off-label use, mum is the word. "Sorry Dr. Smith. I can't answer that question. No information. Nada. Zilch."

However, the times are certainly changing. In a recent landmark criminal case against Vascular Solutions, the actual instructions to the jury included this statement, "It is not a crime for a device company or its representative to give doctors wholly truthful and non-misleading information about the unapproved use of a device." Wow! **That's the first time something like that has ever been uttered by the government!**

In this interview with Mark Duval, President of Duval & Associates, P.A., we learn about other recent First Amendment cases and what the outcomes mean for medtech companies moving forward. Here are some of the topics and questions we cover:

- The 3 key takeways from the recent criminal case against Vascular Solutions and why everyone in medtech should pay attention.
- Why the government's focus on speech vs. conduct is so important.
- The government's recognition that off-label promotion is legal as long as it's "wholly truthful and not misleading".
- Mark's advice for medtech leaders in light of the government's losses in so many First Amendment cases.

SCOTT: Let's dive in and talk all things off-label promotion and where we stand today with the FDA. We'll start with one of your recent Client Alert newsletters, which I highly recommend anyone subscribe to, if they're interested in keeping up-to-date with some of this stuff.

In one of those newsletters, you loosely compared Howard Root, who's the CEO of Vascular Solutions, to Louie Zamperini, who, as many know, is the main character for the movie *Unbroken*. I think in that same piece, you quoted Howard Root with this statement, "This is the most decisive victory since Operation Desert Storm, at only slightly greater expense," which I thought was interesting.

With that said, let's dig into this recent Vascular Solutions case. For those that aren't aware of it, can you provide a high-level overview first, and then we'll dig into some of the key takeaways?

MARK: The Vascular Solutions case involved the Vari-Lase product. If I were to summarize, basically the Bright Tip Vari-Lase produce was indicated for the treatment of varicose veins and varicosities that are associated with the great saphenous vein, and for the treatment of incompetence and reflux of superficial veins in the lower extremities. The government basically had said that they were promoting outside the cleared indication.

As you know, when you get a general intended use statement cleared from the agency, it's like an umbrella, if you will. Under that umbrella, there's a collection or a bundle of specific indications for use to which the product could be put. Sometimes you're debating with the agency, is something an indication that falls under the protective reach of the umbrella and is protected from the elements and is deemed on-label? Or is it outside the protective reach of the umbrella and is deemed off-label? That's often the dispute you're getting into.

Let me give you an example. If you have devices that are cleared for ablating soft tissue, and if you say that they're used to ablate cardiac tissue, that's still soft tissue, but is that on- or off-label in the FDA's mind? If you say it's to treat atrial fibrillation, then is that on- or off-label? In that case, the FDA would definitely say the tool for ablation has definitely become the treatment for a disease, state, or condition and is off-label. That's the conundrum we're often getting in with the agency. When you get a cleared intended use statement, it seems like you're cleared for absolutely everything, but you can promote it for nothing.

So when we're working with management teams, that's often the dilemma with which we're faced, and I help them navigate through that, promotionally speaking. What can we say about our device and what can't we say?

For Vascular Solutions, that's precisely what they got into. They had a short kit, a shorter version of the Vari-Lase procedure kit to be used in treating short vein segments, and then some representatives would talk about using it in the perforator, which the FDA viewed as a shorter segment that presented more problems than just a regular varicose vein, and required another clearance. That was sort of the core of the dispute. They basically went to court over that, and the company originally paid a $520,000 civil settlement to buy its way out of it and seek peace with the government, but the government kept pursuing it. They decided to make it a criminal matter and indict Howard Root as well as the company. That's the genesis of the case.

SCOTT: So in summary, Vascular Solutions had this product that was indicated for the ablation of varicose veins or soft tissue, and yet it was oftentimes being used for shorter segments, and that fell into that gray area you mentioned earlier. Vascular Solutions then proceeded to settle a civil case with the government, but the government then took a step further, and basically decided to pursue criminal action against Howard Root, who's the CEO, as well as Vascular Solutions. Do I have that right?

MARK: Yeah, that's exactly right. I remember a year before the case was actually going to trial, Howard and his public relations expert, Jon Austin, asked me if I would be an outside, unpaid, independent spokesperson to whom they could direct media inquiries to talk about this stuff, and I acquiesced to that. I've never had a financial relationship – still don't – with Howard Root. We've both actually become friends through all of this. I'd been a social acquaintance with him at different industry meetings, etc.

So I got funneled everything in real time so that I could respond to the Wall Street Journal, the Minneapolis Star Tribune, or whoever might have questions about the case. It was just interesting. I remember saying this a year before the case, "Howard, you don't have to concede that this is off-label. Under FDA's General versus Specific Use Guidance document, I feel very firmly, very firmly, that this is an on-label use if you interpret that guidance properly."

In fact, that's what they did in defense. And the crazy thing about the defense was they rested after the prosecution's case. Can you imagine that? The defense, who had 20 witnesses lined up, actually rested after the prosecution rested their case, which just made the jaw of the judge drop as well as the prosecuting attorneys. They presented no cases because they felt they had done a good enough job on cross-examination. Case in point, they took Dr. Neil Ogden, who is a branch chief with whom I work a lot and he's a very highly respected, honest guy. The defense attorneys basically led him through a path of cross-examination that got him to admit

that the use in perforators could be considered on-label. Well, that destroyed the FDA's case right there.

That's the kind of stuff that goes on in these cases. But it was a fascinating case to follow. They basically took him to the General versus Specific Use guidance, and also a modifications guidance, that suggested that in interpreting either of those, one could conclude through FDA's own guidance documents, that this use in perforators was on-label. The King & Spalding lawyers as well as the Fredrikson & Byron lawyers, all did a masterful job in that case

SCOTT: Got it. That's very interesting. Just to clarify one point that you mentioned, the prosecution, which is the government in this situation. They went through their entire list of witnesses. And the defense had their series of witnesses to call as well, but they didn't have to bring any to the stand. They just solely relied on their cross-examination of the prosecution's witnesses, and they won decisively. That's pretty amazing.

MARK: Yeah, and it's gutsy. It's risky to do that, because wouldn't you be tempted to say, "Gee, I don't know. Have we done it? Have we done a good enough job? Should we put on our witnesses? We're all prepared and ready to do that." But they said, "No, it might be better to leave it alone and just go with what's been presented," and boy, they called it right. And they got a unanimous 12 to 0 verdict. So it's pretty spectacular when you think about it. But it also shows the great deficiency and arrogance of the government's position, to be so blindsided that the defense attorneys didn't even have to put on a defense in order to win the case.

SCOTT: Certainly an interesting case on a lot of different fronts, but in that Client Alert newsletter that I mentioned earlier, you laid out three different key takeaways, or three different major implications for medtech companies, and the first one was the government's focus on speech versus conduct. Can you outline that key point? Then we'll get to the other two here in a second.

MARK: You have to recognize that there are these cases that have gone before the Howard Root and Vascular Solutions case, and that'd be the IMS v. Sorrell case and the Caronia case and Amarin and Viscera cases. So this was in a lineage of cases and losses for the federal government. The government had basically been trying to prosecute speech in all of these cases , and the judiciary had basically said, "Look, if you're admitting, government, that it's truthful and not misleading speech, that cannot be the basis for a misbranding and adulteration case." So they've disabused the government of that idea that they can use speech.

So what the government has fancifully turned to is something along the lines of, “Well, we’re not going to prosecute speech anymore, but the conduct underlying that speech.” So in the case of Howard Root and Vascular Solutions, these are the kinds of conduct that they tried to prosecute. They tried to prosecute six different things:

1. The defendant’s decision to launch a special kit designed specifically for perforator veins, which was in response to a competitor’s threat.
2. Their manufacture of that kit with perforator-specific modifications.
3. Their application to the FDA for clearance in and of itself. By the way, Vascular Solutions sought clearance for the use in the perforator veins and didn’t get it because the FDA didn’t like their clinical trial. I didn’t even think, by the way, the company needed to submit an additional 510(k) to get that clearance, and indeed, the courts agreed.
4. Their investment in a clinical trial for the purpose of gaining that clearance.
5. Their decision to launch the product without clearance while adding new deficient directions for perforator use to the labeling.
6. Finally, what the government U.S. attorneys actually said, their effort is to defraud the United States by concealing and lying about their perforator sales activity.

They said these points of conduct are what they were really prosecuting, not the speech.

Well, in essence, what Judge Lamberth has said in the past is that in the regulation of marketing and promotional activities, you can only regulate conduct to the extent that moving one’s lips is conduct, or to the extent that affixing a stamp and distributing information through the mail is conduct. That’s a very important basis for their prosecution.

SCOTT: Mark, just to be clear, you laid out six different points of conduct that the prosecution addressed in the trial, and you’re saying because Vascular Solutions really didn’t ever promote or market based on some of these things, their actions weren’t deemed as “conduct”. Am I understanding that correctly?

MARK: None of the conduct becomes actionable until there’s communication to the outside world. And once there’s communication to the outside world, that’s effectuated through speech, it’s not prosecutable as long as the speech truthful and not misleading. So if you follow that syllogism, that’s how the judge basically said you can’t prosecute this conduct. You’re trying to get at it indirectly what I’ve not allowed you to do directly. Conduct will eventually be speech.

SCOTT: That makes sense. The second point I think you called out was the recognition of off-label promotion within the actual jury instructions in this particular case. Can you provide us with some background on that point as well?

MARK: This really rocked my world, as well as a lot of insiders who are counseling companies like I am. Just before the case, there had been some motions to dismiss. King & Spalding did a brilliant job of forcing the government's hand at declaring what their position was. But at the very end, because they had hammered them that you can't use truthful and not misleading speech as a basis for prosecution, they ended up agreeing to a jury instruction that blew me away. We've always heard about off-label dissemination, but we've never heard about a theory or a concept of off-label promotion.

So if you'll permit me, I'm just going to read – it's very short – I'm going to read this jury instruction, because it's going to blow you away, too, when you appreciate it.

SCOTT: Sure. These were the instructions to the actual jury in the trial, correct?

MARK: This is what was acquiesced to by the prosecution, the U.S. government. They uttered these words for the first time ever: "Doctors may use medical devices that have been approved or cleared for one use or for a different use that has not been cleared or approved by the FDA." We all know that. It goes on to say, "This is often for an unapproved or off-label use. This is not illegal."

Now listen to this: "It is also not a crime for a device company or its representative to give doctors wholly truthful and non-misleading information about the unapproved use of a device." Wow. I can't believe that. "If you find that Vascular Solutions' promotional speech to doctors was wholly truthful and not misleading, then you must find the defendant not guilty of the misbranding offense." That rocked my world, and a lot of experts – in fact, I know an article came out that day in the trade press about the fact that the government just chronicled their position that off-label promotions could be lawful.

So it stands for that proposition today. That's the first time it's ever been uttered by the government, and now it's in the context of a jury instruction, and it's a really important concept that they just uttered.

SCOTT: I can definitely see the importance of that particular point. So in summary, the first point was the government's focus on speech versus conduct. The second point that you just

covered was the way the instructions were addressed to the jury in terms of a medical device company's ability to promote a message that's wholly truthful.

The third point was specific to the FDA's interpretation of general versus specific use. Can you tell us a little bit more about that third point?

MARK: Yeah, and it goes back to the point I made about when they cross-examined Neil Ogden, who was the branch chief, and they got him to basically admit that it was an on-label use. The defense council literally took him through the package insert. They talked about the indications for use statement. They said, "It refers to the ablation of soft tissue?" and his response was, "Yes." "And you'd agree that the veins are soft tissue, correct?" Again, he replied ,"Yes." "The great saphenous vein is made up of soft tissue?" He answered, "Yes, correct." "The short saphenous vein is made up of soft tissue?" He replied, "Correct." "The perforator veins are made up of soft tissue?" And on this, Neil answered, "Correct." "Tributary veins are made up of soft tissue?" He again, replied "Correct."

The second part of the clearance refers to varicose veins, and they took him down the path that yes, perforator veins could be varicose veins. They basically entrapped the branch chief into indirectly admitting that this could be an on-label use. And they also did it with the outside clinician that the government put on as a witness. So, through a number of witnesses, they essentially established that this use certainly could be on-label.

And they challenged FDA's parsing of its General versus Specific Use Guidance document, which like I said often allows for the clearance of a device that can be arguably used anywhere, but can be promoted nowhere. It was pretty fun to watch how they masterfully cross-examined the government's witnesses.

SCOTT: Those are three really important takeaways. Towards the end of this conversation, we'll get to summarize what this all means for medical device companies and how your firm will be using this particular case moving forward.

But just to wrap up and put a bow on this Vascular Solutions story, this was no small task for Vascular Solutions nor Howard Root. It wasn't just the hefty cost, it was also the personal implications to Howard Root himself. I mean, this could've potentially meant jail time as well. But he chose to dig his heels in and pursue this. So I'd like to just get your take on that, and maybe just summarize the case in general with that in mind.

MARK: First, you have to start from the macro view that the government has this expectation that companies are simply going to roll over when they encounter allegations like this - criminal allegations and indictments. Most companies do that for purposes of preserving the stock price, or at least recouping the stock price, sort of getting matters behind them. So the system and the power of the government is completely designed and built through the actual filing of the case. Most companies will necessarily fold, they'll agree to a consent decree, and they'll pay a big fine, and maybe some people will be debarred. The CEO would be fired in this case, and maybe some employees.

But this board of directors – John Irvine is the chairman – and this CEO were incredibly brave. One of the things I know that Howard actually has said is something like, "We could've settled for some money, we could've settled for some limited penalties – maybe plead to a misdemeanor or whatever." But the government was going to continue to pursue and try to debar four of their employees. And they just felt as a company, they needed to stand behind their people, and that they couldn't let the government run amuck. They finally decided to take a principled stand.

And I'll tell you – I told Howard, all the way through this case, I would write him emails, and I'd just say, "I'm praying for you and your wife. This has got to be difficult," what they were individually going through. Because you can't imagine the specter of actually losing and going to jail. But I also told him in the same email, "I believe in your case. You guys are going to win. I believe in the jury." And the jury made him proud. But boy, a lot of risks. Yeah, he really faced a lot of personal exposure, let's face it. They stood up, fought, and they won.

And now, he's gained such notoriety. He's getting invited to speak all over the place, and I'm getting invited to speak with him all over the place. It's been fun. We just were on ReasonTV, which is an online content provider that did a documentary on this. So it's been fun.

SCOTT: On that note, I'm glad you mentioned that documentary, because I would encourage everyone that's listening, to go check that out. I'm sure it's pretty easy to find. Just do a Google search for "ReasonTV Vascular Solutions documentary" or something like that. It's a great piece, and I would definitely recommend everyone watch that.

I remember hearing you talk about this case for the first time at a local meeting here in Minneapolis, and you could see that you were pretty passionate about it. But I personally didn't understand – I had heard about it in the news, but really didn't understand the nuances of the case and what it meant. But just to try to fully grasp the stance that Vascular Solutions took, Howard Root took, it's just cool. If you're in the medtech space, it's just cool to see a

company, especially a public company, take a principled stance. And it's cool to see that they actually ended up winning in such a decisive fashion.

MARK: You know, Scott, it's kind of interesting, because this company took a reactive stance and fought and defended itself, but there are other companies recently, particular in the pharmaceutical arena – and I'm speaking specifically of Amarin and Viscera – who preemptively filed suit against the government to establish their position before it ever really got rolling into a potential for both civil and criminal penalties. You give those companies a lot of credit for going out there and staking out their position – and winning.

So again, there's a high level of inertia going against the government. They keep losing these First Amendment cases.

You probably don't know this, but I want to alert you to this: that just yesterday, the government, the Health Committee on Energy and Commerce has just sent a letter to the Secretary of HHS, Sylvia Burwell asking them why they can't get their act together on policy positions on this off-label promotion issue. They chronicle in the letter the Caronia case, and they talked about the Howard Root/Vascular Solutions case, and about the IMS case.

At the end of it, if you'll permit me – it's very short; I'll read it.

"The fact that such rhetorical ire is spoken on such common sense change is somewhat surprising, particularly given that the provision in question specifically requires 'a conspicuous and prominent statement describing any material differences between the information to be provided and the approved labeling.' It did, however, confirm our suspicions that HHS has become reflexively opposed to enabling FDA to make even minor policy changes in this space, despite their legal footing continuing to crumble. It also shows why it is becoming increasingly apparent that Congress must act."

It says the committee is basically going to start considering this, and they've asked that they contact John Stone from the committee staff to schedule a briefing so that they can talk to the agency and the secretary about what the heck is going on here. You keep promising new guidance on this and yet you keep prosecuting the industry for off-label promotions.

And that was signed by Fred Upton, who's the chairman of that committee, and Joseph Pitts, who's chairman of the subcommittee on Health, as well as the Honorable Frank Pallone, who's a ranking member. So that's brand new news, and we're going to see where that takes us.

They're basically inviting them to come talk to them, because their suggestion is, if you can't get your act together, we're going to do it for you.

SCOTT: That's certainly interesting news, especially considering it just came out. If you keep up with medtech at all, it does seem like we've gotten to a point where there's some momentum here for some significant change. I'm not sure if that's a fair way to say it. That's maybe my own opinion. But it definitely seems like that.

I don't think we'll have time to get into some of these other cases that you had mentioned, like Sorrell v. IMS, and I think you mentioned Caronia. Maybe just real quickly, you mentioned Amarin was a recent one, so can you maybe briefly cover some key points from the Amarin case? And then we'll wrap up this conversation for what it means for medtech companies moving forward.

MARK: This is a case where the company preemptively filed suit against the agency. It was basically a prescription version of a fish oil pill which is typically sold as a dietary supplement, and comes with a disclaimer that you would see on dietary supplements. They simply wanted to use that same disclaimer and make mention of their clinical trial and some of the other clinical trial data that was in the literature to talk about the use of EPA and DHA omega-3 fatty acids that are in fish oil pills. And the agency wouldn't allow it, which was ridiculous. They said the regulatory regime for dietary supplements is different than prescription drugs.

But the point that the company was making in defense is, "Look, the truth is the truth. Either this disclaimer provided for dietary supplements is equally applicable to the prescription version or not, and we should be able to use it in our promotions as well." Well, the government lost big time. Basically, the judge allowed the company, Amarin, to use that disclaimer and talk about some of the other data that's available. It's funny, because Amarin wanted a certain disclaimer that they proposed to the judge, then the FDA countered with another disclaimer that they preferred, and then the judge fashioned his own disclaimer and said: "This is what you're going to use."

But he said also that if other truthful and not misleading information comes to the fore, then we would pursue further refinements to this disclaimer. Essentially, the judge is allowing the information to be in the promotion, but with certain disclosures and disclaimers that would render it wholly truthful and not misleading – which was the standard the judge also had in the Howard Root/Vascular Solutions case.

SCOTT: I know in your Client Alert newsletter, you went through those different scenarios and the final copy or messaging that the judge allowed. It was, or I think it was, significantly different than what the prosecution or the government initially wanted. I think it was a lot more reasonable, to be honest. And easier to understand, from the perspective of an average patient.

MARK: Yeah, they did a good job. By the way, if anybody out there wants to look at our Client Alerts on any or all of these topics, just go to our website at duvalfdalaw.com.

SCOTT: Like I said before, we don't have a lot more time to really go into the details of the Sorrell v. IMS case or the Caronia case, but when you think about those cases and setting the stage for the Vascular Solutions/Howard Root case, when your firm works with medical device companies, what's your advice moving forward?

MARK: What we try and tell management teams all the time is first, you need to sit down and understand this landscape and that it's evolving. And it's not business as usual. The government's not going to stop looking at things, but there is some trepidation.

With one large client, for example, we decided we were going to write the FDA proactively, and we were going to tell them we thought our use of this device in this particular indication was on-label, and here's why. We stated the reasons for it and set forth the legal analysis, and we said, "We'd like to hear back from you. I know the people in the Promotional Advertising Policy staff at CDRH," and I said to Toni Stifano, "We'd like to know from you if you disagree with our analysis. But my client's going to be promoting this, and we'd not like to receive a warning letter if you disagree."

So different companies are taking different strategies. And by the way, that has gone on for four months, and the company has been promoting it lawfully during that time. The FDA got back to us and said, "Hey Mark, we're not going to answer this because it's kind of a one-off, and we're trying to reformulate our position. Your request transcends an industry need to define this area."

But I tell management teams all the time, you've got to sit down and not let your sales and marketing organization be exposed. You need to give them some definition of what you believe the general umbrella and the specific indication statements are that you're going to promote so that they don't feel like they're ever exposed.

And sometimes you believe it's on-label, but FDA may disagree, and sometimes you believe it's on-label, but FDA disagrees with you. But you have to decide, where are we going to draw the line, and how aggressive are we going to be? Fortunately, the lines seem to be blurred now, because we have this concept of off-label promotion, which we never used to have before.

The government, through its jury instruction in the Vascular Solutions case, has said we can provide information about off-label uses if it's put in context, such that it's wholly truthful and not misleading. What "wholly truthful" means in the eyes of the government versus industry is going to be tested going forward, but we need to consider that.

So I just take management teams through that analysis all the time, and we figure out how aggressive we want to be in promotion, and we look at the full breadth of promotional efforts, from sales representatives' work to the establishment and creation of sales collateral materials to your website to your booth panels to your social media and website presence, etc., providing grants for a position, initiated uses or grants for CME courses on off-label uses. Let's look at every way in which you're communicating or touching, interfacing with the marketplace, and what can we do to lawfully be appropriately aggressive yet compliant in all that you say and do.

SCOTT: Very good. I think that's extremely helpful. And again, for everyone, if you're digging this topic and want to know more, I definitely encourage you to go to Mark's practice's website, duvalfdalaw.com and subscribe to those Client Alert newsletters. It's not your typical legal, regulatory sort of content; they're actually really enjoyable to read, and very informational at the same time. So I definitely encourage everyone to do that. Mark, I know we talked about this a little bit in the pre-interview, but you've got a unique way to be very straightforward but in a relaxed, personal way. I've always been a fan of yours.

Let's wrap this up for the sake of time, and we'll get to the last three rapid-fire questions.

First, Mark, what's your favorite nonfiction business book?

MARK: That's kind of funny; I really don't have one. I would say this: I try to conduct my affairs and my life through the Bible. That's probably an odd answer for this interview, but I got to that by way of *The 7 Habits of Highly Effective People*, because it talks about the servant leadership qualities of Jesus. So I try to conduct myself that way.

But the book I'm next getting to is *True North* by Bill George. I worked for Bill. I saw him at a book signing, where he made a presentation, and he signed my *True North* book, and I can't wait to get it, because he's a man who approaches life from a faith perspective as well.

SCOTT: I think a lot of people would appreciate that take. Second question, is there a business leader that you're following right now, or one that's inspiring to you?

MARK: That is a great question too, and there's not a singular business leader I follow. I love the clientele I have. We've had 730 clients over my 13 years, and I work with an amazing array of CEOs and VCs, and it never ceases to amaze me what I can learn just by working in and around these people. Those are the people that inspire me. I love my clientele, and I think I learn a lot from them. And I like to think they learn from me as well.

SCOTT: Lastly, when thinking about your career in healthcare, if we had the option to rewind the clock, what's the one piece of advice you'd tell your 30-year-old self?

MARK: First of all, I got here without a predefined path or thought. I just worked hard, I was intellectually curious about everything that I did, and I tried to do everything with excellence and passion. Ultimately, it just seems like you get led to the place you should be. I think that's how I got here, and I thank God for where I'm at in my practice. It's super fun, and I have great people working for me and around me, and continue to grow. I just enjoy what I'm doing. It's a blast, to be honest. It's a privilege to be in this industry, knowing that you're developing devices and drugs and other products that save and help people's lives.

SCOTT: Very good, Mark. Thanks again for your time. Really appreciate it.