How to Comply with the Sunshine Act: Best Practices and Critical Guidelines

Here are some of the points we are going to cover:

- Origin, scope, and purpose of the Sunshine Act and the problems this legislation hopes to solve.
- How will medtech startups be affected by the legislation?
- Consequences within medical device companies if adequate policies are NOT put in place. Hint: David thinks it's like driving a car without car insurance.
- Policies and procedures that medical device companies need to have in place in order to comply with the Sunshine Act. We'll also cover the 2 exceptions.
- Are there any loopholes in the Sunshine Act that medical device companies can potentially exploit?
- The importance of consistent 'needs assessments' pertaining to HCP consultants.

Scott Nelson: Hello, hello everyone. It's Scott Nelson and welcome to another edition of Medsider, the place where you can learn from medtech and medical device experts on your terms without having to go to school, and on today's call, we have David Hoffmeister who is a partner at Wilson Sonsini Goodrich & Rosati, where he plays a major leadership role in the firm's drug and device regulatory and healthcare law practice within the Life Sciences division of the firm. David was named as one of the 25 leading biotech attorneys in California in 2011 by the Daily Journal and is recognized as one of the leading food and drug regulatory lawyers in the country. So, without further ado, welcome to the call, David. Really appreciate your coming on.

David Hoffmeister: Thanks, Scott. You bet.

Scott Nelson: Okay, so most of our conversation is going to be around the best practices and the critical guidelines for physician payments, more specifically the Sunshine Act. So, if you don't mind, for those listening in the audience, can you provide us with a little bit of a background in regard to physician payments and the Sunshine Act, maybe just a little bit on the origin and the scope and maybe the general overall purpose?

David Hoffmeister: Yeah, you bet. So, the origins of the Sunshine Act go back, I would believe probably 10 or 15 years. I say that because a lot of the enforcement action with regard to false claims and kickbacks in the Office of Inspector General and the Department of Justice's enforcement of those acts and of those laws, they go back a fairly long period of time. But in the drug and device area, really you saw a lot of the major enforcement starting about 10, 15 years ago. Today we see headline news all the time, and just recently we saw a settlement I believe by the GlaxoSmith Locum of three billion dollars for payments to physicians for off-label promotion and for violations of Anti-Kickback, Food/Drug Law Act or False Claims.

So, basically what these companies do when they're under an investigation and they settle with the government, with the Office of Inspector General, the Departments of Justice and the State

Attorney General, is they enter into compliance agreements or corporate integrity agreements or deferred prosecution agreements. In those agreements, and they're generally a five-year period, terms of five years, but in those settlement agreements there's a requirement to disclose payments publicly on the company's website, payments to physicians, and healthcare professionals. Numerous medical device companies, pharmaceutical companies, have entered into these agreements and disclosed, and others are voluntarily disclosing, in addition to being subject to these corporate integrity agreements disclosing.

So, basically the origins I think are from those types of agreements and the disclosure requirements of payments to healthcare professionals under those agreements. So, basically, Congress thought it would be in the best interest of the public and the medical profession to enact the Sunshine Law, which would require all medical device companies and all pharmaceutical companies in the United States to disclose those payments. So, I think that's basically a little overview of where I think that the origins of the law came from.

Scott Nelson: Sure. Okay. That's a great little history lesson in regard to some of this because I speak for me personally but I'm sure some people listening in the audience right now would maybe believe that the Sunshine Act, it seems to be fairly new, I should say, that's the probably the best description. In reality, as you're saying it dates back maybe to some 10, 12 years ago, the initial origins of the act that we see today and we often see headlines in today's news in regard to the Act and we hear so much about it, but it dates back to, say, 10, 15 years ago.

Before we get into some of the compliance, because I'd like to ask you next about some of the cost and more particularly the compliance costs regarding the Sunshine Act. Before we dig in, in your opinion, once this thing is out, let's hypothetically say that there's this website, let's call it sunshineact.com or dot org, whatever you want to call it hypothetically. In your opinion, do you think patients, one, will they even care, and two, will they be able to decipher the data within this website and the information that's disclosed through a website?

David Hoffmeister: I think some patients will care. We know that many, many, many patients and providers, family members of patients, are using the website to research their diseases and their conditions, researching the treatments for those diseases and conditions, and really accessing the Internet and what's on the Internet. WebMD is a huge website provider that provides access to patients and providers. So yeah, I think that there are some folks that are going to be very interested in what type of remuneration their physicians receive from medical device companies.

For example, if you're going to undergo a hip replacement or knee replacement which is going to put you out for six, eight months or so, and it's a pretty invasive procedure and it's a very expensive procedure, I would think that there are folks out there, patients out there, that are going to take a look at the website to determine whether or not they have received remuneration or significant remuneration from the manufacturers of those devices. So yes, I do think that there are going to be smart patients out there that will access this database.

Scott Nelson: Right.

David Hoffmeister: What was your second question, Scott?

Scott Nelson: No, that was really it. The first question was will they care and then two, will they be able to take this information that's available. I guess at this point we still don't know exactly what this will entirely look like. Will they be able to consume and decipher the data to know whether a physician was, for lack of a better description, bribed in the sense in regard to the devices that, that particular physician is currently using versus maybe that physician was involved in a legitimate clinical trial and they were somehow compensated for that. That's kind of the angle or that's the question behind the question I guess, is what I was trying to get at.

David Hoffmeister: Yeah, I think obviously the intent is for the disclosure to be usable by individuals who are interested in accessing that website whether it be patients, whether it be investigators, plaintiffs' attorneys, government attorneys, that it would provide useful information searchable on a number of different fields based on the device manufacturer, based on the recipient of the remuneration, based on the practice of the recipient. So, there's a whole number of fields that you'll be able to search on, but it's really difficult at this point to determine whether or not the bolus of information that's going to be available on the website will provide any really useful information other than maybe to prosecutors or investigators.

Scott Nelson: Sure. Sure. I could see it going a couple of different ways. One is that it's extremely valuable information and it will almost create an entirely new movement of e-patients, engaged patients, and will help foster that environment. The other direction it would be that, like you just said, the material is really hard to consume, is really hard to decipher, and basically, the only folks that get use out of it are attorneys, investigators, etc.

David Hoffmeister: Yeah, I mean, at the end of the day I think that what we all want as an industry representing medical device companies, we want to ensure that we are complying with the most appropriate ethical standards and complying with all applicable rules and regulations where any payments that we make as an industry are transparent and are for useful purposes and for needed services that are actually used by the company, and they're not intended to induce any type of purchase or the reward of a purchase of a device. That's why the medical device companies, AdvaMed supported this, pharma supported this type of legislation. So, again, just to make sure that we're ethical manufacturers and any medical decision whether to use a drug or device should be based on a patient's needs, not based on whether or not they're receiving remuneration or have received remuneration.

Scott Nelson: Sure. Sure. As you just said, I think that's the intention of the act, and certainly, I think the hope of most device companies is that in an effort towards more transparency, it will be a great tool for patients to use in terms of research. So, let's move on to the next topic and discuss the resource constraints, and more particularly the compliance cost regarding the implementation of the Sunshine Act. Can you speak to that?

David Hoffmeister: Yeah. So, I mean, it's a good dovetail into it. This information is not useful to anybody out there. The cost associated with generating that information and displaying that information on a public website is significant. So, if it's useless information, then there's going to

be a lot of costs involved by every pharmaceutical and device manufacturer in the United States to produce this useful data. So, hopefully, it is useful and hopefully, it is transparent.

So, if you read the statute and you read the government's Office of Management and Budget's analysis of the cost to implement the Sunshine Act, it's about $200,000 per company, which is probably in my estimation likely low. That's a big number, and depending on the company and the number of products it sells, entire new departments will be created. There'll be a need for collaboration between the IP department, the sales department, the marketing department. Accounting, legal, compliance, training departments will all be required to participate in this activity.

Scott Nelson: Sure.

David Hoffmeister: So, it's not an insignificant amount. So, if you have a one-product company, then it's probably not going to reach the $200,000 level. But if you're manufacturing and selling several medical devices or pharmaceutical products then this is going to cost you a lot of money. Second of all, not only just to implement the policies and procedures and the training of the entire infrastructure, but also the legal costs associated with the interpretation of what the law is, what needs to be reported, what doesn't need to be reported, when does it need to be reported. It's somewhat complicated and there are not always clear answers.

Scott Nelson: Sure.

David Hoffmeister: So, you're going to have to call up your lawyers and you're going to have to get some types of interpretations.

Scott Nelson: Right. That $200,000 per company, that number. Was that just for the initial implementation to support the compliance of the Sunshine Act?

David Hoffmeister: Yeah.

Scott Nelson: Okay.

David Hoffmeister: Yeah, I think just to put into place the infrastructure for reporting.

Scott Nelson: Right. Yeah. I was going to say, because as you just mentioned, the collaboration that's going to have to go on behind the scenes between marketing, R&D, sales, etc., As you said it's probably going to be a whole new team or a whole new task force devoted just to this act in order to enhance collaboration. I guess if I'm an entrepreneur in the health IT space, I'm looking at this as a huge problem that could potentially be solved through efficient technology. But regardless, is it safe to say it's definitely going to be a significant added cost in an era where a lot of device companies are being squeezed by other things like the 2.3% excise tax and significant increases in the cost to obtain a PMA or a 510(k), etc.?

David Hoffmeister: Exactly. Exactly. We've heard from the industry and the industry has basically said, look, we need at least six months to pressure test our systems after the final regulations go

into effect. Right now, we've only got proposed regulations. There have been substantial comments by the industry about the proposed regulations. We're expecting the final regulations at any time but we're fast approaching the end of the year, and because of the significant costs in infrastructure and the need to report and to collect the data properly and to put into place those infrastructures, there needs to be an adequate time period in which to pressure test these systems.

Scott Nelson: Sure.

David Hoffmeister: I agree, the industry needs at least six months to pressure test this stuff and to digest what the final rules are, because reading the proposed rules, you can see this is a complicated issue and the government's wrestling with a number of the provisions here...

Scott Nelson: Sure.

David Hoffmeister: ...because they're just not easily implemented.

Scott Nelson: Right, and you could see how potentially six months would be enough time for a smaller device company, but the large strategics, the J&Js, the Covidiens, the Medtronics of the world, six months seems actually not even enough time to really get a handle on what exactly it's going to take to comply with the act.

David Hoffmeister: Exactly. So, I mentioned right out of the outshoot that a number of the big companies already have these programs in place where they are publicly making available this information or pursuant to their CIAs. This Sunshine Act is a new requirement, so they have to deal with not only what their CIA requires but also what the Sunshine Act requires. That's even more costs associated with the big guys who have been hit with CIAs.

Scott Nelson: Right. The effect on startup medical device companies is fairly obvious when you're dealing with companies that are forced to be fairly capital-efficient regardless of the act. So, that effect is obvious, but do you see any ancillary effects on hospitals that have recently acquired physician practices?

David Hoffmeister: You know, I really don't because this is a reporting requirement for medical device companies and pharmaceutical companies.

Scott Nelson: Sure.

David Hoffmeister: Now, hospitals have their policies and procedures in place with regard to ethical interactions and the like. I mean, this whole topic comes to the forefront anytime anybody is involved in any type of merger and acquisition process.

Scott Nelson: Right.

David Hoffmeister: So yeah, I would think that the hospitals with their policies and procedures and knowing the need to be transparent. Some hospitals absolutely prohibit any type of

consulting arrangement or speaking arrangement or what have you. So, yeah, I mean I think that the Sunshine Act doesn't apply to them particularly but…

Scott Nelson: Right.

David Hoffmeister: …this is an issue for everybody.

Scott Nelson: Yeah. Yeah. You hit on the button or the card that I was trying to play there, is that you could see how potentially this would affect hospitals potentially in a negative way if it truly does play out in terms of industry collaborating with physicians that are owned by hospitals.

David Hoffmeister: Yeah. Exactly.

Scott Nelson: But in regard to some of these policies that need to be in place, what happens then if a pharma or device company doesn't have the necessary policies in place then?

David Hoffmeister: Okay, so again, when we talk about policies and procedures, there are two sets of policies and procedures that need to be in place. First of all, there are policies and procedures for collecting and reporting remuneration that is provided to healthcare professionals and teaching hospitals. In addition to those policies and procedures and the infrastructure that needs to be developed to track and report, the Sunshine Act is really a backend disclosure law. It really doesn't look at whether or not the payments were actually justifiable or legal. Again, it requires disclosure of payments to physicians and teaching hospitals, and those disclosures will be made public in a public disclosure database. The law doesn't determine or evaluate these expenses or payments whether or not they're legal or justifiable.

Scott Nelson: Okay.

David Hoffmeister: Payments and public disclosures will be evaluated by attorneys of the OIG, whistleblowers, plaintiffs' attorneys, and they'll all have access to the payments and will be able to scrutinize those payments after the fact. So, if a company doesn't have adequate policies and procedures in place that really require the evaluation upfront and documentation of whether the payment should have been made in the first place that the services are truly and actually needed and used by the company. That the services were actually performed, that the fair-market value was actually paid for those services, then the company is going to be setting themselves up for potential investigations and potential enforcement actions.

Scott Nelson: Okay.

David Hoffmeister: So, again, although the law does not mandate that these upfront policies and procedures are in place, failure to have those adequate policies and procedures and to implement those policies and procedures to ensure that these payments are legitimate and in fact actually rendered is going to expose the company to significant downside risk. It's almost like driving without car insurance. You just don't do it.

Scott Nelson: Yeah.

David Hoffmeister: So, when I say you need to have two sets of policies and procedures, you need to have the back end, which is the Sunshine Act, but you also need to have the front end to justify those payments made in the first place.

Scott Nelson: Got you and I'm jotting down that quote right now, "driving without car insurance." That's a good way to describe it. So, in looking at the final product, presuming that the database is there, it's accessible, etc., Do you think we'll see an increase in the number of whistleblower lawsuits, investigations by the OIG, those kinds of things?

David Hoffmeister: I think that there's definitely potential there because, again, you're going to have raw data out there sitting out in the public view for plaintiffs' attorneys. So, the plaintiffs' attorneys—these are going to be like a database similar to a recall database that the FDA has on their website. So, basically, you have plaintiffs' attorneys out there trolling for lawsuits and they review the recall databases. They're going to review this. OIG is going to review these types of databases, and it makes it just that much easier to focus their attention on where they want to go and conduct investigations or inquiries. No question about it.

Scott Nelson: Right. Right now, being so close to the actual implementation of this act, are there still quite a few device companies that don't have the necessary policies and procedures in place in your experience?

David Hoffmeister: I think that a lot of the smaller companies don't have either of the policies and procedures that I've just mentioned. The front policies nor backend policies.

Scott Nelson: Right.

David Hoffmeister: Again, they're waiting for this implementation of the final regulations then to get on their horse to evaluate what they need and to catch up. So, that's why this interview and this program that we're doing is really important to the smaller companies to understand what they need to do and when they need to do it.

Scott Nelson: Right. I can't stress that enough and thanks to you for your willingness to come and educate the Medsider audience on this kind of stuff. It's incredibly valuable information for sure. So, let's jump to the next topic. Are there loopholes that you see that may or may not, or I should say that already currently exist or may exist when you look at how the Sunshine Act will eventually be rolled out, from the perspective of medical device companies?

David Hoffmeister: You know, Scott, there are really no loopholes here as far as the requirement track remuneration to healthcare professionals and teaching hospitals and to report that information. I think that there certainly are exceptions to the law and those exceptions really only apply to companies that are marketing devices that put devices on the market that are 510(k) exempt. So, if all of their products are 510(k) exempt, then they're not required to track or record under the Sunshine Act. But if they have five products that are 510(k) exempt and one product that is not 510(k) exempt, is a Class II device, then all of their products will need to be

reported, assuming that there's Medicare/Medicaid reimbursement or federal government reimbursement for any of those devices.

Scott Nelson: Okay.

David Hoffmeister: So, again, the second exception is that all of the products, the company's selling, and commercializing devices that if those devices are not reimbursed by the federal government under Medicare/Medicaid, then they're not required to report. But if one of the products is covered by federal healthcare programs, then all of the company's products will need to be tracked and remuneration reported.

Scott Nelson: Okay.

David Hoffmeister: So, that's the way the proposal reads. There are a number of different comments that have been made by the industry on that, and basically, the comments have said, "Look, we don't believe that was the intent of the law. Why should the industry have to report all of the remunerations that they provide to physicians with regard to devices that are not covered by Medicare or Medicaid? Why shouldn't we only report those that are covered by Medicare or Medicaid, because that's the government's interest obviously?

Scott Nelson: Okay.

David Hoffmeister: But we'll have to wait and see what the final regulations say on that, but suffice it to say it's a very broad act and it goes all the way down to remuneration of $10 if you make a payment to a healthcare provider of $10 and above or in the aggregate of $100 in the year, then those payments as a general rule are going to have to be tracked and reported.

Scott Nelson: Okay. Okay. And I've got two follow-up questions, but the first one's not necessarily a question, it's more in review. So, really if you've got a non-exempt or I should say a 510(k) exempt product, the Sunshine Act doesn't necessarily apply, or if you've got an FDA-approved device whether it's, let's just call it a 510(k) approved device, but it's not reimbursable by CMS, then the Sunshine Act potentially doesn't apply. Is that…?

David Hoffmeister: That's right. That's right.

Scott Nelson: Okay.

David Hoffmeister: Let's take it one step further. Let's just say that you have an aesthetic laser that you have a number of different indications, and then you have, many of the indications are really cash and carry. They're not reimbursed. They're elective types of procedures. But if the device is also reimbursed by the government for indications that are covered by Medicare or Medicaid, then all payments regardless of the indication are going to have to be reported above $10 and above $100 reported and tracked.

Scott Nelson: Got you. Okay. I certainly wouldn't expect you to have this information readily available, but you have to wonder, in those two scenarios, the 510(k) exempt product or a device that's not reimbursable, I mean, those are few and far between, correct?

David Hoffmeister: Few and far between.

Scott Nelson: Yeah.

David Hoffmeister: Exactly.

Scott Nelson: Yeah.

David Hoffmeister: Not only that, you can have one exempt product, but you can have two non-exempt products, then everything's reported…

Scott Nelson: Sure.

David Hoffmeister: …in your product line.

Scott Nelson: Got you. Okay. Then my second follow-up question to this topic, the topic of loopholes. Let's say I'm a medical device company, and maybe it's because of internal resource constraints, maybe it's for another reason, but say I choose to in essence outsource my physician consulting agreements to a third party. So, if I do that, say I outsource to ABC company that kind of manages the back and forth communication between Dr. Smith in regard to a particular device…

David Hoffmeister: Yeah.

Scott Nelson: …and I'm actually paying this third party to handle all of that communication between the physician and my company. How is that going to be reported then? Is that going to be Dr. Smith gets paid by ABC company or Dr. Smith is paid directly through ABC consulting company but is in effect compensated by a large strategic company? Does that make sense? I don't want to get too confusing.

David Hoffmeister: Yeah, I understand the question and the actual specifics are not finalized in the regulations. They're covered in the proposed regulations. The proposed regulations envision that if company A engages Company B to contract with the physician, the HCP, then company A is required to report the payments by company B to the physician.

Scott Nelson: Okay.

David Hoffmeister: However, if company A doesn't know where the payments are going, has no knowledge where company B is paying the physician then it's reportable, but the details of that have to be finalized in the regulations.

Scott Nelson: Sure.

David Hoffmeister: So, as a general rule, if you hire a consultant to deal with consulting arrangements with HCPs, they will be disclosed by you as the manufacturer.

Scott Nelson: Okay. Okay, so maybe classify that as a potential loophole. You see that probably being closed once the final regulations are put in place.

David Hoffmeister: That's right.

Scott Nelson: Got you. Okay.

David Hoffmeister: It will at least be addressed.

Scott Nelson: Okay. Okay. As we reach towards the conclusion, are there any other tactics regarding physician consulting arrangements and payments to physicians that use a particular medical device as manufactured by company A?

David Hoffmeister: What do they need to have in place before they make these payments?

Scott Nelson: Well, yeah. Any other tactics or potential policies that we haven't already covered that are worth mentioning now in regard to kind of physician consulting arrangements or payments to…?

David Hoffmeister: Yeah. No, again, I think you should go up the front, and you look to determine whether or not, and this is where the government will go in the investigations to determine whether or not the arrangement between the manufacturer and the HCP consultant is a justifiable legal relationship. The company needs to have policies and procedures in place that really determine, and I call it a needs assessment, they need to have a need assessment policy and procedure. Basically, it needs to be a bi-annual or an annual review of where the company's departments that hire HCPs, what do they really need and why do they need it and when do they need it? Do these needs go-to company goals and the like? Does a payment go to strategic areas that the company is interested in, for example, the development of a new indication and you need to run clinical trials for that new indication?

Scott Nelson: Sure.

David Hoffmeister: Well, the company's going to know that right up front and the board of directors is going to buy off on that strategic development. You're going to know upfront that you're going to need to have consultants. You're going to need to have principal investigators for your study. You're going to have to hire a clinical trial site. So, all this is known right upfront. So, what you need to do is systematically evaluate these needs upfront annually or biannually and then stick to those need assessments.

Scott Nelson: Okay. That's a great point. So, in essence, what you're saying is evaluate at least once a year at the minimum, evaluate whether or not in essence this money going out to HCPs in various consulting arrangements is truly beneficial from a clinical standpoint and from an overall strategic standpoint for the company.

David Hoffmeister: Exactly, and to document that in a systematic way, in a procedural way that basically, if somebody comes knocking to say, “Why did you make these payments?” here’s a document that justifies prospectively why we did it, who we evaluated, the due diligence we did, alternative sources of consulting whether or not it’s unrelated to HCP or related to HCP. It’s also an evaluation of current consultants whether or not they’re actually performing as required under their contract, whether or not they’re continually needing to be paid, rendering service, a fair market value associated with the payments that are made to these consultants. So, it’s a systematic evaluation of what your needs are as a company and, number two, for those consultants that have been retained and you’re paying, whether or not they’re actually producing, whether or not the goals have been met, whether or not you need to fire some of these guys.

Scott Nelson: Sure. Sure. Yeah. Very good. That's great stuff. So, you threw a lot, you provided a ton of great information for the audience in regard to physician payments and the Sunshine Act. As we look at the result of this act and the result of the whole topic of physician payments, are there a few things that you’d like to leave people with, absolute-must to-dos, walking away from this interview? What are the one or two things that you really need to pay attention to and maybe even act on right now?

David Hoffmeister: Yeah. I think it’s more guidance for the smaller companies who have taken the wait-and-see approach. I don’t think we have a whole lot more time available to us to take the wait-and-see. I think they have to take a proactive approach. This is going to be required. This is not going away. There are several fines and penalties associated with failure to adequately track and adequately report these payments to HCPs and teaching hospitals. They need to take it seriously. They need to get in place these upfront policies and procedures to justify the payments, to document the need assessment, and they need to get the infrastructure in place to be prepared to report and have those numbers publicly available in a database.

Scott Nelson: Sure. Okay. Very good. Great stuff, David. I can’t thank you enough for your willingness to do this interview. For those listening that want to either learn more about you or the firm and/or maybe potentially even reach out to you to implement some of these policies and procedures if they’re not already implemented, where’s the best place for them to go?

David Hoffmeister: Just go ahead and take a look at our website, wsgr.com. My bio’s on the website, and feel free to send me some emails.

Scott Nelson: Sure. Very good. For those listening to this through iTunes or something like that, I’ll definitely link to that online, David’s bio as well as the URL for the firm. So, that's it for now. If you’ve listened through this 20 to 30 minutes of an interview, just remember folks, you can subscribe to the free Medsider podcast. Just go to the iTunes, do a search for Medsider, subscribe to the podcast for free. That way all of the new interviews will automatically download to your iTunes account for free. It’s a really easy way to consume the content and/or, of course, you can always read the transcripts that are available online as well. So, David, thanks a ton for coming on. Really appreciate it. I definitely encourage everyone to check out wsgr.com should you have

further questions or want some help in regard to the Sunshine Act. So, thanks again, David. I'll have you hold on the line. Anything else that you want to add?

David Hoffmeister: Nope, I'm good, Scott.

Scott Nelson: Alright.

David Hoffmeister: Thanks a lot.

Scott Nelson: Sounds good. I'll have you hold on the line, but thanks everyone for listening to another edition of Medsider. Until the next one take care.