

Episode – **Ethics Talk: Medical Device Representatives in the Surgical Suite**

Guests: Ariel Wampler, MD; Adrian Fugh-Berman, MD

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[mellow music]

TIM HOFF: Welcome to *Ethics Talk*, the *American Medical Association Journal of Ethics* podcast on ethics in health and health care. I'm your host, Tim Hoff. The US medical device industry is massive. Worth \$156 billion in 2017, it's expected to grow to \$208 billion by 2023. And medical devices are everywhere. About one in 10 Americans—that's 32,000,000 people—have an implanted medical device. The sheer scale of this industry makes device regulation both difficult and of utmost importance to public safety. New devices enter US markets through abbreviated FDA pathways that, despite being in place, raise ethical concerns that few know about. Dr Ariel Wampler, the Editorial Fellow who helped create this month's issue on implantable device regulation, recalls first learning about the FDA's 510(k) clearance pathway.

DR ARIEL WAMPLER: If companies can argue that they had, that they were significantly similar to a previously approved or marketed device, then they're able to go through a streamlined, abbreviated process and don't necessarily have to undergo any human clinical testing. I think it was something like 80 percent of devices go through this abbreviated process called 510(k).

HOFF: And the FDA clearance process is not the only part of device regulation worth investigating from an ethics perspective. The ethical problems with pharmaceutical marketing to clinicians have been well-documented. Even though many clinicians tend to claim that they can remain impartial when prescribing drugs for patients, research has long and repeatedly shown that gifts and incentives from the pharmaceutical industry influence clinicians' prescribing behaviors. One response to conflicts of interest is Open Payments, a federal transparency program created when the US Congress passed the 2014 Affordable Care Act. Yet total payments from industry to physicians as a group haven't changed much.

Pharmaceutical marketing in medicine has been viewed by many as ethically suspect for many years. But far less well-known and studied at this point are relationships among device manufacturers, device company representatives, and clinicians taking care of patients, especially at the point of care.

WAMPLER: You know, there's been research done for pharmaceuticals in terms of just how even subtle nudges from pharmaceutical reps can greatly influence provider prescribing behavior. And I think we're starting to look into whether the same can be said for devices. And I'm inclined to believe that because of the often more sustained, regular, and in-depth contact that happens between medical device reps and often surgeons and physicians and other interventional specialties, that there might even be a stronger impact.

HOFF: Joining us this month is Dr. Adriane Fugh-Berman, Professor of Pharmacology and Physiology at Georgetown University in Maryland. Dr. Fugh-Berman is also the Director of Farmed Out, a project that promotes rational prescribing at Georgetown University Medical

Center. With Drs Bonnie O'Connor and Fran Pollner, she's the coauthor of "Salespeople in the Surgical Suite: Relationships between Surgeons and Medical Device Representatives." She spoke with us about the roles of medical device representatives, how they're both similar to and different from pharmaceutical company representatives, and potential pitfalls of not subjecting those relationships to ethical and clinical scrutiny.

Dr. Fugh-Berman, thank you so much for joining me.

DR ADRIANE FUGH-BERMAN: Thank you so much for having me, Tim. [music fades out]

HOFF: The influence that pharmaceutical representatives' relationships with physicians have on treatment decisions is well-documented at this point. A little bit less well-known and perhaps nearly unknown to our audience is the influence of medical device representatives' relationships with physicians. For our listeners who are unfamiliar, can you first tell us what we should know about how device rep/physician relationships differ from pharmaceutical rep/physician relationships?

FUGH-BERMAN: Yeah. So, in some ways, they're quite similar. Of course, in both cases, they're selling some kind of medical therapeutic, but the relationships between medical device representatives are often far closer to the physicians because they're accompanying them into the operating room. They're actually part of the surgical staff—or they're treated as part of the surgical staff—and they are helping the surgeon during procedures.

HOFF: Hmm.

FUGH-BERMAN: So, they tend to, while the pharmaceutical reps maybe bringing lunch and information to physician offices, that's not really the role of the medical device representatives. They're really providing service to surgeons and have a far closer relationship to them.

HOFF: Sure. And I think a number of people would likely be surprised to hear that medical device representatives are often present in the operating room when a surgery is happening. And oftentimes, they're uniquely familiar with the devices being implanted, and their roles in the procedure can be critical, especially for either novel devices or first-in-human device implantation, things like that. Can you talk a little bit about what patients should know about the device representative roles in those cases and what else you think patients should know about the way that device reps work with quote-unquote "traditional" care teams?

FUGH-BERMAN: Yeah. So, that's really interesting because, of course, when you're being surrounded by people in scrubs, you don't know who's who.

HOFF: Sure.

FUGH-BERMAN: So, you may not know who's the nurse and who's the medical device rep there. But let's unpack that idea of the reps having this unique knowledge. So, of course, they would like the surgeons to think that they're needed there. But, you know, when you think about it, why don't the surgeons know more about the devices that they're implanting? Why are they depending on the reps? It's very important to medical device companies to get surgeons used to their particular device and one that comes with service from device reps. But really, should that be necessary? One of the people—as you know,

we've done several articles, including a study on the relationships between medical device reps and physicians—and one medical device rep who's now a physician said to us when we interviewed him that, "Why should a surgeon be allowed to perform procedures if they're not familiar with the device? If you don't know the equipment, you should find another job."

HOFF: Hmm.

FUGH-BERMAN: I thought that was a really interesting perspective.

HOFF: Mmhmm. Given the likely unfamiliarity that patients do have with device reps' roles in surgeries, do you think that raises any kind of questions about informed consent? Specifically, I'm wondering if you think that there's some obligation for kind of a deeper sense of informed consent for things that patients might be surprised by. Obviously, there are a lot of things that happen in the OR that patients aren't necessarily apprised of, but does this strike you as something that they should be told about explicitly?

FUGH-BERMAN: Patients should absolutely be told that there's going to be a device rep in the operating room and what their role is. Sometimes in the informed consent, there is a line that says that there will be a device rep in the room. But as one of the surgeons we interviewed pointed out, if you don't sign that consent, you don't get the operation.

HOFF: Mm.

FUGH-BERMAN: One of the surgeons that we talked to worked in a hospital where there actually was a separate consent for the device rep. And it was interesting. We were doing a focus group of surgeons, and the other surgeons looked at him when he said this. They were aghast. And they're like, they said, "Well, what happens if the patient doesn't sign the consent for the device rep to be in the room?" And the surgeon said, "Well, then the device rep doesn't come in the room."

BOTH: [chuckle]

FUGH-BERMAN: But he said, "But they do hang out in the hallway in case they're needed."

BOTH: [laugh]

HOFF: Huh. That seems odd.

Speaking of the study that you perhaps mentioned in a 2016 article that you co-authored with Drs Bonnie O'Connor and Fran Pollner, you suggest that a surgical assistant role might be developed to help mitigate a device representative's potential conflict of interest. Can you explain a little bit more about how you see this role working?

FUGH-BERMAN: Yes, it would be really great to have. So, there are surgical techs that are employed by the hospital. And of course, some hospitals think it's just really great that there's device reps that they don't have to pay who are pointing out which instruments the surgeon needs to use during an operation. But there is this surgical tech role. And wouldn't it be great if there was a higher level of surgical tech who was familiar with the different sorts of joints or whatever implantable device the surgeon is using? How do you as a patient know whether the device that's being implanted in you is really the best device for

you? Is it just the one that the surgeon is familiar with? Just the one that perhaps he has the best relationship with the device rep over? That's not really a good way to choose devices. Wouldn't it be great if surgeons had a range of devices to choose from and surgical techs who knew how to help them install any of them?

HOFF: Can you draw out a little bit more what the potential conflicts of interest are? Because I think that while it may be relatively clear to you, it might be less clear to our listeners who are familiar with medical device reps essentially only in that very specific role of informing surgeons how a device works. Can you talk a little bit about what's beyond that sort of purely didactic aspect of their job?

FUGH-BERMAN: Yes. And just to provide a little bit of background, too, there's less testing of medical devices than there are of drugs. Medical devices can be approved based on what's called a 510(k) or a substantial equivalence standard.

HOFF: Mmhmm.

A brief clarification here. Devices that go through the FDA's 510(k) pathway receive clearance, which means they can be sold and marketed, while FDA approval is a stricter standard based on whether there is "sufficient valid scientific evidence that provides reasonable assurance that the device is safe and effective for its intended use or uses." Now back to the interview.

FUGH-BERMAN: As long as a medical device is substantially equivalent to one that's already been approved, it can be approved even if it has never been implanted in a human being before. We have a much tighter standard on pharmaceutical drugs. So, of course, once a surgeon knows how to put in one particular joint, say, eventually, they're going to be able to do it without a device rep. So, the companies change their joints or their other implantable devices a little bit. They'll change a screw here and there or change the material that something's made out of. It's easy to get that revision approved by the FDA as a substantially equivalent device, but it may be entirely untested in humans. So, the reps will be pushing the newer devices.

And I remember one of the reps that we interviewed saying that there was a device, a joint, that the company made that lasted 15 years. That's a really long time for an implanted joint, so that's really great.

HOFF: Mm.

FUGH-BERMAN: But there was a new device that came out, and that the reps were told to tell the physicians that it was going to last longer, longer than the 10 or 15 years that the preceding device lasted. And the rep said to us, "How could we possibly know that? That device had only been in use for three years. We didn't have long-term data on it. We had no idea how long it lasted." [laughs] So, really what they were selling was the hope that this device might last longer when they actually had clinical data showing that the previous device lasted, I think it was at least 10 years. I think it might've been 15.

HOFF: Hmm.

FUGH-BERMAN: So that what is being implanted in you may not actually be the best or the device with the most experience. And that's where you're really getting into issues of ethics and issues of public health. So, yeah, I mean, this is really a problem.

HOFF: Yeah. So, it is a problem. It doesn't seem like one that's going to be solved relatively soon. So, how should health professions students prepare themselves for the inevitability of working relationships with representatives? And in this case, either medical device representatives like we're talking about or pharmaceutical reps.

FUGH-BERMAN: Well, in terms of pharmaceutical reps, they should be preparing themselves to never meet with a pharmaceutical rep.

HOFF: Mm. [chuckles]

FUGH-BERMAN: And they should be working to get medical device reps out of the operating rooms.

HOFF: Mmhmm.

FUGH-BERMAN: I will say that the, that we interviewed two device reps who subsequently became physicians, and both of them said they would never have a device rep in their operating room. I thought that was very telling. And we heard a very similar story from a pharmaceutical, a rep, a drug rep who said that when he needed to see a doctor, he went to a doctor who didn't see drug reps.

HOFF: Hmm.

FUGH-BERMAN: Because he didn't want to go to a doctor whose choice of therapeutics was being manipulated by drug reps. And if drug reps are not manipulating prescribers' prescribing choices, they won't come back.

HOFF: Mm.

FUGH-BERMAN: So, what I tell physicians is if a drug rep is coming to see you, they are affecting your prescribing practices. [mellow music returns] Doctors always think they're not. [laughs] But the way you can tell is they come back.

HOFF: Sure. Well, in any case, thank you very much, Dr Fugh-Berman, for joining me and for sharing your expertise on this.

FUGH-BERMAN: Thank you so much.

HOFF: That's our episode for the month. Thanks to Drs Wampler and Fugh-Berman for joining us. Music was by the Blue Dot Sessions. To read our entire issue on implantable device regulation, head to our site, JournalofEthics.org. For all of our latest news and updates, follow us on [Twitter](#) and [Facebook @Journal of Ethics](#). And we'll be back next month with an episode on palliative surgery. Talk to you then.