EPISODE – Author Interview: **"What Should the Public Know About Implantable Material and Device Innovation in the US?"**

Guests: Donna-Bea Tillman, PhD, MPA
Host: Tim Hoff
Transcript by: Cheryl Green

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[bright theme music]

TIM HOFF: Welcome to another episode of the Author Interview Series from the *American Medical Association Journal of Ethics*. I'm your host, Tim Hoff. This series provides an alternative format for accessing the interesting and important work being done by Journal contributors each month. Joining me for this episode is Dr Donna-Bea Tillman, a Senior Consultant at Biologics Consulting in Alexandria, Virginia, where she focuses on digital health, medical imaging, and cardiovascular devices. Dr Tillman is the author of the article *What Should the Public Know About Implantable Material and Device Innovation in the US?* in the September 2021 issue of the Journal, *Implantable Material and Device Regulation*. Dr Tillman, thank you so much for being on the show. [music fades out]

DR DONNA-BEA TILLMAN: It's really great to be here. Thank you.

HOFF: To begin with, what is the key ethics argument in your article?

TILLMAN: So, the key point that I wanted to make was that it's very important for patients and health care providers to understand that while implantable medical devices can offer important health benefits to patients, that these benefits are almost always accompanied by the potential for risk.

HOFF: Mm.

TILLMAN: My father was an economist, and he used to say, "There's no such thing as a free lunch."

HOFF: [chuckles] Yeah, I think that plays well into a couple of the issues that we've done in the past, about decision science in particular, about the way that people process all of that information that they need to take in, in order to weigh all of those various risks and benefits. So, I think that's an important point to make here.

TILLMAN: Yeah. And I also think, you know, when people think about the safety of a device, they tend to think about safety in an absolute sense. But in fact, safety is not a absolute term. It really reflects a balance between prospective risks and benefits. And just because a device may cause adverse events in a small portion of the target population, and those events may even be significant, that does not in and of itself mean that the device is unsafe. And I think that is another important thing that sometimes people have a hard time understanding.

HOFF: What is the most important thing for health professions students and trainees to take from your article?

TILLMAN: So, medicine is complicated, and patients rely on health care professionals to help them make informed decisions, while medical device manufacturers are responsible for ensuring that their device labeling includes important information about how to use devices safely and effectively and what the potential risks may be. Physicians, when they choose to use a device, still have responsibility to ensure that they understand that labeling. And this enables them to select the right device for the right patient, and it also enables them to communicate relevant risk and benefit information to the patient. So, these health care professionals are an important bridge between the medical device manufacturers and the public.

HOFF: Mm. And do you see the sort of current state of medical education curricula as preparing students well for their role as that bridge, or do you think that's something that could be improved?

TILLMAN: You know, I think medical device technology is just growing by leaps and bounds. And I think it's important that health care practitioners and people who are being trained in this space understand some of these, frankly, ethical and these technological issues. I think it's much more complicated than, you know, 300 or 400 years ago where we had people basically prescribing different kinds of herbs and things like that. And now we have artificial hearts and incredibly complicated devices. And so, it is, I think it's harder to be a health care professional today than it was in the past because technology has gotten so complicated.

HOFF: Hmm. And finally, if you could add one more important point to your article, what would that be?

TILLMAN: So, I'm an engineer, and when I think about medical devices, I think about them from that perspective. And I think it's important that people understand that like any other engineering effort, the process of medical design is inherently iterative in nature. When we try to design the ideal device, whether it be a hip or an electrocardiogram, medical device manufacturers have to balance competing design requirements. So, it might be important for a device to be flexible, but it also has to be strong. And these competing requirements require design tradeoffs and an acceptance of the fact that by optimizing for one, it may make it difficult to optimize for the other. [theme music returns]

HOFF: Great. Thank you. Well, Dr Tillman, thank you very much for your time and for being on the show today.

TILLMAN: Thank you!

HOFF: To read Dr Tillman's full article, *What Should the Public Know About Implantable Material and Device Innovation in the US?* along with the rest of the September 2021 issue, visit our site, JournalofEthics.org. Follow us on Twitter and Facebook @JournalofEthics. And we'll be back soon with another episode of *Ethics Talk* from the *American Medical Association Journal of Ethics*.