

EPISODE – Author Interview: “How Pseudoscience Generated US Material and Device Regulations”

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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 my colleague Jorie Braunold, the archivist for the American Medical Association in Chicago, Illinois. Jorie is the author of the article *How Pseudoscience Generated US Material and Device Regulations* in the September 2021 issue of the Journal, *Implantable Material and Device Regulation*. Jorie, welcome to the show and thank you so much for being here. [music fades out]

JORIE BRAUNOLD: Thank you for having me.

HOFF: To begin with, what’s the key ethics point about your article?

BRAUNOLD: I would say the key point is that in the absence of regulation, in order for doctors in the past to treat and cure and retain their patients who hadn’t been getting the result they sought from prior medications or devices, physicians mostly had to learn about these devices from the manufacturers themselves. And many of the theories underlying these devices had a kernel of truth to them, which made it harder for physicians to spot quacks.

HOFF: Hmm.

BRAUNOLD: For instance, electric currents can be used in a medical setting, but not necessarily in the way that device manufacturers were using them, which was very liberally.

HOFF: Mmhmm. [chuckles]

BRAUNOLD: Physicians don’t have the time and resources to do their own research before recommending or condemning medical devices. So, the ways that they learned about these devices were, at the very least I would say, ethically murky.

HOFF: Mmhmm.

BRAUNOLD: The most thorough source of information came from the device makers themselves, and many of those device makers were doctors or had doctors on staff or people who were pretending to be doctors. In fact, many of the people writing into the AMA’s Bureau of Investigation—which is where the lab would check the efficacy of such devices before the existence of the FDA—were doctors themselves who had learned about products from patients who were looking for a cure or manufacturers who were looking to sell or even from fellow doctors who had a stake in the companies. So, the AMA

didn't have time to look into every single device out there. And even once the FDA was created, they could really only regulate the sale and monitor the safety of medical devices. They can't tell doctors what to do when running their businesses or have a say in what they tell their patients or don't tell their patients. So, it's really ultimately up to the doctor's judgment.

And doctors were and are primarily motivated by a desire to help patients. But medicine is also a business, and if they can't recommend a supposed miracle device that their patient wants to use, and they don't have a satisfactory cure to recommend in its stead, then their patients may be more likely to seek answers from a less scrupulous physician or someone who has money at stake in the device. And if their only information that they're getting is from the device makers themselves, you can see how this could create a negative feedback loop.

HOFF: Mm. What's the most important thing for health professions students and trainees to take from your article?

BRAUNOLD: So, as the existence of this issue of the *Journal of Ethics* can attest to, the use of unregulated devices and supplements is not a problem that's gone away with the FDA and better regulations. People can still go online and find pseudoscientific theories and devices that at least sound more promising than what their doctor's offering. Even walking around Walgreens provides patients with a plethora of unregulated options that might appeal to them. And I think that the devices are more appealing if the patients don't trust the medical establishment as a whole or their doctors individually.

HOFF: Mm.

BRAUNOLD: So, the AMA is doing great work to rectify its image, given how many minority communities have been harmed by, and given reason to, mistrust the medical establishment.

HOFF: Mmhmm.

BRAUNOLD: But we still have a far way to go, as can be seen with the vaccine hesitancy in minority communities with COVID today. So, individual doctors also have an important job to do in making sure that their patients feel heard. Even if a doctor can't prescribe an effective and ethical treatment that will completely eliminate a patient's symptoms, patients will be less likely to seek health advice from unethical doctors promising miracle cures or random devices off the Internet if they feel like their doctor is listening to them, understanding them, and providing them with all the available treatment options. If a patient brings up a medical device that's known to be unsafe, then that should absolutely be made clear. If it's simply ineffective, that should be made clear as well. But patients should know that it's ultimately their choice, rather than letting them go away feeling disempowered and maybe more likely to try something risky.

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

BRAUNOLD: So, as I mentioned in the article, people are drawn to the power of new technology and will believe many outrageous claims. The less that's known about a scientific or pseudoscientific concept, the easier it is to get people to believe that it can work miracles. So, right now, new technologies are coming up faster than we can process

them. But what's really surprising is when I was researching these historically disproven medical devices from the 1920s, 100 years ago, how many of them, or at least products relying on the same pseudoscience, are still on the market today.

So, for instance, at the AMA headquarters, we have an exhibit with items from our Historical Health Fraud Collection, which is basically all that remains of the Bureau of Investigation since the FDA was created. And one of the items on display is also mentioned in my article, actually. It's the Sonus Film-O-Sonic, which was created in 1940. And it used song recordings to generate vibrations that were thought to be healing. So, depending on the song, it would cure different diseases.

HOFF: [chuckles]

BRAUNOLD: For instance, *Smoke Gets In Your Eyes*, which is a song from a 1933 musical, was used to treat cancer.

HOFF: Hmm.

BRAUNOLD: So, when I was looking for similar devices, just doing my research, I came across a product for \$879 on the Internet right now that is an acoustic wave therapy device that's marketed as a treatment for erectile dysfunction.

HOFF: Hmm.

BRAUNOLD: And the crazy thing is that the language that's used on the website is so similar to the language used in the advertisements of the early 1900s that it almost feels like all the regulation in the world can't possibly stop companies from using pseudoscience for monetary gain or stop patients from believing these manufacturers, whether it's out of desperation or ignorance. The Internet has really created a new frontier for this, just like the advent of manufacturing and advertising did in the industrial age in the early 20th century. So, in a lot of ways, it feels like we're right back to where we started from, that we had gotten away from the proliferation of these devices with regulations and trust in the medical establishment and lack of options, frankly. And now with the Internet, we're sort of right back to where we were when it was the heyday of snake oil salesmen and quack doctors. [theme music returns]

HOFF: Hmm. Well, that's, [chuckles] that's depressing.

BRAUNOLD: It is! [laughs]

HOFF: But, Jorie, thank you very much for your time and your expertise on this topic.

BRAUNOLD: Thank you so much for having me.

HOFF: To read Jorie Braunold's article, *How Pseudoscience Generated US Material and Device Regulations*, along with the rest of the September 2021 issue, visit our site, JournalofEthics.org. Follow us on [Twitter](https://twitter.com/JournalofEthics) and [Facebook @JournalofEthics](https://facebook.com/JournalofEthics). And we'll be back soon with another episode of *Ethics Talk* from the *American Medical Association Journal of Ethics*.