

## EPISODE – Author Interview: “Who, If Not the FDA, Should Regulate Implantable Brain-Computer Interface Devices?”

Guests: Charles E. Binkley, MD

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 Charles Binkley, the Director of Bioethics at the Markkula Center for Applied Ethics at Santa Clara University in California, where he also leads the Health Care Ethics Internship. Dr Binkley, along with coauthors Michael Pollitt and Dr Brian Green, authored the article *Who, If Not the FDA, Should Regulate Implantable Brain-Computer Interface Devices* in the September 2021 issue of the Journal, *Implantable Material and Device Regulation*. Dr Binkley, thank you very much for joining me and for being on the show. [music fades out]

BINKLEY: Tim, I appreciate the invitation and the opportunity to be with you.

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

BINKLEY: Well, I think there are actually three. So, the first is, how do we separate therapy from enhancement as it's epitomized by brain-computer interface devices? And this has great ethical application for assessing what is safe and what's effective in the context of both therapy and enhancement. We typically think of safe and effective as fairly objective axes for assessment. But actually, when you start to look more closely at these considerations, particularly when it comes to enhancement, individuals may assign different levels of risk and benefit to enhancement devices than they would to therapeutic devices. And so really, we talk in the article a lot about these being more value judgments than they are an objective judgment, and not just only the degree of risk and the degree of benefit, but what's the acceptable ratio between the two of those? And then the third ethical takeaway from the article is, what are the effects of society of even more deeply stratifying access? So, having those people with access and those people without access, particularly to something that will enhance humanity, essentially, creating two different groups within a race.

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

BINKLEY: There's almost certainly going to be more opportunity to think about things, either medications or devices, which both have a therapeutic benefit and potentially have an enhancement aspect to them. So, for instance, take the recently approved drug, aducanumab. Let's say that what we find is not only is it effective at treating or delaying Alzheimer's disease or progression of dementia, but in certain situations may actually slow normal cognitive decline, not just cognitive decline associated with Alzheimer's disease, but just normal cognitive decline that happens throughout the lifespan. So, would that be therapeutic or enhancing? And so, those are the sorts of questions that I think trainees,

medical students, people in the process of entering their careers will have to face as more of these medications and devices come onto the market.

And the other thing that I think all of us are going to have to think more about is what is an acceptable balance between risk and benefit or benefit and burden, if you want to put it that way, particularly in value-laden discussions with patients and helping them make decisions about both these devices and also medications?

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

BINKLEY: Tim, it would really be to think more deeply about what it means to a society to approve something that would enhance part of the society, at least part of the society with access to the device. And these are, these decisions have huge societal repercussions: not only the idea of having a stratified society so that those who are enhanced and those who are unenhanced, but also, what does this say about the nature of humanity? And does it change in some essential way what it means to be a human if you have one group of people who are enhanced and one group of people who are not enhanced? So, some of those deeper philosophical questions we really didn't address, but I think they're very important. [theme music returns]

HOFF: Dr. Binkley, thank you very much for your time and your expertise.

BINKLEY: Thank you, Tim, and thank you to your listeners. Be well.

HOFF: To read the full article along with the rest of the September 2021 issue, [JournalofEthics.org](https://www.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*.