

Why implantable medical devices are a big test for regulators

SEP 7, 2021

Staff News Writer

Some one in 10 Americans will have a medical device implanted into their bodies at some point in their lifetimes, yet less than 1% of these devices have been tested in rigorous clinical trials regarded as standard by U.S. regulators.

The September issue of *AMA Journal of Ethics*[®] (@JournalofEthics) explores implantable material and device regulation, particularly the tension inherent in clinician-investigators' and the FDA's obligation to balance patient-subjects' safety with patients' demand for timely access to technologies and interventions that might improve or extend their lives.

Articles include:

1 "How Should Clinicians and Organizations Assess Risks and Benefits of First-in-Human Implantation of Investigational Devices?"

Heightened caution, improved physician and patient communication, and equitable access are key priorities. You also can listen to the author-interview podcast.

2 "What Should Physician-Researchers Tell Patient-Subjects About Their Relationships With Industry?"

Financial relationships are common, and ethical questions rightly emerge about how conflicts of interest compromise investigators' approaches to research.

3 "What Should the Public Know About Implantable Material and Device Innovation in the U.S.?"

The *AMA Code of Medical Ethics* offers guidance for balancing need for safety with demand for innovation. You also can listen to the author-interview podcast.

4 "How Pseudoscience Generated U.S. Material and Device Regulations"

The AMA's Historic Health Fraud and Alternative Medicine Collection includes images of quack devices from the early 20th century that generated oversight we now take for granted. You also can listen to the author-interview podcast.

Listen and learn

In the journal's August "Ethics Talk" podcast, editorial fellow Ariel Wampler, MD, a plastic and reconstructive surgery resident physician at Lahey Hospital & Medical Center in Burlington, Massachusetts, describes what few know about material and device regulation.

In addition, Adriane Fugh-Berman, MD, professor of pharmacology and physiology at Georgetown University Medical Center, explains why we should ask more questions about device representatives' intraoperative roles during implantations.

The August issue also features two other author-interview podcasts:

- Jeffrey Bedard, MS, a health care consultant and a former medical device representative, talks about his article, "What Should Patients Be Told About Device Representatives' Roles

at the Point of Surgical Care?”

- Charles E. Binkley, MD, director of bioethics at Santa Clara University, in California, expands on his article, co-written with Michael S. Politz and Brian P. Green, PhD, "Who, If Not the FDA, Should Regulate Implantable Brain-Computer Interface Devices?"

Listen to previous episodes of the podcast, “Ethics Talk,” or subscribe in iTunes or other services.

Earn CME

These *AMA Journal of Ethics* CME modules are each designated by the AMA for a maximum of 1 *AMA PRA Category 1 Credit™*:

- How Should Clinicians and Organizations Assess Risks and Benefits of First-in-Human Implantation of Investigational Devices?
- What Should Patients Be Told About Device Representatives’ Roles at the Point of Surgical Care?
- What Should the Public Know About Implantable Material and Device Innovation in the U.S.?
- FDA Device Oversight From 1906 to the Present
- Who, If Not the FDA, Should Regulate Implantable Brain-Computer Interface Devices?
- Is the FDA Failing Women?

Additionally, the CME module “Ethics Talk: Medical Device Representatives in the Surgical Suite” is designated by the AMA for a maximum of 0.25 *AMA PRA Category 1 Credit™*.

The offerings are part of the *AMA Ed Hub™*, an online learning platform that brings together high-quality CME, maintenance of certification, and educational content from trusted sources, all in one place—with activities relevant to you, automated credit tracking and reporting for some states and specialty boards.

Submit manuscripts and artwork

The journal’s editorial focus is on commentaries and articles that offer practical advice and insights for medical students and physicians. *Submit a manuscript* for publication. The journal also *invites original photographs, graphics, cartoons, drawings and paintings* that explore the ethical dimensions of health or health care.

A look ahead

Upcoming issues of the *AMA Journal of Ethics* will focus on palliative surgery, health care and homelessness and health justice and diversity in medical school admissions. Sign up to receive email alerts when new issues are published.