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### FROM THE EDITOR

#### How Differently Should the FDA Regulate Drugs and Devices?

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In 2000, it was estimated that 20 to 25 million Americans had an implanted device,<sup>1</sup> but between 2003 and 2007, less than 1% of devices underwent the 2 large, human clinical trials mandated for US Food and Drug Administration (FDA) pharmaceutical approval.<sup>2,3</sup> Only high-risk devices that are lifesaving or life-supporting are required to submit clinical data to demonstrate their safety and efficacy, also known as the premarket approval (PMA) pathway. Many devices are cleared through premarket notification (PMN), also known as the **510(k) pathway**, which is permitted for low-to-moderate risk devices or those that are, according to manufacturers, essentially equivalent to those already on the market.

Widespread **patient harm** due to medical devices has been chronicled in recent journalistic exposés,<sup>4,5,6,7</sup> congressional hearings,<sup>8</sup> and the 2018 documentary, *The Bleeding Edge*.<sup>9</sup> Examples of such harms include cobalt poisoning due to artificial hips, inadequate or excessive delivery of insulin from implantable pumps, and spinal cord stimulators that deliver painful shocks. The device industry and its regulators are now facing **increased scrutiny** for lax premarket clearance standards,<sup>10,11</sup> suspect advertising practices,<sup>12,13</sup> undisclosed conflicts of interest,<sup>14,15,16,17</sup> deficient postmarket surveillance,<sup>18,19</sup> and inappropriate and inaccurate reporting of injuries and deaths.<sup>20,21,22,23</sup>

The FDA must balance **timely access** to life-extending or life-improving technologies with rigorous safety. The US device approval process is already longer and more stringent than that of Europe, leading many physicians to lament their inability to offer pioneering solutions to disease and disability.<sup>24</sup> A 2010 industry survey reported that PMA devices take on average 54 months from first communication to reach American patients compared with 11 months for European patients. Similarly, PMN pathway devices take on average 31 months from first communication to be cleared in the United States compared with about 7 months in Europe.<sup>25</sup> Moreover, regulatory changes to further improve safety could make devices prohibitively expensive and therefore are unlikely to be supported by patients, physicians, and payers.<sup>26,27,28</sup>

Device industry critics argue that most serious recalls have involved 510(k)-cleared devices<sup>29</sup> and that public protection requires that more devices undergo PMA, with submission of clinical data. Given that medications with adverse effects can usually be discontinued without additional risk, while device removal can cause serious

complications, it might be reasonable to expect implanted devices to meet even higher safety benchmarks than drugs. Additionally, patients harmed by FDA-approved drugs can sue pharmaceutical companies, but the *Riegel v Medtronic* Supreme Court precedent leaves those harmed by FDA-cleared devices without recourse to seek damages from device manufacturers.<sup>30</sup>

Industry advocates, however, point out that less than 1% of all 510(k) and PMA devices that were cleared or approved between 2004 and 2009 have ever been subject to a Class I recall (utilized for major injuries or death).<sup>25</sup> Conducting clinical studies for implantable devices is often more complicated and expensive than for drugs and can be ethically problematic. For example, the closest equivalent to a placebo control pill would be sham surgery, which carries considerably more risk.<sup>31</sup> Even with painstaking design and testing, devices can cause harm if used improperly; companies tend to argue that it's inappropriate for them to be held liable if physicians make poor patient-selection decisions or lack the motor skills needed to implant or operate a device. Device makers appreciate the need for evidence-based approval, but they call for FDA reviewers with more field-specific expertise, as well as for more transparent and predictable regulatory processes in order to efficiently bring their devices to US markets.<sup>25</sup>

How might regulators exercise **sufficient caution** without stifling innovation? Which processes should be used to **mitigate bias** in device research and development and user education, when most experts have industry ties? Which entities should bear **ultimate responsibility** for prevention and compensation for patient harm from devices? This issue of the *AMA Journal of Ethics* invites clinicians, researchers, device representatives, and patient-safety champions to reflect on these and other questions.

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