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Part I - AI and Data as Medical Devices

W. Nicholson Price II
University of Michigan Law School, wnp@umich.edu

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Introduction

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It may seem counterintuitive to open a book on medical devices with chapters on software and data, but these are the frontiers of new medical device regulation and law. Physical devices are still crucial to medicine, but they – and medical practice as a whole – are embedded in and permeated by networks of software and caches of data. Those software systems are often mindbogglingly complex and largely inscrutable, involving artificial intelligence and machine learning. Ensuring that such software works effectively and safely remains a substantial challenge for regulators and policymakers. Each of the three chapters in this part examines different aspects of how best to meet this challenge, focusing on review by drug regulators and, crucially, what aspects of oversight fall outside that purview.

Kerstin Vokinger, Thomas Hwang, and Aaron Kesselheim tackle the question of how food and drug regulators should oversee AI head-on in "Lifecycle Regulation and Evaluation of Artificial Intelligence and Machine Learning-Based Medical Devices." A crucial difference between AI-powered software systems and classic devices, including software devices, is that AI-powered systems are frequently plastic: that is, they change more regularly (or at least can), given new data and new information about the world in which they are deployed. Vokinger and colleagues highlight how American and European regulators are fitting such plastic AI approaches into existing frameworks and suggest that accomplishing the regulatory task requires a combination of strong prospective evidence, ongoing oversight after approval, and transparency to agencies and others.

It is to those others that Barbara Evans and Frank Pasquale turn in "Product Liability Suits for FDA-Regulated AI/ML Software." Regulators are only one part of the oversight picture; tort law lurks in the background to pick up the slack where products result in injury. The relationship between the FDA and tort suits for injuries caused by medical technology is complex, and mostly focused on preemption – when can plaintiffs sue in state court where the products involved are FDA-approved?[1] Evans and Pasquale focus on another aspect of the relationship: the very fact of FDA

[1] See, e.g., Charlotte A. Tschider, Medical Device Artificial Intelligence: The New Tort Frontier, 46 BYU L. Rev. 1551 (2021).

regulation for at least some clinical decision support software helps define the involved software as a "product" – neatly resolving the product/service distinction that has bedeviled tort liability for software more generally. Opening the door to product liability suits generates new possibilities for tort law to enforce requirements on AI-powered software systems. Evans and Pasquale explore the potential for novel tort suits brought on this basis, notably to address questions of explainability and the adequacy of training datasets. Here, too, the analysis highlights the boundary-crossing nature of AI-powered software, as these issues could be tackled by tort law, regulators, or both.

Finally, Craig Konnoth broadens the regulatory oversight focus beyond just artificial intelligence in "Are Electronic Health Records Medical Devices,?" considering the appropriate regulation of electronic health records (EHRs) more generally. Konnoth asks about the EHRs into which clinical decision support and other software are embedded, and which connect different parts of the health system (sometimes with greater success than others). Such interstitial technologies are a persistently challenging target for agency oversight, where different actors have the differing expertise and jurisdiction. Konnoth argues that here, too, the oversight role of the FDA may fruitfully be complemented by another: in this case, the Office of the National Coordinator for Health Information Technology, which could oversee the networking-focused aspects of electronic health records.

Collectively, these chapters demonstrate the challenge of regulating and overseeing the AI- and data-powered software which increasingly shapes medical practice, both behind the scenes and within the examining room. These technologies bring immense potential along with real risk, but present new regulatory challenges due to their opacity, their plasticity, and the speed with which they are being incorporated into the health system. Ensuring the right sort of oversight so that medical devices centered on AI and big data are safe, effective, and deployed in such a way as to actually help the health system demands concerted action from stakeholders across the board.