

## THE FUTURE OF MEDICAL DEVICE REGULATION

Regulators have been more permissive for medical devices compared to their drug and biologic counterparts. While innovative products can thereby reach consumers more quickly, this approach raises serious public health and safety concerns. Additionally, the nature of medical devices is rapidly changing, as software has become as important as hardware. Regulation must keep pace with the current developments and controversies of this technology. This volume provides a multidisciplinary evaluation of the ethical, legal, and regulatory concerns surrounding medical devices in the United States and European Union. For medical providers, policymakers, and other stakeholders, the book offers a framework for the opportunities and challenges on the horizon for medical device regulation. Readers will gain a nuanced overview of the latest developments in patient privacy and safety, innovation, and new regulatory laws. This book is also available as Open Access on Cambridge Core.

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# The Future of Medical Device Regulation

INNOVATION AND PROTECTION

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Contents

<i>List of Figures</i>	<i>page</i> x
<i>List of Tables</i>	xi
<i>List of Contributors</i>	xii
<i>Acknowledgments</i>	xiv
 <b>Introduction</b>	
I. Glenn Cohen, Timo Minssen, W. Nicholson Price II, Christopher Robertson, and Carmel Shachar	1
 <b>PART I AI AND DATA AS MEDICAL DEVICES</b>	
 <b>Introduction</b>	
W. Nicholson Price II	11
 <b>1 Lifecycle Regulation and Evaluation of Artificial Intelligence and Machine Learning-Based Medical Devices</b>	 13
Kerstin N. Vokinger, Thomas J. Hwang, and Aaron S. Kesselheim	
 <b>2 Product Liability Suits for FDA-Regulated AI/ML Software</b>	 22
Barbara J. Evans and Frank Pasquale	
 <b>3 Are Electronic Health Records Medical Devices?</b>	 36
Craig Konnoth	
 <b>PART II EUROPEAN REGULATION OF MEDICAL DEVICES</b>	
 <b>Introduction</b>	
Timo Minssen	47

4	<b>Cybersecurity of Medical Devices: Regulatory Challenges in the European Union</b> Elisabetta Biasin and Erik Kamenjasevic	51
5	<b>The mHealth Power Paradox: Improving Data Protection in Health Apps through Self-Regulation in the European Union</b> Hannah van Kolfschooten	63
6	<b>The Interaction of the Medical Device Regulation and the GDPR: Do European Rules on Privacy and Scientific Research Impair the Safety and Performance of AI Medical Devices?</b> Janos Meszaros, Marcelo Corrales Compagnucci, and Timo Minssen	77
7	<b>AI, Explainability, and Safeguarding Patient Safety in Europe: Toward a Science-Focused Regulatory Model</b> Barry Solaiman and Mark G. Bloom	91
8	<b>Regulation of Digital Health Technologies in the European Union: Intended versus Actual Use</b> Helen Yu	103
<b>PART III DESIGNING MEDICAL DEVICE REGULATIONS</b>		
	<b>Introduction</b> I. Glenn Cohen	115
9	<b>IP and FDA Regulation of De Novo Medical Devices</b> Mateo Aboy and Jacob S. Sherkow	117
10	<b>A “DESI” for Devices? Can a Pharmaceutical Program from the 1960s Improve FDA Oversight of Medical Devices?</b> Matthew Herder and Nathan Cortez	129
11	<b>Digital Home Health During the COVID-19 Pandemic: Challenges to Safety, Liability, and Informed Consent, and the Way to Move Forward</b> Sara Gerke	141
<b>PART IV THE IMPACT OF MEDICAL DEVICE REGULATION ON PATIENTS AND MARKETS</b>		
	<b>Introduction</b> Christopher Robertson	161

12	<b>Clouded Judgment: Preventing Conflicts of Interest in Drug Courts</b> Jody Lynée Madeira, Barbara Andraka-Christou, Lori Ann Eldridge, and Ross D. Silverman	165
13	<b>Disrupting the Market for Ineffective Medical Devices</b> Wendy Netter Epstein	179
14	<b>Preventing Medical Device-Borne Outbreaks: The Case of High-Level Disinfection Policy for Duodenoscopes</b> Preeti Mehrotra, David J. Weber, and Ameet Sarpatwari	192
15	<b>Regulating Devices that Create Life</b> Katherine L. Kraschel	203
<b>PART V MEDICAL AND LEGAL OVERSIGHT OF MEDICAL DEVICES</b>		
	<b>Introduction</b> Carmel Shachar	215
16	<b>Ensuring Patient Safety and Benefit in Use of Medical Devices Granted Expedited Approval</b> Sanket S. Dhruva, Jonathan J. Darrow, Aaron S. Kesselheim, and Rita F. Redberg	217
17	<b>Compulsory Medical Device Registries: Legal and Regulatory Issues</b> Efthimios Parasidis and Daniel B. Kramer	229
18	<b>Professional Self-Regulation in Medicine: Will the Rise of Intelligent Tools Mean the End of Peer Review?</b> Anthony P. Weiss and Barak D. Richman	244
19	<b>Regulating Posttrial Access to In-Dwelling Class III Neural Devices</b> Megan S. Wright and Joseph J. Fins	256
20	<b>Strengthening the Power of Health Care Insurers to Regulate Medical Device Risks</b> David Rosenberg and Adeyemi Adediran	268

Figures

2.1	The FDA’s jurisdiction to regulate CDS software under the Cures Act	<i>page</i> 26
6.1	The processing of health data for developing AI medical devices	87
7.1	Example of an ANN	94

Tables

5.1	Health data protection in app store policies	<i>page</i> 70
17.1	Hypotheses	235
17.2	Specifications and study goals	236

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xiii

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