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.

I. Glenn Cohen is James A. Attwood and Leslie Williams Professor of Law, Deputy Dean, and Faculty Director at the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.

Timo Minssen is Professor of Law and Director of the Center for Advanced Studies in Biomedical Innovation Law (CeBIL) at the Faculty of Law, University of Copenhagen, Denmark.

W. Nicholson Price II is Professor of Law at the University of Michigan School of Law.

Christopher Robertson is Professor and N. Neal Pike Scholar in Health & Disability Law at the School of Law, Boston University.

Carmel Shachar is Executive Director of the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.
The Future of Medical Device Regulation

INNOVATION AND PROTECTION

Edited by

I. GLENN COHEN
Harvard Law School

TIMO MINSEN
University of Copenhagen

W. NICHOLSON PRICE II
University of Michigan

CHRISTOPHER ROBERTSON
Boston University

CARMEL SHACHAR
Harvard Law School
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   For Peter Barton Hutt, who taught me everything I know about FDA and much more.

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Contributors

Mateo Aboy, University of Cambridge
Adeyemi Adediran, J.D. 2021, Harvard Law School
Barbara Andraka-Christou, University of Central Florida
Elisabetta Biasin, KU Leuven Centre for IT & IP Law
Mark G. Bloom, TechNomos, Inc.
I. Glenn Cohen, Harvard Law School
Marcelo Corrales Compagnucci, University of Copenhagen
Nathan Cortez, SMU Dedman School of Law
Jonathan J. Darrow, Harvard Medical School
Sanket S. Dhruba, University of California, San Francisco
Lori Ann Eldridge, Indiana University
Wendy Netter Epstein, DePaul University College of Law
Barbara J. Evans, University of Florida
Joseph J. Fins, Weill Cornell Medical College
Sara Gerke, Penn State Law
Matthew Herder, Schulich School of Law, Dalhousie University
Thomas J. Hwang, Brigham and Women’s Hospital; Harvard Medical School
Erik Kamenjasevic, KU Leuven Centre for IT & IP Law
Aaron S. Kesselheim, Brigham and Women’s Hospital; Harvard Medical School
Craig Konnoth, University of Colorado Law School

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www.cambridge.org
List of Contributors

Daniel B. Kramer, Beth Israel Deaconess Medical Center; Harvard Medical School
Katherine L. Kraschel, Yale Law School
Jody Lynee Madeira, Maurer School of Law, Indiana University
Preeti Mehrotra, Beth Israel Deaconess Medical Center; Harvard Medical School
Janos Meszaros, KU Leuven Centre for IT & IP Law
Timo Minssen, University of Copenhagen
Efthimios Parasidis, The Ohio State University
Frank Pasquale, Brooklyn Law School
W. Nicholson Price II, University of Michigan School of Law
Rita F. Redberg, University of California, San Francisco
Barak D. Richman, Duke University School of Law
Christopher Robertson, Boston University School of Law
David Rosenberg, Harvard Law School
Ameet Sarpatwari, Brigham and Women’s Hospital; Harvard Medical School
Carmel Shachar, Harvard Law School
Jacob S. Sherkow, University of Illinois College of Law
Ross D. Silverman, Indiana University
Barry Solaiman, Hamad Bin Khalifa University
Hannah van Kolfschooten, University of Amsterdam
Kerstin N. Vokinger, University of Zurich
David J. Weber, University of Maryland School of Medicine
Anthony P. Weiss, Beth Israel Deaconess Medical Center; Harvard Medical School
Megan S. Wright, Penn State Law
Helen Yu, University of Copenhagen
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1 Melyssa Eigen, Brian Brooks, and Nathan Rabb.