

Big Data, Health Law, and Bioethics

Edited by

I. GLENN COHEN

Harvard Law School

HOLLY FERNANDEZ LYNCH

Perelman School of Medicine, University of Pennsylvania

EFFY VAYENA

Swiss Federal Institute of Technology (ETH Zurich)

URS GASSER

Berkman Klein Center for Internet & Society, Harvard University



CAMBRIDGE
UNIVERSITY PRESS

Contents

<i>List of Editors and Contributors</i>	page xi
<i>Acknowledgments</i>	xvii
Introduction	1
I. Glenn Cohen, Holly Fernandez Lynch, Effy Vayena, and Urs Gasser	
PART I SHIFTING PARADIGMS: BIG DATA’S IMPACT ON HEALTH LAW AND BIOETHICS	15
Introduction	15
Urs Gasser	
1 Big Data and Individual Autonomy in a Crowd	19
Barbara J. Evans	
2 Big Data’s Epistemology and Its Implications for Precision Medicine and Privacy	30
Jeffrey M. Skopek	
3 Correlation versus Causation in Health-Related Big Data Analysis: The Role of Reason and Regulation	42
Tal Z. Zarsky	
4 Big Data and Regulatory Arbitrage in Healthcare	56
Nicolas P. Terry	
PART II OVERCOMING THE DOWNSIDES OF BIG DATA	69
Introduction	69
I. Glenn Cohen	

5	The Future of Pharmacovigilance: Big Data and the False Claims Act	73
	Efthimios Parasidis	
6	Big Data's New Discrimination Threats: Amending the Americans with Disabilities Act to Cover Discrimination Based on Data-Driven Predictions of Future Disease	85
	Sharona Hoffman	
7	Who's Left Out of Big Data? How Big Data Collection, Analysis, and Use Neglect Populations Most in Need of Medical and Public Health Research and Interventions	98
	Sarah E. Malanga, Jonathan D. Loe, Christopher T. Robertson, and Kenneth S. Ramos	
8	Potential Roadblocks in Healthcare Big Data Collection: <i>Gobeille v. Liberty Mutual</i>, ERISA, and All-Payer Claims Databases	112
	Carmel Shachar, Aaron S. Kesselheim, Gregory Curfman, and Ameet Sarpatwari	
	PART III THE INTERNET OF THINGS (IOT) AND HEALTH BIG DATA	125
	Introduction	125
	<i>Nathan Cortez</i>	
9	Avoiding Overregulation in the Medical Internet of Things	129
	Dov Greenbaum	
10	Data Policy for Internet of Things Healthcare Devices: Aligning Patient, Industry, and Privacy Goals in the Age of Big Data	142
	Marcus Comiter	
	PART IV PROTECTING HEALTH PRIVACY IN THE WORLD OF BIG DATA	157
	Introduction	157
	<i>Effy Vayena</i>	
11	Thought-Leader Perspectives on Risks in Precision Medicine Research	161
	Laura M. Beskow, Catherine M. Hammack, Kathleen M. Brelsford, and Kevin C. McKenna	

12	From Individual to Group Privacy in Biomedical Big Data Brent Mittelstadt	175
13	Big Data and Informed Consent: The Case of Estimated Data Donna M. Gitter	193
	PART V OVERSIGHT OF BIG DATA HEALTH RESEARCH: PROPOSALS FOR IMPROVEMENT	205
	Introduction <i>Holly Fernandez Lynch</i>	205
14	Is There a Duty to Share Healthcare Data? I. Glenn Cohen	209
15	Societal Lapses in Protecting Individual Privacy, the Common Rule, and Big Data Health Research Laura Odwazny	223
16	The Common Rule and Research with Data, Big and Small Liza Dawson	237
17	Big Data, HIPAA, and the Common Rule: Time for Big Change? Margaret Foster Riley	251
	PART VI BIG DATA, FDA, AND LIABILITY CONSIDERATIONS	265
	Introduction <i>Jerry Avorn</i>	265
18	Data Sharing that Enables Postapproval Drug and Device Research and Protects Patient Privacy: Best Practice Recommendations Ameet Sarpatwari, Bradley A. Malin, Aaron S. Kesselheim, Joshua J. Gagne, and Sebastian Schneeweiss	269
19	Big Data and Human Medical Judgment: Regulating Next-Generation Clinical Decision Support Jeffrey M. Senger and Patrick O'Leary	283
20	Medical Malpractice and Black-Box Medicine W. Nicholson Price II	295
	PART VII INTELLECTUAL PROPERTY RIGHTS FOR HEALTH BIG DATA	307
	Introduction <i>Rachel E. Sachs</i>	307

21	Big Data and Intellectual Property Rights in the Health and Life Sciences	311
	Timo Minssen and Justin Pierce	
22	The Pathologies of Data-Generating Patents	324
	Ted Sichelman and Brenda M. Simon	
	Epilogue: Professional Cooperation and Rivalry in the Future of Data-Driven Healthcare	337
	Frank Pasquale	
	<i>Index</i>	341