# AMERICAN JOURNAL OF LAW & MEDICINE

Volume 44, Numbers 2 & 3 • 2018

#### **BOARD OF EDITORS**

#### **Faculty Advisors**

Kevin Outterson, J.D., LL.M. Kathryn Zeiler, M.S., J.D., Ph.D. *Boston University School of Law* 

Faculty Editor-in-Chief Emeritus Frances H. Miller, J.D. Boston University School of Law Editor Edward J. Hutchinson American Society of Law, Medicine & Ethics

Founding Editor John A. Norris, J.D., M.B.A. *Health Discovery Corp.* 

#### EDITORS

Gail B. Agrawal, J.D., M.P.H. University of Iowa College of Law

Michael Baram, J.D. Boston University School of Law

Charles H. Baron, LL.B., Ph.D. Boston College Law School

Jay A. Gold, M.D., J.D., M.P.H. MetaStar Inc., Madison

Ernest M. Haddad, J.D. Boston University School of Law

Clark C. Havighurst, J.D. Duke University School of Law

Nathan Hershey, LL.B. University of Pittsburgh Graduate School of Public Health (Retired)

David A. Hyman, M.D., J.D. University of Illinois College of Law

Sheila Jasanoff, J.D., Ph.D. Harvard University Kennedy School of Government

Timothy S. Jost, J.D. Washington and Lee University School of Law

Stephen Latham, J.D., Ph.D. Yale University Interdisciplinary Center for Bioethics

Silvia A. Law, J.D. New York University School of Law David T. Morris, J.D., M.B.A. AbbVie, Chicago

Joseph P. Newhouse, Ph.D. Harvard University

Irwin N. Perr, M.D., J.D. University of Washington School of Medicine

Harvey E. Pies, J.D., M.P.H. Blue Cross and Blue Shield of Florida

> Arti K. Rai, J.D. Duke University Law School

Philip R. Reilly, M.D., J.D. Third Rock Ventures, LLC

Marc A. Rodwin, J.D., Ph.D. Suffolk University Law School

Mark A. Rothstein, J.D. University of Louisville School of Medicine Institute for Bioethics, Health Policy and Law

> David S. Szabo, J.D. Edwards Wildman Palmer LLP

> > Linda V. Tiano, J.D. *Healthfirst, Inc.*

Sidney D. Watson, J.D. Saint Louis University School of Law

# AMERICAN JOURNAL OF LAW & MEDICINE

#### INTERNATIONAL BOARD OF EDITORS

Koichi Bai Director, Institute of Medical Humanities Kitasato University School of Medicine JAPAN

> Erwin Deutsch Faulty of Law University of Göttingen GERMANY

Bernard M. Dickens, Ph.D., LL.D. Faculties of Law and Medicine University of Toronto CANADA

Honorable Justice Michael D. Kirby President, Court of Appeal Supreme Court of New South Wales AUSTRALIA M.A.M. de Wachter Director, Institute of Bioethics THE NETHERLANDS

Christopher Newdick Reader in Health Law University of Reading UNITED KINGDOM

> Amos Shapira Faculty of Law Tel Aviv University ISRAEL

> Peter D.G. Skegg Faculty of Law University of Otago NEW ZEALAND

# STUDENT BOARD OF EDITORS 2017-2018

### Editor-in-Chief Andrea-Gale Okoro

#### **Executive Editor**

Nicholaas H.P. Honig

# Kathleen Henry

Managing Editors Melissa Kraus

Catherine Mullaley

#### **Projects Editor**

Amar J. Patel

Administrative Editor Vincent Uy

#### Symposium Editors

Sana Shakir Jordan Shelton

**Note Editors** 

#### **Articles Editors**

Monica Chou Carmen Riethman Aaron I. Wiener Christina Zandri Eric Dunbar Vlada Feldman Arielle Heinke Jessica A. Scarbrough Nicholas Stone

#### **Communications Editor**

Michael E. Onah

#### **Staff Members**

Victor Absil Marisa Bartolotta Sydney Burns Emily Chamberlin Kelly Christensen Cambrey Dent Williams Dixon Diego Duarte Colleen Flaherty Xavier (Brandon) Frank Rose Garson Victor Gibson Christopher Gillis David Habib Yue (Amy) Han Nia Johnson Olivia King Anna Kozlowski Hongpyo Lee Molly Maidman Jessica Matthis Kendahl Melvin Kelly Moran Sam Nofer Matthew Parker Michael Ragan David Shore Kristen Wice

# LAW & MEDICINE

# is pleased to introduce its student board of editors for 2018-2019

#### **Editor-in-Chief**

Nia Johnson

**Executive Editor** Christopher Gillis

Williams Dixon

Managing Editors Kelly Moran

Kristen Wice

**Administrative Editor** 

**Emily Chamberlin** 

#### **Projects Editor**

Matthew Parker

Symposium Editors

Olivia King Anna Kozlowski

#### **Articles Editors**

#### **Notes Editors**

Cambrey Dent Yue (Amy) Han Molly Maidman David Shore Kelly Christensen Xavier Frank David Habib Kendahl Melvin

**Communications Editor** Sydney Burns

# LAW & MEDICINE

Volume 44, Numbers 2 & 3 • 2018

#### ARTICLES

- **155 Preface:** The 21st Century Cures Act—A Cure for the 21st Century? *Andrea-Gale Okoro*
- **157 The 21st Century Cures Potpourri:** Was It Worth the Price? *Jerome P. Kassirer*
- **161 Real-World Evidence in the Real World:** Beyond the FDA *Joan H. Krause S Richard S. Saver*
- 181 Off-Label Marketing's Audiences: The 21st Century Cures Act and the Relaxation of Standards for Evidence-Based Therapeutic and Cost-Comparative Claims *Sam F. Halabi*
- **197 Real-World Data Analytics Fit for Regulatory Decision-Making** Sebastian Schneeweiss & Robert J. Glynn
- 219 Practice-Based Research Networks and the Mandate for Real-World Evidence Elizabeth Hall-Lipsy, Leila Barraza & Christopher Robertson
- 237 The Challenge of Regulating Clinical Decision Support Software After 21st Century Cures Barbara Evans & Pilar Ossorio
- 253 Fast-Forward to the Frightening Future: How the 21st Century Cures Act Accelerates Technological Innovation...at Unknown Risk to Us All Anthony W. Orlando & Arnold J. Rosoff
- **269 21st Century Cures Act and Medical Device Regulation:** Departure from Principles or Catching the Wave *Eleanor D. Kinney*
- **291 A RAT by Another Name:** 21st Century Cures Act and Stem Cell Therapies *Margaret F. Riley*
- **309 21st Century Citizen Pharma:** The FDA & Patient-Focused Product Development *Jordan Paradise*

# LAW & MEDICINE

Volume 44, Numbers 2 & 3 • 2018

- **329** Expansion of the Priority Review Voucher Program Under the 21st Century Cures Act: Implications for Innovation and Public Health *Michael S. Sinha, Nina Jain, Thomas Hwang & Aaron S. Kesselheim*
- 343 New and Improved? 21st Century Cures Act Revisions to Certificates of Confidentiality Leslie E. Wolf & Laura M. Beskow
- **359 21st Century Cures for the Opioid Crisis:** Promise, Impact, and Missed Opportunities *Leo Beletsky*
- 387 How the 21st Century Cures Act Can Mitigate the Ever Growing Problem of Mass Incarceration *Jennifer S. Bard*
- **403** The Evolution of Federal Regulation of Human Drugs in the United States: An Historical Essay *Peter B. Hutt*

#### NOTES & RECENT TRANSACTION COMMENTS

- 453 The Growing Importance of Mental Health Parity Jessica A. Scarbrough
- 475 Massachusetts Approves Mass. Eye & Ear and Partners HealthCare Merger Kendahl L. Melvin