Volume 48, Number 4 • 2022

ARTICLES

- **307** Shattering the Mirage: The FDA's Early COVID-19 Pandemic Response Demonstrates a Need for Reform to Restore Agency Credibility *Christina Fuleihan*
- 343 Preventive Care: Improving Health of Medicare, Medicaid, and Children's Health Insurance Program Patients Through Access to Fresh Fruit and Vegetables Weston McClain
- **380** Recalibrating Transplant Eligibility Criteria: Ensuring Equitable Access to Organ Transplantation for Intellectually Disabled Persons *Adam Peña*
- **412 Pelvic Exam Laws in the United States: A Systematic Review** *Mihael Plantak, Scott M. Alter, Lisa M. Clayton, Patrick G. Hughes, Richard D. Shih, Monica Mendiola, and Joshua J. Solano*
- 420 Straight Teeth and Misaligned Interests: Courtrooms Are Crowded with SmileDirectClub Litigation Chaninah Zweihorn

NOTES

- 435 Hairdos and Help-seeking: Mandatory Domestic Violence Training for Salon Workers Julia Novick
- 447 Synthetic Biology: State Regulation in the Biomedical Context Julia Watson

RECENT CASE DEVELOPMENTS

- 469 The Balancing Act in Regulation Between the FDA and the Court's Role in Promoting Children's Health: *In re: Gerber Products Company Heavy Metals Baby Food Litigation Daniela del Campo*
- **472 Opioid Litigation: Lessons Learned from a Retail Pharmacy Settlement** *Shannon A. Gonick*
- 481 Puerto Rico's Attempts to Address a Public Health Crisis Struck Down by the United States Court of Appeals for the First Circuit *Minji Kim*

A Journal of the American Society of Law, Medicine & Ethics www.aslme.org



Published by the American Society of Law, Medicine & Ethics and Boston University School of Law. Copyright held by the Trustees of Boston University.





The American Journal of Law & Medicine (AJLM) is North America's leading health law journal devoted exclusively to the analysis of issues at the nexus of law and medicine. Its broad editorial scope includes health law and policy; updates on significant legal decisions and developments affecting health care; legal, ethical and economic aspects of medical prac¬tice, research and education; book reviews; and much more. The editors invite the submission of original manuscripts on medicolegal topics. For details, see the inside back cover.

The American Journal of Law & Medicine is published by Cambridge University Press on behalf of the Trustees of Boston University and the American Society of Law, Medicine & Ethics.

ISSN: 0098-8588

E-ISSN: 2375-835X

Copyright © 2023 by Trustees of Boston University. All rights reserved. No portion of the contents may be reproduced in any form without written permission from the publisher.

Printed in the USA by The Sheridan Group

Editorial Office

American Journal of Law & Medicine, 765 Commonwealth Avenue, Suite 1702, Boston, MA 02215 USA

E-mail: ajlm@bu.edu

Submission Guidelines: For submission guidelines, please contact the editorial office at ajlm@bu.edu or go to cambridge.org/ajlm/submit

Subscribe or Recommend a Subscription to your Librarian: Go to cambridge.org/ajlm/subscribe or email subscriptions_newyork@cambridge.org (in the USA, Canada or Mexico) or journals@cambridge.org (elsewhere). **Copyright and Permissions:** To request permission for republish¬ing, reproducing, or distributing material from this journal, please visit the desired article at cambridge.org/ajlm and click "Rights & Permissions." For addi¬tional information, please see cambridge.org/about-us/rights-permissions.

Advertising and Reprints: Contact ad_sales@cambridge.org. Acceptance of advertising in this journal in no way implies endorsement of the advertised product or service by Cambridge University Press, the Trustees of Boston University, American Society of Law, Medicine & Ethics or the journal editor(s). We reserve the right to reject any advertising it deems as inappropriate for this journal.

Member Subscription Information: American Society of Law, Medicine & Ethics member inquiries, change of ad¬dress, back issues, claims, and membership renewal requests should be addressed to Membership Director, American So¬ciety of Law, Medicine & Ethics, 765 Commonwealth Avenue, Suite 1704, Boston, MA 02215; telephone: (617) 262-4990 ext. 15. Requests for replacement issues should be made within six months of the missing or damaged issue. Beyond six months and at the request of the American Society of Law, Medicine & Ethics, the publisher will supply replacement issues when losses have been sustained in transit and when the reserve stock permits.

Claims or Change of Address for Non-Members:

Should be directed to subscriptions_newyork@ cambridge.org (in the USA, Canada or Mexico) or journals@cambridge.org (elsewhere).

Discover the Entire AJLM Back Archive: cambridge.org/ajlm/read

ADMINISTRATIVE OFFICERS OF BOSTON UNIVERSITY SCHOOL OF LAW ROBERT A. BROWN, Ph.D., President

ANGELA ONWUACHI-WILLIG, J.D., M.Phil., Ph.D., Dean; Professor of Law

FREDERICK TUNG, J.D., Associate Dean for Academic Affairs; Howard Zhang Faculty Research JAMES E. FLEMING, J.D., Ph.D., Associate Dean for Research and Intellectual Life and Professor of Law

KRISTIN COLLINS, J.D., Associate Dean for Intellectual Life; Peter Paul Career Development Professor; Professor of Law

MARGARET MAISEL, J.D., Associate Dean for Experiential Education, Clinical Professor of Law

OFFICERS OF THE AMERICAN SOCIETY OF LAW, MEDICINE & ETHICS JAIME S. KING, J.D., Ph.D., President LINDSAY F. WILEY, J.D., M.P.H., IMMEDIATE PAST PRESIDENT ELLIOT L. SAGALL, M.D. (dec.), Founder and First President

Volume 48, Number 4 • 2022

BOARD OF EDITORS

Faculty Advisors

Kevin Outterson, J.D., LL.M. Kathryn Zeiler, M.S., J.D., Ph.D. Christopher Robertson, M.A., 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. Locke Lord

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

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

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 2022-2023

> Editor-in-Chief Katrina Morris

Senior Articles Editor Leah Gervin

Executive Editor Rory Hanrahan

Managing Editors Sabrina Geisler Savannah Luschei Sheridan Organ Alex Utz Articles Editors John Busse Anna Gunning Julia Novick John Toomey

Special Projects Editor

Minji Kim

Administrative Editor

Jessica Gedallovich

Communications Editor Morgan Hill

Staff Members

Angelo Atangan Anna Braman Tess Cushing Daniela del Campo Lis Delvalle Mendoza Nicole Doherty Sean Dooling Devan Eaton Shannon Gonick Andrew Grant Kaye-Alese Green Isabella Grillo Allison Herr Dillon Kim Akindele Kitwana Rachele Lajoie Anna Lowney Isaac Margolis Domenique Masi Lawrence McCarthy Madison McMahan Hannah Merry Tess Oatley Jason J. Perez Benavides David Peterson Steven Russell Notes Editors Phil Dutko Annabel Kupke David Quattrochio Madeline Reyes Alexandra Wainwright

Symposium Editors

Ryan Platt Gwendolyn Walker

Ethan Savitch Sarah Shahabi Kimberly Shatford Etty Singer Ani Soultanian Danielle Stewart Dia Su Tyler Thomas Erin Wolter Chanho Yoo

AMERICAN JOURNAL OF

LAW & MEDICINE

Volume 48, Number 4 • 2022

ARTICLES

- 307 Shattering the Mirage: The FDA's Early COVID-19 Pandemic Response Demonstrates a Need for Reform to Restore Agency Credibility *Christina Fuleihan*
- 343 Preventive Care: Improving Health of Medicare, Medicaid, and Children's Health Insurance Program Patients Through Access to Fresh Fruit and Vegetables *Weston McClain*
- 380 Recalibrating Transplant Eligibility Criteria: Ensuring Equitable Access to Organ Transplantation for Intellectually Disabled Persons Adam Peña
- **412** Pelvic Exam Laws in the United States: A Systematic Review Mihael Plantak, Scott M. Alter, Lisa M. Clayton, Patrick G. Hughes, Richard D. Shih, Monica Mendiola, and Joshua J. Solano
- 420 Straight Teeth and Misaligned Interests: Courtrooms Are Crowded with SmileDirectClub Litigation Chaninah Zweihorn

NOTES

- 435 Hairdos and Help-seeking: Mandatory Domestic Violence Training for Salon Workers Julia Novick
- **447** Synthetic Biology: State Regulation in the Biomedical Context Julia Watson

RECENT CASE DEVELOPMENTS

469 The Balancing Act in Regulation Between the FDA and the Court's Role in Promoting Children's Health: *In re: Gerber Products Company Heavy Metals Baby Food Litigation* Daniela del Campo

- **472 Opioid Litigation: Lessons Learned from a Retail Pharmacy Settlement** *Shannon A. Gonick*
- 481 Puerto Rico's Attempts to Address a Public Health Crisis Struck Down by the United States Court of Appeals for the First Circuit *Minji Kim*