

Annals of Health Law

Volume 29
Issue 1 *Winter 2020*

Article 2

2020

Foreword

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Recommended Citation

Isabella Masini *Foreword*, 29 *Annals Health L.* (2020).

Available at: <https://lawcommons.luc.edu/annals/vol29/iss1/2>

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Foreword

The *Annals of Health Law and Life Sciences* Editorial Staff is proud to present our Winter 2020 Issue. Each year, our Editorial Board seeks out articles covering important and contemporary topics within the health law and life sciences law community. The health care and life sciences matters addressed in the Winter 2020 Issue particularly furthers the *Annals* tradition of covering a broad range of current and intriguing topics. These selected pieces contribute to the continued recognition of *Annals of Health Law and Life Sciences* as one of the country's preeminent health and life sciences law and policy journals.

The first article, authored by George Horvath, discusses a new way the FDA can address physicians' off-label prescribing practices. Horvath examines and compares the approved uses of drugs and the off-label drug uses. Horvath then speaks to the FDA's traditional approach to addressing the risks of off-label uses, and critiques whether regulation of manufacturers' off-label promotion is the proper approach. Horvath reviews scholars' proposals that have been put forward to address the risks associated with off-label drug use. Horvath concludes by providing his own proposal that involves a modification of drug labels that provides physicians with information about how well supported, or unsupported, their off-label prescriptions are.

The second article, authored by Craig Konnoth, compares the micro- and macro-level regulation developed in the 21st Century Cures Act to address electronic health data. Konnoth first explains the history of health data regulation and how the 21st Century Cures Act has altered how health information is structured by providers and health care entities. Konnoth assesses the micro-level of regulation of electronic health records through the creation of a voluntary certification program to incentivize. He then examines the macro-level regulation the Cures Act promotes the national health information network on which electronic health records are transmitted. Konnoth posits additional incentives for the voluntary program and network to ensure successful implementation of electronic health data regulation.

The third article, authored by Alexandra Foulkes, Jessica Roberts, Paul Appelbaum, Wendy Chung, Ellen Wright Clayton, Barbara Evans and Gary Marchant, exhibits a fifty-state survey assessing whether clinical laboratories are "health care providers" for the purposes of medical malpractice. The authors strive to address which body of law states apply to clinical genetic laboratories when facing legal liability. The authors find that six states expressly include laboratories or laboratory personnel in their statutory

definition of health care provider, fifteen states have judicial opinions that treat laboratories as health care providers, and four states have caselaw concluding that laboratories are not health care providers. However, twenty-five states have yet to decide this matter. The authors conclude that the legislatures in these states should provide clarity regarding the potential medical malpractice liability of clinical genetics laboratories.

The fourth article, authored by Katherine Drabiak, provides insight into the balance between state's police power of removing non-medical exemptions to vaccinations and public health policies. Drabiak explores the role of non-medical exemptions, reasons for parental vaccine hesitancy, and nuances involved in parental decision-making. Drabiak analyzes observations and applications of the Supreme Court of the United States' decisions and dicta in *Jacobson v. Massachusetts* and *Prince v. Massachusetts*. Drabiak exposes how current legislation that removes non-medical exemptions to vaccinations may exceed the permissible scope of the state's police power based on Constitutional and jurisprudential limits by clarifying the development of law in the areas of substantive due process, informed consent, a child's right to an education, and parental decision-making. Drabiak completes the analysis of vaccine law with a discussion of public health ethics and policy solutions that prioritize accountability, transparency, and trust.

The fifth article, authored by Jackson Williams, explores the question as to whether states shall implement reference-based pricing for health care services or products to contain health care costs. Williams begins by categorizing current reference-based pricing techniques and discusses the negotiating or leverage dynamics and practical and legal implications of each. Williams explores referenced-based pricing policy implementation in states such as California, Montana, and North Carolina. Williams concludes that further experimentation of reference-based pricing policies is warranted.

On behalf of the entire *Annals of Health Law and Life Sciences* Editorial Staff, I would like to thank George Horvath, Craig Konnoth, Alexandra Foulkes, Jessica Roberts, Paul Appelbaum, Wendy Chung, Ellen Wright Clayton, Barbara Evans, Gary Marchant, Katherine Drabiak, and Jackson Williams for contributing their extraordinary talent and knowledge to this outstanding issue. This issue is the manifestation of the authors' scholarship and passion, as well as their exceptional collaboration and professionalism. The Editorial Board and I would like to thank every member of the *Annals* team for their enthusiasm, commitment, and diligence throughout the editing process. I would also like to express my sincerest gratitude to my colleagues on the Executive Board: Christina Perez-Tineo, Nicolette Taber, Alesandra Hlaing, Raquel Boton, Hannah Lehmann, and Jacalyn Smith. Additionally, I would like to acknowledge the outstanding efforts of our Senior Editors: Haley Comella, Jan Michael Dervish, Elizabeth Heredia, and Rachel Kemel. Finally, we would like to thank the amazing faculty at the Beazley Institute for Health Law and Policy for their continued support of

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our endeavors. The success of this issue would not have been possible without the hard work and dedication of everyone involved.

It is with great pride that we present the Winter 2020 Issue of *Annals of Health Law and Life Sciences*.

Sincerely,

Isabella Masini
Editor-in-Chief
Annals of Health Law and Life Sciences