Utah Law Review

Volume 2021 | Number 4 Article 1

11-2021

Preface

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PREFACE

When the *Utah Law Review* editors selected the topic for this symposium issue in early February 2020, we did not anticipate—nor would we have wished for—how exceptionally timely the topic would become over the next year-and-a-half. By the time we were extending invitations to participate in the fall 2020 symposium event, most teaching and learning at the law school, including the annual Lee E. Teitelbaum law review symposium, had moved online. As in so many aspects of life during the pandemic, our conversations turned to COVID-19. The extent and forms of regulation of medical research in the U.S. are sources of persistent controversy. COVID-19 only added fuel to the fire, pressing urgent needs for information and innovation.

The panelists for the symposium event, including the seven who wrote for this symposium issue, did a superb job of placing the topic of the moment within the long-running debates about the law and ethics of medical research. Sometimes that place was one of continuity. Yet authors also highlighted how the disruption of the pandemic has spurred new ways of doing things—and made calls for legal reforms to support further innovation. Some of our authors addressed topics at the intersection of privacy and the advancement of medical research that will matter for continued efforts to improve individual and public health, including combatting COVID-19.

For Ana Santos Rutschman, a leading expert on vaccine clinical trials and the author of the first article in this issue, the COVID-19 pandemic represents both continuity and change. Rutschman reflects on how COVID-19 vaccine development is part of the long-running evolution of how vaccine data are gathered and disseminated. In particular, she addresses how the data infrastructure for COVID-19 vaccine clinical trials has been shaped by existing laws and long-term ethical issues in medical research. And yet Rutschman also sees the potential for the COVID-19 pandemic to serve as an inflection point causing us to reevaluate laws and ethical norms that govern the conduct of medical research. Rutschman argues that the data sharing policy adopted by the European Medicines Agency, the European counterpart to the U.S. Food and Drug Administration, provides a model for quickly expanding access to information about the approval process for drugs and vaccines—not only for COVID-19, but for clinical trial data generally.

Building on a forthcoming theoretical article to be published in the *Florida State Law Review*, Clark D. Asay and Stephanie Plamondon Bair explore how COVID-19 demonstrates that adversity—at least adversity that has certain "Goldilocks" characteristics—can actually be conducive to innovation. Their article highlights several important steps that policymakers can take to shape the nature and amount of adversity that potential innovators will face during the next public health emergency. Instead of banking on existing IP regimes, Asay and Plamondon Bair propose a set of policy reforms, including increasing government funding in basic research to counteract the classic problem of overinvestment in the last crisis. The article also calls into question whether intellectual property rights are necessary to encourage innovation and whether, in some instances, patents, copyright, and trade

secret laws may be counter-productive, at least during a crisis at the scale of a global pandemic. Among the innovative responses to the adversity of the COVID-19 pandemic featured in the article is the creation of the Open COVID Pledge, through which dozens of major intellectual property rights holders have donated their rights for use by others who intend to make use of those rights to help fight COVID-19.

The legal innovation of the Open COVID Pledge, which has been adopted by the WHO's COVID Technology Access Pool (C-TAP), will undoubtedly be looked to as a model for future patent pledges. In his contribution to this symposium issue, Jorge L. Contreras, one of the co-founders of the Open COVID Pledge, presents the authoritative account of the creation and operation of the Pledge. In a style accessible to readers without IP backgrounds, Contreras explains how the Pledge fits into the history of IP regulation and biomedical innovation and how it compares to other open licensing models. The article then provides a comprehensive explanation of the process through which a group of experts from diverse fields, including science, engineering, and law, came together to create a readily-adoptable, open legal framework under which some of the world's largest IP holders have, to-date, pledged nearly 500,000 patents and patent applications, as well as significant copyrighted material. After describing the profile of pledgors and pledges, adoption trends by industry, and pledgers' motivations, Contreras reflects on the strengths and challenges of the Open COVID Pledge model. Contreras's first-hand observations about the future direction of the Open COVID Pledge model will be invaluable to others seeking to make particular innovations more accessible.

W. Nicholson Price II makes his own call for a new model of regulation. But instead of IP, Price is concerned about current health policy governing the use of artificial intelligence ("AI") on health information. Describing a state of "ongoing dysfunction," Price draws our attention to how AI weakens legal protections for health privacy because deidentification procedures, on which so much of health privacy law is based, can be undone by AI. What's more, AI expands the possibilities for inferring health information from unprotected data sources that we do not traditionally think about as "health information." At the same time, the privacy protections we do have hinder the development of effective health care AI by creating biases in research datasets. Price's conclusion is a bold one: the need for a new privacy bargain between patients and the health system grounded on communitarian principles that prioritize improving the health system for everyone. Price has thrown down the gauntlet to scholars and practitioners of health care AI law to reconceive the current balance between individual health care privacy and access to AI's benefits.

In our final article, Leslie E. Wolf and Laura M. Beskow argue that there are significant gaps in protections provided by one particular legal mechanism for protecting individually identifiable information: Certificates of Confidentiality. Originally authorized in 1970 to encourage participation in research on illegal drug use, Certificates now protect a broad range of sensitive, identifiable research data from compelled disclosure in legal proceedings. The 21st Century Cures Act further strengthened Certificates' protections. Nonetheless, Wolf and Beskow argue, areas of the law remain—at the least—in need of clarification. For example, how should

clinical-research institutions handle Certificate protection for research data in the electronic health record? And to what degree do disclosures permitted by federal, state, and local law pare back Certificates' protections? As Wolf and Beskow point out, NIH could provide at least some answers through educational materials for institutions and their in-house legal counsel. Currently, clinical-research institutions that aim to respect Certificate protections and provide meaningful informed consent are left with insufficient guidance from NIH, including, the mere direction to seek advice from an institution's legal counsel on the question of research data in the electronic health record.

The issue closes with the Proceedings from our Fall 2020 Lee E. Teitelbaum Utah Law Review symposium event on the law and ethics of medical research, which was sponsored by the College of Law's Center for Law and Biomedical Sciences. Students from the S.J. Quinney College of Law have summarized the four panel discussions at the event: Privacy and Confidentiality Issues in Sharing Medical Research Data; Clinical Trials-Legal and Ethical Issues in the Age of COVID-19; Intellectual Property and Medical Research; and Medical Research as a Public Health Initiative. We hope that these notes lead some of you to view the full video recorded conversations among a lively group of scholars and practitioners. The panel recordings are posted on the S.J. Quinney College of Law YouTube channel at https://perma.cc/LKF2-CKQ5.

Finally, thank you to the junior staff and editors of the *Utah Law Review* for their work getting these articles ready for publication. As the last issue of the volume, assignments for these articles came at the end of an already exceptionally demanding year, and we appreciate that people hung in there. A special thank you to editor-in-chief Rossetti Farrell for her enthusiasm for this symposium topic and her unwavering support as we moved the law review's flagship event online for the first time. Our thanks also go to Chrystal Beagley, Spencer Cope, Jonelle White, Melinda Rogers, Kristina Monty, and Angela Turnbow of the professional staff of the S.J. Quinney College of Law, who did the heavy lifting to turn our vision of the virtual symposium and this issue of the law review into reality. We also would like to express our appreciation for the support of the faculty of the Center for Law and Biomedical Sciences, Teneille Brown, Jorge Contreras, Erika George, and Amelia Smith Rinehart, as well to *Utah Law Review*'s faculty advisor RonNell Andersen Jones and Dean Elizabeth Kronk Warner for their commitment to the symposium and student governance of the *Utah Law Review*.

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October 1, 2021