FOREWORD

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On February 22, 2013, the *Saint Louis University Journal of Health Law and Policy* and the Center for Health Law Studies at Saint Louis University School of Law sponsored their Annual Health Law Symposium entitled, "Regulating Dual-Use Research in Life Sciences." The symposium brought together an interdisciplinary group of experts both in the life sciences and in law for an engaging day of lecture and discussion about how best to protect against the misuse of discoveries in the life sciences while still pursuing their many benefits. In particular, the symposium sought an answer to what role the law should play in striking that balance.

Little did we know that, on the very day of the symposium, the federal government would release notice of a proposed rule-making on dual use research of concern (DURC)[1] to go along with guidelines it had issued eleven months earlier.[2] As a result, the symposium became more than an opportunity for the panel of speakers to lecture on the topic of regulating DURC. It became a forum for a creative dialogue among the gathered panelists as well as faculty, students, and guests about the new proposed rules and how they add to or detract from the twin goals of promoting research for the life sciences while securing the public against the risk that such research is misused. This issue presents articles written for the symposium and then re-written in light of the fruitful discussion held during the gathering.

The issue features a diverse set of articles because the collection of authors has expertise not only in law, but also in laboratory research and international diplomacy, and this variety is apparent in the different perspectives from which each author addresses the role of law in managing DURC. That said, there are common themes among the articles. Chief

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1. *See* U.S. DEP'T OF HEALTH & HUMAN SERVS., UNITED STATES GOVERNMENT POLICY FOR INSTITUTIONAL OVERSIGHT OF LIFE SCIENCES DUAL USE RESEARCH OF CONCERN 11 (2013), https://www.phe.gov/s3/dualuse/documents/oversight-durc.pdf.

2. *See* U.S. DEP'T OF HEALTH & HUMAN SERVS., UNITED STATES GOVERNMENT POLICY FOR OVERSIGHT OF LIFE SCIENCES DUAL USE RESEARCH OF CONCERN 1, 2 (2012), *available at* http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf.

among them is a theme of trust. Most of the articles acknowledge that successfully managing DURC requires trust between the public at large and the research enterprise, between the research and national security communities, and among countries that share a global public health commons. Accordingly, this raises the question of what, if any, role the law plays in establishing and maintaining such trust. Another related theme among all of the articles is that the law, by itself, cannot sustain a successful regime for managing DURC. In addition to law, professionalism among scientists is necessary as well as leadership from research institutions. Moreover, biodiplomacy must fill in wherever the international rule of law is weak.

The issue opens with an article by Dr. David Franz, who brings a wealth of laboratory and leadership experience to his scholarship, following a distinguished career in the U.S. Army Medical Research and Material Command. Dr. Franz is skeptical that law is a helpful tool in managing DURC. Instead, he makes a persuasive case that leadership among researchers and within laboratories is the lynchpin to minimizing the security risks associated with DURC.

A recent example of scientific self-censorship is apropos of Franz's thesis. A group of scientists and physicians identified a new neurotoxin produced by botulism that is dangerous to humans and for which there is no current antidote. Concerned that publishing the genetic sequence of the new neurotoxin could lead to deliberate and harmful misuse of the new toxin, the scientists and physicians who made this discovery chose not to reveal the sequencing in any publication concerning the neurotoxin.[3] Based on professional values and without the intervention of the law, these scientists and researchers struck an appropriate balance between public security and public health.

Dr. Carole Baskin and Dr. Todd Richardson's article is also written from the perspective of research professionals. They trace the history of DURC and its oversight in the U.S. and, in light of that history, critically examine the government's policy and proposed regulations. In so doing, they highlight potential flaws, including most notably, the regulations' reliance on Institutional Biosafety Committees (IBCs) to assure compliance, even though those committees lack the expertise and training to conduct a dual use review. Additionally, they warn that legal risks associated with the complicated relationship among the Select Agents regulations, export control laws, and the proposed DURC regulations will chill important life sciences research. They close by arguing for the development of best

3. *See* David A. Reelman, Editorial *"Inconvenient Truths" in the Pursuit of Scientific Knowledge and Public Health*, 209 J. INFECTIOUS DISEASES 170 (2014).

practices for DURC management led by scientific accreditation organizations.

Professor Vickie Williams takes us next in a distinctly constitutional direction, examining the doctrine of unconstitutional conditions and its application to any censorship of government funded DURC. Researchers and research institutions cannot be forced to waive their free speech rights as a condition of receiving federal funding for their research. Professor Williams argues that, if, as a condition of funding, researchers conducting DURC must agree to allow the government to review and potentially redact portions of their research papers prior to publication, such a regulatory regime is an unconstitutional invasion of researchers' free speech rights. She explores how federal regulations might be crafted to avoid such a constitutional pitfall.

Professor Victoria Sutton moves the discussion from the domestic to the international stage, demonstrating that biodiplomacy is essential to the successful management of DURC. She makes the case that public health is high on the list of international priorities. Yet, the rule of law is not uniformly respected nation-to-nation. Accordingly, she concludes that threats to global public health, including DURC, will fall within the realm of international politics and biodiplomacy.

Finally, my own contribution is a reply to Dr. Franz. I argue that the right kind of legal regulation plays an essential role in managing DURC because the law is a powerful tool that can both signal that the scientific community is trustworthy and provide an oversight mechanism to promote public confidence in scientific self-regulation. The article makes the case that, while imperfect, the proposed federal regulations have the potential to be the right kind legal intervention.

Advances in the life sciences have defined our time as the "Biological Century."[4] "Never before in history," says David Relman, "has an area of science offered as much potential for novel insight and predictive understanding of the world, as well as opportunities for enhancing the human condition, as have the life sciences."[5] At the same time, however, these same insights can be misused to threaten public safety and national security. Our hope is that the articles in this issue contribute to a better understanding of how best to manage dual use risks and what role the law can play in doing so.

4. David A. Relman, *The Biological Century: Coming to Terms with Risk in the Life Sciences*, 11 NATURE IMMUNOLOGY 275, 275 (2010).

5. *Id*.