Regulating the Future of Medicine
Reading Group

Yale Law School

Spring Term 2018
Tuesdays, 6:00 pm to 7:30 pm, Room 109
Group Leaders: Mason Marks, MD and David Lehr

Introduction

Medical science and technology change so rapidly that regulation cannot keep pace. New technologies such as 3D-printing, gene editing with CRISPR, artificial intelligence, and mobile health technologies are changing the healthcare landscape. At the same time, healthcare costs are rising, and disparities in access to medical care are increasing. As we move further into the 21st Century, society will face challenging questions concerning the regulation of new medical technologies and how to ensure that new treatments remain accessible to those who need them.

This reading group is designed to familiarize students with the ethical and legal issues raised by the changing healthcare system and rapidly emerging medical technologies. Each week, students will read articles by leading health law scholars. The readings will expose students to diverse legal subject areas including patent law, administrative law, health law, constitutional law, FDA regulation, and privacy law. In the interest of promoting scientific literacy among law students, the group will also read pieces from leading biological science and medical journals including Science, Nature, the New England Journal of Medicine, and the Journal of the American Medical Association.

A few readings will be assigned each week, with additional readings suggested for those desiring more information on each week's topic. Though a background in science or healthcare would be helpful, no prior knowledge is assumed or required for participation. The group will meet for 1.5 hours per week on Tuesdays from 6:00 pm to 7:30 pm in Room 110. Note that the group will NOT meet the first and last weeks of class. Participants are expected to complete all assigned readings in preparation for discussion. Additionally, all participants must attend at least 750 minutes (12.5 hours) of group meetings to receive academic credit.

Reading List

Week 1 (1/23/18): Introduction & The Future of the FDA

1. Jerry Avorn & Aaron Kesselheim, *The 21st Century Cures Act – Will It Take Us Back In Time?*, 372 NEW ENG. J. MED. 2473 (2015). (3 pp.)
2. Richard Sloane, *Social Media and Pharmacovigilence: A Review of the Opportunities and Challenges*, 80 BRIT. J. CLINICAL PHARMACOLOGY 910 (2015). (7 pp.)
3. Spencer Phillips Hey, I. Glenn Cohen, Eli Y. Adashi & Aaaron S. Kesselheim, *Influence, Integrity, and the FDA: An Ethical Framework*, 357 SCIENCE 876 (2017). (2 pp.)
4. Patricia J. Zettler, *Pharmaceutical Federalism*, 92 IND. L. J. (2017). (56 pp.)

5. Arti K. Rai, *Risk Regulation and Innovation: The Case of Rights-Encumbered Biomedical Data Silos*, 92 NOTRE DAME L. REV. 1645 (2017). (28 pp.)

Week 2 (1/30/18): Medical Data Privacy

1. Craig Konnoth, *Governing Health Information*, 165 U. PA. L. REV. 1317 (2017). (60 pp.)
2. Bonnie Kaplan, *Selling Health Data: De-Identification, Privacy, and Speech*, CAMBRIDGE Q. HEALTHCARE ETHICS (2014). (16 pp.)
3. Sharona Hoffman, *Citizen Science: The Law and Ethics of Public Access to Medical Big Data*, 30 BERKELEY TECH. L.J. 1741 (2015). (65 pp.)

Further Readings:

4. Wendy K. Mariner, *Reconsidering Constitutional Protection for Health Information Privacy*, 18 U. PA. J. CONST. L. 975 (2016). (80 pp.)
5. Paul Ohm, *Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization*, 57 UCLA L. REV. 1701 (2010). (77 pp.)

Week 3 (2/6/18): Reproductive Technologies

1. Bob Zhao, *Mitochondrial Replacement Therapy and the Regulation of Reproductive Genetic Technologies in the United States*, 15 DUKE L. & TECH. REV. 121-138 (2017). (18 pp.)
2. I. Glenn Cohen, *Artificial Wombs and Abortion Rights*, 47 HASTINGS CTR. RPT. (2017). (1 p.)
3. Tamar Lewin, *Babies from Skin Cells? Prospect Is Unsettling to Some Experts*, N.Y. TIMES (May 16, 2017), https://www.nytimes.com/2017/05/16/health/ivg-reproductive-technology.html. (~1 p.)
4. Lauren R. Roth, *Reproductive Selection Bias*, 27 HEALTH MATRIX: J. L. MED. 263 (2017). (50 pp.)

Week 4 (2/13/18): Mobile Health Apps and Digital Health Technologies

1. Elizabeth A. Brown, *The Fitbit Fault Line: Two Proposals to Protect Health and Fitness Data at Work*, 16 YALE J. HEALTH POL'Y L. & ETHICS (2016). (50 pp.)
2. Nathan G. Cortez, Nicolas Terry & I. Glenn Cohen, *Questions About the FDA's New Framework for Digital Health*, HEALTH AFFAIRS BLOG (Aug. 16, 2017), http://www.healthaffairs.org/do/10.1377/hblog20170816.061554/full/. (~2 pp.)
3. Nathan G. Cortez, I. Glenn Cohen & Aaron S. Kesselheim, *FDA Regulation of Mobile Health Technologies*, 370 NEW ENG. J. MED. 372 (2014). (8 pp.)

Week 5 (2/20/18): The Next Generation of Psychiatric Drugs

1. Mary O'Hara and Pamela Duncan, *Why 'Big Pharma' Stopped Searching for the Next Prozac*, GUARDIAN (Jan. 27, 2016), https://www.theguardian.com/society/2016/jan/27/prozac-next-psychiatric-wonder-drug-research-medicine-mental-illness. (4 pp.)

2. Robert Mikos, *On the Limits of Supremacy: Medical Marijuana and the States' Overlooked Power to Legalize Federal Crime*, 62 VAND. L. REV. 1421 (2009). (63 pp.)
3. Mason Marks, *Psychedelic Medicine for Treating Mental Illness and Addiction: Overcoming Social and Legal Obstacles*, N.Y.U. J. LEGIS. & PUB. POL'Y (Forthcoming, 2018). (47 pp.)
4. Alex Kreit, *Controlled Substances,Uncontrolled Law*, 6 ALB. GOV'T L. REV. 332 (2013). (28 pp.)

Week 6 (2/27/18): Genomics and Personalized Medicine

1. Bryan Cwik, *Designing Ethical Trials of Germline Gene Editing*, 377 NEW ENG. J. MED. 1911 (2017). (3 pp.)
2. Katherine Drabiak, *Caveat Emptor: How the Intersection of Big Data and Consumer Genomics Exponentially Increases Information Privacy Risks*, 27 HEALTH MATRIX: J. L. MED. 143 (2017). (38 pp.)
3. Leland L. Black, *Patenting and Protecting Personalized Medicine Innovation Post-Mayo, Myriad, and Limelight*, 95 N.C. L. Rev. 493 (2017). (29 pp.)

Week 7 (3/6/18): Stem Cells and Regenerative Medicine

1. Douglas Sipp et al., *Marketing of Unproven Stem Cell-Based Interventions: A Call to Action*, 9 SCI. TRANSLATIONAL MED. (2017). (4 pp.)
2. Timo Minssen and Marc Mimler, *Patenting Bioprinting-Technologies in the US and Europe- The 5th Element in the 3rd Dimension*, 3D Printing, Intellectual Property & Innovation – Insights from Law & Technology (Forthcoming, 2017). (27 pp.)
3. Senator Bill Frist, *The Promise and Peril of Embryonic Stem Cell Research: A Call for Vigilant Oversight*, 2 YALE J. HEALTH POL'Y L. ETHICS 167 (2013) (9 pp.)
4. Michael Eisenstein, *Regulation: Rewriting the Regenerative Rulebook*, 540 NATURE 64 (2016). (3 pp.)

Week 8 (3/20/18): Intellectual Property, Innovation, and Access to Medicine

1. Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rivzi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J. L. & TECH. 275 (2017). (80 pp.)
2. Amy Kapczynski, *Order Without Intellectual Property Law: Open Science in Influenza*, 102 CORNELL L. REV. 1539 (2017). (75 pp. plus appendices)
3. Arti K. Rai and Jacob S. Sherkow, *The Changing Life Science Patent Landscape*, 34 NATURE BIOTECHNOLOGY 291 (2016). (3 pp.)
4. Rachel E. Sachs, *Promoting Demand-Side Innovation: Prizes for Payers*, 4 J. L. & BIOSCIENCES 391 (2017). (6 pp.)
5. W. Nicholson Price II & Timo Minssen, *Will Clinical Trial Data Disclosure Reduce Incentives to Develop New Uses of Drugs?*, 33 NATURE BIOTECHNOLOGY 685 (2015). (2 pp.)

Further Readings:

6. Rebecca S. Eisenberg & W. Nicholson Price, II, *Promoting Healthcare Innovation on the Demand Side*, 4 J. L. & BIOSCIENCES 3 (2016). (46 pp.)
7. Ian Ayres and Lisa Larrimore Ouellette, *A Market Test for Bayh-Dole Patents,* 102 CORNELL L. REV. 271 (2017). (61 pp.)

Week 9 (3/27/18): Artificial Intelligence and Black Box Medicine

1. Nicholson Price, *Regulating Black Box Medicine,* MICH. L. REV. (Forthcoming, 2018). (62 pp.)
2. Jonathan Kay, *How Do You Regulate a Self-Improving Algorithm,* ATLANTIC (Oct. 25, 2017), https://www.theatlantic.com/technology/archive/2017/10/algorithms-future-of-health-care/543825/. (4 pp.)
3. Mason Marks, *Emergent Medical Data*, BILL OF HEALTH (Dec. 22, 2017), http://blogs.harvard.edu/billofhealth/category/contributors/mason-marks/. (4 pp.)

Further Readings:

4. David Lehr & Paul Ohm, *Playing with the Data: What Legal Scholars Should Learn About Machine Learning*, 51 U.C. DAVIS L. REV. 653 (2017). (65 pp.)

Week 10 (4/3/18): Future of Informed Consent

1. George J. Annas, *Informed Consent: Charade or Choice?,* 45 L. MED. & ETHICS (2017). (2 pp.)
2. Christine Grady, *The Changing Face of Informed Consent,* 376 NEW ENG. J. MED. 856 (2017). (9 pp.)
3. Erica S. Spatz, Harlan Krumholz, and Benjamin W. Moulton, *The New Era of Informed Consent: Getting to a Reasonable-Patient Standard Through Shared Decision Making,* 315 JAMA 2063 (2016). https://jamanetwork.com/journals/jama/fullarticle/2516469 (4 pp.)
4. Scott R. Peppet, *Regulating the Internet of Things: First Steps Toward Managing Discrimination, Privacy, and Consent,* 93 TEX. L. REV. 85 (2014). (78 pp.)
5. *IRB Waiver of Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects,* FDA, https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM566948.pdf (5 pp.)

Week 11 (4/10/18): Medical and Surgical Robotics

1. Drew Simshaw, Nicolas Terry, Kris Hauser & M.L. Cummings, *Regulating Healthcare Robots: Maximizing Opportunities While Minimizing Risks*, 22 RICH. J.L. & TECH. 3 (2016). (39 pp.)

2. Guang-Zhong Yang et al., *Medical Robotics- Regulatory, Ethical, and Legal Considerations for Increasing Levels of Autonomy,* 2 SCI. ROBOTICS 1 (2017). (2 pp.)
3. Bernd Carsten Stahl and Mark Coeckelbergh, *Ethics of Healthcare Robotics: Towards Responsible Research Innovation,* 86 ROBOTICS AND AUTONOMOUS SYSTEMS 152 (2016). (9 pp.)