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Foreword i

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Mobile Health Innovation and Interagency Collaboration
Rachel E. Sachs 1

The growth of the mobile health industry has opened up tremendous possibilities for gathering and using data to solve vexing problems of human illness. Many scholars have analyzed the safety of mobile health applications or the privacy of the data they gather. This article expands the existing scholarly focus in two ways. First, it focuses on the innovation incentives created by our existing legal framework and the ways in which the combination of innovation policy levers affects innovation choices made by mobile health companies. Second, it considers the ways in which administrative agencies with different statutory responsibilities both do and can collaborate to optimize incentives for innovation in mobile health.

Zika and the Regulatory Regime for Licensing Vaccines for Use During Pregnancy
Sam Halabi 20

The public health emergency surrounding the spread of the Zika virus has resurrected and brought into sharper relief some of the most vexing questions in bioethics: the appropriate circumstances, if any, in which fetal tissue research is permissible; when and how the government may sponsor statements shaping reproductive decisions; and how to balance the health and rights of both women and their unborn children when health threats target both. This latter question has come to the fore in the Zika context. Because the virus inflicts its heaviest (known) toll in utero, even knowledge obtained through computer modeling or animal studies will implicate if not require application of that research to pregnant women as human research subjects. This article argues that the regulatory approach adopted by the U.S. Food and Drug Administration (and mimicked by competent national regulatory authorities elsewhere) toward pregnant women as human research subjects, while understandable, should be reviewed in light of medical advances that promise substantial benefits for both maternal and infant health. Under that approach, FDA effectively allocates difficult maternal immunization regulation to the CDC's Advisory Committee for Immunization Practices, the World Health Organization's Strategic Advisory Group of Experts on Immunization, and other national immunization technical advisory groups.

As a result of this system there is no vaccine licensed for use specifically during pregnancy. This regulatory idiosyncrasy is more than just an interesting quirk in the legal landscape for immunization. There is good evidence showing that pregnant women refuse immunizations based on information in package inserts which ranges from statements about there being no information to “safety and effectiveness of [X vaccine] have not been established in pregnant women” The inability of public health authorities to connect statements regarding maternal health with product information deters important interventions that may help both pregnant women and their unborn children.

Improving the current system for development and licensure of maternal immunizations is critical not only for public health emergencies like Zika but for the next generation of preventative health measures that are likely to make major gains in global public health. Although additional childhood and adolescent vaccines are being developed, immunizations for pregnant women represent a next step, supported by a great deal of preliminary evidence, in the effort to ensure that mothers remain healthy during pregnancy and children are born with as great a chance as possible to lead healthy lives. Vaccination of women during pregnancy is considered to be the most plausible strategy

The CRISPR-Cas9 Tool of Gene Editing: Cheaper, Faster, Riskier?

Barry R. Furrow33

I propose to examine the CRISPR (Clustered Regularly-Interspaced Short Palindromic Repeats) technology and its development from the perspective of a regulator of scientific and ethical risks. I will argue that this research may create substantial risks, that claims by scientists that self-regulation is sufficient have limited power, and that an entity is needed to assess new technologies such as CRISPR and make strong recommendations to Congress. Like the recombinant DNA controversy, CRISPR presents the continuing question of uncertainty in research, particularly when the tool is so seductive in its power to conduct research on cell germlines.¹

Camouflaging State Biosimilar Laws as Pro-Patient Legislation

Katherine Macfarlane.....52

Biologics, the most effective medications used to treat chronic debilitating autoimmune diseases such as rheumatoid arthritis, are also the most expensive, even for those with top shelf insurance. Biosimilars, which replicate biologics through the use of similar living organism extracts, will impact biologics’ American sales—biosimilars are generally much cheaper than biologics. Legal scrutiny in the biologic/biosimilar arena has focused on the Amgen v. Sandoz litigation, market share, and the biosimilar FDA approval process, established through the Biologic Price Competition and Innovation Act. Less coverage has been devoted to state-level battles over biosimilars. States have considered how biosimilars should be named, even though there is FDA guidance on the issue. Many state laws impose patient and physician consent requirements on insurance companies or pharmacists that seek to substitute biosimilars for biologics, even though the FDA does not require any additional action once an interchangeable biosimilar is exchanged for a biologic. This article will consider why state laws are impeding biosimilar market access. It will also consider the way these laws have been proposed as “patient-friendly” legislation, and succeeded in part based on that sympathetic label. It will ask how “patient-friendly” laws

1. See generally Barry R. Furrow, *Governing Science: Public Risks and Private Remedies*, 131 U. PA. L. REV. 1403 (1983) (examining the rDNA controversy of the 1980s and the limits of regulation of that gene modification technology).

may actually limit access to medication that patients need to walk, breathe, or, sometimes, keep on living. Finally, it will propose how to involve patients at the state legislative level so that those with patient's true interests at heart advocate for or against a biosimilar law.

The Priority Review Voucher Program at the FDA: From Neglected Tropical Diseases to the 21st Century Cures Act

Ana Santos Rutschman 71

The priority review voucher program at the Food and Drug Administration (FDA) was established in 2007 to incentivize research and development (R&D) in traditionally underfunded diseases. While shrouded in controversy and criticism, the program has recently been bolstered by the passage of the 21st Century Cures Act, which prevented the vouchers from sunseting and furthered the overall scope of the program. As the voucher program reaches the end of its first decade, this article discusses its impact, with a focus on recent developments. The article builds on literature suggesting that the voucher program has been ineffective in incentivizing research on neglected diseases. It is the first to consider the expansion of the vouchers to cover R&D on Ebola and Zika, arguing that the expansion was attributable to misguided bipartisan political support and is likely to result in further cross-subsidization benefiting R&D on mainstream diseases. Finally, this is also the first scholarly piece to discuss the likely impact of the 21st Century Cures Act on the program.