Annals of Health Law

Volume 26
Issue 2 *Summer 2017*

Article 1

2017

Table of Contents

Annals of Health Law

ANNALS OF HEALTH LAW

THE HEALTH POLICY AND LAW REVIEW OF
LOYOLA UNIVERSITY CHICAGO SCHOOL OF LAW

Beazley Institute for Health Law and Policy

VOLUME 26, ISSUE 2 SUMMER EDITION 2017

CONTENTS

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

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]

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).