Annals of Health Law

Volume 22
Issue 3 *Summer 2013*

Article 1

2013

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 22, ISSUE 3 SUMMER EDITION 2013

CONTENTS

In this paper, the authors analyze the evolution of the Mexican legal framework that culminated in the creation of the System of Social Protection in Health (SSPH) and its operative branch, Popular Health Insurance or Seguro Popular. This insurance scheme extended health care coverage with financial protection to all Mexicans citizens in 2012. First, we discuss the nature of social rights, including the right to health care. The authors then describe the evolution of the contents of the legal instruments (the Constitution, the social security laws and the General Health Law) that supported the transition in Mexico from health care as the subject of charity to health care as a labor right and then as a social or citizen right. Finally, the authors discuss how the creation of the SSPH established the regulatory and financial conditions to guarantee the exercise of the right to the protection of health. There are three lessons of the evolution of the framework that gave legal support to the expansion of health coverage in Mexico. First, the introduction of the right to the protection of health into the Mexican Constitution in 1983 identified UHC as an achievable vision. Second, the establishment of the SSPH placed access to comprehensive health care outside of the public assistance realm, guaranteeing its justiciability and establishing the rules to assure its financial sustainability. Finally, the recent Mexican reform illustrates the potential to expand coverage with financial protection to reach the poor and non-salaried workers by decoupling access to social protection in health from salaried employment and transforming it into a right of citizenship.

The central concern of this paper is to determine whether a physician who competently diagnosed an African female patient of HIV/AIDS infection has a legal obligation to *disclose the test result to the patient's husband or partn*er. The paper argues that although most western jurisdictions have settled in favor of disclosure, this is not a

sufficient warrant for adopting a similar regime in Africa. It advocates an Africentric response, one that focuses squarely on the vulnerable circumstances of women in Africa *and the havoc that would be wrought in these women's lives and well*-being by the imposition of a mandatory disclosure framework.

Prosecutions of Pharmaceutical Companies for Off-Label Marketing: Fueled By Government's Desire to Modify Corporate Conduct or Pursuit of a Lucrative Revenue Stream?
Lise T. Spacapan & Jill M. Hutchison 407

Every year, health care fraud and abuse places a significant financial strain on the federal government. This article specifically discusses fraud and abuse cases involving pharmaceutical companies that allegedly promote their products for off-label purposes, which are not approved by the United States Food and Drug Administration. First, the authors provide a discussion of the applicable federal regulations under the Federal Food, Drug and Cosmetic Act. Next, the authors look at the Department of Justice*'s enforcement of regulatory violations and call into question the DOJ's aggressive* approach. The authors then provide several examples of government prosecutions and spotlight some of the fundamental challenges to those prosecutions. The authors then discuss the added financial costs following DOJ scrutiny and the relevant health policy issues that are implicated. In conclusion, the authors question whether these current trends in government conduct actually benefit the public or simply generate a substantial revenue stream.

Dear Doctor Letters: Lessons in Statutory Interpretation, Preemption, Proximate Causation, and Subsequent-Remedial Measures
James W. Huston, Ellen Nudelman Adler & Joanna L. Simon 445

In this article, the authors discuss the current use and the potential legal implications of Dear Doctor letters. Dear Doctor letters are used to communicate important information between pharmaceutical manufacturers and the professionals who prescribe and administer drugs. This article first discusses the applicable FDA regulations and guidance material, including the standards for when, how, and to whom Dear Doctor letters should be issued. Next, the article reviews the extent to which federal preemption principles apply to Dear Doctor letters as outlined by the Supreme Court in the landmark case Pliva v. Mensing. The article then analyzes the role of Dear Doctor letters in litigation in a post-Mensing world, including whether Dear Doctor letters can be used to show causation and whether Dear Doctor letters are admissible evidence at trial. The article concludes with practical tips related to sending out Dear Doctor letters.