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Viral Sovereignty, Intellectual Property, and the Changing Global System for Sharing Pathogens for Infectious Disease Research

Sam Halabi 101

Access to biological samples is crucial to the research and development process that leads to diagnostics, therapeutics, and vaccines to address new and reemerging infectious diseases. However, access to biological samples has become an increasingly substantial barrier to this crucial step in the research and development process. Governments are increasingly asserting sovereign rights over biological resources, including human pathogens, insisting that transfer of biological samples be accompanied by agreements that specify the benefits those governments might receive with respect to future biomedical products.

The principal mechanism by which samples are shared under this system is the material transfer agreement (MTA). MTAs are contracts protected by law. If one of their provisions is not followed, the contract is breached and the wronged party has the right to bring action against the other, such as suing for damages. MTAs are used in connection with the transfer of materials for safekeeping purposes (for instance, storage in gene banks), research or commercial use.

International research collaborations in the field of infectious disease increasingly require researchers to be more extensively knowledgeable about MTA negotiations. Joint ventures and collaborations between scientists in biodiverse but resource-scarce countries in Africa, Asia, and South America are growing in importance to the identification, sampling, biobanking, and research of potentially human pathogenic viruses. Identifying these zoonotic viral threats in high-risk areas where diseases are most likely to emerge raises complex problems of material acquisition and transfer that may inhibit the research and development process.

Many biodiverse-rich countries do not have well-developed or adequate scientific capacities and resources to document and monitor the transfer of their biodiversity.

This article analyzes the substantial changes under way in the global system for infectious disease research as embodied by changing practice in negotiating MTAs. Instead of the open system of sharing bacterial and viral human pathogens that characterized the research system for much of the 20th Century, notions of “viral sovereignty”, access made contingent on sharing research benefits, and acrimonious negotiations are far more common. The increasing barriers to the flow of research material and related data, like genetic sequencing information, are posing threats to the development of diagnostics, therapeutics, and vaccines. The article assesses the extent of these barriers and proposes some win-win approaches that may address the global inequalities behind material transfer negotiation issues.

Successes and Failures of Social Health Insurance Schemes in Africa – Nigeria versus Ghana and Rwanda: A Comparative Analysis

Dr. Obiajulu Nnamuchi 127

There is no doubt that for countries in Africa, a social health insurance (SHI) system represents perhaps the best avenue toward achieving universal health coverage (UHC) – the goal of every health system. First, the underlying ideology behind SHI, namely, solidarity, is consistent with African cosmology.

Additionally, because SHI involves a public-private sector partnership to raise funds for health care, the system addresses one of the greatest lingering challenges facing health systems and families in the region: the rising cost of health care. These two factors have led to success stories in some countries (Rwanda and Ghana), in that they have seen significant jumps in access to health care. But these same factors have also led to failures in other countries, for instance, Nigeria. The task of this paper is to determine not only the reasons for the failure in Nigeria but also to determine why Rwanda and Ghana are succeeding. Ultimately, the aim of this paper is to distill experiences from the success stories and use those lessons to transform health care financing in Nigeria and other similarly situated emerging health systems.

HIPAA’S Privacy Rule and State Privacy Laws: Roadblocks to Medical Organizations’ Self-Policing Expert Medical Testimony

Miles J. Zaremski 149

As part of the wave of medical malpractice reforms over the last several decades, efforts were initiated to ensure the reliability and credibility of expert witness opinion and testimony, which is the sine qua non of necessary proof for any such claim or lawsuit. Governing bodies of professional medical organizations and societies have crafted rules and regulations for their members that wish to

provide expert medical witness testimony. Where such testimony does not conform to these organizations' standards, sanctions can be levied, including membership expulsion. Such self-policing has found favor with courts.

Before sanctions are imposed, however, necessary administrative investigations and hearings are conducted, focusing on the foundation of the organization member's expert opinions. But in these proceedings, there is a significant problem which has never been examined or analyzed in the legal literature or in any published appellate court decision: the submission of the patient's medical information by either the complaining party or the responding expert in violation of HIPAA's Privacy Rule or state privacy laws. This article examines and confronts the roadblocks to the self-policing mechanisms of professional medical organizations that they present. It concludes by proposing alternative methodologies and relief that may overcome the legal and regulatory roadblocks presented by HIPAA's Privacy Rule and state laws.