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Introduction

Melanie Santiago

SYMPOSIUM:

ELIMINATING LEGAL, REGULATORY, AND ECONOMIC BARRIERS TO BIODEFENSE VACCINE DEVELOPMENT

INTRODUCTION

> It is by now a troublesome cardinal tenet of the Nation's counterterrorism policy that, "limited research, development, and production capability for certain vaccines is one of the largest hurdles currently facing military and civilian responders as they prepare for biological threats."
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> Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction, Third Annual Report to the President and the Congress vi (2001).

On September 11, 2001, the United States became acutely aware of its vulnerability to terrorist attacks from above. While this attack was devastating, the subsequent anthrax attacks shortly thereafter were perhaps equally unsettling, reminding us of the potential destruction that may be wreaked by biological terrorism. As a result of the first event, we now encounter security efforts to prevent another air attack each time we go to an airport. As a result of the second, the U.S. government, pharmaceutical companies, and research institutions have begun to put into place initiatives that will help protect us from the intentional use of biological or other dangerous pathogens. One component of these initiatives is the development and distribution of vaccines that may be administered to military and civilian populations in advance of, or in response to, a bioterrorist threat. The development and administration of such vaccines, however, is fraught with significant obstacles ranging from reluctance on the part of manufacturers to invest in the development and production of a vaccine without assurances that their intellectual property will be protected and that they will have a definite end user; concerns on the part of manufactures about regulatory approvals and liability if a vaccine has unanticipated side effects; concerns from public health officials about their ability to vaccinate a sufficient number of the population for the vaccine to be effective as well as their authority to forcefully vaccinate individuals under emergency circumstances; and, lastly, fears of physicians, hospitals and other health care providers over their liability in administering the vaccines.

This issue of the *Journal of Health Care Law & Policy* is devoted to these concerns. The articles that appear in the issue are based on several papers that were presented at a conference entitled **"Eliminating Legal, Regulatory, and Economic Barriers to Biodefense Vaccine Development,"** hosted by the University of Maryland School of Law's Law & Health Care Program (L&HCP),

the University's Center for Health and Homeland Security (CHHS), and the Mid-Atlantic Regional Center of Excellence for Biodefense and Emerging Infectious Diseases (MARCE) on June 9, 2004. The conference brought together health professionals in the fields of vaccine development, distribution, and administration, as well as several public health experts to discuss the legal, regulatory, and economic obstacles to biodefense vaccine development and distribution. Papers delivered at the conference examined the financial market for vaccines, the role of the U.S. Food and Drug Administration's regulatory process, intellectual property issues, informed consent, and manufacturer and institutional liability in the manufacture and distribution of biodefense vaccines. The symposium agenda follows this introduction.

Contributors to this issue of the *Journal* include Michael Greenberger, Law School Professor and Director, Center for Health and Homeland Security, University of Maryland School of Law; Wendy E. Parmet, George J. and Kathleen Waters Matthews University Distinguished Professor of Law, Northeastern University School of Law; Gail H. Javitt, Adjunct Professor, University of Maryland School of Law and Policy Analyst, Genetics and Public Policy Center, Phoebe R. Berman Bioethics Institute, Johns Hopkins University; Cynthia M. Ho, Clifford E. Vickrey Research Professor, Loyola University of Chicago School of Law; and Elin Gursky, Principal Deputy for Biodefense at the National Strategic Support Directorate of Analytic Services, Inc. (ANSER).

Perhaps one of the most significant obstacles to the development and production of vaccines to protect against bioterrorist threats in the U.S. are concerns of liability on the part of vaccine manufacturers. While the United States has begun to implement a biodefense strategy that includes vaccine research, development, and mass vaccination programs, the viability of these programs will be in doubt if there is not adequate financial support to protect vaccine manufacturers, sellers, and distributors from liability and to compensate those injured by the vaccines. Professor Michael Greenberger addresses this problem in his contribution to this issue of the *Journal.* His article details the inadequacy of the federal liability and compensation scheme and its inability to effectively remedy injuries stemming from the smallpox vaccine. Professor Greenberger suggests that the problem is so critical to the Nation's protection in the event of a biological or chemical attack that the United States government itself must financially back a robust, well-tailored liability and compensation regime.

Another obstacle to biodefense vaccine development and administration is the lengthy and complicated procedure by which new vaccines are approved by the United States Food and Drug Administration. In her article, Gail H. Javitt comments on the need for regulatory flexibility in the face of emergent threats. In so doing, Professor Javitt reflects on the 1991 Gulf War and the actions of the Department of Defense in obtaining regulatory approval to administer certain, as yet unapproved vaccines, to members of the armed forces. While critics argue that

such action constitutes prohibited human experimentation, she takes issue with that claim. Instead, she proposes a clear line between research and treatment activities, arguing that a vaccine's safety and effectiveness can be under investigation while it is administered as a prophylactic or a therapy. Professor Javitt maintains that people receiving such drugs should be fully informed of the risks, while arguing that administering tentatively-approved vaccines and therapies will promote the public health.

In a time of bioterrorist threat, public health authorities will be saddled with the responsibility of distributing and administering vaccines to the civilian population. While laws may allow for vaccination without consent in times of medical emergency, public health authorities and bioethicists argue over whether as a matter of public policy individuals should be forcibly vaccinated against their will. Professor Wendy Parmet weighs in on this debate in her article, "Informed Consent and Public Health: Are They Compatible When It Comes to Vaccines?" She takes issue with the seemingly divergent notions that: 1) compulsory vaccination should be authorized for the public health, and 2) no patient should be vaccinated without giving informed consent. Rather, she argues that the two notions are compatible, and contends that informed consent actually serves to promote public health.

Another impediment to a viable vaccine industry is the high degree of legal uncertainty over questions relating to who, in the long line of development of a vaccine (from research to commercialization), actually "owns" (or has the intellectual property interest in) a vaccine, i.e., who has the right to control and reap financial reward for the vaccine discovery. In her article, Cynthia M. Ho reviews the intellectual property issues surrounding the development of biodefense vaccines, including the legal and political problems associated with compulsory licensing of drugs such as Cipro, the only drug available to combat anthrax, following September 11, 2001. Professor Ho examines the scope of intellectual property rights to such vaccines under both domestic and international law, and offers an analysis designed to afford the reader a proper understanding of both the patent barriers to the development of biodefense vaccines and potential avenues to avoid them.

In 2002, President Bush established the Phase I civilian smallpox vaccination program, designed to vaccinate medical, public health, and other emergency responders against the possible threat of a smallpox outbreak. In her article, Elin Gursky, Sc.D., presents a case study of the Phase I civilian smallpox vaccination program. She provides a fascinating historical perspective on the program and describes the problems the program encountered based on an empirical survey of public health authorities in states with high and low vaccination rates in the Phase I program. Among the problems cited were lack of legal protections for vaccine administrators and others involved in the process of screening, systemic failures, and lack of funding to States to properly implement the program as mandated by

the federal government. She expresses the hope that the lessons learned from the Phase I civilian smallpox program will be applied to, and improve, ongoing bioterrorism preparedness efforts.

Though not a presenter at the Symposium, Franklin H. Alden, Jr., a student at the University of Maryland School of Law and Associate Editor for the *Journal of Health Care Law & Policy*, contributes a thoughtful analysis of the Model State Emergency Health Powers Act, and compares it to similar Maryland legislation. Mr. Alden's article echoes a number of the sentiments expressed by other Symposium authors by arguing that legislatures should carefully maintain the personal liberties of citizens in the event of a health emergency.

The *Journal of Health Care Law & Policy's* foremost goal is to provide a forum for the interdisciplinary discussion of leading issues in health law, policy, and bioethics. In keeping with the *Journal's* goal, it is my hope that this issue stimulates ideas and discussion on the topic of biodefense vaccine development for all our readers. On behalf of the *Journal of Health Care Law & Policy*, I would like to thank the sponsors and participants of the symposium for their contributions and the staff, editorial board, and faculty advisors for their hard work and dedication in producing this issue of our *Journal*.

Melanie Santiago
Editor in Chief

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AGENDA

Welcome and Introductions

Michael Greenberger, Director, Center for Health and Homeland Security, University of Maryland

Diane Hoffman, Associate Dean and Director, Law & Health Care Program, Universityof Maryland School of Law

Donald Burke, Director for Immunization Research, Johns Hopkins Bloomberg School of Public Health and Co-Director of the Mid-Atlantic Regional Center of Excellence forBiodefense and Emerging Infectious Diseases (MARCE)

Challenges to the Development of a Vibrant Vaccine Industry

Lance K. Gordon, President, VaxGen, Inc.

Is Bioshield the Answer?

Philip Russell, Special Advisor on Vaccine Development and Production, Officeof Public Health Preparedness, U.S. Department of Health and Human Services

The Role of the FDA

Margaret O'K. Glavin, Assistant Commissioner for Counter-Terrorism, U.S. Food and Drug Administration

The Need for Regulatory Flexibility in the Face of Emergent Threats

Gail H. Javitt, Adjunct Professor, University of Maryland School of Law and Policy Analyst, Genetics and Public Policy Center, Phoebe R. Berman Bioethics Institute, Johns Hopkins University

The Role of Intellectual Property Policy