ELIMINATING LEGAL, REGULATORY, and ECONOMIC BARRIERS to BIODEFENSE VACCINE DEVELOPMENT

Wednesday, June 9, 2004

The University of Maryland
School of Law
500 West Baltimore Street
Baltimore, MD 21201-1786
ELIMINATING LEGAL, REGULATORY, and ECONOMIC BARRIERS to BIODEFENSE VACCINE DEVELOPMENT

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."


This symposium will focus on the legal, regulatory, and economic obstacles to biodefense vaccine development and distribution, including examination of 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. The symposium is intended to be a springboard to launch further detailed research, guidance, and proposals pertaining to this critical area by the participating institutions. Selected papers, proceedings, and excerpts from the conference will be published in a forthcoming issue of The Journal of Health Care Law and Policy.

The target audience for this conference includes policy makers, academics, and industry leaders in the areas of public health, medical research, bioterrorism, vaccine development, food and drug regulation, and intellectual property law.
AGENDA

8:00 am - 8:30 am
Registration and Continental Breakfast

8:30 am – 8:45 am
Welcome and Introductions

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

   Diane Hoffmann, Associate Dean and Director, Law & Health Care Program, University of 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 for Biodefense and Emerging Infectious Diseases (MARCE)

8:45 am – 10:00 am
The Role of Government and the Private Sector in Vaccine Development and Distribution

   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, Office of Public Health Preparedness, U.S. Department of Health and Human Services

10:00 am – 10:20 am
Break

10:20 am – 11:00 am
The Role of FDA

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

11:00 am – 11:40 am
The Need for Regulatory Flexibility in the Face of Emergent Threats

   Gail Javitt, Policy Analyst, Genetics and Public Policy Center, Phoebe R. Berman Bioethics Institute, Johns Hopkins University
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<th>Time</th>
<th>Session</th>
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<tr>
<td>11:40 am – 12:20 pm</td>
<td>The Role of Intellectual Property Policy</td>
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<td>Cynthia Ho, Associate Professor, Loyola University School of Law, Chicago, IL</td>
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<td>12:20 pm – 1:45 pm</td>
<td>Lunch</td>
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<td>Luncheon Speaker</td>
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<td>Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases (NIAID)</td>
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<td>The NIH Biodefense Research Agenda</td>
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<td>2:00 pm – 2:40 pm</td>
<td>Issues of Consent and Standard of Care in the Administration of Vaccines in Response to a Bioterrorist Threat</td>
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<td>Wendy Parmet, Professor of Law, Northeastern University School of Law, Boston, MA</td>
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<td>2:40 pm – 3:20 pm</td>
<td>The Smallpox Vaccination Project: A Case Study</td>
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<td>Elin Gursky, Senior Fellow for Biodefense and Public Health, Advancing National Strategies and Enabling Results (ANSER) Institute for Homeland Security</td>
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<td>3:20 pm – 3:40 pm</td>
<td>Break</td>
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<tr>
<td>3:40 pm – 5:15 pm</td>
<td>Liability Issues Associated with Vaccine Development and Distribution</td>
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<td>Michael Greenberger, Director, Center for Health and Homeland Security, University of Maryland</td>
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<td>Edward Richards, Harvey A. Peltier Endowed Professor and Director, Program in Law, Science and Public Health, Louisiana State University, Baton Rouge, LA</td>
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<td>5:15 pm – 6:00 pm</td>
<td>Reception</td>
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<td>6:00 pm – 6:15 pm</td>
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The Law & Health Care Program (L&HCP) at the University of Maryland School of Law was established in response to a growing demand for health law expertise by lawyers and health professionals enabling them to address today’s health law issues from both a legal and interdisciplinary perspective. The Program combines an interdisciplinary approach to education with research on emerging medical, health policy, and law-related issues.  www.law.umaryland.edu/maryhealth/

The Center for Health and Homeland Security (CHHS) was created by University of Maryland President David J. Ramsay shortly after the attacks of September 11, 2001. CHHS and the six constituent professional schools which form its core (the University of Maryland Schools of Medicine, Law, Dentistry, Pharmacy, Nursing, and Social Work) work on a broad range of scientific, policy, and legal issues pertaining to the war on terrorism. By developing and coordinating research, training, and scholarly programs related to counterterrorism, the Center provides a resource for health professionals and the public on crisis and consequence management issues. CHHS also actively assists states and localities in emergency preparedness planning.  www.umaryland.edu/healthsecurity/

The Mid-Atlantic Regional Center of Excellence for Biodefense and Emerging Infectious Diseases (MARCE) is a consortium of 16 universities, led by the Center for Vaccine Development of the University of Maryland School of Medicine. The consortium was recently awarded a $42 million grant from the National Institute of Allergy and Infectious Diseases to develop new and improved vaccines, diagnostic tools, and treatments to help protect the country from the threat of bioterrorism and naturally occurring infectious diseases. MARCE has served in the Mid-Atlantic region as a resource to local, state, and federal agencies in preparing for terrorism.  http://marce.vbi.vt.edu/
William C. Bertrand, Jr., JD is Vice-President, General Counsel and Corporate Compliance Officer for MedImmune. Prior to joining MedImmune, he was Associate General Counsel at Pharmacia Corporation, with global responsibility related to legal issues surrounding the commercialization of CELEBREX. He also served as Litigation Counsel at Pharmacia & Upjohn, where he handled product liability litigation for a wide range of products, commercial litigation, general liability litigation, and insurance recovery.

Donald S. Burke, MD is Director for Immunization Research at the Johns Hopkins Bloomberg School of Public Health. He joined Hopkins in 1997 and is serving in multiple leadership capacities within the Bloomberg School of Public Health and the School of Medicine: Professor of International Health and Epidemiology, Associate Chair and Director of the Disease Prevention and Control Program, and Director of the Center for Immunization Research. He received his medical degree from Harvard Medical School.

Anthony S. Fauci, MD has been Director of the National Institute of Allergy and Infectious Diseases (NIAID) since 1984 where he oversees an extensive research portfolio of basic and applied research to prevent, diagnose, and treat infectious and immune-mediated illnesses, including HIV/AIDS and other sexually transmitted diseases, illness from potential agents of bioterrorism, tuberculosis, malaria, autoimmune disorders, asthma and allergies. Dr. Fauci received his medical degree from Cornell University Medical College.

Margaret O’K. Glavin, MA is Assistant Commissioner for Counterterrorism at the U.S. Food and Drug Administration. Prior to her FDA appointment, Ms. Glavin was a Visiting Scholar at Resources for the Future (RFF), a prominent think tank on environmental and natural resources. Prior to her work at RFF, she served as the highest ranking career food safety official at the U.S. Department of Agriculture. She is the recipient of the Presidential Rank Award of Distinguished Executives, the highest award given to Federal Executives. She is a graduate of Georgetown University and holds a master’s degree from Trinity College.

Lance K. Gordon, PhD is President of VaxGen, Inc. Dr. Gordon has more than 20 years of experience in the vaccine industry, developing both new vaccine products and companies. Prior to joining VaxGen, Dr. Gordon served as CEO and as a member of the Board of Directors of two vaccine companies, Oravax and North American Vaccines. Dr. Gordon received his PhD in Biomedical Science, Immunology from the University of Connecticut and completed his postdoctoral fellowship as an NIH fellow at the Division of Allergy and Immunology, Washington University Medical School, St. Louis.

Michael Greenberger, JD is the Director of the Center for Health and Homeland Security at the University of Maryland and a professor at the School of Law. He was a partner for over 20 years in the Washington, DC law firm of Shea & Gardner before joining the Clinton Administration in 1997. In 1999, he began service as the Justice Department’s
FACULTY cont.
Principal Deputy Associate Attorney General, where within his portfolio of responsibilities were several counterterrorism projects, including organizing a nationwide counterterrorism war game, TOPOFF I. Professor Greenberger has written about, and has appeared frequently in the media on, counterterrorism health security issues and he has designed and teaches two courses in this area for University law and medical students.

Elin Gursky, ScD is a Senior Fellow for Biodefense and Public Health at the ANSER Institute for Homeland Security. As a practitioner and epidemiologist, she has focused on communicable diseases and global health security threats including emerging pathogens and bioterrorism. She received her doctorate from the Johns Hopkins School of Public Health (now the Johns Hopkins Bloomberg School of Public Health).

Cynthia Ho, JD is the Vickrey Research Professor of Intellectual Property Law at Loyola University of Chicago School of Law, where she also serves as the Director of the Intellectual Property Program. After graduation from law school, she became an associate with the New York firm of Fish & Neave, one of the largest firms specializing in intellectual property. She is registered to practice before the U.S. Patent and Trademark Office. Professor Ho now teaches courses on Intellectual Property, Patent Law, Comparative Patent Law, Policy and Health Care, as well as Civil Procedure. She received her JD from Duke University School of Law.

Diane Hoffmann, JD, MS is Professor of Law at the University of Maryland School of Law and has been Associate Dean for Faculty and External Affairs and Director of the Law & Health Care Program since 1999. After completing law school, she was an associate with the firm of Dewey, Ballantine, Bushby, Palmer & Wood in Washington, D.C. where she worked on legal issues in the areas of health, environmental, and food and drug law. Professor Hoffmann’s teaching and research activities are in the areas of health law, end of life care, ethics committees, genetics and human subjects research. She received her undergraduate degree from Duke University, her master’s degree in Health Policy from Harvard School of Public Health, and her law degree from Harvard Law School.

Gail Javitt, JD, MPH is a Policy Analyst with the Genetics and Public Policy Center, Phoebe R. Berman Bioethics Institute at the Johns Hopkins University. Prior to her current position, she was a Greenwall Fellow in Bioethics and Health Policy at Johns Hopkins and Georgetown Universities (2000-2002). From 1995-1999 she was an associate with the law firm of Covington & Burling, where she specialized in FDA regulatory issues. She received her law degree from Harvard Law School and her MPH from Johns Hopkins Bloomberg School of Public Health.

Wendy E. Parmet, JD is the Matthews Distinguished Professor and Professor of Law at Northeastern University School of Law and Program Director of the law school’s JD-MPH program with Tufts University School of Medicine. She is co-founder of the new Public Health Advocacy Institute. Professor Parmet teaches Constitutional Law, Public Health Law, Health Law, Bioethics, Disability Law and Federal Courts, and she has published articles on discrimination and health law, as well as AIDS law. She received her law
FACULTY cont.
degree from Harvard Law School and her undergraduate degree from Cornell University.

Edward P. Richards III, JD, MPH is the Harvey A. Peltier, Sr. Professor, and Professor and Director, Program in Law, Science, and Public Health at the Louisiana State University Law Center. He maintains a website on medical, public health, and biotechnology law: http://biotech.law.lsu.edu. Professor Richards has published extensively, including the books Medical Care Law (Aspen 1999) and Law and the Physician: A Practical Guide (Little, Brown 1993). He received his JD from the University of Houston and his MPH, focusing on disease control and risk analysis, from the University of Texas School of Public Health.

Philip K. Russell, MD is professor emeritus at Johns Hopkins School of Hygiene and Public Health. He has authored or co-authored over 100 publications on infectious diseases and he has served as adviser to and a member of numerous infectious disease and vaccine initiatives. He currently serves as Special Adviser in the Office of Public Health Preparedness, U.S. Department of Health and Human Services. Dr. Russell received his bachelor’s degree from Johns Hopkins University and his medical degree from the University of Rochester.

HOTEL INFORMATION
A block of rooms has been reserved at the Radisson Plaza Lord Baltimore Hotel. The hotel is located at 20 West Baltimore Street, Baltimore Maryland 21201, www.radisson.com/lordbaltimore. Rooms are available at a reduced rate by calling the Reservation Line: (800) 333-3333 and mentioning the University of Maryland School of Law. Reservations at the reduced rate will be available until May 18, 2004. Reservations after this date will be on a first-come, first-served basis.

DIRECTIONS AND PARKING
From I-95 take route 395 (downtown Baltimore) and exit on Martin Luther King, Jr. Boulevard. Turn right at fourth traffic light onto Baltimore Street. Turn left at second traffic light onto Paca Street. Go 1/4 block and turn right into the Baltimore Grand Garage at 5 North Paca Street. The Law School entrance is at the corner of Baltimore and Paca Streets. Parking fees are the responsibility of the participants.

FOOD SERVICE
A continental breakfast, lunch, and reception are included in the registration fee. If you have special dietary concerns or requirements, please contact Lu Ann Marshall, at 410-706-4128 or lmarshal@law.umaryland.edu.

SPECIAL ACCOMMODATIONS OR QUESTIONS
If you require special accommodations to attend or participate, or if you have additional questions, please contact Lu Ann Marshall at the numbers above, or at (1-800-735-2258 TTY/Voice) at least five business days in advance.
REGISTRATION FORM
ELIMINATING LEGAL, REGULATORY, and ECONOMIC BARRIERS
to BIODEFENSE VACCINE DEVELOPMENT

Please complete form and return to:
Lu Ann Marshall
University of Maryland School of Law
500 West Baltimore Street, Baltimore, MD 21201-1786
or register online (charge or check) at
www.law.umaryland.edu/conferences.asp

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Registration Fee:  $75