



Supporting Organizations:



November 13, 2006

8:30 – 4:30 *Pre-Conference Symposium:*
SUPPLY CHAIN READINESS FOR PANDEMIC INFLUENZA RESPONSE

November 14, 2006

8:15 – 8:30 Welcome & Introduction by the Conference Co-Chairs
Frank M. Rapoport, *Partner, McKenna Long & Aldridge LLP*
Bill Helming, *Vice President, Biodefense and Public Health Practice,*
PRTM Management Consultants

Keynote Address:

8:30 – 9:15 CONGRESSIONAL STRATEGY FOR NATIONAL INFLUENZA PREPAREDNESS

The Honorable Mike Rogers, Congressman (R-MI)

This keynote address will provide a blueprint for Congress' strategy regarding national influenza preparedness, including legislative actions, intended outcomes, progress, expected challenges, and next steps.

9:15 – 9:45 *Morning Refreshment and Networking Break Sponsored by: **Baxter***

Shaping the Pandemic Influenza Market

9:45 – 10:30 COORDINATING FOR GLOBAL PREPAREDNESS THROUGH PUBLIC-PRIVATE COLLABORATION

Anne Schuchat, M.D., *Rear Admiral, United States Public Health Service; Assistant Surgeon General; Director, National Center for Immunization and Respiratory Diseases (proposed), Centers for Disease Control and Prevention*

10:30 – 11:15 EUROPEAN PERSPECTIVES ON THE OPPORTUNITIES FOR PUBLIC-PRIVATE COLLABORATION

Franz Kracher, Ph.D., *Project Officer, Unit SANCO C3 – Health Threats, DG Health and Consumer Protection, Director C Public Health and Risk Assessment, European Commission*

11:15 – 11:45 *Networking Break Sponsored by:*



11:45 – 12:30 EMERGING VACCINE TECHNOLOGIES INFLUENCE ON PANDEMIC PREPAREDNESS POLICY AND THE PANDEMIC INFLUENZA MARKET

James Young, Ph.D., *President, Research & Development, MedImmune, Inc.*

12:30 – 2:00 *Group Luncheon*

Development of Technologies and Products for Preparedness

2:00 – 3:30 Industry/Government Panel Discussion
INVESTING IN DEVELOPMENT FOR PANDEMIC INFLUENZA PREPAREDNESS

Companies developing new technologies and medicines for combating pandemic influenza rely on external funding to help them balance risks in drug development. Meanwhile, the government looks to support a portfolio of technologies and medicines under development in order to manage its own risks. Pandemic preparedness is also beginning to attract private equity investment, and several venture funds now focus on biodefense and public health. Independent foundations and non-governmental organizations offer additional support for development programs for pandemic preparedness.

- How does the government's portfolio-based approach to risk management create opportunities for industry?
- How do efforts to develop influenza vaccines and antivirals parallel biodefense programs sponsored by the Department of Defense?
- What opportunities do venture capital and private equity groups see in the influenza market, and how will they structure their investments to exploit them?
- How will independent foundations and other sources of funding support pandemic preparedness?

- What are the implications for intellectual property rights when the government supports development?

Moderator:

Frank M. Rapoport, *Partner*, McKenna Long & Aldridge LLP

Panelists:

Kim C. Bush, *President*, Baxter

Erik A. Henchal, Ph.D., FAAM, *Associate Director, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration (FDA)*

Sarah R. Landry, *Director of Public Policy-Vaccines*, GlaxoSmithKline

Garry Redlich, *Managing Director*, Implicit Bioscience Pty Ltd.

Robin Robinson Ph.D., *Acting Associate Director for Influenza Programs, Office of Research and Development Coordination, Office of Public Health Emergency Preparedness, Department Of Health & Human Services (DHHS)*

Sharon Seiler, Ph.D., *Vice President – Senior Biotechnology Analyst*, Punk, Ziegel & Company

3:30 – 5:00

Networking Reception Sponsored by:

PRTM

Management
Consultants

November 15, 2006

Production for the Pandemic Market

8:30 – 9:00

EVOLUTION OF THE PANDEMIC PREPAREDNESS MARKET

Keynote Address:

Gerry Parker DVM, Ph.D., MS., *Principal Deputy Assistant Secretary of Public Health and Emergency Preparedness, U.S. Department of Health & Human Services (DHHS) (invited)*

For years, the U.S. Government has worked closely with industry to prepare for and manage seasonal influenza. Lessons from these collaborations are helping to form the government's plans for pandemic influenza. Preparedness requires thorough planning, from Development through Production, Supply, and Administration of medicines and supplies. Through planning across these steps, the government's strategy for preparedness continues to evolve and shape the potential market.

- How are the government's strategy and plans creating opportunities for companies at all steps in the end-to-end preparedness framework?
- What is the government's strategy for purchasing products and services for preparedness, and how is that strategy evolving?

- How will companies leverage products and capabilities designed for the seasonal flu market?
- Beyond vaccines, what implications does the pandemic influenza market have for antivirals, antibiotics, and diagnostics?

9:00 – 9:30

Morning Refreshment and Networking Break Sponsored by:  ImmuneRegen
IR BIOSCIENCES HOLDINGS, INC.

9:30 – 11:00

Industry/Government Panel Discussion

KEY CONSIDERATIONS FOR PRODUCTION IN THE PANDEMIC SETTING

Production of vaccines, antivirals, and antibiotics for combating a pandemic will take place on an unprecedented scale. Preparedness demands that key questions be addressed in advanced. Production capacity needs to be built well in advance and requires public-private collaboration. Decisions on when and how to produce medicines and how they will be financed will also need to address industrial policy concerns related to fair competition in the market.

- What level of surge production capacity is required, and how is government working with industry to bring it online?
- When rapid scale-up of production is required, how will it be financed?
- What is the government's industrial policy for pandemic production- i.e., how many players can the market support, and what is fair competition?
- How will we manage readiness for a pandemic outbreak even before the new cell culture capacity is online?

Moderator:

Frank M. Rapoport, *Partner*, McKenna Long & Aldridge LLP

Panelists:

James Matthews, Ph.D., *Senior Director, Health and Science Policy*,
Sanofi Pasteur SA

Mike McGuire, *Vice President, Anti-Infectives Marketing*, Roche

Hal Siegel, Ph.D., *Senior Director of Product Development and Regulatory Affairs*,
ImmuneRegen BioSciences, Inc.

Rahul Singhvi, Ph.D., *President and CEO*, Novavax Inc.

Friso van Voorthuizen, Ph.D., *Global Director Pandemic Preparedness &
Manufacturing Liaison*, Solvay Pharmaceuticals B.V.

James Young, Ph.D., *President, Research & Development*, MedImmune, Inc.

Supply for Pandemic Preparedness

11:00 – 12:30

Industry/Government Panel Discussion

SUPPLYING THE PANDEMIC MARKET

Thorough coordination of the supply chain for medicines and supplies will be required to effectively manage an outbreak of pandemic proportions. Effective communication across drug manufacturers, distributors, and public entities at the federal, regional, state, and local levels will be critical. Companies are seeing new opportunities in participating in links in the pandemic supply chain. Critical questions on how to

manage stockpiles and how to get medicines and supplies to health facilities will be addressed.

- What are the steps in the pandemic supply chain, and how is preparedness creating opportunities for industry?
- How will the government and other organizations purchase vaccines, drugs, and other supplies, and how will purchasing decisions be made?
- How will medicines and supplies get from manufacturers to health facilities? How much will we need?
- How are drug distributors being included in preparedness plans?
- How should stockpiles of medicines and supplies be managed?

Moderator:

Bill Helming, *Vice President, Biodefense and Public Health Practice,*
PRTM Management Consultants

Panelists:

Steven A. Adams, MPH, *Director (Acting), Division of Strategic National Stockpile,*
Centers for Disease Control and Prevention (CDC)

Claude Grant, *Senior Vice President, Quality and Regulatory Affairs,* Cardinal Health

Chris Ground, *Senior Vice President, National Accounts,* FFF Enterprises, Inc.

Neil Herson, *President,* ASD Healthcare

John A. Muckstadt, *Acheson/Laibe Professor of Business Management and*
Leadership Studies, School of Operations Research and Industrial Engineering,
Cornell University

Tom T. Shimabukuro, M.D., MPH, MBA, *Pandemic Influenza Vaccine*
Coordinator, Health Services Research and Evaluation Branch, Immunization
Services Division, National Center for Immunization and Respiratory and Diseases,
Centers for Disease Control and Prevention (CDC)

12:30

Conference Adjourns