

# SEE INSIDE FOR THE FULL PROGRAM!

22-24 January,  
The Baltimore Marriott Waterfront Hotel, Baltimore, MD



## Driving Progress

Attend the Baltimore Vaccine Forum 2007 to hear from and meet over 50 of the sector's highest profile figures, including:

- **Dr Norman W. Baylor**, Director, Office of Vaccines Research & Review (OVR), CBER, US Food & Drug Administration
- **Dr Allan Jarvis**, Senior Vice President, Corporate Development, sanofi pasteur
- **Dr Jeffrey Kelman, MD**, Chief Medical Officer, Center for Beneficiary Choices, Centers for Medicare & Medicaid Services (pending confirmation)
- **Dr John Shiver**, Vice President, Vaccine & Biologics Research, Merck Research Laboratories
- **Hannah E. Kettler, PhD**, Program Officer, Global Health Policy & Finance, Bill & Melinda Gates Foundation
- **Lota Zoth**, Senior Vice President & Chief Financial Officer, MedImmune, Inc
- **Thomas R. Fuerst, PhD**, Director, Vaccines & Biologics, Office of Public Health Emergency Medical Countermeasures, Office of Public Health Emergency Preparedness, US Department of Health & Human Services
- **Béatrice De Vos, MD, BCPM**, Head, Global Medical Affairs, GlaxoSmithKline Biologicals
- **Dr Steve Chatfield**, Chief Scientific Officer, Emergent BioSolutions
- **Amie Batson**, Senior Health Specialist, World Bank
- **Dr Hartmut Ehrlich**, Vice President, Global Clinical Research & Development, Baxter BioScience
- **Michael D. Blum, MD, MPH**, Vice President, Medical Pharmacovigilance, Global Safety Surveillance & Epidemiology, Wyeth Research
- **Bill Helming**, Vice President, BioDefense & Public Health, PRTM
- **Peter Khoury, PhD**, Vice President, Global Marketing, Baxter BioScience, Vaccines
- **Phillip L. Gomez III, PhD, MBA**, Director, Vaccine Production, Vaccine Research Center, NIAID, NIH

- **Mark Feinberg, MD, PhD**, Vice President, Policy, Public Health & Medical Affairs, Merck Vaccine Division
- **Matthew Geller, PhD**, Head of Healthcare Investment Banking, Senior Managing Director, Investment Banking, Roodman & Renshaw, LLC
- **Dr Vincent I. Ahonkhai**, Vice President, Regulatory Affairs, Vaccines, GlaxoSmithKline
- **Capt. Raymond A. Strikas, MD**, Seasonal & Pandemic Influenza Coordinator, US Public Health Service, National Vaccine Program Office, Department of Health & Human Services
- **Douglas J. Pon, PhD**, Assistant Vice President, Vaccine Licensing, Global Business Development, Wyeth Pharmaceuticals
- **Fuad El-Hibri**, Chairman & CEO, Emergent BioSolutions
- **Dr Hélène Pora**, Vaccine Application Director, Pall Life Sciences
- **Dr Jeffrey B. Ulmer**, Head, Immunology & Cell Biology, Novartis Vaccines
- **Stephen M. Sammut**, Senior Fellow, Wharton Health Care Systems & Venture Partner, Burrill International
- **James P. Tursi, MD, FACOG**, Director of Medical Affairs - North America, Cervical Cancer Vaccines, GlaxoSmithKline
- **Dr Masato Tashiro**, Director, Department of Virology III (Viral Diseases & Vaccine Control), National Institute of Infectious Diseases, (Japan) WHO Collaborating Centre for Reference & Research of Influenza
- **Dr Ronald W. Ellis**, Senior Vice President, Research & Development, AVANT Immunotherapeutics, Inc
- **Christopher D. Earl, PhD**, President & CEO, BIO Ventures for Global Health
- **Drs Ben Machielse**, Senior Vice President, Operations, MedImmune, Inc

- **Myron M. Levine, MD, DTPH**, Professor & Director, University of Maryland School of Medicine, Center for Vaccine Development
- **Dr Ali Allouche**, Director of Translational Medicine, Novartis Vaccines
- **Thomas P. Monath, MD**, Partner, Kleiner Perkins Caufield & Byers, Pandemic & Biodefense Fund
- **Dr Bram Palache**, Global Scientific Communications & Public Affairs Director, Influenza Vaccines, Solvay Pharmaceuticals BV
- **Professor Alexander von Gabain**, CSO, Intercell AG
- **Dr Theresa Tam, MBBS (UK), FRCPC**, Director, Immunization & Respiratory Infections Division, Public Health Agency of Canada
- **Dr Rahul Singhvi**, President & CEO, Novavax Inc
- **Sharon R. Seiler, PhD**, Vice President - Senior Biotechnology Analyst, Punk, Ziegel & Company
- **Dr David L. Urdal**, CSO & Vice Chairman of Board of Directors, Dendreon
- **Dr Elizabeth M. Sutkowski**, Scientific Reviewer, Office of Vaccines Research & Review (OVR), CBER, US Food & Drug Administration
- **Adrian Dana, MD, FAAP**, Senior Director, Clinical Risk Management & Safety Surveillance, Merck Research Laboratories
- **Wade Bolton, PhD**, Vice President, Custom BioPharma Solutions & Services, Beckman Coulter, Inc
- **Frank M. Rapoport**, Partner, McKenna Long & Aldridge LLP
- **Garvin L. Warner, PhD**, Senior Director, Therapeutic Area Head for Inflammation & Vaccines, Drug Safety & Metabolism, Wyeth Research
- **Robert L. Davis, MD, MPH**, Director, Immunization Safety Office, Office of the Chief Science Officer, Centers for Disease Control & Prevention

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- **Harry A. Seifert, MD, MSCE**, Director, North America Safety Evaluation & Risk Management, GlaxoSmithKline Biologicals
- **Dr Rick Bright**, Vice President of Vaccine Research, Novavax Inc
- **Wendy Taylor**, Founder, Vice President of Strategy & Operations, BIO Ventures for Global Health
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- **Mark A. Tomai**, Division Scientist, Pharmaceutical Research, 3M Pharmaceuticals
- **Pramod K. Srivastava, PhD**, Professor & Chairman of the Department of Immunology, University of Connecticut School of Medicine

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The Baltimore Marriott Waterfront, 700 Aliceanna Street  
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The conference fee does not include accommodation. We have negotiated substantially discounted rates for all attendees at the Baltimore Vaccine Forum at The Baltimore Marriott Waterfront. An accommodation booking form will be sent to you in your welcome pack, and you must use this form in order to qualify for the discounted rate which is only guaranteed for bookings received by the 20th of December 2006.

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# Monday January 22nd 2007 | Separately bookable pre-conference workshop

## National and regional approaches to pandemic, pre-pandemic and inter-pandemic influenza preparedness

7.30 Registration & buffet breakfast in the exhibition area

### MORNING PLENARY SESSION

#### Government, industry and regulatory perspectives on funding, licensing, stockpiling, pre-pandemic priming, research priorities, and technology choices for pandemic influenza preparedness

##### 9.00 Chair's introduction

**Bill Helming**, Vice President, BioDefense & Public Health, PRMT

##### 9.20 Questions & discussion

##### 9.25 US Government Keynote Address

###### What have been the outputs from the most recent round of funding?

- Preparedness plans to date and Pandemic Plan implementation
  - Demand and capacity forecasts – how should facilities be used in the inter-pandemic period?
  - Stockpiling policy
  - Research priorities – recombinant vaccines, protein-based vaccines
  - How close are we to a pan-protective vaccine?
  - Pre-pandemic / non-pandemic use of pandemic vaccines – the risk/benefit equation
- Speaker to be announced

##### 9.55 Questions & discussion

##### 10.05 How does the financial market view the opportunities and risks present in the influenza vaccine sector?

- Why vaccines have emerged as an exciting area for the financial community
  - Seasonal 'flu vs pandemic avian 'flu threat, and other potential areas for vaccine development
  - New technologies for vaccine development and the opportunities and risks they present
    - Vaccine manufacturing: Complexity of the process
  - The competitive landscape and market growth opportunities
    - Sales issues
  - Corporate partnerships for biotech vaccine companies: What can a biotech company do by itself? When do they need a partner?
  - Financing vehicles for vaccine companies: Public financing, private financing, creative financing
  - Case study: Novavax
- Matthew Geller, PhD**, Head of Healthcare Investment Banking, Senior Managing Director, Investment Banking, Rodman & Renshaw, LLC

##### 10.30 Questions & discussion

##### 10.35 Industry panel discussion

###### Leveraging recent funding to advance pandemic influenza R&D

- Updates on timelines for cell-based manufacturing
- How does a pharma or biotech company currently assess the market for
  - Pandemic vaccine?
  - Seasonal influenza vaccine?
- When to switch from seasonal to pandemic manufacture – how are the decisions being made?
- Managing liability risk through pre-purchase agreements
- Impact of recommending bodies on seasonal influenza vaccination rates
- Timelines and process for approval of pandemic vaccines and emergency-use authorization
- Distribution and allocation of pandemic vaccine
- How realistic is the achievement of true collaborative development of a pandemic influenza vaccine?

###### Panellists:

**Lota Zoth**, Senior Vice President & Chief Financial Officer, MedImmune, Inc  
**Dr Vincent I. Ahonkhai**, Vice President, Regulatory Affairs, Vaccines, GlaxoSmithKline  
**Dr Bram Palache**, Global Scientific Communications & Public Affairs Director, Influenza Vaccines, Solvay Pharmaceuticals BV

##### 11.25 Morning coffee in the exhibition area

##### 11.55 Short presentations & panel discussion

###### What is the progress with Crisis Management Plans for pandemic influenza preparedness? Comparing US with Europe and Asia

- How are crisis management plans being structured and tested?
- How will priorities be set in terms of who gets what and when?
- In the event of a true crisis, would closed borders mean that each country should be self sufficient in vaccine production?
- What steps are being taken for the integration of prophylactic and therapeutic drug programs, both antiviral and immunomodulatory, as part of the crisis management plan?

###### Panellists:

**Capt. Raymond A. Strikas, MD**, Seasonal & Pandemic Influenza Coordinator, US Public Health Service, National Vaccine Program Office, Department of Health & Human Services  
**Dr Masato Tashiro**, Director, Department of Virology III (Viral Diseases & Vaccine Control), National Institute of Infectious Diseases, (Japan) WHO Collaborating Centre for Reference & Research of Influenza  
**Bettie Voordouw, MD, PhD, MPH**, Senior Clinical Assessor, Anti-infectives, Medicines Evaluation Board

##### 1.00 Buffet lunch in the exhibition area

### Followed by your choice of 3 highly interactive workshops:

#### WORKSHOP 1

##### Regulator / industry interface

Focusing on areas where further clarification, cooperation and coordination is required by all parties involved in pandemic influenza preparedness in order to achieve greater regulatory harmonization

##### 2.30 Moderator's introduction

**Dr Norman W. Baylor**, Director, Office of Vaccines Research & Review (OVRR), CBER, US Food & Drug Administration

##### Regulators representing US, Canada, Europe and Japan will discuss and compare the following major policy areas and invite feedback from industry

- Clarifying current regulatory strategies for pandemic and pre-pandemic influenza
- Safety
  - Drawing up targeted risk management plans for each population group
  - When is the optimal time to request safety data for children – pre- or post-licensure?

- Efficacy
  - Comparing correlates of immunity
  - What are typical end points for these novel vaccines?
  - Licensing pre-pandemic vaccines – what data should be required?
- Collaborating on research priorities
  - Demonstrating a clinical benefit beyond immunogenicity

##### 3.55 Afternoon tea in the exhibition area

- Post-licensure commitments for pandemic flu vaccines – what will they look like?
  - Harmonizing post-exposure testing
  - Improving pharmacovigilance and building more efficient data sharing capabilities
  - Use of boosters
  - Tracking for concomitant use with antivirals and pneumococcal for at risk groups
- Panel discussion
  - Consider two scenarios:
    - 1) We have time to follow a "typical" regulatory path that checks all the boxes but at a faster than formal pace
    - 2) The pandemic starts tomorrow!
- Panel discussion
  - Which areas of regulatory policy are industry struggling with, and how can the regulator respond?
    - What are the particular regulatory hurdles faced by non-conventional vaccines?

Panellists:  
**Dr Masato Tashiro**, Director, Department of Virology III (Viral Diseases & Vaccine Control), National Institute of Infectious Diseases, (Japan) WHO Collaborating Centre for Reference & Research of Influenza  
**Dr Theresa Tam, MBBS (UK), FRCPC**, Director, Immunization & Respiratory Infections Division, Public Health Agency of Canada  
**Bettie Voordouw, MD, PhD, MPH**, Senior Clinical Assessor Anti-infectives, Medicines Evaluation Board

##### 5.25 End of workshop 1 – delegates to reconvene for the closing plenary session

“ This meeting provides an excellent snap-shot of key strategic issues and trends in the field, with many key players in attendance ”

Dr Ronald Ellis, Senior Vice President, Research & Development, AVANT Immunotherapeutics, Inc, commenting on the 2006 Baltimore Vaccine Forum

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#### OR | WORKSHOP 2

##### Harnessing novel influenza vaccine manufacturing technologies to address global shortages: Making the business case for building capacity with new technology

##### 2.30 Moderator's introduction

**Dr Ali Allouche**, Director of Translational Medicine, Novartis Vaccines

##### 2.50 Questions & discussion

##### 2.55 Case study

###### The role of cell culture technology for the control of pandemic influenza

- The need for pandemic preparedness: the vaccine perspective
  - World wide influenza vaccine production
  - Pandemic vaccine formulation using cell culture technology
- Dr Bram Palache**, Global Scientific Communications & Public Affairs Director, Influenza Vaccines, Solvay Pharmaceuticals BV

##### 3.20 Questions & discussion

##### Update on leading live attenuated, recombinant protein and DNA vaccine manufacturing – scalability, capacity and performance

##### 3.25 Case study

###### A recombinant hemagglutinin protein vaccine for influenza produced in insect cells

- Baculovirus technology
    - Speed, cost and safety
    - Rapid response to emerging strains
    - No need to handle live viruses
    - Authentic antigen (no changes due to adaptation of the virus to egg or cell culture)
  - Production of a new HA vaccine against any emerging strain
  - Worldwide surge production capacity for recombinant HA production
  - Overall update on status of FluBIØk™ (clinical, manufacturing, regulatory perspective)
- Drs Manon Cox, MBA**, Chief Operating Officer, Protein Sciences Corporation

##### 3.50 Questions & discussion

##### 3.55 Afternoon tea in the exhibition area

##### 4.25 Case study

###### Update on leading live, attenuated vaccine manufacturing – scalability, capacity and performance

- What are the technological alternatives available in the manufacturing process?
  - What timelines and yields can be expected?
  - How scalable will these techniques be in a pandemic crisis?
  - How rapidly can they be adapted to new strains?
  - What are the possible advantages of LAIV in a pandemic?
  - What potential regulatory hurdles exist and how are they being addressed?
- Drs Ben Machiels**, Senior Vice President, Operations, MedImmune, Inc

##### 4.50 Questions & discussion

##### 4.55 Case study

###### The industrialization of PMED DNA vaccine supply

- Identifying the optimum strategic option for the placement of initial capacity
  - Identifying the optimum time for process and device design freeze to focus on scale-up and industrialisation
  - Ensuring the efficient transfer of process technology to commercial production site
  - Minimizing the degree of change between Phase III supplies and ultimate commercial production characteristics
  - The process of generating detailed global demand picture and ensuring that supply and demand are reconciled
  - Capacity build options to ensure the timely delivery of peak sales
- Bill Henry**, Global Vice President of Manufacturing, PowderMed

##### 5.20 Questions & discussion

##### 5.25 End of workshop 2 – delegates to reconvene for the closing plenary session

#### OR | WORKSHOP 3

##### Latest preclinical and clinical trial results for pandemic and inter-pandemic influenza vaccines

##### 2.30 Moderator's introduction

###### Evaluating the latest trial results from US research programs for novel pandemic influenza vaccines

- H5, H7 and H9 – latest trial results in different population groups and with/without adjuvants

##### 2.50 Questions & discussion

##### 2.55 Case study

###### Baxter's whole virus, cell-culture derived H5N1 pandemic influenza vaccine

- Manufacturing process and capacity
- Preclinical evaluation
- Clinical development plan and initial phase I/II results
- Implications for pandemic planning

**Dr Hartmut Ehrlich**, Vice President, Global Clinical Research & Development, Baxter BioScience

##### 3.20 Questions & discussion

##### 3.25 Case study

###### Common epitope vaccine – what's coming out of research?

- Potential roles for protective immunity against conserved linear epitopes
- Immune response differences for vaccine vs natural infection
- Defining the functional immune response
- Potential issues for vaccine development

**Dr John Shiver**, Vice President, Vaccine & Biologics Research, Merck Research Laboratories

##### 3.50 Questions & discussion

##### 3.55 Afternoon tea in the exhibition area

##### Update on the latest trial results with adjuvants for pandemic influenza vaccines and dose sparing

##### 4.25 Virus-like particle (VLP) vaccines for seasonal and pandemic influenza

- VLP vaccines and their potential for broadened immunity
  - Immunogenicity of influenza VLP vaccines
  - Cross-reactive immune responses raised by influenza VLP vaccines
  - VLP vaccines: The right vaccine for rapid response to a pandemic stress
- Dr Rick Bright**, Vice President of Vaccine Research, Novavax Inc

##### 4.50 Questions & discussion

##### 4.55 Case study

###### Dose-sparing strategies for pandemic influenza vaccines

- Foreseeing a shortage of vaccine should the pandemic H5N1 strain of avian flu leap from birds to humans, the World Health Organization has advocated investigations into dose-sparing strategies, such as the use of whole-virion vaccine and adjuvants
  - Aluminium adjuvanted whole virus vaccines may constitute a potential dose-sparing approach crucial for a global supply of pandemic vaccine
  - Virosome-based vaccines may be an alternative option as they may induce superior T cell response as compared to whole killed vaccines
  - Pre-clinical and clinical study results with different H9N2 vaccines will be discussed
- Professor Jaap Goudsmit**, Chief Scientific Officer, Crucell

##### 5.20 Questions & discussion

##### 5.25 End of workshop 3 – delegates to reconvene for the closing plenary session

REGISTER NOW AND TAKE THE OPPORTUNITY TO PROPOSE A TOPIC FOR A WORKING LUNCH SESSION



#### THEN | AFTERNOON PLENARY SESSION

##### 5.30 Panel discussion

###### Comparing international approaches to pre-pandemic vaccine benefit/risk assessment

###### Panellists:

**Dr Norman W. Baylor**, Director, Office of Vaccines Research & Review (OVRR), CBER, US Food & Drug Administration  
**Bettie Voordouw, MD, PhD, MPH**, Senior Clinical Assessor, Anti-infectives, Medicines Evaluation Board

##### 6.00 Close of day 1, followed by a cocktail reception in the exhibition area

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# Funding advancements in vaccine R&D and manufacturing for the benefit of the developed and developing world

7.30 Registration & buffet breakfast in the exhibition area

## MORNING PLENARY SESSION

### Leveraging public and private funding, procurement and distribution mechanisms for developed and developing world vaccines

- 9.00 **Chair's introduction**  
Approaches to accessing new products and technologies to stimulate vaccine R&D  
**Dr Allan Jarvis**, Senior Vice President, Corporate Development, sanofi pasteur
- 9.20 **Keynote Address**  
**Funding and procurement update from US Government – what are the current strategies and priorities?**
- Pandemic influenza versus biodefense versus developing world vaccines
  - Pandemic Planning incentives and All-hazards Preparation Bill
  - Clarifying the procurement and funding awards process
  - Approach to strategic partnerships
  - Working with primary healthcare providers to ensure preparedness plans are optimized
- Speaker to be announced
- 9.45 *Questions & discussion*
- 9.50 **Panel discussion**  
**Update on Bioshield II**
- Clarifying supply and demand levels
  - Progress on establishment of new procurement agency
  - What actually makes a 'licensable product' in the biodefense arena? Does it really provide an earlier revenue stream and quicker path to market?
  - European regulator's perspective on licensable biodefense products and stockpiling
- Panelists:  
**Thomas R. Fuerst, PhD**, Director, Vaccines & Biologics, Office of Public Health Emergency Countermeasures, Office of Public Health Emergency Preparedness, US Department of Health & Human Services  
**John M. Clerici**, Partner, McKenna Long & Aldridge LLP
- 10.40 **Panel discussion**  
**How does the financial community assess the short- and long-term profitability of vaccine candidates and vaccine biotechs?**
- Risk profiles of therapeutic versus prophylactic vaccines
  - Vaccines, infectious disease and corporate strategy
  - The role of strategic alliances
  - Attracting private equity and mezzanine funding
  - The impact of outsourcing on capital needs
- Panelists:  
**Stephen M. Sammut**, Senior Fellow, Wharton Health Care Systems & Venture Partner, Burrill International  
**Thomas P. Monath, MD**, Partner, Kleiner Perkins Caufield & Byers, Pandemic & Biodefense Fund  
**Fuad El-Hibri**, Chairman & CEO, Emergent BioSolutions  
**Matthew Geller, PhD**, Head of Healthcare Investment Banking, Senior Managing Director, Investment Banking, Rodman & Renshaw, LLC

11.10 *Morning coffee in the exhibition area*

- 11.40 **Perspective on neglected diseases**  
**Funding and incentives update: What are the current strategies and priorities for funding innovation and delivery?**
- What are the current and proposed mechanisms for the big 3: malaria / TB / AIDS vaccines?
  - How do we fund the development, manufacturing and distribution of vaccines for other neglected diseases?
  - How do we achieve the right balance of "push" and "pull" financing, and how will partnerships with leading vaccine innovators help?
- Christopher D. Earl, PhD**, President & CEO, BIO Ventures for Global Health

12.10 *Questions & discussion*

- 12.15 **Panel discussion**  
**Making adult and paediatric vaccines available, and affordable, for the developing world**
- Transitioning vaccines from the developed to the developing world – what's the trigger?
  - Funding mechanisms
  - 2 tier pricing
  - Advanced marketing commitments – working or not?
  - What came out of G8?
  - Procurers of vaccines for the developing world – World Bank, UNICEF and USAID. What are their challenges of delivery and procurement?
- Panelists:  
**Hannah E. Kettler, PhD**, Program Officer, Global Health Policy & Finance, Bill & Melinda Gates Foundation  
**Mark Feinberg, MD, PhD**, Vice President, Policy, Public Health & Medical Affairs, Merck Vaccine Division  
**Amie Batson**, Senior Health Specialist, World Bank  
**Béatrice De Vos, MD, BCPM**, Head, Global Medical Affairs, GlaxoSmithKline Biologicals  
**Myron M. Levine, MD, DTPH**, Professor & Director, University of Maryland School of Medicine, Center for Vaccine Development

1.00 *Buffet lunch in the exhibition area*



REGISTER NOW AND TAKE THE OPPORTUNITY TO PROPOSE A TOPIC FOR A WORKING LUNCH SESSION

Followed by your choice of a main session or two focused breakout sessions:

## MAIN SESSION

### Delivering new adult and paediatric vaccines into the developing world: Tackling efficiency, effectiveness and economic challenges

- 2.20 **Chairman's Introduction & case study**  
**Enteric disease targets and approaches to development and commercialization**
- Unmet needs
  - Promising technical approaches
  - Strategic needs and combinations
  - Meeting needs of developed and developing world markets
- Dr Ronald W. Ellis**, Senior Vice President, Research & Development, AVANT Immunotherapeutics, Inc
- 2.50 **Case study**  
**Vaccine clinical manufacture and scale-up strategies with particular emphasis on high-risk candidate vaccines for HIV/biodefense where their primary use might be in the developing world**
- Scalable manufacturing (vertical and horizontal)
  - Managing public/private partnerships
  - Investigational drug regulatory filing strategies
- Dr Phillip L. Gomez**, Director, Vaccine Production, Vaccine Research Center, NIAID, NIH
- 3.10 *Questions & discussion*
- 3.15 **Case study**  
**The case for investment in tuberculosis vaccines**
- The global market for TB vaccines
  - Market demand by segment
  - Drivers of demand
  - Social case for investment
  - Challenges and opportunities for innovation
- Wendy Taylor**, Founder, Vice President of Strategy & Operations, BIO Ventures for Global Health
- 3.35 *Questions & discussion*
- 3.40 **Next generation of pediatric vaccines for the developing world**
- Rotavirus vaccines
  - Pneumococcal vaccines
  - Malaria vaccines
- Donald W. Kelemen, PhD**, Senior Commercialization Officer, The PATH Malaria Vaccine Initiative
- 4.00 *Questions & discussion*
- 4.05 **Panel discussion**  
**How can industry, government and NGOs work together to tackle the efficiency issues?**
- 4.30 *End of main afternoon session followed by afternoon tea in the exhibition area*

“The shared lessons format was very effective. As I have come to expect from Phacilitate conferences, the venue and meeting management was exceptional”

Drew Hannaman, Vice President, Research & Development, Ichor Medical Systems, Inc commenting on the 2006 Baltimore Vaccine Forum

Phacilitate  
VACCINE FORUM  
BALTIMORE 2007

## OR | BREAKOUT SESSION 1

### Applying translational medicine and biomarkers to improve the safety and vaccine candidates: How might they be used to predict and assess clinical adverse events?

Highly interactive workshop for a maximum of 30 participants

- 2.20 **Moderator's introduction**  
**How close are we to the application of translation medicine and biomarkers for vaccines in a way that has been used in oncology for some time?**
- Advances in measuring specific host immune responses to infection and vaccines
- Correlation of vaccine-induced immunity to protection
  - What genes are up or down graded as a result of infection?
  - Can protective patterns of immune responses or gene expression be identified?
- Dr John Shiver**, Vice President, Vaccine & Biologics Research, Merck Research Laboratories
- 2.40 **Case study**  
**Title to be announced**  
**Garvin L. Warner, PhD**, Senior Director, Therapeutic Area Head for Inflammation & Vaccines, Drug Safety & Metabolism, Wyeth Research
- 3.00 *Questions & discussion*
- 3.05 **Case study**  
**Biomarkers for protein-based subunit vaccines**
- What can be translated directly from the experience with conjugates into the development of biomarkers for protein-based vaccines, and what cannot?
  - At which stage of development could surrogate markers for novel protein vaccines be selected? How might these help to de-risk and speed up the clinical phases?
  - How complex can these assays be?
  - How do the different components of novel vaccines (protein antigens and adjuvants) influence the choice of assays?
- Eszter Nagy, MD, PhD**, Vice President, Pre-clinical Research & Development, Intercell AG
- 3.25 *Questions & discussion*
- 3.30 **Regulatory update**  
**Working with industry to optimize the application of biomarkers to vaccines**  
Speaker to be announced
- 3.50 *Questions & discussion*
- 3.55 **Panel discussion**  
**How will the use of biomarkers impact the ability to assess clinical adverse events?**
- When will we see changes in preclinical and first-into-man studies for vaccines following recent adverse events - what are the implications for vaccine protocols and biomarker acceptance?
  - Will there be an additional new step between animal toxicity studies and man?
  - How might dosing strategies for first-into-man evolve and how will it affect the regulators' view of risk?
- Panelists:  
**Wade Bolton, PhD**, Vice President, Custom BioPharma Solutions & Services, Beckman Coulter, Inc  
**William M. Egan, PhD**, Executive Director, PharmaNet Consulting
- 4.30 *End of breakout session 1 followed by afternoon tea in the exhibition area*

## OR | BREAKOUT SESSION 2

### Eliminating points of failure at the manufacturing stage: Optimizing process validation, consistency and stability to speed up commercialization

Highly interactive workshop for a maximum of 30 participants

- 2.30 **Moderator's introduction**  
**Overview of the main issues encountered during vaccines manufacturing**
- How can they be solved?
  - What technologies could contribute to address these issues?
  - How to integrate them during product development
- Dr Hélène Pora**, Vaccine Application Director, Pall Life Sciences
- 2.40 **Optimizing clinical product development and manufacturing strategy using impact analysis tool on proposed FDA cGMP regulations**
- Current regulatory situation:
    - International regulation requirements (FDA vs EMEA)
    - Draft FDA guidelines on GMP
    - cGMP in Clinical Product Development
  - Highlights of regulatory critical requirements – how to identify them?
    - Regulation review
    - Evaluation of their impact on:
      - Product development strategy
      - Manufacturing steps
      - QA and validation
  - Integrating technologies and resources to achieve cGMP compliance
    - Use of disposable equipment
    - Developing closed process system
    - Scheduling early validation efforts
- Luc Dubois**, President, Validapro BioSciences
- 3.10 **Purification challenges and strategies in vaccine manufacturing**
- With new technologies applied in up-stream vaccine production, downstream purification is facing a lot of challenges and new strategies are needed and will be presented for developing practical, robust and scalable processes for:
    - Viral vaccines (rotaviruses, adenoviruses, flu viruses etc)
    - Plasmid DNA-based vaccines
    - Polysaccharide-based vaccines
    - Protein-based vaccines
  - Expediting product development using a platform purification technology: case study for multivalent recombinant protein vaccine
  - Enhancing process throughput, binding capacity, product safety with disposable membrane chromatography technology: case studies
- Dr John X. Zeng**, Manager, Purification Process Development, GlaxoSmithKline Biologicals
- 3.40 **Case study**  
**A holistic vaccine solution to the pandemic influenza threat**
- Novavax is leveraging its proprietary recombinant virus like particle (rVLP) technology to create a VLP based pandemic influenza vaccine
  - A rVLP vaccine can be customized to emerging strains of avian influenza faster than inactivated virus vaccines
  - The rVLP vaccines have shown good immunogenicity in animal studies and hold the promise of a single dose vaccine
  - A flexible, portable manufacturing process has been developed that will allow easier technology transfer and global deployment of this vaccine
- Dr Rahul Singhvi**, President & CEO, Novavax Inc
- 4.10 **Panel discussion**
- 4.30 *Afternoon tea in the exhibition area*

## THEN | AFTERNOON PLENARY SESSION

### Optimizing partnership strategies to build and strengthen R&D pipelines for both large and small vaccine companies

- 5.00 **Chair's introduction**
- 5.05 **How are R&D partnerships driving new product development in the vaccine industry – for both developed and developing world need?**
- Dr Allan Jarvis**, Senior Vice President, Corporate Development, sanofi pasteur
- 6.00 *Close of day 2, followed by a cocktail reception in the exhibition area*

- 5.25 **Debating the partnership and business development strategies in the vaccine value chain – how should smaller companies optimize links with antigen-focused traditional vaccine companies?**
- Panelists:  
**Peter Khoury, PhD**, Vice President, Global Marketing, Baxter BioScience, Vaccines  
**Dr Steve Chatfield**, Chief Scientific Officer, Emergent BioSolutions  
**Douglas J. Pon, PhD**, Assistant Vice President, Vaccine Licensing, Global Business Development, Wyeth Pharmaceuticals  
**Professor Alexander von Gabain**, CSO, Intercell AG

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www.phacilitate.co.uk/bv

# Assessing emerging market opportunities, routes to commercialization and long-term follow up for traditional and non-traditional vaccine targets

7.30 Registration & buffet breakfast in the exhibition area

## MORNING PLENARY SESSION

### Focusing on the short- and long-term vaccine pipeline: Prioritizing your next targets based on development pathways, launch strategies and reimbursement

#### 9.00 Chair's introduction

##### What is the current status of the vaccine industry pipeline?

- Forecasting what is likely to be launched in next 5 years
- Forecasting what is likely to be launched in next 10 years
- How might this influence decision-making by big pharma and biotechs alike?

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

9.25 Questions & discussion

#### 9.30 CMS perspective: Reimbursement models for novel vaccines

**Dr Jeffrey Kelman, MD**, Chief Medical Officer, Center for Beneficiary Choices, Centers for Medicare & Medicaid Services (pending confirmation)

9.55 Questions & discussion

#### 10.00 Application of technology to develop a vaccine pipeline

**Dr Steve Chatfield**, Chief Scientific Officer, Emergent BioSolutions

10.25 Questions & discussion

10.30 Morning coffee in the exhibition area

#### 11.00 Building and delivering a rich vaccine pipeline for all

- Role of adjuvants
- Present new vaccines in pipeline for all ages
  - Rotarix (infants)
  - Streptococcus/ NTH Infla (children)
  - HPV (adolescents/ women of all ages)
  - Flu Improved (elderly)
- Pipeline prioritization based on medical need and on population (with examples)

**Béatrice De Vos, MD, BCPM**, Head, Global Medical Affairs, GlaxoSmithKline Biologicals

11.25 Questions & discussion

#### 11.30 Learning from recent adult / adolescent vaccine launches: Comparing lifecycle development, routes to approval and marketing/pricing strategies

- How will immunization of adolescents be encouraged?
- Should vaccines for adolescents and adults be marketed more aggressively than those for paediatric use?
- What are the economic implications for those developing and marketing vaccines for adolescents and adults?

**Mark Feinberg, MD, PhD**, Vice President, Policy, Public Health & Medical Affairs, Merck Vaccine Division

11.55 Questions & discussion

#### 12.00 Panel discussion

##### Which emerging vaccine markets hold most promise over the next 5 and 10 years?

- How should big pharma and SMEs alike approach these market opportunities?
- From a public health perspective, what kind of vaccines will really provide the greatest public health bang for the vaccine development buck?
- How might developing countries position themselves to be beneficiaries of these vaccine targets?
  - Dual use prophylactic / therapeutic vaccines / therapeutic antibodies
  - Additional adolescent targets
    - Hep C
    - Travellers market / developing world vaccines
- To what extent does one deliver what the other really needs?
  - Diseases with pandemic potential
    - Noral virus
    - SARS
    - West Nile virus
    - Dengue
    - Avian flu
  - Reservoir targeted vaccines – what are the potential timelines for deployment and how might they be reimbursed?

Panelists:

**Professor Alexander von Gabain**, CSO, Intercell AG

**Myron M. Levine, MD, DTPH**, Professor & Director, University of Maryland School of Medicine, Center for Vaccine Development

**Dr Ronald W. Ellis**, Senior Vice President, Research & Development, AVANT Immunotherapeutics, Inc

**Peter Khoury, PhD**, Vice President, Global Marketing, Baxter BioScience, Vaccines

12.50 Buffet lunch in the exhibition area

Followed by your choice of a main session or two focused breakout sessions:

## MAIN SESSION

### Evaluating progress with innate versus adaptive immunity and next generation immunostimulants / adjuvants

#### 1.45 Chair's introduction

##### To what extent do we understand the role of innate versus adaptive immunity – what degree of control has been demonstrated to date?

- Harnessing the innate immune response for vaccine adjuvants
- Delineating the role of immune potentiators and delivery systems in vaccine adjuvants
- Synergistic effects of combined immune potentiators and delivery systems
- Rational design of novel immune potentiators
- Potential for stand-alone use of adjuvants as immune stimulants and modulators

**Dr Jeffrey B. Ulmer**, Head, Immunology & Cell Biology, Novartis Vaccines

2.05 Questions & discussion

#### 2.10 Regulatory considerations in the safety assessment of adjuvanted preventive vaccines

- Key components in nonclinical safety evaluation of preventive vaccines
- Current CBER approach to toxicology testing of vaccines/novel vaccine adjuvants
- Relevant clinical trial considerations

**Dr Elizabeth M. Sutkowski**, Scientific Reviewer, Office of Vaccines Research & Review (OVR), CBER, US Food & Drug Administration

2.30 Questions & discussion

#### Next generation adjuvants – what's in the pipeline?

#### 2.35 Case study

##### Development of VaxImmune, a CpG ODN TLR9 agonist that bridges innate and adaptive immunity, as a vaccine adjuvant for prophylactic and therapeutic vaccines

- Novel synthetic agonists of Toll-like receptors (TLR) as vaccine adjuvants
- TLR 9 activates plasmacytoid dendritic cells to bridge innate and adaptive immunity
- Development of VaxImmune, a CpG ODN TLR9 agonist, as a universal vaccine adjuvant for prophylactic or therapeutic indications
- Reliability of animal models to predict efficacy of CpG ODN in humans
- Formulation of CpG ODN to enhance immunogenicity or alter specific aspects of the adaptive immune response

**Dr Heather L. Davis**, Vice President, Pharmacology R&D, Coley Pharmaceutical Canada

2.55 Questions & discussion

#### 3.00 Case study

##### The use of TLR7/8 agonists as vaccine adjuvants

- Adjuvant properties of small molecule synthetic TLR 7/8 agonists
- Using TLR7/8 agonists in combination with anti-CD40
- Immunogenicity of TLR7/8-antigen conjugates
- Novel formulations of TLR7/8 agonists to increase vaccine efficacy

**Mark A. Tomai**, Division Scientist, Pharmaceutical Research, 3M Pharmaceuticals

3.20 Questions & discussion

#### 3.25 Case study

Speaker to be announced

3.45 Questions & discussion

3.50 Afternoon tea & close of the Phacilitate Vaccine Forum Baltimore 2007

“ An outstanding contribution to understanding the problems of bringing vaccines to the public and of we might overcome these obstacles ”

Dr Ian Livey, Director, Bacteriology & Preclinical Research, Baxter BioScience commenting on the 2006 Baltimore Vaccine Forum

Phacilitate  
VACCINE FORUM  
BALTIMORE 2007

## OR BREAKOUT SESSION 1

### Update on late stage clinical trials results for therapeutic and prophylactic cancer vaccines

Highly interactive workshop for a maximum of 30 participants

#### 1.45 Moderator's introduction

**Sharon R. Seiler, PhD**, Vice President - Senior Biotechnology Analyst, Punk, Ziegel & Company

##### A series of late stage case studies from the most advanced companies in the field, each exploring the latest clinical trial results, their clinical development strategy and the route to approval

#### 1.50 Case study

##### Development of the GSK cervical cancer candidate vaccine

- The origin of the GSK cervical cancer candidate vaccine
- The novel adjuvant system included in the vaccine and reason for its inclusion
- Reviewing data to date including recent published studies
- Discussing the status of the vaccine with regulatory agencies

**James P. Tursi, MD, FACOG**, Director of Medical Affairs - North America, Cervical Cancer Vaccines, GlaxoSmithKline

3.10 Questions & discussion

#### 2.15 Case study

##### Update on Phase III trials of GVAX® immunotherapy for prostate cancer

Cell Genesys (name of speaker to be announced)

2.35 Questions & discussion

#### 2.40 Progress in the development of Provenge (sipuleucel-T) for the active immunotherapy of prostate cancer

- The prostate cancer continuum and the unmet need for new treatments
- Development history of Provenge in prostate cancer
- Endpoints suitable for evaluation of active immunotherapy in prostate cancer
- Regulatory and clinical development milestones

**Dr David L. Urdal**, CSO & Vice Chairman of Board of Directors, Dendreon

3.00 Questions & discussion

#### 3.05 Case study

##### Testing the efficacy of vaccithery with heat shock protein gp96 (Oncophage) in adjuvant renal cell carcinoma: Results of a randomized Phase III trial

**Pramod K. Srivastava, PhD**, Professor & Chairman of the Department of Immunology, University of Connecticut School of Medicine

3.25 Questions & discussion

#### 3.30 Panel discussion

##### Comparing and contrasting routes to market strategies for prophylactic and therapeutic cancer vaccines

3.50 Afternoon tea & close of the Phacilitate Vaccine Forum Baltimore 2007

## OR BREAKOUT SESSION 2

### Long-term follow up for new and existing vaccines: To what extent is current pharmacovigilance practice adequate?

Highly interactive workshop for a maximum of 30 participants

#### 1.45 Moderator's introduction

**Robert L. Davis, MD, MPH**, Director, Immunization Safety Office, Office of the Chief Science Officer, Centers for Disease Control & Prevention

#### 1.50 Reviewing the FDA's current pharmacovigilance practice guidances for vaccines - what are the current plans for assessing adverse events?

- Examples from recently licensed vaccines
- Phase IV studies
- Pharmacoepidemiologic studies and passive surveillance
- FDA and International Conference on Harmonization: relevant guidance

**M. Miles Braun, MD, MPH**, Director, Division of Epidemiology, OBE, CBER, US Food & Drug Administration

2.10 Questions & discussion

#### What post-licensing commitments are in place for recently approved vaccine components? Are they being driven by industry or the regulator?

- Contrasting post-marketing commitments for live viral vaccines with subunit vaccines
- Improving the sharing and coordination of surveillance data regionally, nationally and internationally

#### 2.15 Case study

##### Risk management planning - recent experience

- Examples from 3 recent vaccine approvals - Rotateq, Zostavax, and Gardasil
- US vs European regulatory perspectives
- Challenges in global execution

**Adrian Dana, MD, FAAP**, Senior Director, Clinical Risk Management & Safety Surveillance, Merck Research Laboratories

2.35 Questions & discussion

#### 2.40 Case study of vaccine pharmacovigilance at Wyeth

**Michael D. Blum, MD, MPH**, Vice President, Medical Pharmacovigilance, Global Safety Surveillance & Epidemiology, Wyeth Research

3.00 Questions & discussion

#### 3.05 Case study

##### Post-marketing assessment of vaccine safety during pregnancy

- What are the limitations of clinical trials?
- Are pregnancy registries the answer?
- What can observational studies add?

**Harry A. Seifert, MD, MSCE**, Director, North America Safety Evaluation & Risk Management, GlaxoSmithKline Biologicals

3.25 Questions & discussion

#### 3.30 Panel discussion

##### Redefining the adult vaccine dosing schedule

- Learning from the recent mumps and measles outbreaks in US and Europe – what are the causes?
- Harmonizing dosing schedules worldwide

Panelist:

**William M. Egan, PhD**, Executive Director, PharmaNet Consulting

3.50 Afternoon tea & close of the Phacilitate Vaccine Forum Baltimore 2007

## Phacilitate calendar of events

### Oncology Leaders' Forum 2006

30 October - 1 November,  
The Hilton La Jolla Torrey Pines, San Diego, CA  
[www.phacilitate.co.uk/oncology](http://www.phacilitate.co.uk/oncology)

### Cell & Gene Therapy Forum 2007

22 - 24 January,  
The Baltimore Marriott Waterfront Hotel, Baltimore, MD  
[www.phacilitate.co.uk/cgtherapy](http://www.phacilitate.co.uk/cgtherapy)

### R&D Leaders' Forum Spring 2007

5 - 7 March,  
The Westin, Philadelphia, PA  
[www.phacilitate.co.uk](http://www.phacilitate.co.uk)

### Phacilitate Vaccine Forum Munich 2007

30 May - 1 June,  
The ArrabellaSheraton Grand Hotel, Munich, Germany  
[www.phacilitate.co.uk/mv](http://www.phacilitate.co.uk/mv)

# An unparalleled networking opportunity

The Baltimore Vaccine Forum offers you the perfect chance to network with numerous vaccine sector leaders. Extended refreshment breaks, buffet lunches and themed cocktail receptions will all be held in the exhibition area, and you are also invited to attend the Group Dinner taking place on Tuesday 23rd January 2007.

Supporting the excellent informal networking will be our Pre-event Meeting Request Service, and the chance to book complimentary meeting rooms, ideal for confidential discussions.

## Optional Group Dinner

# The Swinging Sixties

Tuesday 23rd January 2007

This year's Group Dinner takes place directly following day two's cocktail reception in the Grand Ballroom of the Baltimore Marriott Waterfront Hotel. Enjoy delicious food in a '60s atmosphere, complete with the sounds that defined a generation – an unmissable opportunity to continue networking with your fellow attendees in fun, informal surroundings.

The price for the dinner is \$99 / £55 and you can book your place at the same time as you register for the conference. Please contact Natalie England at [Natalie@phacilitate.co.uk](mailto:Natalie@phacilitate.co.uk) (+44 (0)20 7839 6180) with any questions.

## The exhibition



Over 26 companies have already confirmed they will be showcasing themselves in the exhibition area, shared with Phacilitate's 3rd annual Cell & Gene Therapy Forum. They include:

- Aldevron
- Althea Technologies
- AppTec
- AVANT Immunotherapeutics, Inc
- Baxter Healthcare
- BD Medical – Pharmaceutical Systems
- Beckman Coulter
- Benchmark Research
- Biologics Consulting Group
- Cognate BioServices, Inc
- Covance Research Products
- Cytonome Inc
- DVC LLC, A CSC Company
- Emergent BioSolutions
- ERA Consulting Group
- Eufets AG
- Ichor Medical Systems
- MaxCyte Inc
- McKenna Long & Aldridge, LLP
- Miltenyi Bioprocess
- Molecular Medicine BioServices
- Omnia Biologics
- Pall Life Sciences
- PharmaNet, Inc
- Progenitor Cell Therapy
- Prologue Research
- PRTM
- SGS Life Science Services

"This meeting is a quality production with excellent attention to detail. This translates to a relaxed atmosphere conducive to discussions and involvement - a perfect foil to the seniority and influence of the delegates"

Ian C. Sellick, Director of Marketing, Pall Life Sciences

"An excellent venue to meet sponsors focused on clinical development programmes. Phacilitate are the best conference organisers we have met"

Roy Fraser, Director of Client Services, Synexus Clinical Research plc

"This was the right sized conference having just enough people to be able to contact without feeling overwhelmed. It also had the right type of people - the "decision-makers"

Dr May de las Alas, Business Development Associate, Ichor Medical Systems, Inc

**Just 6 booth spaces remain available – for more information please contact David McCall at**  
**E: [david@phacilitate.co.uk](mailto:david@phacilitate.co.uk)**  
**T: +44 (0)20 7839 6151**

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## Sponsor:



Emergent BioSolutions Inc. is a biopharmaceutical company dedicated to protecting life through the development, manufacture, and commercialization of Immunobiotics™, which are novel products that direct the immune system to prevent and treat life-threatening diseases. These include products for prophylactic and therapeutic use against serious diseases where there exists significant unmet or underserved medical needs and against biological agents which may potentially be used as weapons of bioterrorism. The Company currently employs more than 450 people with sites in Maryland, Michigan, the United Kingdom, Germany, and the Republic of Singapore. More information about Emergent BioSolutions is available at [www.emergentbiosolutions.com](http://www.emergentbiosolutions.com).

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 East Hills, NY 11548, USA  
 Toll Free: 800.717.7255  
 Tel: 516.484.5400 Fax: 516.801.9548  
 Email: [biotech@pall.com](mailto:biotech@pall.com)  
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### Cocktail reception sponsor



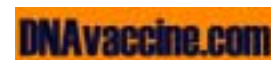
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