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28-30 January, The Grand Hyatt, Washington, DC

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WASHINGTON 2008

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- RADM W. Craig Vanderwagen, MD**, Assistant Secretary for Preparedness & Response, US Department of Health & Human Services (HHS)
- Rajiv De Silva**, President, Novartis Vaccines USA
- Carol A. Dahl, PhD**, Chief of Staff, Global Health Program & Director, Global Health Technologies, Bill & Melinda Gates Foundation
- Dr Allan P. Jarvis**, Senior Vice President, Corporate Development, sanofi pasteur
- Dr Norman W. Baylor**, Director, Office of Vaccines Research & Review (OVRR), CBER, US Food & Drug Administration
- Dr David C. Kaslow**, Vice President, Infectious Diseases & Vaccines Franchise, Merck Research Laboratories
- Dr Gary J. Nabel**, Director, Vaccine Research Center, National Institute of Allergy & Infectious Diseases, NIH
- Anne Schuchat, MD, RADM**, US Public Health Service, Assistant Surgeon General, Director, National Center for Immunization & Respiratory Diseases, Centers for Disease Control & Prevention
- Dr William Gruber**, Vice President, Clinical Research, Wyeth Vaccines
- Thomas R. Fuerst, PhD**, Director, Vaccines & Biologics, Office of Research & Development Coordination, Office of Public Health Emergency Preparedness, US Department of Health & Human Services
- Dr John W. Shiver**, Vice President, Worldwide Basic Research Franchise Head, Vaccines, Merck Research Laboratories

- Catarina Flyborg**, Leader, Vaccine Initiative, GE Healthcare Life Sciences
- Stephen M. Sammut**, Senior Fellow, Wharton Health Care Systems & Venture Partner, Burrill & Company
- Dr Luc Hessel**, Chairman, Influenza Vaccine Supply International Task Force, Executive Director, Medical & Public Affairs, Europe, Sanofi Pasteur MSD
- Dr Robert Kadlec**, Director, BioDefense & Public Health, PRM Management Consultants
- Beatrice De Vos, MD, BCPM**, Vice President, Global Medical Affairs, sanofi pasteur, Lyon
- Dr Sharon R. Seiler**, Vice President - Senior Biotechnology Analyst, Punk, Ziegel & Company
- Fuad El-Hibri**, Chairman & CEO, Emergent BioSolutions
- Dr Michael Pfeleiderer**, Head of Section: Viral Vaccines, Paul-Ehrlich-Institut
- Dr Peter Khoury**, Vice President, Global Marketing, Baxter BioScience, Vaccines
- Dr Paul Offit**, Chief, Division of Infectious Diseases, The Children's Hospital of Philadelphia
- Frank Malinoski, MD**, Senior Vice President, Medical & Scientific Affairs, MedImmune, Inc
- Dr Michael G. Kurilla**, Director, Office of BioDefense Research Affairs, Associate Director for BioDefense Product Development, DMID, NIAID, NIH, DHHS
- Dr Michael Krams**, Assistant Vice President, Adaptive Trials, Clinical Development, Wyeth Research

- Dr Hélène Pora**, Vaccine Application Director, Pall Life Sciences
- Dr Una S. Ryan**, President & CEO, AVANT Immunotherapeutics, Inc
- Peter J. Hotez, MD, PhD**, President, Sabin Vaccine Institute, Walter G. Ross Professor & Chair, Department of Microbiology, Immunology, & Tropical Medicine, The George Washington University
- Michael Lytton**, General Partner, Oxford Bioscience Partners
- Robert V. House, MSPH, PhD**, President & Chief Scientific Officer, DynPort Vaccine Company LLC, A CSC Company
- Dr Bruce G. Weniger**, Chief, Vaccine Technology, Immunization Safety Office, Centers for Disease Control & Prevention
- Drs Ben Machielse**, Executive Vice President, Operations, MedImmune, Inc
- Professor Alexander von Gabain**, CSO, Intercell AG
- Frank M. Rapoport**, Partner, McKenna Long & Aldridge LLP
- Dr Rahul Singhvi**, President & CEO, Novavax Inc
- Dr Chandresh Harjivan**, Principal, Life Sciences, PRM Management Consultants
- Dr Adrian Dana**, Senior Director, Clinical Risk Management & Safety Surveillance, Merck Research Laboratories
- Jeffrey J. Stoddard, MD**, Vice President, Medical & Scientific Affairs, Risk Management & Postmarketing Programs, Covance

- Dr Krishna Mohan**, President, Bharat Biotech Intl Ltd
- Louis I. Hochheiser, MD**, Medical Director, Clinical Policy Development, Humana, Inc
- Raafat Fahim, PhD**, Chief Operating Officer & General Manager, Nabi Biopharmaceuticals
- Dr Alan Shaw**, President & CEO, VaxInnate Corporation
- Jan Delaere**, Director, Manufacturing Strategy, Flu Pandemic Vaccines, GlaxoSmithKline Biologicals
- Dr Thomas K. Zink**, Chief Medical Officer & Senior Vice President, Medical & Regulatory Affairs, Emergent BioSolutions
- Kimberlee Wallace, PhD**, Director, GMP Operations & Process Research, NIH Vaccine Research Center
- Dr Ronald W. Ellis**, Senior Vice President & Chief Technical Officer, NasVax Inc, United States (a subsidiary of NasVax Ltd, Israel)
- Tom Privette, PhD**, Vice President, Strategic Partnering, Covance
- Donald Beeman**, Chairman & CEO, LigoCyt Pharmaceuticals, Inc
- John Clerici**, Partner, McKenna Long & Aldridge LLP
- Dr Clement Lewin**, Vice President of Marketing, Policy & Strategy, Acambis
- Dr John McNeil**, Director, Research & Development, PATH-MVI
- Dr Akira Homma**, Director, Bio-Manguinhos/Oswaldo Cruz Foundation/MoH
- Dr Guillermo Herrera**, Director of Global Medical Affairs, Wyeth

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The conference fee does not include accommodation. We have negotiated substantially discounted rates for all attendees at the Washington Vaccine Forum at The Grand Hyatt Hotel. 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 4th of January 2008.

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MORNING PLENARY SESSION

Developing a coordinated approach to signalling: US policy and funding for vaccine R&D, licensing, commercialization and routes of administration

9.00 Chair's introduction
Dr Peter Khoury, Vice President, Global Marketing, Baxter BioScience, Vaccines

9.10 What will be the consequences of the US government's pursuit of the "ideal vaccine?"
Dr Robert Kadlec, Director, BioDefense & Public Health, PRTM Management Consultants

9.30 How is HHS evolving to enable effective emergency preparedness and response? Strategic planning and policy

- How is the structure of the authority, and its cooperation and coordination with other government departments, evolving and with what objectives?
- What is BARDA's roadmap for the next 2-5 years and beyond?
 - What does BARDA want from industry and how is government addressing technology watch?
 - Contrasting biodefense and pandemic influenza: Lessons learnt for engaging large companies in government procurement
 - Milestone payments: How will risk sharing work in practice?
- The role of vaccines versus therapeutics in preparedness and response
- Clarifying the scale, scope, timing and eligibility of funding for new influenza and biodefense mechanisms
- International relationships in preparedness and response
 - US participation in international projects for countermeasures
 - Strategies for mass administration in the US and abroad

RADM W. Craig Vanderwagen, MD, Assistant Secretary for Preparedness & Response, Department of Health & Human Services (HHS)

9.55 HHS perspective: Update on policy decisions and availability of government funding for the domestic vaccine schedule and global vaccine initiatives

- Update on the National Vaccine Plan and communication with industry
 - What value do US funding mechanisms provide to vaccine manufacturers and how might this change in the short and long term:
 - VFC program
 - Section 317 public health services act
 - How will Medicare part D impact the new generation of vaccines?
 - Impact of PDUFA
 - How will the funding gap be addressed for adult vaccines?
 - The latest US funding initiatives for global health vaccines: What approach is government taking?
 - The role of government policy in sustaining and fostering innovation
 - Where would government like to see innovation happening
 - Delivery?

- Novel targets?
- Novel manufacturing techniques?
- Vaccines versus therapeutics: How do broad-spectrum platform technologies fit with innovation goals?
- The government's approach to aligning government labs, academia and industry (strategies for large and small pharma)

Dr Robin Robinson, Acting Associate Director, Office of Research & Development Coordination, Office of the Assistant Secretary for Preparedness & Response, US Department of Health & Human Services (*invited*)

10.20 Questions & discussion

10.30 NIH perspective: How are funding and policy decisions, and opportunities for vaccine research, early development and technology transfer, being signalled to industry?

- What are the current NIH funding priorities for influenza, biodefense, paediatric, adolescent/adult vaccines, and also vaccines for global health?
- How is NIH coordinating with other government agencies to communicate funding priorities and research opportunities to industry?
- Clarifying the restrictions that apply to NIH funded projects, particularly regarding the use of facilities outside the US
- How is NIH approaching technology transfer, particularly for global health projects?

Dr Gary J. Nabel, Director, Vaccine Research Center, National Institute of Allergy & Infectious Diseases, NIH

10.55 Questions & discussion

11.00 Morning coffee in the exhibition area

11.40 CDC perspective on progress with updating the National Vaccine Plan: What are the implications for industry?

- Update on ACIP influenza recommendations and plans for promotion of influenza vaccine use
- How does public health address setting vaccine priorities given the context of current immunization schedules?
- Making the case for the remaining vaccines on the Institute of Medicine's recommendation list - public health and industry considerations for vaccines against: Cytomegalovirus, Group B strep, Staphylococcus aureus (methicillin resistant), Group B meningococcus, and RSV

Anne Schuchat, MD, RADM, US Public Health Service, Assistant Surgeon General, Director, National Center for Immunization & Respiratory Diseases, Centers for Disease Control & Prevention

12.05 Questions & discussion

12.10 FDA perspective: Working with industry to facilitate the licensure of new vaccines, and with international regulatory authorities to harmonise the approval process

- The impact of regulatory requirements for vaccine approval on development of new vaccines
- The role of the Vaccines and Related Biological Products Advisory Committee
- How does the Critical Path Initiative impact vaccine development?
- 'Design space' in ICH guidance: Can it be applied to vaccines? How well can you link product quality attributes to product outcome?

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

12.35 Questions & discussion

12.40 Panel discussion
Addressing the evolving challenges for the paediatric vaccines sector

- Debating whether and why paediatricians and the public are losing interest in vaccines: Are they no longer accepting that vaccines are essential?
 - Reimbursement issues for paediatricians - managing the capital outlay
- Managing the increasingly packed schedule - what will be recommended?
- Growing the 5+ year old market
- Maternal antibodies - how close are we to overcoming immunization issues?
- Addressing patient recruitment issues

Panellists:
Dr William Gruber, Vice President, Clinical Research, Wyeth Vaccines
Dr John W. Shiver, Vice President, Worldwide Basic Research Franchise Head, Vaccines, Merck Research Laboratories
Dr Paul Offit, Chief, Division of Infectious Diseases, The Children's Hospital of Philadelphia
Frank Malinoski, MD, Senior Vice President, Medical & Scientific Affairs, MedImmune, Inc

1.10 Buffet lunch in the exhibition area

OR

Optional working lunch
Electroporation technology applications in gene transfer
 (Highly interactive discussion-based session for a maximum of 12 participants)
 Moderator: **Drew Hannaman**, Vice President, R&D, Ichor Medical Systems, Inc

Followed by your choice of 3 highly interactive parallel sessions:

FOCUS SESSION 1

Pandemic and seasonal influenza vaccines: Assessing progress in international approaches to regulation and preparedness policy

2.20 Chair's introduction
Measuring US government progress with issuing contracts for 2nd and 3rd generation products

- Recombinant vaccine
- Universal vaccine
- New cell-based technologies
- VLPS
- Adjuvants for pandemic influenza

Dr Robin Robinson, Acting Associate Director, Office of Research & Development Coordination, Office of the Assistant Secretary for Preparedness & Response, US Department of Health & Human Services (*invited*)

2.45 Presentations & discussion
To what extent are FDA and EMEA aligned? Are their requirements now equivalent?

- Comparing approaches to
 - Challenge studies
 - Assessment of benefit:risk
 - New paediatric vaccine guidelines
 - Licensure of non-HA vaccines
- Comparing the quality and efficacy of new and existing vaccines - is there harmonization?
- Progressing towards harmonization of international tests for HI and standardized reagents and serological assays
 - What are the guiding principles around immunogenicity as a surrogate for efficacy?
 - Will harmonization be resolved through
 - Basic research?
 - Pre-competitive collaboration?
 - International collaboration and cooperation?
- Comparing approaches to novel adjuvants: What are the regulatory concerns and how does industry need to address them?
 - Sharing and comparing potency and safety data - what is the risk of autoimmune problems and allergies?
 - How likely is cross-licensing of a successful adjuvant for pandemic influenza so that it become the adjuvant of choice?
- Pre-pandemic strategies: What are the key differences in policy?
- Stockpiling policy
 - How much cross-protection do we want?
 - What new data is coming from animals and challenge models?
 - How will the product be licensed? How many strains will it cover and for what duration?
 - What degree of antigenic drift will stockpiles be effective against? Should we rotate H5/7/9?
 - What are the stability and formulation issues?
 - How does US stockpiling affect vaccine availability globally?
- Should the US/EU/Japan agree on a "standard" set of regulations for quality concerning pandemic vaccines? Is this even possible?

Dr Norman W. Baylor, Director, Office of Vaccines Research & Review (OVR), CBER, US Food & Drug Administration
Dr Michael Pfeleiderer, Head of Section: Viral Vaccines, Paul-Ehrlich-Institut

3.50 Panel discussion
Increasing the acceptance and take-up of the seasonal influenza vaccine: To what extent is the morbidity of influenza underappreciated or poorly communicated?

- Assessing policy differences between the US and Europe that might impact acceptance and take-up
- Are physicians undervaluing the benefit:risk of the vaccine?
- Public perception of safety and handling issues for live attenuated viral vaccines
- How effective are seasonal influenza vaccines, especially for the most at risk population groups?
- How will the additional influenza manufacturing capacity in the US be absorbed?
 - How will utilization be stimulated fast enough to absorb all the new players?

Panellists:
Dr Luc Hessel, Chairman, Influenza Vaccine Supply International Task Force, Executive Director, Medical & Public Affairs, Europe, Sanofi Pasteur MSD
Frank Malinoski, MD, Senior Vice President, Medical & Scientific Affairs, MedImmune, Inc.
Dr Peter Khoury, Vice President, Global Marketing, Baxter BioScience, Vaccines

4.30 End of focus session followed by afternoon tea in the exhibition area

OR | FOCUS SESSION 2

Aligning the vaccine development path with the Critical Path Initiative: Applying learn & confirm methodologies, adaptive trials and challenge models to increase efficiency

2.20 Chair's introduction
Beyond "Shoot and Bleed" models: Should we develop new challenge models in humans to measure immune responses?

- Limitations of measuring immune responses in the absence of exposure to target pathogen
- Current "challenge" models in humans: how have they helped in product development?

- Characterizing immunogenicity in "challenge" models
- Alternatives to "live challenge": when does it make sense to do a subunit "challenge" and what does it really tell us?
- How might challenge models enable the development of more relevant immunogenicity markers for later stage trials?
- Building capabilities for new challenge models

Dr David C. Kaslow, Vice President, Infectious Diseases & Vaccines Franchise, Merck Research Laboratories

2.45 Questions & discussion

2.50 Case study
Incorporating adaptive trials in vaccine development

Dr Michael Krams, Assistant Vice President, Adaptive Trials, Clinical Development, Wyeth Research

3.15 Questions & discussion

3.20 Going beyond the standard biomarkers and correlates of protection for infectious diseases

- Extracting maximum value from future investment in exploratory biomarkers for vaccines
- Making earlier and better decisions to avoid phase III failure at all costs
- Establishing guiding principles around immunogenicity as a surrogate for efficacy
 - How is endpoint validation evolving?

Dr John W. Shiver, Vice President, Worldwide Basic Research Franchise Head, Vaccines, Merck Research Laboratories

3.45 Questions & discussion

3.50 Panel discussion
How can the Learn and Confirm model be applied to vaccine development so that dose and regimen are optimized pre-phase III?

- What tools do we have for Proof of Concept?
- How much does the L&C model shorten development time by?
- How is it operationalized?

4.30 End of focus session followed by afternoon tea in the exhibition area

OR | BREAKOUT SESSION

Practical advice for small companies seeking to access government funding: Navigating the RFP process

Highly interactive workshop for a maximum of 30 participants

2.20 Moderator's introduction
What every small vaccine company needs to know about accessing government funding: What are the pros and cons of the grant process?

- What constraints are likely to be encountered?
- How do milestone payments work in practice?

John Clerici, Partner, McKenna Long & Aldridge LLP

2.45 Questions & discussion

2.50 Case study: Effective and timely lobbying strategies to maximize your chances of being granted government funding

- Engaging lobby groups - who, how and when?
- What is the optimum way to track an RFP from its inception?
 - How can lobbying help?
- How do you manage the uncertainty of government grants and contracts?

Donald Beeman, Chairman & CEO, LigoCyte Pharmaceuticals, Inc

3.15 Questions & discussion

3.20 Case study: Acambis' experience with the RFP process
Sharing Acambis' experience in planning, preparing and submitting RFPs to the United States Government

- Scanning the environment to identify potential opportunities
- Monitoring and tracking an opportunity prior to the RFP
- Responding to the RFP
- Lessons learned

Dr Clement Lewin, Vice President of Marketing, Policy & Strategy, Acambis

3.45 Questions & discussion

3.50 Panel discussion
Why would small companies want to do business with the government?

- Comparing pros and cons of government funding versus the alternatives
- Given the timeline for vaccine development, can a small company remain independent for several years with reliance on Phase II data for partnering?

4.30 End of breakout session followed by afternoon tea in the exhibition area

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



THEN | AFTERNOON PLENARY SESSION

5.10 Panel discussion
What are the policy and economic implications for those developing and marketing adolescent and adult vaccines?

- Has the time come for adult immunization? What's the value of immunizing adults?
- Pharmacoeconomics and reimbursement: How will adult and adolescent vaccines be categorized and paid for?
- How will the public be educated about their use and value?
- How will they be scheduled?
- Should there be an enforcement mechanism for adolescent vaccines and what would it look like?

- What are the routes of administration for these vaccines?
 - How might non-traditional players become involved?
- Should vaccines for adolescents and adults be marketed more aggressively than those for paediatric use?
- Defining further targets for adult and adolescent vaccines

Panellists:
Dr Una S. Ryan, President & CEO, AVANT Immunotherapeutics, Inc
Dr William Gruber, Vice President, Clinical Research, Wyeth Vaccines
Dr John W. Shiver, Vice President, Worldwide Basic Research Franchise Head, Vaccines, Merck Research Laboratories

5.50 Close of day 1 followed by a themed cocktail reception in the exhibition area

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7.30 Registration & buffet breakfast in the exhibition area

MORNING PLENARY SESSION

Vaccine economics and lifecycle management: How are financial markets, payers, pharma and biotech companies assessing benefit:risk and the potential value of new vaccine candidates?

9.00 **Chair's introduction**
Dr Una S. Ryan, President & CEO, AVANT Immunotherapeutics, Inc

9.10 **Analyst perspective: How does the financial community assess value and benefit:risk in the vaccines sector and what investing trends are forecast?**

- What do recent deals say about the value of vaccines?
 - How do you value MedImmune at \$15.6 billion?
- How have HPV vaccines altered the commercial value of vaccines?
- Assessing the risk profiles of
 - Therapeutic versus prophylactic vaccines
 - Paediatric versus adolescent/adult vaccines
- Analyzing the economics of niche markets such as the travellers vaccine market: Will they be sold as consumer products, prescription products, or reimbursed products and how will this impact value?
- In the face of increased consolidation how will the vaccine industry continue to grow?
- Licensing and partnering: The value of biotech is generally increasing rapidly due to weak pipelines in Big Pharma – why aren't we seeing this so much in vaccines?
 - Is it because margins still haven't reached the levels of therapeutics?
Dr Sharon R. Seiler, Vice President - Senior Biotechnology Analyst, Punk, Ziegel & Company

9.35 *Questions & discussion*

9.40 **Payer's perspective: How is the assessment of benefit:risk, value and price being approached for new vaccines?**

- How should industry demonstrate value?
Louis I Hochheiser, MD, Medical Director, Clinical Policy Development, Humana, Inc

10.05 *Questions & discussion*

10.10 **Biopharma perspective: Building and managing a vaccine pipeline - considerations for development stage biopharma companies**

- Prophylactic and therapeutic vaccine distinctions
- Importance of therapeutic focus
- Aligning licensing and acquisition strategy with pipeline strategy
Fuad El-Hibri, Chairman & CEO, Emergent BioSolutions

10.35 *Questions & discussion*

10.40 *Morning coffee in the exhibition area*

11.20 **Keynote address**
Industry perspective on economic pressures for new vaccine development: Demonstrating value to patients and payers through rigorous benefit:risk assessment, and applying lifecycle management to remain competitive

- Benefit/risk management in vaccine development
- The role of vaccine pharmacoeconomics in clinical development
- Lifecycle management in vaccine development
- Vaccine manufacturing: Opportunities and challenges in a global marketplace
Rajiv De Silva, President, Novartis Vaccines USA

11.45 *Questions & discussion*

11.50 **Presentation followed by panel discussion**

What is suddenly making the vaccines world so attractive for pharma companies?

- Opportunities but hidden problems?
Beatrice De Vos, MD, BCPM, Vice President, Global Medical Affairs, sanofi pasteur, Lyon

How are pharma, biotech and the VC community capitalizing on business opportunities in vaccines?

- Analyzing market entry / re-entry strategies
 - Technology transfer
 - In-licensing
 - Co-distribution agreements
- How is the value of vaccine businesses/franchise changing? What is pharma looking for from biotech?
 - Building a venture financed vaccine company to appropriate inflection points for significant partnerships with pharma
 - Balancing the benefits of a large pharma partnership against alternative relationships, including with companies in Asia
 - Integrating a vaccine business into pharma
- What is the perceived benefit:risk and value in
 - Adult/adolescent vaccines
 - Therapeutic vaccines
 - Vaccines for global health
 - Vaccines for biodefense
- Approaches to commercialization for remaining tough targets

Panellists:
Dr Douglas J. Pon, Assistant Vice President, Vaccine Licensing, Global Business Development, Wyeth Pharmaceuticals
Michael Lytton, General Partner, Oxford Bioscience Partners
Raafat Fahim, PhD, Chief Operating Officer & General Manager, Nabi Biopharmaceuticals

12.50 *Buffet lunch in the exhibition area*

Followed by your choice of 3 highly interactive parallel sessions:

FOCUS SESSION 1

Pandemic and seasonal influenza vaccines: Which new technology platforms and adjuvants are promising a significant impact on efficacy, dose reduction, duration of response and capacity?

2.00 **Chair's introduction**
Creating order out of chaos: Which adjuvants will prevail?

- Update on a mechanism-based understanding of how a vaccine works
 - Fundamental biology – what are the targets for adjuvants?
- What are the lead products being explored in the clinic and what are the experiences to date?
- Is TLR the right approach? What are the alternatives? Other receptor agonists?
- What are the current (very significant) regulatory issues with adjuvants and how are they considered in the context of a fully licensed product?
 - What are the risks of reactogenicity?
Professor Alexander von Gabain, CSO, Intercell AG

2.20 *Questions & discussion*

2.25 **Integrating modern technologies for economical vaccine manufacturing**

- Improving analytical tools as a dose-sparing strategy
- Combining disposable manufacturing technologies towards the mobile plant
- Applying lessons-learned from biopharmaceutical manufacturing on vaccine production
Catarina Flyborg, Leader, Vaccine Initiative, GE Healthcare Life Sciences

2.45 *Questions & discussion*

2.50 **Update on VLP vaccines for seasonal and pandemic influenza**

- Latest clinical results
- What is the potential for broadened immunity?
- What leadtimes and yields can be expected?
- How scalable will these techniques be in a pandemic crisis?
- How rapidly can they be adapted to new strains?
- How will they perform in crisis conditions?
- What are the regulatory hurdles and how are they being addressed?
Dr Rahul Singhvi, President & CEO, Novavax Inc

3.10 *Questions & discussion*

3.15 **Update on universal antigen vaccine**

- Latest clinical results
- What is the potential for broadened immunity?
- What leadtimes and yields can be expected?
- How scalable will these techniques be in a pandemic crisis?
- How rapidly can they be adapted to new strains?
- How will they perform in crisis conditions?
- What are the regulatory hurdles and how are they being addressed?
Dr Alan Shaw, President & CEO, VaxInnate

3.35 *Questions & discussion*

3.40 **Panel discussion**
Who is taking the lead in developing a surrogate assay than HI for existing and new influenza vaccines?

- Characterizing cellular responses and cytokine profiles in addition to antibody responses
- What non-HI-based antibody assays are being used, and how will they be validated for new vaccines not based on HI?
- Designing clinical trials to assess safety and immunogenicity of novel adjuvants
Panellist:
Dr Ronald W. Ellis, Senior Vice President & Chief Technical Officer, NasVax Inc, United States (a subsidiary of NasVax Ltd, Israel)

4.10 *End of focus session followed by afternoon tea in the exhibition area*

OR | FOCUS SESSION 2

Minimizing cost of goods through effective capacity management, application of novel platform and technology solutions, and public/private partnerships

2.00 **Chair's introduction**
How is the increasing cost of goods affecting choices of platform and technology solutions?

- What is the new thinking behind bioprocess decisions to decrease costs of goods?
- Should platform innovations focus more on decreasing COGs or increasing efficacy? Is this trade-off reasonable?
Dr Hélène Pora, Vaccine Application Director, Pall Life Sciences

2.25 *Questions & discussion*

2.30 **Production of the VRC HIV vaccine for efficacy trial: Public/private collaboration in vaccine development**

- Establishing scalable production methodologies
- Working with public/private partnerships during development
- Aligning cGMP production with clinical timelines
Kimberlee Wallace, PhD, Director, GMP Operations & Process Research, NIH Vaccine Research Center

2.55 *Questions & discussion*

3.00 **Live attenuated intranasal vaccine (LAIV): Novel process technologies and alternate delivery mechanisms' impact on process development, capacity management and, ultimately, COGs**

- The future prospect of developing LAIV through cell-culture manufacturing technology -increases scalability and flexibility, removes the supply risk
- New manufacturing and delivery device technologies allow for a comprehensive strategy, not just for pandemic preparedness, but also the ability to make seasonal flu vaccine accessible to larger populations and developing countries.
- How to leverage these advantages to strategically balance the need for pandemic preparedness with the traditional mantra of "do not expand without demand"
Drs Ben Machielse, Executive Vice President, Operations, MedImmune, Inc

3.25 *Questions & discussion*

3.30 **Panel discussion**

- Projections of capacity improvements to be gained through innovation
- Handling post-licensure manufacturing changes that take the manufacturer outside the license

4.10 *End of focus session followed by afternoon tea in the exhibition area*

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THEN | AFTERNOON PLENARY SESSION

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

4.50 **Panel discussion**
Rebuttal to the anti-vaccine movement: What approach should the vaccine industry take?

- How can the public be reassured about vaccine safety? What role can pharmaceutical companies play in the public debate about vaccine safety?
- How to influence the media

- Update on latest US litigation
Panellist:
Dr Paul Offit, Chief, Division of Infectious Diseases, The Children's Hospital of Philadelphia

5.30 *Close of day 2 followed by a themed cocktail reception in the exhibition area*

OR | BREAKOUT SESSION

What is the direction of vaccines for biodefense? How are they now positioned alongside broad-spectrum technologies, and how will markets be developed beyond government procurement?

Highly interactive workshop for a maximum of 30 participants

2.00 **Moderator's introduction**
Biopreparedness: Vaccines for prevention or therapeutics for response? Where should industry focus?

- What is preparedness?
- What is the role of vaccines in biodefense in the short- and long-term?
- Examining the intersection of vaccines and therapeutics
 - Where are we with respect to products to answer Category A bioterrorism agent threats?
 - Where do vaccines sit with regard to broad-spectrum platform technologies?
- Can a market be made without a government purchaser?
- Dual use vaccines – how to transition to a commercialized product
Dr Michael G. Kurilla, Director, Office of BioDefense Research Affairs, Associate Director for BioDefense Product Development, DMID, NIAID, NIH, DHHS

2.25 *Questions & discussion*

2.30 **Enabling the future acceleration of biodefense product development: How can we ensure a robust manufacturing infrastructure to respond to public health threats?**

- **Dr Thomas Fuerst**, Director, Vaccines & Biologics, Office of Public Health Emergency Medical Countermeasures, Office of Public Health Emergency Preparedness, US Department of Health & Human Services

2.55 *Questions & discussion*

3.00 **Case study**
What checklist should companies use before embarking on biodefense vaccine product development programs

- Funding and procurement issues
- Partnerships and outsourcing – where do the risks lie?
- Regulatory hurdles to be aware of
- Development issues - how large do trials need to be to power the study?
Robert V. House, MSPH, PhD, President & Chief Scientific Officer, DynPort Vaccine Company LLC, A CSC Company

3.25 *Questions & discussion*

3.30 **Panel discussion**

- How to develop more effective public-private partnerships in the advanced development and acquisition of countermeasures for significant public health threats
- Broad-spectrum platform technologies - anti-virals / antibiotics – are they a practical reality? What will the regulatory hurdles be?
- In the absence of public funding for these products, what approaches can be taken to develop a sustainable market?
Panellist:
Dr Thomas K. Zink, Chief Medical Officer & Senior Vice President, Medical & Regulatory Affairs, Emergent BioSolutions

4.10 *End of breakout session followed by afternoon tea in the exhibition area*



Driving Progress

Comments from participants in the 2007 event included:

“I continue to find Phacilitate vaccine meetings to have strong speakers and agendas on a range of very timely topics”

Dr Ronald W. Ellis, Senior Vice President & Chief Technical Officer, NasVax Inc, United States (a subsidiary of NasVax Ltd, Israel)

“Excellent opportunity to connect with the vaccine industry's key players”

Dr Silke Fetzer, Head of Product Management, Cell Culture & Vaccine Operational Marketing, GE Healthcare

7.30 Registration & buffet breakfast in the exhibition area

MORNING PLENARY SESSION

Delivering innovation globally through technology transfer, public-private partnerships, funding vehicles and licensing mechanisms

9.00 **Chair's introduction**
Dr Chandresh Harjivan, Principal, Life Sciences, PRTM Management Consultants

9.05 **NGO perspective**
Innovation in science and technology: a critical path to addressing global health inequities

- Global health inequity - the problem
- Innovations in science and technology can contribute to health solutions
- Global access is the target
- Partnerships can drive solutions - industry is a key partner

Carol A. Dahl, PhD, Chief of Staff, Global Health Program & Director, Global Health Technologies, Bill & Melinda Gates Foundation

9.35 *Questions & discussion*

9.40 **Update on the success of the latest funding and risk-sharing mechanisms: What is the progress with the first Advanced Market Commitment, and how attractive are the alternatives?**

- What are the risks of the AMC approach for manufacturers and how can they be minimized?
- Dual-market vaccines (PCV, HPV, Rotavirus) versus developing world vaccines (HIV, malaria, TB)
 - Will AMCs be enough for developing world vaccines?
 - How to manage the "tail commitment"
- What progress is being made with alternative funding mechanisms?
 - Accelerated Development & Introduction Program (ADIP)
 - Venture capital funded opportunities
 - Private sector approaches
- Risk sharing by developing nations: What are the countries in greatest need of vaccines doing to share the risk with NGO's, PPP's and industry?
- What role are middle-income countries playing in funding and risk sharing for the development of vaccines nationally and globally?
- Are developing world manufacturers being incentivized to invest in R&D for new vaccines?

Stephen M. Sammut, Senior Fellow, Wharton Health Care Systems & Venture Partner, Burrill & Company

10.05 *Questions & discussion*

10.10 **Keynote address**
Delivering innovative new vaccine products to industry through licensing and partnering mechanisms

- Analysing the different types of transaction that may be adopted to introduce innovation in vaccine development and delivery - what are the pros and cons of each?
 - Licensing mechanisms
 - Funding vehicles
 - Collaborative R&D
 - Options structures
 - JVs

Dr Allan Jarvis, Senior Vice President, Corporate Development, sanofi pasteur

10.35 *Questions & discussion*

10.40 *Morning coffee in the exhibition area*

11.20 **How and where will new products for the developing world be approved?**

- How can western agencies adequately assess benefit:risk in developing world populations?
- What is the benefit of Article 58 versus full marketing authorization?
 - How appropriate are the standard data requirements and evaluation criteria to the developing world?
 - How is the scientific opinion going to be used? How does it relate to the WHO qualification process?
- Why has the first AMC been applied to a vaccine that is already licensed?
- Building regulatory capacity in the developing world to enable licensure
- Overcoming the hurdles in the regulatory process for dual pricing / dual markets
 - Is there a good pathway for hybrid trials with dual intent?
 - How will FDA and other agencies accommodate this?

Dr Michael Pfeleiderer, Head of Section: Viral Vaccines, Paul-Ehrlich-Institut

11.55 *Questions & discussion*

12.00 **Panel discussion**
How is innovation being fostered, qualified and delivered by government, NGOs and private sector for international public health needs, pandemic influenza and biodefense?

- On what basis are industry, biotechnology, and non-profit partnerships making decisions about how to fill their pipelines?
- How sure are they that they are investing in vaccines that government and NGOs want?
 - If there is a gap between the development of push and pull products, how can it be closed through better signalling between all parties?
 - Using the guiding principles of portfolio management throughout the value chain to prioritize product development
- How are the problems with technology transfer being addressed and what more needs to be done to improve the chances of success?
- How are NGOs and government undertaking technology scanning and decision making to prioritise areas of innovation?
- A new paradigm of strategic partnering to improve vaccine development productivity
 - Business environment: Big Pharma's focus on reducing R&D spend
 - Disaggregating vaccine development - a shift in R&D models
 - Strategic partnering examples throughout the development continuum
 - Evolution of the CRO industry
 - Assuring a collaborative relationship

Panelists:
Peter J. Hotez, MD, PhD, President, Sabin Vaccine Institute, Walter G. Ross Professor & Chair, Department of Microbiology, Immunology, & Tropical Medicine, The George Washington University
Dr John McNeil, Director, Research & Development, PATH-MVI
Tom Privette, PhD, Vice President, Strategic Partnering, Covance
Dr Guillermo Herrera, Director of Global Medical Affairs, Wyeth
Frank M. Rapoport, Partner, McKenna Long & Aldridge LLP

12.50 *Buffet lunch in the exhibition area*

Followed by your choice of 3 highly interactive parallel sessions:

FOCUS SESSION 1

Best practice safety and risk management for early through to late stage vaccine development

2.00 **Chair's introduction**
How well defined and communicated are acceptable safety limits in clinical trials and how does risk management change over time?

- Defining and communicating appropriate safety limits for each population group
- Establishing appropriate risk management plans
- Will government funded vaccines be more focused on safety rather than efficacy?
- What is the current regulatory view on the long-term safety of adjuvants?

2.25 *Questions & discussion*

1.30 **Case study**
Building safety and risk management into product lifecycle

- Role of risk management in early clinical development strategy
- Safety & risk management at the transition from Phase II to III
- Risk management in postmarketing to end of lifecycle

Dr Adrian Dana, Senior Director, Clinical Risk Management & Safety Surveillance, Merck Research Laboratories

2.55 *Questions & discussion*

3.00 **Panel discussion**
Making the decision to proceed to phase IV: What will be the impact of PDUFA?

- Comparing experiences with post-marketing surveillance programs
- Overview of PDUFA IV
- Phase IV market trends
- Optimizing post-marketing vaccine risk assessment
- Predictive toxicology, biomarker qualification, missing clinical trial data
- What are the ongoing issues around the role of federal agencies and industry in post-licensure monitoring?

Panelist:
Jeffrey J. Stoddard, MD, Vice President, Medical & Scientific Affairs, Risk Management & Postmarketing Programs, Covance

3.40 *Afternoon tea and close of the Washington Vaccine Forum 2008*

OR FOCUS SESSION 2

Innovations in dose sparing and delivery devices: To what extent are they inducing a broader and more protective immune response, as well as reducing cost and increasing manufacturing capacity

2.00 **Chair's introduction**
Update on intradermal immunization to meet pressing public health needs in pandemic preparedness and disease control

- What does the 200+ year history of the ID route reveal about safety and efficacy?
- Recent experience with seasonal and avian influenza antigens by this dose-sparing route
- Potential needle-free and high-speed delivery methods for mass campaigns and pandemic preparedness
- Exciting future technologies to take advantage of skin as an organ of the immune system

Dr Bruce G. Weniger, Chief, Vaccine Technology, Immunization Safety Office, Centers for Disease Control & Prevention

2.25 *Questions & discussion*

2.30 **Update on the safety, efficacy and benefit:risk of nasal and other non-standard delivery mechanisms for vaccines**

- To what extent are they enabling dose sparing?

Speaker to be announced

2.55 *Questions & discussion*

3.00 **Panel discussion**
How are new developments in formulation, dose reduction and delivery impacting capacity and distribution of vaccines for global health?

- Progress with temperature stable, orally administered vaccines
- Progress with single dose vaccines
- New developments for nasal and other routes of administration
- To what extent will these innovations affect purchase decisions?

Panelist:
Dr Ronald W. Ellis, Senior Vice President & Chief Technical Officer, NasVax Inc, United States (a subsidiary of NasVax Ltd, Israel)

3.30 *Afternoon tea and close of the Washington Vaccine Forum 2008*

OR BREAKOUT SESSION

Manufacturing vaccines on a global basis: Tackling quality, efficiency and economics

Highly interactive workshop for a maximum of 30 participants

2.00 **Moderator's introduction**
What are the options/approaches for vaccine manufacturing to meet global health demands?

- Centralized or decentralized manufacturing model? Global? Local? Global?
- Cost and price impacts
- How is quality assessed and controlled?
- Approaches to building manufacturing competency in developing and middle income countries
 - Meeting global needs with financially stretched markets
- How close are we to generic vaccines?
- Handling post-licensure manufacturing changes

Jan Delaere, Director, Manufacturing Strategy, Flu Pandemic Vaccines, GlaxoSmithKline Biologicals

2.25 *Questions & discussion*

Case studies focusing on India and Latin America as manufacturing hubs

2.30 **India as a manufacturing hub: How can we achieve consistent quality and compliance with the world's regulatory authorities?**

- Formulation of a quality strategy for the product under discussion.
- Due diligence exercise to:
 - cGMP gap analysis between local regulatory requirements and global standards
 - cGMP compliance ability analysis
 - Infrastructure status and up-gradation needs
- Formation of formal intra or inter-organizational management structures & teams
- Extensive scientific / regulatory dialogues followed by implementation team's creation
- Adoption of WHO pre-qualification guidelines wherever available or being developed
- Import / export permissions to be addressed
- Opportunity to access newer markets through such exercises
- Specific examples to be provided for 3 vaccines under global partnership

Dr Krishna Mohan, President, Bharat Biotech Intl Ltd

2.55 *Questions & discussion*

3.00 **Brazil as a manufacturing hub**
Dr Akira Homma, Director, Bio-Manguinhos/Oswaldo Cruz Foundation/MoH

3.25 *Questions & discussion*

3.30 *Afternoon tea and close of the Washington Vaccine Forum 2008*

This is the full agenda at it stands at date of printing. However, the panel and program alike will continue to evolve as we approach the event, ensuring that only the most current and relevant topics are addressed in Washington this coming January. Please visit www.phacilitate.co.uk/wv at any time to update yourself with the latest developments.

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Phacilitate calendar of events

- Oncology Leaders' Forum 2007**
 14-16 November,
 The Marriott Long Wharf Hotel, Boston, MA
www.phacilitate.co.uk/oncology
- Cell & Gene Therapy Forum 2008**
 28-30 January,
 The Grand Hyatt, Washington, DC
www.phacilitate.co.uk/cgtherapy
- R&D Leaders' Forum Spring 2008**
 10-12 March,
 The JW Marriott, Buckhead, Atlanta, GA
www.phacilitate.co.uk
- Phacilitate Vaccine Forum Geneva 2008**
 14-16 May,
 The Hotel Président Wilson
www.phacilitate.co.uk/gv

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We are offering a strictly limited number of sponsorship and exhibition opportunities to companies seeking to raise their profile with this uniquely influential audience.

The exhibition at the 2007 Baltimore meeting was a tremendous success, with 100% of exhibitors stating on their evaluation forms that they achieved their major objectives in participating. We are already well on the way to selling out the 2008 floorplan - at the same point prior to the Baltimore '07 event, we had half as many confirmed exhibitors, and the floorplan ended up being sold out months before the meeting.

"Another well-organized conference, with excellent networking opportunities with top-level decision-makers"

Exhibitor, Dr May de las Alas, Business Development Associate, Ichor Medical Systems, Inc, speaking about her experience at the Baltimore 2007 meeting

As you can see, the best booth spaces are running short. To receive more information on exhibiting, or to find out about available sponsorship options (ranging from full event, workshop and cocktail reception packages to minor sponsorships, such as conference documentation, delegate bags, event stationery and documentation inserts) please don't hesitate to contact **David McCall Tel: +44 (0)20 7839 6151, or Email: david@phacilitate.co.uk**

AND REMEMBER! As an exhibitor at this meeting, you will have equal access to delegates and speakers from both the Washington Vaccine Forum 2008 and the Cell & Gene Therapy Forum 2008 - over 500 senior life science executives with the authority to impact your business!



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- Booth 2 McKenna Long & Aldridge
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- Booth 7 Covance
- Booth 8 PharmaNet
- Booth 11 Bridge Pharmaceuticals, Inc
- Booth 17 Cobra Biomanufacturing
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