PACIFIC HEALTH SUMMIT

SEATTLE - LONDON

2011 Summit Challenge

VACCINES

Harnessing Opportunity in the 21st Century

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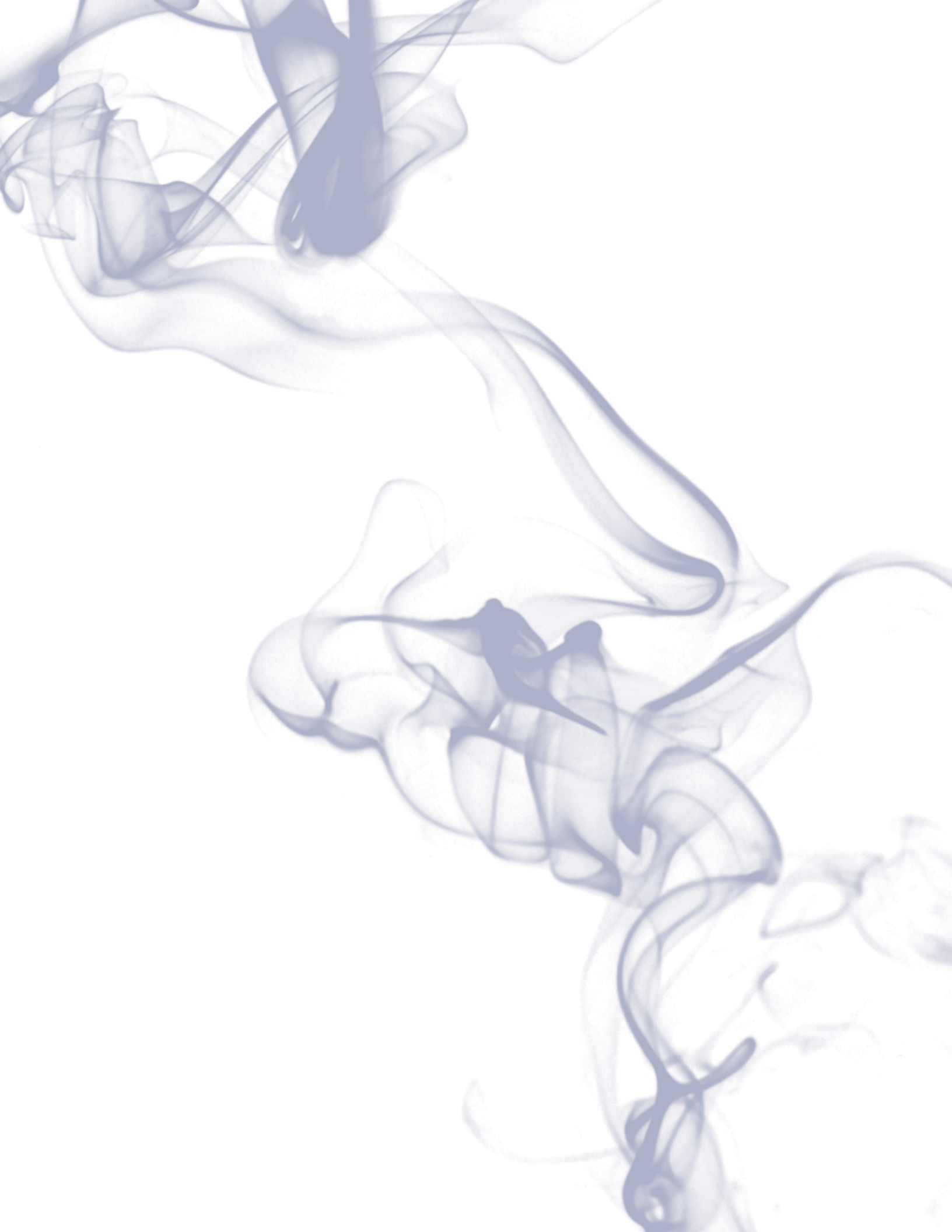


Foreword

Each essay in this collection articulates a personal vision from a key leader in the 2011 Pacific Health Summit process. Together, the essays offer a jumping-off point for our discussions in June, when international leaders will convene to actively engage and partner around the theme of vaccines.

Each Summit attendee has been personally sought out because he or she has the motivation, vision, and influence to make a tangible impact. You also have the unique ability to spread the collaborative spirit and results of our discussions beyond Seattle.

Be proactive about leveraging this experience. Use this gathering to connect with "unlike minds," and be bold about transforming your conversations into lasting results.

Our goals in June include new cross-sector understanding, innovative partnerships, and action-oriented outcomes appropriate for each attendee. We all are working toward better health and healthcare, more lives saved, and increased access to safe, affordable vaccines. But the most compelling, concrete outcomes from this Summit experience will be distinct for everyone.

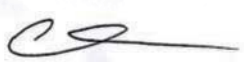
What do you want out of this experience? Here are a few ways to engage and take advantage of the Summit:

- Connect with "unlike minds" and be open to new ideas. The Summit convenes high-level leaders from over 35 countries and across sectors. Be proactive about seeking out participants whom you would otherwise never meet or pursue as partners. The collaborations and ideas that result will surprise you.

- Be intentional about transforming conversations into concrete results. A spontaneous conversation between two Summit participants in 2007 led to a groundbreaking, novel vaccine research institution that launched two years later. A dinner in 2009 led to a transformational agreement between companies to share TB drug formulations in the hopes of creating more effective treatments for the 21st century. Where will your next conversation take your work?

- Speak up, and speak frankly. The format of the Summit is truly interactive. You are a leader with valuable insight and concrete ideas. Please share them!

The success of your time at the Summit will depend on you making the most of this experience.
Thank you for your passion, open mind, and commitment to harnessing this opportunity and creating results.



Claire Topal
Managing Director
Pacific Health Summit

Conceptual Foundation

Why We Are Here

Vaccines are widely seen as one of the most powerful and effective tools in the global health arsenal. Time and time again, we have witnessed their ability to save lives and prevent debilitating disease at a remarkably low cost. Despite this profound impact, we face a daunting set of challenges for the discovery, development, and delivery of vaccines. But today's opportunities to meet these complexities are more exciting and accessible than ever.

What are these challenges? The science has never been as exciting, nor as complex. More players in more countries are developing and manufacturing these critical tools, all the while juggling demands for large, reliable supplies of vaccines, using advances in technology, while still being expected to deliver at ever-lower prices. Meanwhile, regulatory bodies are trying to keep pace with vaccine innovation to ensure the highest standards of quality and safety. Once vaccines have been created, the global community continues to grapple with how much they should cost and how to pay for access.

Yet even when these problems are addressed, vaccination remains a critical challenge in many countries. Not everyone agrees on which vaccines are most critical or how to balance them with other health and budgetary priorities. And we have yet to fully understand and address the cultural barriers that fuel suspicion of immunization efforts.

Despite these complications, more people recognize the value of vaccines than at any other time in history. There is unprecedented investment and commitment to making vaccines safe, affordable, and accessible for all. Against this backdrop, the Summit provides a unique venue to convene key stakeholders from across sectors in a frank conversation aimed at producing action-oriented collaboration and understanding.

Summit Context

- Geographic focus: While the Summit addresses vaccines in a global context, low- and middle-income countries face disproportionately significant funding, delivery, and access challenges. The Summit will acknowledge these disparities.
- Vaccine focus: Summit discussions will use numerous vaccine and vaccination lenses through which to address key opportunities and challenges.

Goals

The 2011 Pacific Health Summit aims to do the following:

- Highlight the changing landscape of the vaccine field, evolving roles of different stakeholders, and implications for the future of research, development, manufacturing, funding, delivery, and distribution of vaccines, as well as immunization sentiment more broadly.
- Provide a launching pad for cross-sector and cross-region innovation, collaboration, and investment.
- Give each participant a new understanding and appreciation of their own and other sectors' roles in the interconnected landscape of this field.
- Augment momentum created by the arc of related events and initiatives in 2010-2011.

Shared Problems, Shared Solutions

Michael Birt

Executive Director
Pacific Health Summit

Director
Center for Sustainable Health
Biodesign Institute
Arizona State University

Welcome to Seattle and the 2011 Pacific Health Summit. The Summit's mission is to "connect science, industry, and policy for a healthier world," and each year we focus on a key, timely issue in health. The decision to make vaccines the theme of the 2011 Summit was straightforward and enthusiastically adopted by the Summit's Executive Committee. Vaccines have been a focus of the Summit's mission since our inaugural meeting in 2005. But, as we began to prepare for this year's Summit, we took note of a world reshaped by powerful forces bringing demographic, social, economic, and political change to every point on the global compass. Vaccines, too, now face a dramatically more complex and challenging landscape than a decade ago.

Tackling challenging issues elicits the Summit's unique strength. We have invited top leaders from science, industry, and policy to bring their ideas and construct collaborations that will meet the complex demands the world of vaccines grapples

> ***We offer our full support and encouragement, but the ultimate test of success rests with you—and your ability to move from thoughtful discussion to transformative action.***

with today. In that spirit we have gathered you here in Seattle to take full advantage of this timely juncture to work with your peers and colleagues.

This is an issue of great urgency. As a global community, we now share an increasingly common experience of disease. Infectious diseases such as SARS, tuberculosis, HIV/AIDS, and flu travel in any direction, heedless of borders. But the world now faces a new health emergency—chronic diseases also know no boundaries. Cancer, diabetes, and heart disease are the global passengers to longer life spans, processed-food diets, smoking, and other lifestyle choices.

But we also have powerful tools at our disposal. First and foremost is our strong belief in the ability of science and human intellect to produce solutions for these problems. No field offers more promise and hope to find those solutions than vaccines. In our inaugural Summit Challenge in 2005 we noted that huge investments were being made in both the life sciences and applied technologies around the Pacific Rim. Even in the short history of the Summit, we have seen this phenomenon blossom into a global profusion of cross-border and cross-sector collaborations.

From its inception, the Pacific Health Summit has demonstrated a capacity to bring together "unusual suspects" in support of a mission to find common cause and response. We offer our full support and encouragement, but the ultimate test of success rests with *you*—and your ability to move from thoughtful discussion to transformative action. As we note every year, our Summit Challenge is nothing less than a personal call to action to each and every one of us.

Containing Costs Without Impeding Vaccines' Invisible Hand

Olivier Charmeil

CEO
Sanofi Pasteur

Adam Smith's "invisible hand" metaphor, which describes the collateral benefit derived from a free market economy, offers a unique lens for our Summit discussions on vaccines.[1] By supplying goods or services that meet the demand of a free market, sellers in the Smithian model generate a profit, which is redistributed to society through reinvestment in the business, personal purchases, or investment in other businesses. While the seller's bottom line is financial, the process has an indirect, positive impact on the broader society—the "invisible hand." I believe that vaccine R&D, vaccine production, and vaccination constitute such a Smithian process.

Vaccines directly benefit society through their acknowledged role as the most important contributors to global health improvement after clean water and good sanitation. The complexity of vaccine R&D and production, vaccination, and vaccination follow-up also provides a significant and sustainable source of employment across a broad range of public and private institutions. This constitutes vaccines' indirect benefit.

> ***The challenge is to contain vaccine-related costs in the short-term without impeding the long-term economic sustainability and benefit of vaccines and vaccination. Balanced responses can come from a number of directions.***

Yet every stakeholder faces significant budgetary constraints in today's economy. To manage these constraints, we must all contain costs and seek new drivers of economic stability and growth. One result of broad attempts to contain costs has been to put a downward pressure on the prices of vaccines. While understandable, the risk of this pressure is that if we focus solely on cost containment and forget the potential of vaccines as drivers of healthy economic growth, we damage the invisible hand of vaccination more than we encourage it. The challenge is to contain vaccine-related costs in the short-term without impeding the long-term economic sustainability and benefit of vaccines and vaccination.

Balanced responses can come from a number of directions. Governments and policymakers can continue to provide clear, broad early vaccination recommendations and funding in middle- and high-income countries to achieve optimal immunization rates. The international community can reinforce and support vaccination through recommendations regarding international standards as well as through international aid to low- and middle-income countries. Additionally, government financing, innovative financing mechanisms, and appropriate tax incentives that already support and encourage vaccination and public, private, and public-private initiatives could also help ensure the sustainability of vaccine discovery, development, and provision.

The challenge for us at the Summit is to ensure that we create a corporate, public, and policy environment that will allow the vaccination industry, in all its breadth and complexity, to flourish and continue to invest in lifesaving tools. This provides a win-win-win: a win for the individual who is protected; a win for the researchers, developers, producers, and healthcare workers who can continue to do their jobs to the best of their abilities; and a win for the world as a whole, for which broad vaccination coverage means healthier and happier populations.

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1. Adam Smith, *An Inquiry into the Nature and Causes of the Wealth of Nations*, vol. I, in The Glasgow Edition of the Works and Correspondence of Adam Smith, vol. II, ed. R. H. Campbell and A. S. Skinner (Indianapolis: Liberty Fund, 1981), available from Online Library of Liberty, http://oll.libertyfund.org/title/220.

Vaccine Development Needs Shared Partnerships

Lawrence Corey

President & Director
Fred Hutchinson Cancer Research Center

Almost all indices of health improvement rank vaccines as the most cost-effective biomedical intervention in the medical armamentarium. Yet the field of vaccine discovery, development, and implementation is not crowded with entrepreneurial competition—perhaps a curious disconnect with the health impact that accompanies each new vaccine. Why might this be so?

The current lack of effective vaccines for HIV, TB, and malaria sheds insight into this matter. Vaccine development for these infections is scientifically and organizationally challenging. The mechanisms of immune protection are not understood, and animal models to accurately guide vaccine designs are not validated and are inordinately expensive, limiting their use. Moreover, the complexity of these pathogens and their immune evasion strategies make it likely that multiple vaccine "types" will be needed to develop an effective immune response.

In addition, clinical development of TB, HIV, and malaria vaccines requires iterative clinical trials in humans. This is expensive; funds to produce vaccine prototypes are limited, especially for vaccines developed by nonprofit agencies. Each vaccine must be studied individually and then in combination. Often such constructs come from different developers, further

> ***…the field of vaccine discovery, development, and implementation is not crowded with entrepreneurial competition… a curious disconnect with the health impact that accompanies each new vaccine. Why …?***

complicating their production and preclinical toxicity testing. Co-development of such products is best done in a coordinated fashion with open data-sharing, yet partnerships and processes to share development risk and reward are not well-established. Defining the dose and schedule of a combination vaccine regimen requires trials that need to be "adapted" based on early results—a strategy used frequently in cancer therapy but that is novel to vaccine development.

Such "out of the box" concepts appear disquieting and, in my experience, too uncertain for the risk and low profit margins of commercial vaccine houses. This means that the public sector must assert its interest in this arena to assume some of the risks and lead the development of effective public-private partnerships. This approach will have positive spin-offs. Coordinating information between groups through open access to scientific insights in early preclinical development is something the vaccine field could lead. Complementary and coordinated development at all stages along the vaccine pipeline could help us find more effective scientific solutions sooner.

Importantly, there is a need to educate regulatory agencies and affected communities so that they can understand the process of iterative clinical trials. Policymakers must lead here, and commercial companies need to understand the importance of open access and shared risk and coordination for eventual success. The Summit is a major step in bringing these issues to the forefront and helping start these dialogues.

May the discussions begin.

The Changing Face of Developing Country Vaccine Manufacturers: Today's Balancing Act

Mahima Datla

Senior Vice President
Biological E Ltd.

Suresh Jadhav

Executive Director
Serum Institute of India Ltd.

Globally, vaccine manufacturers have historically been polarized. One group, consisting of large multinational corporations, has been represented by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), whereas others have belonged to the Developing Country Vaccine Manufacturers Network (DCVMN).[1]

The formation of the GAVI Alliance, increasing global investments in immunization, enhanced procurement mechanisms, and access to previously unavailable financing tools have all played a significant role in creating unique opportunities for the vaccine industry as a whole, and DCVMN members in particular.

This evolution of DCVMN is evident in the many member success stories. Its manufacturers, once primarily focused on traditional/EPI vaccines, are expanding their capabilities to develop new vaccines. Today, thirteen manufacturers from developing countries are prequalified to supply vaccines to UN agencies. DCVMN members are also playing a pivotal role in helping to meet the Millennium Development Goals, and they continue to be instrumental in the introduction of new vaccines—such as the meningococcal A conjugate vaccine and the pentavalent vaccine—at affordable prices.

> ***In this rapidly evolving environment… it is important to evaluate the historical business models of our members. The factors for success in the past are radically different than they are likely to be henceforth…***

In this rapidly evolving environment, however, it is important to evaluate the historical business models of our members. The factors for success in the past are radically different than they are likely to be henceforth:

- In the 1990s, the need for access to technology was limited to only a few vaccines.
- Business objectives used to be focused on generating profits based on low cost of goods sold (COGS) and not necessarily on investment in innovation.
- New vaccines will need tremendous resources in comparison to the past.

The balancing act we face today is to evolve a business model that sustains innovation *and* meets business objectives, while managing to keep vaccine prices affordable. International funding agencies are now increasingly willing to work closely with the DCVMN to develop innovative vaccines, but we continue to grapple with several key questions regarding this balance:

- To drive innovation, do we depend on NGO support or seek commercial partnership opportunities?
- Do we alter the way we do business and generate adequate profits to fund innovation, or should we find other ways to manage competitiveness?

There are many opportunities to address these challenges, and any vision of the future must take into account the specific aspirations of each company. But how do we manage these aspirations and still walk the tightrope?

The fact remains that the loss of human lives from vaccine-preventable diseases continues to be significant. This is underscored by the morbidity and mortality that plague populations that do not have equitable access to newer vaccines—a harsh reality that should be unacceptable to the vaccine industry as a whole. Ultimately, the success of our industry's strategies should be measured by the difference we end up making in changing this reality!

By participating in this Summit, DCVMN members look forward to interacting with other stakeholders in the vaccine industry and engaging in critical international discussions on making lifesaving vaccines available at affordable prices for the developing world.

1. Formed in 2000, DCVMN is a voluntary, public health–driven alliance of vaccine manufacturers from developing countries aiming to provide a consistent and sustainable supply of quality vaccines at affordable prices to developed as well as developing countries.

Collective Action in the 21st Century of Vaccines

Ciro A. de Quadros

Executive Vice-President
Albert B. Sabin Vaccine Institute

We have seen tremendous progress since the World Health Organization (WHO) initiated the Expanded Program on Immunization (EPI) in 1974. Immunization coverage now exceeds 90% in some of the world's poorest countries. Regional eradication of polio, measles, and rubella has been achieved in the Americas, and worldwide eradication of polio is close at hand.

We have also witnessed a major biotechnology revolution that has generated new vaccines, including those for rotavirus and HPV, and made significant advances in the development of vaccines for HIV, malaria, and tuberculosis. The 21st century will truly be known as the "Century of Vaccines."

However, these accomplishments highlight major inequities in the world: vaccines are not available to all, as I strongly believe they should be.

Efforts are underway toward greater access, notably through the GAVI Alliance and other financial mechanisms such as the International Financial Facility for Immunization (IFFIm) and the Advance Market Commitment (AMC). But these initiatives alone do not provide a

> *We must change the existing paradigm in which international agencies employ a paternalistic approach. Countries should* ***own*** *their programs….*

sustainable solution. The Pacific Health Summit presents an opportunity for new understanding and for catalyzing more strategic action.

We must act collectively on five fronts:

1. The industrialized world must increase its support for immunization programs in developing countries, either directly or through existing international systems.
2. Support for adequate technology transfer and creative partnerships is key to increasing production capacity in the emerging economies that already manufacture vaccines. This will result in lowering both production costs and commercial prices.
3. Vaccine producers in the industrialized world must redesign their commercial strategies to make their products universally accessible—not only to poorer countries or the poor in general, but also to lower-income *and* middle-income nations, where major inequities still exist.
4. Procurement mechanisms similar to the Revolving Fund for vaccine procurement operated by the Pan American Health Organization (PAHO) would benefit other regions. Such mechanisms assure suppliers that products will move quickly and continuously to market, create scaled economies that allow manufacturers to offer more affordable prices, and help countries mobilize their own resources to finance programs.
5. Country ownership. We must change the existing paradigm in which international agencies employ a paternalistic approach. Countries should *own* their programs, as in the Americas, where nations have steadily increased their programs' financing to over 98%. PAHO helped countries reach this milestone by working with ministries of health, as well as with parliaments and ministries of finance.

If we act together on these measures, we can build a world where today's inequities are yesterday's problems.

Creativity and Commitment to Reach Beyond the Usual Suspects

Chris Elias

President & CEO
PATH

Co-Chair
Decade of Vaccines Collaboration

Pedro Alonso

Director
Institute for Global Health
of Barcelona

Co-Chair
Decade of Vaccines Collaboration

Around the world, vaccines protect individuals, families, communities, and entire nations from disease. In rich and poor countries alike, immunization not only saves lives; it creates a "foundation of health" on which future health and prosperity can be built. What could be simpler? Yet, as all of us participating in the Pacific Health Summit know, getting the right vaccines to the people who need them most is deceptively complex.

We know that to fully achieve the potential of vaccines in the next decade, we need to reach beyond the "usual suspects" in global health:

- We must reach and engage maternal and child health programs, malaria programs, and water and sanitation programs, among others, to leverage immunization platforms and achieve greater progress by integrating vaccines with other effective interventions.
- We must reach ministers of finance and the executive branches of national governments, in addition to ministers of health, to establish greater country ownership and sustainability of immunization programs.

> ***We must learn how the private sector builds robust supply chains and inventory management systems that lower delivery costs for products and increase the effectiveness of human resources.***

- We must learn how the private sector builds robust supply chains and inventory management systems that lower delivery costs for products and increase the effectiveness of human resources.
- We must engage and empower local communities to generate greater awareness and demand for immunizations in order to increase district-level coverage up to and beyond 80%.

The Global Vaccine Action Plan being prepared by the Decade of Vaccines Collaboration is intended to build on the success of previous immunization efforts and create greater alignment and coordination across the international community. Its success depends on the creativity and commitment of all of us at the Summit. Together, we can forge stronger alliances across the public and private sectors to innovate and expand the delivery systems for vaccines.

We invite you to engage with members of the Decade of Vaccines Collaboration Working Groups to help identify new strategies for demand generation and local advocacy. We hope that together we can save millions of lives in this decade, and lay the foundation for saving millions more in the decades ahead.

Immunization for the One-Billion Poorest People: Daunting but Doable

Julie Gerberding

President
Vaccines
Merck & Co.

Throughout my career I have been privileged to visit the frontlines of health protection in all regions of the world. I have seen firsthand the tremendous benefit and hope that immunization can bring, but I have also witnessed the sadness and fear experienced by the many people who lack access to vaccines. This reality is not only harsh, but unwarranted in this era of astonishing biomedical capability. No single partner attending the Pacific Health Summit can solve this problem alone, but by acting together, we can achieve the daunting but doable goal of creating affordable, sustainable access to all vaccines for the one-billion poorest people.

The Summit provides us with a tremendous opportunity to advance these collaborations. There is already a strong precedent, including the MSD Wellcome Trust Hilleman Laboratories and the Merck-QIAGEN collaboration on cervical cancer prevention, both of which resulted from discussions at previous Summits.

My hope is that the focus on vaccines at this year's Summit will prompt even more innovation and initiate diverse private and public sector partnerships that greatly amplify our potential for individual impact.

> *I have seen firsthand the tremendous benefit and hope that immunization can bring, but I have also witnessed the sadness and fear experienced by the many people who lack access to vaccines. This reality is not only harsh, but unwarranted in this era of astonishing biomedical capability.*

I believe that success will require the development of low-cost transformative innovations in four key dimensions:

- **Design:** Innovative designs for new vaccines to address unmet and emerging health needs are crucial, as well as new manufacturing and product models to keep costs low and encourage government and private sector investment and accountability.
- **Development:** Innovations that expedite approval and registration of vaccines are important. Expanded support for development consortia, investment pools, and other means of sharing the risks and costs of global development are critical enablers for R&D.
- **Delivery:** Innovations that facilitate ongoing uptake will become even more crucial when immunization programs expand to include older children and adults. Opportunities for new customized solutions and engagement of other health and non-health sector partners are key.
- **Demand:** Demand for vaccines depends on an informed public, as well as on vaccine makers and advocates. Engaging at the community level is imperative, but we must also focus on research and assessment to motivate policymakers and other stakeholders to initiate and sustain long-term investments.

Investing in sustainable solutions for the developing world will benefit people everywhere and potentially usher in a new era of vaccinology. If we demonstrate true innovation and commitment to partnership, collaboration, and collective action, this new era can achieve its greatest possible success—prompt and secure access to vaccines for those who most need their benefits.

Continuing Summit Threads: Improving Healthcare and Reducing Costs

Lee Hartwell

Chief Scientist
Center for Sustainable Health
Biodesign Institute
Arizona State University

President Emeritus
Fred Hutchinson Cancer Research Center

We began the first Pacific Health Summit with the hope of improving healthcare and reducing costs, with an emphasis on prevention and early disease detection. In the ensuing seven years, we have featured many different health issues that affect the developing as well as the developed world, and each topic underscores the need for greater efforts at prevention and early detection, as well as more definitive evidence to guide medical care. This year's Summit on vaccines presents the same challenges and opportunity.

One continuing Summit thread is the goal of identifying more effective biomarkers to vastly improve the quality, efficiency, and affordability of healthcare in the 21st century. Since the Summit's inception, considerable progress has been made in advancing technology to identify biomarkers that can support these goals. We are all aware of the tremendous advances in DNA sequencing technology that now enable full genome assessment of cancer mutations as an aid to new targeted therapeutics. In this same period, new molecular entities (microRNAs) have been discovered, technologies have improved for detecting antibody and T-cell responses to disease, and new, advanced technologies have been developed, providing an unprecedented ability

> ***…each [Summit] topic underscores the need for greater efforts at prevention and early detection…. This year's Summit on vaccines presents the same challenges and opportunity.***

to assay any human protein sensitively, quantitatively, and inexpensively. Research literature is replete with newly discovered biomarkers for all common diseases resulting from the application of these technologies.

The opportunity that now lies within our reach is to launch a systematic and comprehensive program to validate the best panel of markers for each important clinical decision in disease management. We cannot expect either academic institutions or commercial companies to undertake this large and financially unrewarding effort alone. Such a project will require a public-private partnership as a precompetitive step toward effective commercial tests. Technology is no longer the limitation. However, intellectual property considerations can be a barrier. We need to support efforts to prevent the patenting of natural human molecules and encourage patent protection at a later stage of development—when a panel is reduced to a commercial test platform. Or we need to find ways to pool individual patent interests to facilitate and incentivize the aggregation of the best-performing markers into an effective panel. These challenges are not unique to biomarkers; they also apply to our discussions about vaccines.

Many of the outcomes of the Pacific Health Summit are often unknown, and the solutions and collaborations develop in the hallways. I hope that some of the productive hallway conversations at this Summit will enable us to achieve these goals, which lie at the heart and origin of the Summit's mission.

Public Confidence in Vaccines—What Is at Stake and What Can We Do about It?

Heidi Larson

Senior Lecturer
Department of Infectious Disease Epidemiology
London School of Hygiene & Tropical Medicine

Michael Watson

Vice President
Global Immunization Policy
Sanofi Pasteur

Philip Campbell

Editor-in-Chief
Nature

In today's highly interactive, consumer-driven world, powered by the speed and penetration of the Internet and social media, more and more people have the luxury of choice. While we applaud the empowerment of choice, it also presents a significant challenge for public health. The fact is that the immense, positive impact of vaccines relies almost universally on successful, broad public acceptance.

Public (mis)perceptions of vaccines are fueled by a variety of factors, motivations, and groups. Highly organized anti-vaccination movements, the rare but impactful cases of healthcare professionals advising against vaccination, and modern civil society's generalized suspicion of "establishment" or "expert" opinions and political motives are all examples of what collectively serves to undermine public confidence in vaccines.

While we are in essence "preaching to the choir," for those of us gathered at the Pacific Health Summit, we must remember that building, rebuilding, and maintaining trust cannot wait for a crisis of public refusal. Prevention is always more cost-effective than crisis management. We must work together across sectors to address the growing threat of an apprehensive or vaccination-averse public, and take the following steps to

> ***…building, rebuilding, and maintaining trust cannot wait for a crisis of public refusal. Prevention is always more cost-effective than crisis management.***

earn the trust of those who want choice and participation in decisionmaking regarding vaccines and vaccination.

1. **Listen.** We must practice conscious listening to public concerns. Mindful listening will also allow us to more quickly detect, define, and respond to new concerns as they spring up.

2. **Understand.** We also must seek to better understand the unique characteristics and motivations of our different audiences. Decision making is driven by a complex interplay of factors; the public health and vaccination communities must review, test, revise, and apply this new understanding of decisionmaking to vaccines and vaccination.

3. **Engage.** Today's consumers are far less accepting of one-way broadcasts of messages and advice from "experts." They expect to be able to engage in dialogue as a means to form opinions and gain their trust to allow them to make their choices. Doing everything possible to maximize consumer confidence is normal in the business world, yet there are still hurdles to overcome before making consumer confidence a well-executed priority in the public health world. Public health must earn the public's confidence.

These three areas offer solid starting points for discussions with individuals and institutions with a stake in the vaccination community—including manufacturers, marketers, scientists, health workers, and the media. Together we must complement the fact-based information already out there with greater engagement with and responses to the concerns of friends, families, and consumers.

We invite our fellow Summit participants to join us in a renewed, collaborative effort to address public confidence concerns about vaccines and immunization.

Our Greatest Achievements Are Still Ahead of Us

Mark Lester-Swindell

President
Vaccines
Pfizer Inc.

I could not be more pleased with the selection of vaccines as a focal point for our work together at the 2011 Pacific Health Summit. The development of vaccines for the prevention of serious diseases is an extraordinary story of medical achievement—one in which we are proud to have played a significant role. As we all know, in order to realize the full global benefits of vaccination, it is essential to ensure that vaccines reach those in the poorest countries where the disease burden is often greatest.

Through our participation in the Advance Market Commitment (AMC), an innovative program involving private-public partnerships to accelerate the introduction of new vaccines in least-developed countries on an affordable and sustainable basis, Pfizer is proud to share GAVI Alliance's and its donors' goal to help save the lives of seven million children by 2030.

In December 2010, under the auspices of the AMC, Pfizer's pneumococcal conjugate vaccine became the first used in the national immunization program (NIP) of a GAVI-eligible country—Nicaragua. Pneumococcal conjugate vaccines were selected as the first candidates for the AMC because pneumococcal disease is the leading vaccine-preventable cause of death in children younger than five.

A few months later, our vaccine is now also available under the AMC in the NIPs of Yemen, Sierra Leone,

> ***It is truly historic for a newer vaccine to be launched in a developing country within one year of its introduction in the United States and Europe, given the previous average 15-year lag.***

Guyana, Democratic Republic of Congo, Honduras, and Mali. It is truly historic for a newer vaccine to be launched in a developing country within one year of its introduction in the United States and Europe, given the previous average 15-year lag.

This early success indicates that the AMC concept holds promise as a potential mechanism for the accelerated introduction of other newer vaccines. But this is not the time for us to rest on our laurels; the race to get needed vaccines to children continues to confront considerable hurdles, and our "Summit Challenge" is for each of us to proactively play a role in overcoming those hurdles:

- ***Industry*** must continue its substantial investments in R&D for new vaccines and manufacturing capacity to ensure robust production of those vaccines in sufficient quantities.
- ***Developing countries, the World Heath Organization (WHO), and the United Nations Children's Fund (UNICEF)*** must continue improving immunization and health delivery systems.
- The ***global donor community*** must continue identifying sources of sustainable funding.
- The ***scientific community and media*** must communicate the important public health impact of vaccines.
- ***International and regional policymakers*** must provide an environment conducive to differential pricing of vaccines.

I look forward to engaging in a fruitful discussion this June on how we can—together—overcome these remaining challenges to vaccine uptake and further build on existing momentum and success.

A Prescription to Transform World Health

Sheri McCoy

Vice Chairman
Executive Committee
Johnson & Johnson

Vaccination is one of the greatest public health achievements of the twentieth century. Significant advances in vaccination have helped to eradicate smallpox and diphtheria and to greatly reduce the incidence of diseases such as measles, mumps, and pertussis. Through innovation and collaboration, scientists, medical professionals, governments, and NGOs have saved more lives through vaccines than have technological advances in motor vehicle safety, medical advances in coronary heart disease and stroke, and access to safer, healthier foods.

Despite significant progress, infectious diseases continue to be the second-leading cause of death globally. New treatments, however, have significantly reduced the number of lives these diseases claim. Vaccines, both therapeutic and prophylactic, can have a substantial impact.

As both a mother who was able to have her own children immunized and a committed industry member, I am passionate about a future where all children have access to the transformative promise of preventative medicine. Through the recent acquisition of Crucell, Johnson & Johnson has made a commitment to vaccines and to prevention as part of our mission to transform

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human health. I am looking forward to exploring at the Summit how to bring both therapeutic and preventive solutions to address infectious diseases in resource-poor countries, emerging markets, and the developed world.

Our commitment to transforming world health does not stop with our acquisition of Crucell. It takes an integrated approach, and this is why we engage in the Summit process. Working with governments, NGOs, and industry organizations is critical to the success of robust vaccine development and distribution programs globally. I look forward to communicating across private and public groups to foster ongoing innovation in the development of vaccines and preventive health programs.

Education is a critical component of effective immunization and successfully tackling infectious diseases more broadly. Our safe birth programs, for example, reach more women and children, and prevent more illness, through the combined efforts of businesses and governments. Working across various stakeholder groups is also central to providing effective access to medicines to treat HIV, TB, and other diseases. Our collaboration with the International Partnership for Microbicides, a nonprofit product development partnership, enables us to provide a royalty-free license for the development of a vaginal microbicide for HIV/AIDS prevention.

Through scientific innovation and the discussions at the Pacific Health Summit, the future of preventive medicine is filled with great possibilities. We all have critical roles to play in reducing suffering and cost, as well as in ultimately bringing hope and health to millions around the world.

Enabling a Learning Healthcare System

Peter Neupert

Corporate Vice President
Health Solutions Group
Microsoft Corporation

I have had the opportunity to participate in almost every Pacific Health Summit since its inception. I always find the gathering fascinating because of the mix of people—all of whom bring a real passion for helping improve global health, but who each start from very different experiences and worldviews. While vaccines is the thematic lens for the 2011 Summit, regardless of the specific theme, our discussions always touch on the critical importance of technology in advancing global health.

I spend a significant amount of time thinking about the global need to create more value in the healthcare system by offering better healthcare at the same or lower costs, as well as about the role technology can play in helping us achieve this goal. Vaccines are tremendously valuable, low-cost tools for prevention—stopping illness before it starts, and leading to positive outcomes at reduced costs for both the patient and the healthcare system.

Today, we have vaccines that protect against a number of preventable diseases, and with advances in research, we can discover vaccines for other deadly diseases. Technology has an important role to play in the discovery, development, and delivery of vaccines—by enabling a learning healthcare system.

> *A learning healthcare system, combined with ongoing controlled clinical trials, can help us learn much more quickly which vaccines work best, and for whom.*

A learning healthcare system provides feedback loops in near real-time for every stakeholder in the process (researcher, clinician, and patient), collecting evidence from the day-to-day practice of medicine to inform medical research, clinical practice, and personal health management. Information technology (IT) helps research environments scale across stakeholders and resources, which leads to shorter cycle times and more rapid learning.

Specifically, IT enables a learning healthcare system by:

- Making it easier and faster to collect data from healthcare providers about their patients with particular diagnoses and treatments
- Enabling the collection of patient-generated data (for example, information on the patient's reaction to a vaccine, and data collected through wireless medical devices such as blood pressure cuffs and glucometers)
- Making data anonymous and aggregating it with information available in other research databases to offer researchers a richer set of data for understanding the impact of treatments, particularly among certain patient populations
- Illuminating trends in data across similar patient populations to both patients and clinicians, there by empowering them with information to enable shared decisionmaking around diagnoses and treatment plans

A learning healthcare system enables rapid progress and more effective healthcare because researchers have access to real-world data on thousands of patients in near real-time, so they are able to quickly learn what the outcomes have been from specific approaches to addressing a particular medical condition. A system like this, combined with ongoing controlled clinical trials, can help us learn much more quickly which vaccines work best, and for whom.

Overcoming Innovation Pile-Up: The Importance of Innovative Financing and Delivery Strategies

Jean Stéphenne

Chairman & President
GlaxoSmithKline Biologicals

The vaccine field has experienced a tremendous renaissance over the past 30 years, one that I feel privileged to have witnessed and to have helped shape since I joined GlaxoSmithKline (GSK) Biologicals in 1974. Working in partnership with visionary organizations, we have launched vaccines for Hepatitis B, rotavirus, pneumonia, and many other diseases, which have saved millions of lives.

But today the introduction of new life-saving vaccines is in jeopardy. The vaccine community is facing an "innovation pile-up" of tremendous proportions. The groundbreaking science that brought us new vaccines has far outpaced the growth of the financial and logistical resources needed to implement them. The development of new financing mechanisms and innovative strategies to strengthen health systems is critical.

The recently launched Advance Market Commitment (AMC) to fight pneumococcal disease is a prime example of how transformative financing strategies can overcome barriers to access and deliver vaccines to developing countries in record time. By bringing together donors and offering predictable demand—long-term, high-volume contracts—the AMC has enabled vaccine makers

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to offer pneumococcal vaccines at an unprecedented 90% discount over industrialized country prices.

Mechanisms such as the AMC also help vaccine producers make the case to invest in new manufacturing capacity. For example, the promise of the AMC encouraged GSK to develop a highly specialized plant in Singapore, where the pneumococcal vaccine will be manufactured for global markets. The AMC was launched less than a year ago, but initial signs point to success. At GSK, we hope to continue to engage with partners in equally innovative vaccine financing mechanisms in the future.

In order to realize the potential of these innovative mechanisms, we also need to strengthen health systems by improving cold chain capacity, building infrastructure, and training health workers. For our part, we have established a business unit devoted to advancing access in the least-developed countries and have pledged to reinvest 20% of profits generated in these markets back into infrastructure projects that benefit local communities. We realize these are small steps. But in partnership with others, we can make sustained progress toward building infrastructure, increasing access, and improving health outcomes.

As a community, we need to enhance existing innovative financing strategies, pioneer new mechanisms, and strengthen health systems. Additionally, vaccine evaluations should take full account of benefits and costs, so that policymakers can reach well-informed implementation decisions.

I applaud the Pacific Health Summit for bringing communities together around the critical issue of immunization and look forward to working in partnership to craft solutions that will ensure sustainable supplies of new and existing vaccines for all.

Updating Our Armory: Accelerating R&D Progress and Vaccine Efficacy

Mark Walport

Director
Wellcome Trust

Vaccines are an essential weapon in the public health armory for saving lives and improving health and welfare. While there is a great urgency to expand coverage and do better with existing tools, there is also a huge need for new vaccines to help prevent some of the world's most important infectious diseases. Vaccines are complex biological medicines, and this complexity makes their development and path to market more expensive than other pharmaceuticals. The journey from research laboratory to marketplace requires long-term investment and costs on average U.S. $500-800 million.

Despite recent progress in improving access to vaccines and immunization, I believe we can do better.

First, we must continue to unravel the basic mechanisms of immune responsiveness while ensuring that we turn this new knowledge into clinical benefit. For example, adjuvant development is moving from "dark art" to molecular science, but this has yet to be implemented effectively in clinical practice.

Second, we must recognize that vaccine development requires effective partnerships between academia and industry, as well as between public and private funders of

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R&D. More collaboration is needed along with increased openness of data. We owe it to the volunteers in clinical trials to share research data; doing so maximizes the value of their participation.

Third, we must be much more efficient in the conduct of clinical trials. Clinical Phase 3 vaccine trials, which demonstrate the safety and effectiveness of vaccines, are incredibly expensive and involve multiple trial sites and thousands of people. In many cases, rationalization of vertical R&D programs and use of shared clinical research sites could reduce costs and improve the quality of trials.

Vaccine development is ripe for adaptive trial design. For example, measurement of immunological responses as part of a trial could enable adjustments to the dosing of antigen and adjuvant to maximize the chances of clinical success and minimize side effects. We should also think radically about registration and licensing procedures and requirements.

Given that vaccines require high population coverage to provide maximum benefit, their costs to health systems are usually significant. Strong working relationships are needed between those in the global public health community who will use new vaccines and those who develop them in order to choose the best vaccine targets. It is a tough challenge to optimize "push" and "pull" mechanisms in order to ensure a stable operating environment for those involved in vaccine R&D over the long term.

Together, we can make a difference to the global effort of developing and optimizing the vaccines we need. I challenge participants in this year's Pacific Health Summit to identify and realize the many opportunities to improve vaccine research, development, production, and uptake.

A Decade of Vaccines, A Decade of Action

Tachi Yamada

President
Global Health Program
Bill & Melinda Gates Foundation

Rajeev Venkayya

Director
Global Health Vaccine Delivery
Bill & Melinda Gates Foundation

Immunization is one of the most powerful and cost-effective health interventions available. A few doses of a vaccine, usually administered early in life, can prevent life-threatening diseases for a lifetime. Vaccines reduce the burden of disease and improve productivity in communities, ultimately contributing to economic development and an improved standard of living.

Unfortunately, many people around the world don't have access to the vaccines many of us take for granted. As a result, 3,000 children die every day from vaccine-preventable pneumonia and diarrhea. Measles and meningitis outbreaks continue in Africa. Polio is making its last stand in some of the most vulnerable populations in the world. The inequity is staggering, and it requires urgent action.

In January 2010, Bill and Melinda Gates called for the next ten years to be the Decade of Vaccines. This was a call to action for donors, national governments, academia, the private sector, and the public, to elevate awareness and priority of immunization, to ensure that children everywhere have access to a basic set of

> *Everyone must play a role.*

vaccines, and to invest in research and development of new and better vaccines against diseases of the poor.

Everyone must play a role. Governments in low- and middle-income countries should ensure that their immunization programs reach all children, and contribute to the financing of vaccine procurement. Donors should ensure that immunization initiatives such as the GAVI Alliance, the Global Polio Eradication Initiative, and routine immunization programs in countries have sufficient resources to achieve their ambitious objectives. Industry should continue to invest in the discovery and development of vaccines targeting diseases of the poor, with public and private donors sharing these development costs. Vaccine manufacturers should tier their prices according to a country's ability to pay. And people everywhere should treat immunization as a basic human right, holding their governments and others accountable for guaranteeing that children everywhere have access to these lifesaving interventions.

Through collective effort over the coming decade, we can eradicate polio. We can remove the scourge of epidemic meningitis from Sub-Saharan Africa. We can make pneumonia, diarrhea, malaria, and HPV vaccines available to the populations that need them most. We can make significant progress in the development of vaccines against tuberculosis and HIV. And we can save over five million lives before the end of the decade.

No mother should ever lose a child to a disease that could have been prevented with a vaccine. Let us emerge from this year's Summit energized and committed to these ambitious goals. It is our collective responsibility to do nothing less.

About the Summit

Mission

The mission of the Pacific Health Summit is to connect science, industry, and policy for a healthier world through discussions that join scientific advances and industrial innovation with appropriate policies for the prevention, early detection, and early treatment of disease.

Participants and location

Every June, the Summit assembles 250 leaders from science, industry, policy, civil society, public health, and academia to discuss how to realize the dream of a healthier world. Through formal and informal discussions over two days, we hope to build the foundations of creative partnerships and enlist new partners in global health. The Pacific Health Summit took place in Seattle, USA from 2005 through 2009, and in 2010 began rotating between Seattle and London, UK. The 2011 Summit will take place in Seattle.

Operations

The Summit is a year-round process. In addition to the June meeting, the Summit provides an ongoing forum for world leaders to improve health by collaborating on problems and solutions, sharing best practices, and forging effective partnerships. The Center for Health and Aging at The National Bureau of Asian Research serves as Secretariat for the Pacific Health Summit.

Thematic focus

Each year the Pacific Health Summit focuses on a single theme designed to tackle an important program in global health. This year our theme is "Vaccines: Harnessing Opportunity in the 21st Century." Past Summit themes include maternal and newborn health (2010), MDR-TB (2009), malnutrition (2008), and pandemic influenza (2007).

Geographical focus

Although our initial focus was the Asia-Pacific region, over the years the Summit has expanded globally. Recognizing that there are no borders around the human and financial cost of disease, we focus worldwide on innovation and opportunities.

Organization

The Summit is co-presented by The National Bureau of Asian Research, Fred Hutchinson Cancer Research Center, Bill & Melinda Gates Foundation, and the Wellcome Trust. The Summit is governed by a Senior Advisory Group, chaired by Tachi Yamada in 2011. The Summit's Executive Director is Michael Birt and Managing Director is Claire Topal.

Connecting science, industry, and policy for a healthier world

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