

# WORLD VACCINE WASHINGTON

2-5 April 2018 Renaissance Washington DC  
Downtown Hotel



## WORLD VACCINE CONGRESS WASHINGTON 2018 PRE-CONGRESS SPEAKER INTERVIEWS

Ahead of the 18<sup>th</sup> World Vaccine Congress taking place in Washington D.C. on April 2-5, we've caught up with some of the prominent speakers who have joined our speaker faculty.

Here are their thoughts and insights on the latest opportunities and challenges impacting the vaccine industry worldwide:



**COREY CASPER**  
Chief Medical Officer  
IDRI

**Q: What do you think remains to be the biggest challenge in enabling effective vaccine development and access?**

**CC:** There are several challenges to the rapid development of modern vaccines. First, to develop better vaccines for existing targets or novel vaccines will require a multidisciplinary approach, inclusive of optimizing the pathogen target (antigen, attenuated organism, etc.), adjuvant, and formulation. The expertise for these fields lie in disparate areas, such as pharma, academic and non-profits. IDRI is addressing this issue by bringing together these stakeholders to optimize vaccine design, like in its Global Health Vaccine Center of Innovation, but funding is modest and larger investments could lead to more rapid progress. Second, the regulatory hurdles to bringing a novel vaccine construct through development are substantial, with regulators being quite cautious for new adjuvants, technologies (nucleic acid vaccines), or formulations. Finally, the lack of a well-defined market for many of the more pressing vaccine-preventable illnesses (ie. Leishmaniasis, leprosy, tuberculosis) make the enormous cost of developing these vaccines a

tremendous hurdle and not feasible with governmental or philanthropic funding.

**Q: What changes have you seen in the last 12 months that could suggest things are changing in the way we deal with these issues?**

**CC:** The expansion of IDRI's Global Health Vaccine Center for Innovation and the enthusiasm for other new partnerships between pharma and non-profit research institutes has increased over the past year leaves me optimistic that we will have new models for dealing with novel vaccine development. Regulatory authorities are now seeing / reviewing more candidates with innovative technologies, which will hopefully lead to more comfort in reviewing and more efficiency in approving new vaccine technologies.

**Q: How will aspects of your talk or the talks of other presenters focus on these issues?**

**CC:** I will address IDRI's model of being a "non-profit global health biotech", where we seek to accelerate the advancement of new vaccines through multidisciplinary partnerships and serve as a place where vaccines can be developed from basic molecular discovery through to late phase clinical trials leading to licensure / registration.

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**CYNTHIA M. DUKES**

VP, Global Project  
Management

ICON Clinical Research

**Q: How much efficacy is enough? Why have vaccine efficacy levels been decreasing over time and is that level enough?**

**CD:** Efficacy tolerance is very antigen dependent. For conditions such as rabies nothing less than 100% is acceptable; however, for other conditions such as influenza or RSV a lower tolerance is acceptable.

**Q: Are vaccines going to be more of a companion technology rather than replacement technology as seen in the past, and why?**

**CD:** Most likely yes.

**Q: What other challenges are preventing effective clinical development of new vaccines?**

**CD:** Demonstrating vaccine efficacy will continue to be a challenge. Correlates of efficacy will need to be developed as not all vaccines can prove efficacy in classical double blind placebo controlled studies.

**Q: How will aspects of your talk or the talks of other presenters focus on these issues?**

**CD:** Executing clinical studies and collection of high quality data to support the safety, reactogenicity, immunogenicity and efficacy remains the cornerstone of vaccine approval. Utilizing technology to improve the quality and timeliness of data collection contributes to

more rapid development and approval of needed vaccines.



**DORIT RUBINSTEIN REISS**

Professor of Law

UC Hastings College of the  
Law

**Q: What has been the impact of vaccine hesitancy around the world and what are the most effective approaches to promoting vaccination?**

**DR:** Vaccine hesitancy around the world has directly led to outbreaks of measles in Europe that has, in the past year and a half, killed people and children in, for example, Romania, France, and Italy, among others. In Australia, research showed that 54 children have died from preventable diseases between 2005-2014. Other countries have also seen outbreaks that vaccines could and should prevent, if use. So vaccine hesitancy directly lead to outbreaks and deaths, suffering, and costs.

Education is crucially important to address hesitancy, as is building trust, but as a legal scholar my focus is on legal tools to respond. In the U.S. generally school immunization mandates have been shown extremely effective. California saw a dramatic rise in vaccine rates after tightening its exemption laws. Other countries are considering mandating vaccines in different ways, including France, Italy, and Australia.

Other approaches to consider are imposing costs on those who refuse to vaccinate, either direct costs, as with Australia's No Jab No Pay program, or through a tax or fee - or tort liability after the fact.

**Q: How will aspects of your talk or the talks of other presenters focus on these issues?**

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**DR:** My talk will provide the legal framework to examine these issues, and the other panelists will cover the legal developments in several countries.



**EDWARD WILSON**

Director

JSI

**Q: What technology has had the biggest impact on vaccine supply chains over the last 10 years?**

**EW:** Information, communication and telecommunications technology. Dr. Cheyne mentioned the cellphone but it has also been data networks, smartphones, and tablets that have enabled data collection and feedback at lower and lower levels in the supply chain.

**Q: What are the biggest challenges to ensuring that vaccine supply chains can cope with increased demand?**

**EW:** Well, volume and agility. Making sure there is enough storage and delivery capacity to meet the increase in demand and that the supply chain is responsive enough to respond to changes or peaks in demand.

**Q: How will aspects of your talk or the talks of other presenters focus on these issues?**

**EW:** By highlighting the importance of data visibility and use and examples of improved visibility and use.



**EMILY BANCROFT**

President

VILLAGEREACH

**Q: What technology has had the biggest impact on vaccine supply chains over the last 10 years?**

**EB:** There is no 'magic bullet' that has revolutionized vaccine supply chains over the last ten years. Instead, a range of technologies working in concert with one another have contributed to more effective and efficient supply chains. Developments in cold chain technology, data gathering and analytics, even in transportation have all had significant impacts on the availability of vaccines. These technologies all must work in-sync with each other to provide both the infrastructure and information needed to ensure vaccines are available where and when they are needed and in the right condition. We must also ensure these technologies are appropriate and available at all levels of the supply chain. As a global community, we have greatly improved the systems, infrastructure and financing to ensure sufficient vaccines reach low-resource countries, but the real impact comes when these technologies and systems work all the way down to the last mile as well.

**Q: What are the biggest challenges to ensuring that vaccine supply chains can cope with increased demand?**

**EB:** In order to ensure that vaccine supply chains can cope with increased demand, we must move beyond existing dogma and administrative systems and examine the system holistically to create flexible, responsive supply chains. The global immunization community has been highly successful at developing an initial supply chain design that worked across multiple geographies to bring vaccines to large portions of the population. These

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supply chains were built to meet countries where infrastructure was at the time, and to meet the needs of initial immunization campaigns. Over time, increased demand, increasing number of vaccines, and increasing requirements in vaccine handling adds new pressures on the supply chain today. New technologies and new infrastructure allows countries to think differently about how to run their supply chains in ways that are flexible and can respond to the changing needs of their countries.

Our biggest challenge now is renewing focus on reaching the final 20% of children who do not have access to immunizations. The cost and complexity of reaching rural, underserved, or hard-to-reach communities will be greater than reaching the first 80%, so we must be efficient and thoughtful about our work. Redesigning and reengineering supply chains must be done in a forward-looking manner to ensure these systems can address unanticipated developments in the future.

**Q: How will aspects of your talk or the talks of other presenters focus on these issues?**

**EB:** As new technologies mature and more governments are looking to improve their vaccine delivery, collaboration and sharing is more important than ever. Hearing from our colleagues about their work, learning from each other across geographies, and forging new partnerships will amplify each individual organizations' impact. Learning from and working with the private sector is a great source of inspiration and innovation, and there is still a lot of opportunity to build these relationships. I will be sharing the lessons VillageReach has learned over the last 17 years working on improving vaccine supply chains to ensure more children are immunized, and how our thinking and the tools we use to drive this work have changed over time.



**GEOFFREY GLAUER**

Senior Consultant Supply Chain

HHS- ASPR- BARDA

**Q: What technology has had the biggest impact on vaccine supply chains over the last 10 years?**

**GG:** The shift from water-based refrigerants that change phase at 0°C to phase change materials that are centered around 4-6°C and -20°C has impacted numerous products particularly clinical supplies where the stability of the product has not been fully vetted due to time constraints. The opportunity to qualify insulated packages with materials that buffer the product from ambient temperature changes allows for tighter controls on qualified shipments.

**Q: What are the biggest challenges to ensuring that vaccine supply chains can cope with increased demand?**

**GG:** Consistent supply from manufacturers has been an issue during the past few years, even for well-established companies products. Difficulties are compounded by the comparatively long lead times of production and testing. Unexpected disease outbreaks such as Yellow Fever have impacted the ability to supply important markets. Packaging, logistics, transport and final delivery methodologies have not been regular constraints to the vaccine supply chain.

**Q: How will aspects of your talk or the talks of other presenters focus on these issues?**

**GG:** Aspects of the above questions will be blended into the presentation, however, the planning aspects of pandemic response will need to include a much broader

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approach to the issue. Pandemic response has much more to do with long-term planning on multiple levels heavily involving public health authorities with support from private industry.



**HEIDI J LARSON**  
Professor of Anthropology,  
Risk and Decision Science  
**LONDON SCHOOL OF  
HYGIENE AND  
TROPICAL MEDICINE**

**Q: What are the emerging challenges in vaccine pharmacovigilance and active surveillance?**

**HL:** Capacity in mid-low income countries.

**Q: What has been the impact of vaccine hesitancy around the world and what are the most effective approaches to promoting vaccination?**

**HL:** Vaccine hesitancy has had impacts on vaccine acceptance around the world, although the specific vaccine concerns and reasons for hesitancy are highly varied. Addressing vaccine hesitancy needs very different strategies than “promoting vaccination.” In fact, promoting vaccination is situations where there is hesitancy can actually aggravate the situation and increase vaccine resistance.

**Q: How will aspects of your talk or the talks of other presenters focus on these issues?**

**HL:** There is a talk by Paul Offit which will provide some valuable insights.



**JAMES CHEYNE**  
Independent Supply Chain  
Consultant Co-Founder of  
WHO's Cold Chain Unit,  
**HEALTH SERVICE  
LOGISTICS**

**Q: What technology has had the biggest impact on vaccine supply chains over the last 10 years?**

**JC:** In my view in low income countries: cell phones. Here is a picture taken in a shop in Chad recently where the owner had bought a solar panel and a battery and was offering a phone charging service for 20 Euro cents per phone. Not the tidiest shop I have seen but clearly offering a useful service. Picture by Francois Gasse.



**Q: What are the biggest challenges to ensuring that vaccine supply chains can cope with increased demand?**

**JC:** There is a tidal wave of new technologies that is revolutionising the data available for supply chain for the day-to-day and month-to-month management to get supply chains running reliably and faster. The emerging challenge now is, and has been for a long time, effective

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training and supervision to use the new data effectively. There are no apps for this activities these yet - it's not about the technology it's about the people.

**Q: How will aspects of your talk or the talks of other presenters focus on these issues?**

**JC:** I propose to focus on how the vaccine researchers and manufacturers at the congress can contribute to making the vaccine supply chains easier to manage.



**DR JOHN NIELAND**  
Chief Operating Officer  
**2A PHARMA**

**Q: What has been the impact of such a high numbers of combination therapy studies and how do we judge which strategy is best?**

**JN:** Combination therapy studies can be a good approach dependent on what the target is. If the target is a cancer than you for sur need more targets and therefore a combination is perfect. If you are going for a protective vaccine than I do not know if this is the best approach.

**Q: Will next-gen efforts to develop cancer vaccines be more effective or should we be shifting our focus to neoantigens and other I/O strategies?**

**JN:** I think the focus on next gen vaccines should be on the way the vaccines are made and how they will induce the desired effect. The vehicle is one of the critical aspects. How can we modulate the immune system to

react as we wish. Not just focus on one aspect of the immune system, but a systemic approach.

**Q: How will aspects of your talk or the talks of other presenters focus on these issues?**

**JN:** 2A Pharma has a vaccine platform vehicle where antigens are incorporated in the AAV virus capsid protein. This guarantees that in the immune system both the innate, and adoptive immune response is activated, including NK cells, DCs, macrophages, neutrophils, monocytes, Helper T cells, Cytotoxic T cells, and B cells. 2A Pharma's vaccines have an antigen added as part of the capsid structure, which will be optimally recognized by the immune system and an immune response will be extremely efficiently induced to it. In addition in this capsid several antigens can be introduced at the same time, thereby having the possibility for a combination approach as we use for our HPV vaccine where both the HPV16 as well as the HPV 31 epitopes of the HPV-L2 protein are included, ensuring coverage of a broad palette of HPV types.



**DR PETER HOTEZ**  
Dean, National School of  
Tropical Medicine,  
Director, Texas Children's  
Hospital Center  
**BAYLOR COLLEGE OF  
MEDICINE**

**Q: What do you think remains to be the biggest challenge in enabling effective vaccine development and access?**

**PH:** I believe that there are two major challenges: first new global funding mechanisms for vaccines have focused mostly on pandemic threats rather than the chronic and debilitating neglected tropical diseases. We

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still need financial instruments to address the NTDs, the most common afflictions of the world's poorest people. A second issue is the rise of a global antivaxer movement that is presenting new challenges to global access.

**Q: What changes have you seen in the last 12 months that could suggest things are changing in the way we deal with these issues?**

**PH:** I believe things have gotten worse on both fronts highlighted above. We have very little if any dialogue about how to support vaccine development for NTDs, while the global Antivax movement continues with only modest responses from the international health community.

**Q: How will aspects of your talk or the talks of other presenters focus on these issues?**

**PH:** I believe that my talks might uniquely focus on the urgency of NTD vaccines for the world's poorest people, while at the same time, address the global antivaxer movement through my unique perspective as a vaccine scientist and autism parent.

**Q: What has been the impact of vaccine hesitancy around the world and what are the most effective approaches to promoting vaccination?**

**PH:** drops in vaccine coverage in 18 us states that allow non medical exemptions, with measles outbreaks in Texas 2013, California 2014-15, and Minnesota 2017, with measles outbreaks across Europe including the UK and Romania, and the potential to affect large middle-income countries.

**Q: How will aspects of your talk or the talks of other presenters focus on these issues?**

**PH:** I will discuss this in the context of my role as both vaccine scientist and autism parent, based on my new book that "vaccines did not cause Rachel's autism".



**THOMAS  
VERSTRAETEN**

Owner

P95

**Q: What are the emerging challenges in vaccine pharmacovigilance and active surveillance?**

**TV:** The integration of increasingly available large electronic databases in the monitoring of vaccine safety globally.

**Q: What has been the impact of vaccine hesitancy around the world and what are the most effective approaches to promoting vaccination?**

**TV:** In my opinion, the worst impact has been on HPV uptake. The missed prevention of cervical cancer in millions of women worldwide is nothing short of a disaster. I believe collaboration between local and international experts as supported by the HPV prevention board are a good means to work on this.

**Q: How will aspects of your talk or the talks of other presenters focus on these issues?**

**TV:** I will talk about the safety of adjuvants. Providing robust data as we will do will help reply to some of the anti-vaccine challenges that will certain arise as (newly) adjuvanted vaccines become more widely used.