

## **CAMB - Gene Therapy and Vaccine Program/ Immunology Graduate Program CAMB 609/IMUN 609: Vaccines and Immune Therapeutics – 2019**

### Prerequisites:

Biology, Biochemistry, or Immunology courses at the advanced college level, permission of the instructors

Director: Professors: David Weiner, Paul Offit and Stanley Plotkin

Class Coordinator: Ms. Jeneice Hubert ([jhubert@wistar.org](mailto:jhubert@wistar.org))

Vaccination is perhaps the most successful medical technological intervention. The goal of this course is to expand on students' general understanding of the immune system and to focus this understanding towards the application of modern vaccines and immune therapies in the 21<sup>st</sup> century. The course will provide the student a sense of how these principles are applied to vaccine and immune therapeutic development. The course covers basic vaccine science and describes how this science is translated through clinical, regulatory, ethical, and political issues to result in a final vaccine product. The courses' goal is to leave the student with an understanding of the implications of modern vaccines/immunotherapies and their impact on world health.

Initial lectures review immune mechanisms believed to be responsible for vaccine induced protection from disease. Subsequent lectures build on this background to explore the science of vaccines for diverse pathogens, including agents of bioterrorism as well as vaccines and immunotherapies for cancer. An appreciation for the application of laboratory science to clinical development and clinical trials of vaccines are provided. An important focus on the regulatory, safety, and ethical implications of vaccines in different world situations based on true world examples are presented. The financial implications of specific vaccines with these implications for global health is a focus of the course.

The course is presented in lecture style consisting of multiple distinguished guest lecturers who are experts in their particular area of vaccine development. There are required readings to provide the student context and background for the diverse lectures. Students are graded on **course participation**, and a final project/exam which the students will present. The project is to design a vaccine strategy for a current disease or pathogen of importance that does not yet have an effective vaccine or immune therapy and present this to the class. Strategies used should build on the material presented in the class lectures.

The course is intended for graduate students or medical students in various MS, Ph.D., or MD/Ph.D. programs on the campus, as well as local scientists and professionals in the community.

As a prerequisite, students should have taken biology, biochemistry, or immunology courses at the advanced college level. This course is offered in the fall semester.

# Vaccines and Immune Therapy

## CAMB 609/IMUN 609

### Instructors:

Dr. Paul Offit

[offit@email.chop.edu](mailto:offit@email.chop.edu)

Dr. Stanley Plotkin

[stanley.plotkin@vaxconsult.com](mailto:stanley.plotkin@vaxconsult.com)

Dr. David Weiner

[dweiner@wistar.org](mailto:dweiner@wistar.org)

### Faculty Course Leaders:

Dr. Mohamed Abdel-Mohsen

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Dr. Farokh Dotiwala

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Dr. Daniel Kulp

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Dr. Kar Muthumani

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Dr. Ami Patel

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### Course Coordinator:

Ms. Jeneice Hubert

[jhubert@wistar.org](mailto:jhubert@wistar.org)

**CAMB/IMM 609: Vaccines & Immune Therapy Fall 2019**

Time: 3:00 PM – 5:00 PM

Location: Grossman Auditorium  
1<sup>st</sup> Floor

The Wistar Institute  
3601 Spruce Street

Instructors: David Weiner, Paul Offit, Stanley Plotkin

Class Coordinator: Jeneice Hubert

<u>Date</u>	<u>Title</u>	<u>Lecturer</u>
Sept 19	Welcome/Vaccine History	David Weiner – Wistar
Sept 25	Cellular Immune Responses	Michael Betts - PENN
Sept 26	the Hemophilus influenza type B Vaccine: A Scientific Biography	William Egan - GSK
Oct 2	B Cells, Antibodies, & Humoral Immune Response	David Allman – PENN
Oct 3	Structure-based vaccine design	Daniel Kulp - Wistar
Oct 9	<b>Yom Kippur</b>	<b>NO CLASS</b>
Oct 10	Rotavirus Vaccines	Paul Offit - CHOP
	Correlates of Protection by Vaccines	Stanley Plotkin – Emeritus Professor of Pediatrics
Oct 16	Progress Towards the Development of A Prophylactic Vaccine for HCMV	Amy Espeseth – Merck
	Adoptive Cell Therapy for Cancer	Marco Ruella – UPENN

<u>Date</u>	<u>Title</u>	<u>Lecturer</u>
Oct 17	the Role of antibodies in RSV prevention: the story of Nirsevimab	Tonya Villafana – Medimmune
	<b>TBA</b>	Mark Esser - Medimmune
Oct 23	Immunotherapy for the treatment of HPV diseases: T cells as key players	Matthew Morrow – Inovio
Oct 24	Cure-HIV	Luis Montaner - Wistar
Oct 30	Vaccine Development for Emerging Infectious Diseases: Are we addressing lessons learned from the Ebola outbreaks?	Swati Gupta - IAVI
	Responding to the Zika epidemic Through rapid development of vaccines	Jon Heinrichs – Sanofi Pasteur
Oct 31	The Challenge of Successful Vaccines Development & Delivery	Emilio Emini – Bill & Melinda Gates Foundation
Nov 6	Overview of the Advisory Committee on Immunization Practices (ACIP) Example: Hepatitis A Disease and Vaccines	Michelle Goveia – Merck
Nov 7	Vaccines for Infectious Diseases that Disproportionately Impact the Poor	Penny Heaton – Bill and Melinda Gates Medical Research Institution
Nov 13	Vaccine Safety	Paul Offit - CHOP
Nov 14	Maternal Immunization, Are we now on track to protect infants from	Kathrin Jansen – Pfizer

<u>Date</u>	<u>Title</u>	<u>Lecturer</u>
Nov 20	Developing vaccines against emerging infections outside of the usual regulatory framework	Gary Kobinger – PHA Canada
Nov 21	Regulatory Considerations for Preventative Vaccines	Doran Fink – FDA
	Understanding Vaccine Safety After Licensure	Meghna Alimchandani - FDA
Nov 27	<b>THANKSGIVING</b>	<b>NO CLASS</b>
Nov 28	<b>THANKSGIVING</b>	<b>NO CLASS</b>
Dec 4	Meningococcal Vaccines	Nicole Brown - CDC
	Personalized Cancer Vaccines	Gerald Linette – UPENN
Dec 5	Pneumococcal Conjugate	William Gruber – Pfizer
Dec 11	Vaccine Confidence-Fact, Fiction, Perception	Ruxandra Draghia - Merck
Dec 12	<b>EXAMS</b>	<b>Examiners - TBD</b>

# Course Requirements

- **Reading - Vaccinated: One Man's Quest to Defeat the World's Deadliest Diseases, (will be provided)**
  - *By Paul A. Offit, M.D.*
- **Please attend all classes**
  - ***If you would like to have something to eat be here 10 minutes early.***
  - ***Do not come late***
  - ***Attendance will be recorded***
- ***Participate in class lectures***
- **Final Exam (Design a vaccine)**
  - ***Paper of Poster-Master Students***
  - ***Paper of Power Point Presentation (PhD students will be required to present in front of class).***

# Final Exam: Project

- Assigned a Pathogen/ Disease for which there is no current vaccine/immune therapy
- What is the pathogen and why is it important to design a vaccine?
- **Present the relevant immune response.**
- Design a vaccine and defend your platform.
- Experiments needed (if any)?
- Define a **correlate** of protection.
- Develop release/potency criteria - animal models?
- Define your clinical trial test population.
- Define the economic need of your vaccine - Who does it benefit?
- How will you pay for its development? Who will give you the \$\$?
- 10 Minute lightening talk - 8 slides + reference slide

**David B. Weiner, Ph.D.**

Executive Vice President at The Wistar Institute,  
Director of The Wistar Vaccine Center,  
W.W. Smith Charitable Trust Professor in Cancer Research

Preeminent immunologist and vaccine expert, **David B. Weiner, Ph.D.**, is executive vice president of The Wistar Institute, director of the Wistar Vaccine Center, and the W. W. Smith Charitable Trust Professor in Cancer Research. Dr. Weiner directs a translational research laboratory in the area of Molecular Immunology. His group is one of the

pioneering research teams in establishing the field of DNA vaccines and immune therapies. Important reports from his lab include the first DNA vaccine studied for HIV as well as for cancer immune therapy, the early development of DNA encoded genetic adjuvants including the particularly relevant IL-12, advances in gene optimization, and advances in electroporation technologies resulting in improved gene delivery among others. His group worked with collaborators to become the first to move DNA technology into human study. His laboratory's work helped revitalize the field through advancement of new synthetic DNA design and modification of EP delivery approaches resulting in potent immune induction as well as the first successful Phase IIb DNA efficacy study (for HPV immune therapy) in humans.

Weiner is the recipient of numerous honors including election as a fellow to both the American Association for the Advancement of Science in 2011 and the International Society for Vaccines in 2012. He is the recipient of the NIH Director's Transformative Research Award and received the Vaccine Industry Excellence Award for Best Academic Research Team in 2015 at the World Vaccine Congress. Weiner was honored with the prestigious Hilleman Lectureship in 2015 at the Children's Hospital of Philadelphia Grand Rounds session and received a Stone Family Award from Abramson Cancer Center for his groundbreaking work on DNA vaccines for cancer immune therapy.

In March 2016, Weiner returned to Wistar from his position at The University of Pennsylvania School of Medicine as professor of Pathology and Laboratory Medicine. From 1990 to 1993, Weiner held a joint position as assistant professor of Pathology and Laboratory Medicine at The Wistar Institute and the University of Pennsylvania School of Medicine.

Weiner graduated with a B.S. in biology from SUNY at Stony Brook, in Stony Brook, N.Y., a M.S. in biology from the University of Cincinnati and a Ph.D. in developmental biology from the University of Cincinnati College of Medicine.



**JENEICE HUBERT**

Weiner Lab Coordinator

Assistant to: Dr. David B. Weiner

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**Michael Betts, Ph.D.**

Associate Professor of Microbiology in the Microbiology Graduate Group Affiliations Department at University of Pennsylvania.

**Dr. Betts's** laboratory studies human T lymphocyte function in order to understand the role of these cells in controlling or eliminating viral pathogens and providing protection from infection. Our primary interest is in determining how and if the human CD8<sup>+</sup> T cell response to HIV controls viral replication. We also study the immune response against a variety of other human pathogens, including Epstein-Barr virus, cytomegalovirus, influenza, and vaccinia virus. Importantly, the techniques we utilize can be applied to the study of the cell-mediated immune response against any human pathogen, including emerging pathogens and bioterrorism agents. We are also very interested in characterizing the human T cell response to various vaccine regimens against a variety of human pathogens designed to generate cell-mediated immunity in order to understand the underlying principles of vaccine-mediated immune protection.



Human T lymphocytes have numerous functions, including the ability to produce various cytokines and chemokines, as well as mediate cell death through perforin- or fas-mediated cytotoxicity. Our research utilizes the most cutting-edge techniques to measure human T lymphocyte responses through the use of polychromatic flow cytometry. This technique allows for the simultaneous examination of up to 18 separate parameters on lymphocytes. By measuring multiple T cell functions simultaneously, we can characterize the complexity of the CD4<sup>+</sup> and CD8<sup>+</sup> T cell response to HIV, EBV, CMV, Flu, and vaccinia. Not surprisingly, the T cell responses to these different viruses are quite variable; however, common response patterns do exist, and the importance of these patterns in the control of viral replication is the subject of future studies.



### **William Egan, Ph.D.**

After receiving a PhD degree in Chemistry from Princeton University and serving as a post-doctoral fellow in the Division of Physical Chemistry at the Lund Institute of Technology (Sweden), Dr. Egan joined the National Institutes of Health in 1975. In 1977, Dr. Egan began his FDA career at the Bureau of Biologics (currently, the Center for Biologics Evaluation and Research) where he was a researcher-reviewer in the Division of Bacterial Products. In 1981, Dr. Egan became the Chief of the Biophysics Laboratory and, following an organizational restructuring of Biologics in the early 1990's, Dr. Egan became the Associate Director for Research for the Office of Vaccines Research and Review (OVRR) and, in 1995, the Deputy Director for OVRR. In December 1999, Dr. Egan became the Acting Director for OVRR, a position he again assumed in 2003 and held until January 2005, when he retired from FDA. Dr. Egan then joined the consulting division of Pharma-Net, a global CRO, as Vice President, Consulting. Dr. Egan remained at Pharma-Net until January 2012, when he joined Novartis Vaccines, which was subsequently acquired by GSK Vaccines in 2014. Dr. Egan is currently a Senior Advisor in the Technical Research and Development group at GSK Vaccines

Dr. Egan's research career has focused on the structure (including dynamic structure) and function of bio-macromolecules, including proteins, DNA, and bacterial polysaccharides, primarily through the use of NMR spectroscopy and molecular dynamics modelling. Dr. Egan is the author and co-author of over 110 scientific publications.

## David M. Allman, Ph.D.

Associate Professor of Pathology and Laboratory Medicine in the Pathology and Laboratory Medicine Graduate Group Affiliations Department at the University of Pennsylvania.

**Dr. Allman's** research interests are Plasma cell differentiation and B cell development. His lab's main focus concerns the mechanisms underlying differentiation within the B cell lineage. We are currently focusing on two aspects of B cell development and differentiation.

1) A central interest in my lab concerns the differentiation of antibody-secreting plasma cells from naïve and memory B cells. We are primarily interested in the following questions: a) How long do plasma cells live and what signals regulate their survival? b) Do plasma cells located at sites other than the bone marrow, such as within the gut mucosa, utilize the same survival mechanisms as those in the marrow? c) To what extent does persisting antigen or chronic infection promote lasting antibody responses? d) What are the regulatory networks, transcriptional and otherwise, that underwrite the differentiation of an activated B cell into an antibody-secreting plasma cell?

**Background:** High-affinity neutralizing antibodies play central roles in combating infections and constitute the chief mechanism underlying the vast majority of effective vaccines. Once induced, antigen-specific antibodies can be found in the serum long after infection or vaccination. A key question in immunology is how this works: Are lasting antibody responses mediated by memory B cells, induced periodically to generate short-lived plasma cells by persisting antigen? Or does the durability of serum antibody titers reflect the activity of long-lived plasma cells?

It is generally accepted that, once generated in peripheral lymphoid tissues, some new plasma cells home to the bone marrow where they survive for months to years in mice, and perhaps decades in people. However, the vast majority of newly generated plasma cells fail to become long-lived. Given that certain vaccines fail to induce long-term protective immunity; it follows that these antigens or immunization strategies fail to induce the formation of long-lived plasma cells. We would like to understand why.

To this end, we are striving to understand the factors underlying plasma cell lifespans, and why some plasma cells become long-lived, while others do not. We are examining this issue on both the cellular and molecular levels. With a cellular perspective, we have developed strategies to identify newly formed versus long-lived plasma cells in the bone marrow. This capacity also allows us to evaluate different types of antigens and immunization strategies for their capacity to induce short- and long-lived plasma cells. From these experiments we have learned that the bone marrow plasma cell pool is exceptionally dynamic, containing large fractions of newly formed plasma cells that must compete effectively for presumably limiting survival niches. Hence, we are working to define the components of these niches and determine how to manipulate them. For a molecular perspective, we have also developed genome-wide gene expression data sets for short- and long-lived plasma cells in the bone marrow and in the gut mucosa.



These data that have inspired new hypotheses about the biochemical and transcriptional pathways underlying adoption of the plasma cell fate by naïve B cells and the role of mitosis in this process. In related work, we are focused on elucidating the influence of microbe-lymphocyte interactions in the gastrointestinal tract on systemic immunity, particularly the generation and maintenance of serum IgA responses.

2) The second main focus in my laboratory concerns how specific transcription factors promote the earliest phases of B cell development from multipotent progenitors.

Background: To generate early B-lineage cells, the development of alternative lineages such as T cells, innate lymphoid cells, and myeloid lineage cells must be suppressed. Previous work on this question concentrated heavily on the transcription factor Pax5 and its capacity to both promote B cell differentiation and inhibit alternative fates. However, we recently showed that Early B Cell Factor-1 (EBF), another transcription factor required for early B lymphopoiesis, both promotes B cell development and represses myeloid and T-lineage development independently of Pax5. Recent work in the lab has shown that EBF accomplishes this task by actively and directly repressing the T cell and innate lymphoid cell-requisite transcription factor Gata3. To test this hypothesis further we developed synthetic Zinc-finger proteins to perturb interactions between EBF and discrete cis elements in the Gata3 locus and test the impact of these perturbations on early B and T cell development. The latter studies revealed a general strategy for perturbing interactions between known transcription factors and relevant regulatory cis elements in a wide variety of experimental systems; we are applying this general approach to several differentiation pathways including early plasma cell differentiation.



**Daniel Kulp, Ph.D.**

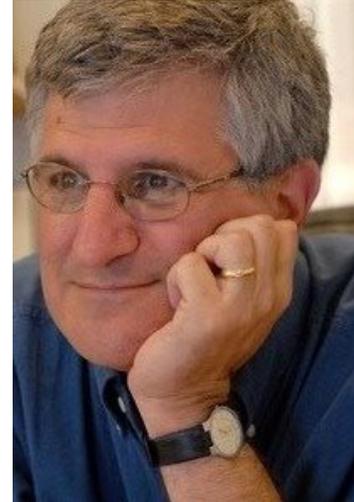
Associate Professor,  
Vaccine & Immunotherapy Center

Dr. Kulp has more than 15 years of experience developing molecular design software and leading protein engineering projects. He joined Wistar from The Scripps Research Institute and International AIDS Vaccine Initiative where he was a principal scientist.

Dr. Kulp received a bachelor's degree in Computer Science and Molecular Biology & Biochemistry from Rutgers, The State University of New Jersey, followed by a Ph.D. in Biochemistry and Molecular Biophysics from the University of Pennsylvania. He completed postdoctoral training in structure-based and experimental protein engineering at Los Alamos National Laboratory.

## Paul A. Offit, M.D.

Director of the Vaccine Education Center at the Children's Hospital of Philadelphia, Maurice R. Hilleman Professor of Vaccinology, Professor of Pediatrics at the Perelman School of Medicine at the University of Pennsylvania.



Dr. Offit is a recipient of many awards, including the J. Edmund Bradley Prize for Excellence in Pediatrics from the University of Maryland Medical School, the Young Investigator Award in Vaccine Development from the Infectious Disease Society of America, and a Research Career Development Award from the National Institutes of Health. Dr. Offit has published more than 160 papers in medical and scientific journals in the areas of rotavirus-specific immune responses and vaccine safety. He is also the co-inventor of the rotavirus vaccine, RotaTeq, recommended for universal use in infants by the CDC; for this achievement Dr. Offit received the Luigi Mastroianni and William Osler Awards from the University of Pennsylvania School of Medicine, the Charles Mérieux Award from the National Foundation for Infectious Diseases; and was honored by Bill and Melinda Gates during the launch of their Foundation's Living Proof Project for global health. In 2009, Dr. Offit received the President's Certificate for Outstanding Service from the American Academy of Pediatrics.

In 2011, Dr. Offit received the Humanitarian of the Year Award from the Biologics Industry Organization (BIO), the David E. Rogers Award from the American Association of Medical Colleges, the Odyssey Award from the Center for Medicine in the Public Interest and was elected to the Institute of Medicine of the National Academy of Sciences. In 2012, Dr. Offit received the Distinguished Medical Achievement Award from the College of Physicians of Philadelphia and the Drexel Medicine Prize in Translational Medicine for the Drexel University College of Medicine. In 2013, Dr. Offit received the Maxwell Finland award for Outstanding Scientific Achievement from the National Foundation for Infectious Diseases, the Distinguished Alumnus award from the University of Maryland School of Medicine, and the Innovators in Health Award from the Group Health Foundation. In 2015, Dr. Offit won the Lindback Award for Distinguished Teaching from the University of Pennsylvania and was elected to the American Academy of Arts and Sciences.

In 2016, Dr. Offit won the Franklin Founder Award from the city of Philadelphia and The Porter Prize from the University of Pittsburgh School of Public Health. Dr. Offit was a member of the Advisory Committee on Immunization Practices to the Centers for Disease Control and Prevention and is a founding advisory board member of the Autism Science Foundation and the Foundation for Vaccine Research. He is also the author of seven medical narratives: *The Cutter Incident: How America's First Polio Vaccine Led to Today's Growing Vaccine Crisis* (Yale University Press, 2005), *Vaccinated: One Man's Quest to Defeat the World's Deadliest Diseases* (HarperCollins, 2007), for which he won an award from the American Medical Writers Association, *Autism's False Prophets: Bad Science, Risky Medicine, and the Search for a Cure* (Columbia University Press, 2008), *Deadly Choices: How the Anti-Vaccine Movement Threatens Us All* (Basic Books, 2011), which was selected by Kirkus Reviews and Booklist as one of the best non-fiction books of the year, *Do You Believe in Magic?: The Sense and Nonsense of Alternative Medicine* (HarperCollins, 2013), which won the Robert P. Balles Prize in Critical Thinking

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from the Center for Skeptical Inquiry and was selected by National Public Radio as one of the best books of 2013, *Bad Faith: When Religious Belief Undermines Modern Medicine* (Basic Books, 2015), selected by the New York Times Book Review as an “Editor’s Choice” book in April 2015; and *Pandora’s Lab: Seven Stories of Science Gone Wrong* (Random House, 2017). The book, *Lost in Translation: Some Hard-Earned Advice About How to Communicate Science to the Public*, is in preparation.



### **Stanley A. Plotkin, MD**

Dr. Stanley A. Plotkin is Emeritus Professor of the University of Pennsylvania. Until 1991, he was Professor of Pediatrics and Microbiology at the University of Pennsylvania, Professor of Virology at the Wistar Institute and at the same time, Director of Infectious Diseases and Senior Physician at the Children's Hospital of Philadelphia. For seven years, he was Medical and Scientific Director of Sanofi Pasteur, based at Marnes-la-Coquette, outside Paris. He is now consultant to vaccine manufacturers and non-profit research organizations.

He is a member of the Institute of Medicine of the National Academy of Sciences and the French Academy of Medicine. His bibliography includes over 700 articles and he has edited several books including a textbook on vaccines. He developed the rubella vaccine now in standard use throughout the world, is codeveloper of the newly licensed pentavalent rotavirus vaccine, and has worked extensively on the development and application of other vaccines including anthrax, oral polio, rabies, varicella, and cytomegalovirus.

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**Amy S. Espeseth, Ph.D.**, is executive director of Infectious Disease and Vaccines at Merck Research Laboratories. In this role, Dr. Espeseth leads discovery research on prevention and treatment of disease caused by respiratory and herpes viruses.

Dr. Espeseth joined Merck in 1998 as a postdoctoral scientist in the Department of Antiviral Research. Since then, she has served in positions of increasing responsibility in multiple scientific disciplines including HIV antivirals, Alzheimer's disease research, RNA therapeutics, and Vaccines. She has been in her current position since 2016. Dr. Espeseth has also served as a lecturer at Gwynedd-Mercy College and as a scientific writer at Pharmaceutical Information Associates.

Dr. Espeseth received a Ph.D. in microbiology and immunology from Duke University. She holds a B.A. in liberal arts from the University of Virginia. Espeseth conducted post-doctoral research at The Salk Institute for Biological Studies.

## Marco Ruella, MD

Assistant Professor,  
Division of Hematology/Oncology,  
Center for Cellular Immunotherapies  
Scientific Director,  
Lymphoma Program at the  
Hospital of the University of Pennsylvania



Marco Ruella, MD, is Assistant Professor of Medicine in the Division of Hematology/Oncology and the Center for Cellular Immunotherapies and Scientific Director of the Lymphoma Program at the Hospital of the University of Pennsylvania. His research focuses on the study of the mechanisms of relapse after chimeric antigen receptor T cell (CART) immunotherapies with the goal of rationally designing combined innovative immunotherapies for relapsing/refractory leukemia and lymphoma. He is the author of numerous peer-reviewed publications on targeted immunotherapies for hematological cancers and is an inventor in several patents on CAR T therapy. His work has been recognized through numerous awards including the inaugural SITC EMD-Serono Cancer Immunotherapy Clinical Fellowship (2014), the AACR-BMS Oncology Fellowship in Clinical Cancer Research (2015), the ASH Scholar Award (2016), a NIH K99-R00 award (2017), the “Paola Campese” Award Leukemia Research (2017), the Cancer Support Community Award (2018), and most recently the 2018 American Society of Hematology Joanne Levy, MD, Memorial Award for Outstanding Achievement. Dr. Ruella obtained his medical degree with high honors and completed his specialization in clinical hematology at the University of Torino, Italy. After completing his fellowship, he was an attending physician in the Hematology and Cell Therapy Division of the Mauriziano Hospital and an instructor at the Biotechnology School at the University of Torino. From 2012, he was a postdoctoral fellow, and then an instructor at the University of Pennsylvania in the Center for Cellular Immunotherapies where he worked with Drs. June and Gill until appointment to his current position in 2018.

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**Tonya Villafana, PhD, MPH, Senior Director**, is a Product Development Team Leader in the Infectious Disease & Vaccines Innovative Medicines Unit at MedImmune. In this role she is responsible for leading cross functional product development teams for vaccines and monoclonal antibodies in MedImmune’s respiratory virus portfolio (RSV and influenza). She joined MedImmune in 2009.

Tonya served as the International Federation of Pharmaceutical Manufacturers and Associations World Bank Fellow from 2011-2013 on secondment from MedImmune/Astra Zeneca. Prior to joining MedImmune, Tonya was Director of Portfolio Management at the PATH Malaria Vaccine Initiative where she was responsible for the oversight of MVI’s vaccine candidate portfolio. She served as Chair of MVI’s Portfolio Management Committee and was a member of the RTS,S malaria vaccine product development team.

Prior to MVI, she was the Site Director of the HIV Vaccine Initiative at the Botswana Harvard School of Public Health AIDS Initiative Partnership for HIV Research and Education. As Site Director, she established sites to conduct the first HIV vaccine trials in the southern African region in collaboration with the NIH HVTN and collaborated with local and international institutions for the conduct of HIV vaccine research.

Tonya has served on several committees and Boards including the Malaria Clinical Trials Alliance, as a technical advisor to WHO on HIV, malaria, and RSV vaccine research and development. She has worked closely with the Bill and Melinda Gates, Foundation, PAHO, WHO, IFPMA, DFID and other internal organizations and NGOs. In 2004 she was awarded the Site Director of the Year Award by the HVTN. Tonya received a PhD in immunology from Cornell University Graduate School of Medical Sciences and an MPH from Harvard School of Public Health.



**Mark T. Esser, Ph.D.** – Sr. Director of Translational Medicine for Vaccines and Infectious Diseases at MedImmune, Inc. responsible for MedImmune’s overall biomarker, diagnostic and precision medicine strategy in infectious disease from preclinical candidate through proof of concept. Dr. Esser oversees a portfolio of vaccine and monoclonal antibody programs in respiratory diseases, serious bacterial infections and virally induced cancers. He was director of the Vaccine and Biologics Center of Excellence at PPD and at Merck he held positions of increasing responsibility and was instrumental in the approval of Gardasil™ in 2006. Dr. Esser is widely recognized for his contributions to vaccine research and global health.



**Dr. Matthew Morrow**

Director,  
Immunology and Biomarkers  
Inovio Pharmaceuticals Inc.

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**Luis J. Montaner, D.V.M., D.Phil.**

Vice President, Scientific Operations and  
Director, HIV-1 Immunopathogenesis Laboratory  
at the Wistar Institute  
Herbert Kean, M.D., Family Professor

**Dr. Luis J. Montaner** is Director of the HIV-1 Immuno-pathogenesis Laboratory and has enjoyed an active research partnership with community health center Philadelphia FIGHT for more than 20 years. In 2016, he was awarded a \$23 million Martin Delaney Collaboratory grant from NIH to advance the cure agenda. He currently serves as Editor-In-Chief of the Journal of Leukocyte Biology with an editorial staff of over 50 investigators. In December 2014, Dr. Montaner was named the Herbert Kean, M.D. Family Professor, an endowed professorship that recognizes high-risk, high-reward research. His research is primarily focused on innate effectors, immune regulation of infection, activation measurements on ART, and translational human immunology-based studies. Dr. Montaner has received numerous distinctions for his work on behalf of people living with HIV/AIDS, including the Jonathan Lax Award from Philadelphia FIGHT, the Founders' Award from the AIDS Fund of Philadelphia, the Penn CFAR Red Ribbon Award for Medical Research, and a Recognition and Honors Resolution from the Philadelphia City Council. Dr. Montaner and his team have recently completed enrollment in the largest HIV Cure research clinical trial to date.

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## SWATI GUPTA

Vice President, Research Integration & Innovation

Swati Gupta leads integration of the IAVI research and development portfolio and the organization's global network of laboratories. She is leveraging IAVI's platforms and expertise to expand product development efforts beyond HIV, including in emerging infectious disease.



Previously, she was an Executive Director with Merck Vaccines, where she worked on the development of innovative partnership models to address cross-cutting issues related to vaccine science and technology. As part of this role, she worked with key external stakeholders to facilitate accelerated Ebola vaccine development efforts to enhance preparedness for the ongoing public health crisis and for potential future outbreaks.

From 2000 to 2014, Gupta was in the Department of Epidemiology at Merck Research Laboratories where she led a number international, prospective cohort studies in support of vaccine and infectious disease products in development, including research on diseases such as HIV, HPV, influenza, dengue, and C.difficile. From 1998 to 2000, Dr. Gupta worked as a scientist in HIV Surveillance at the Communicable Disease Surveillance Centre (British equivalent of the US CDC) in the UK. She has also worked at the Bureau of Tuberculosis Control at the New York City Department of Health.

Gupta holds a doctorate in epidemiology from the Johns Hopkins Bloomberg School of Public Health and a Master of Public Health infectious disease epidemiology from Yale University School of Medicine.

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## **Jon Heinrichs Ph.D.**

### **Sanofi Pasteur**

Associate Vice President, Segment Head, Early and Pre-Development Projects

Jon Heinrichs is an Associate Vice President and Segment Head in Global Project Leadership at Sanofi Pasteur in Swiftwater, PA where he leads vaccine projects in the Pre-Development and Early Development spaces. Prior to joining Sanofi, Dr. Heinrichs headed the Microbial Vaccine Research group at Merck Research Labs where he led a team of scientists developing vaccines for several bacterial pathogens. Dr. Heinrichs previously held positions of increasing responsibility at the biotechnology company MedImmune (now part of AstraZeneca). Dr. Heinrichs earned his doctoral degree in microbiology and molecular genetics from Rutgers University and the University of Medicine and Dentistry of New Jersey and completed a post-doctoral fellowship in the Laboratory of Bacterial Pathogenesis and Immunology at The Rockefeller University.

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**Emilio A. Emini, Ph.D.** - Director of the Tuberculosis and HIV Program at the Bill and Melinda Gates Foundation. In this role, Dr. Emini leads the foundation's efforts to control the global TB and HIV epidemics.



Prior to his current role, Dr. Emini served as Senior Vice President of Vaccine Research and Development at Pfizer Inc., a position into which he transitioned subsequent to Pfizer's acquisition of Wyeth Pharmaceuticals in late 2009. At Wyeth, he led the R&D program that resulted in licensure of Prevenar 13, Pfizer's vaccine for the prevention of pneumococcal disease. Prior to joining Wyeth, Dr. Emini also served as Senior Vice President of Vaccine Development at the International AIDS Vaccine Initiative.

Dr. Emini joined the pharmaceutical industry in 1983 at the Merck Research Laboratories where, as Executive Director of the Department of Antiviral Research, he led the biological research that resulted in the development of one of the first highly active antiretroviral therapies for the treatment of HIV infection. As head of vaccine research at Merck beginning in 1996, he led a research team that was involved in the successful development of multiple pediatric and adolescent vaccines.

In 2006, Dr. Emini was awarded the Distinguished Alumnus Award from the Cornell University Graduate School of Medical Sciences. He is a Fellow of the American Academy of Microbiology, a Fellow of the International Society for Vaccines, a Fellow of the College of Physicians of Philadelphia, and a former Trustee of the National Foundation for Infectious Diseases. Dr. Emini also served as a member of the National Preparedness & Response Science Board, an advisory committee to the U.S. Secretary of Health and Human Services.



**Michelle Goveia, M.D., M.P.H.** -Medical Director,  
Global Vaccines Medical Affairs at Merck Vaccines

Michelle Goveia, MD, MPH is a Medical Director in the Global Medical Affairs department at Merck Vaccines. She joined Merck in 2002 supporting the clinical development and regulatory interactions for numerous vaccines including rotavirus, hepatitis A, and varicella-containing vaccines. She is currently responsible for increasing global access to Merck's pediatric and hepatitis vaccines worldwide, which include managing vaccine-related scientific data and recommendations for rotavirus, hepatitis A and B, Hib, and a hexavalent combination vaccine.

Prior to joining Merck, she was an Epidemic Intelligence Service Officer at the Centers for Disease Control and Prevention, stationed at the California State Health Department. While there she worked with environmental and occupation health issues, including investigation of a new disease among renal patients, was involved in surveillance activities after the World Trade Center events and in the anthrax investigations in New York City and Washington DC.

Dr. Goveia received her B.S. degree from the University of Michigan, medical and public health degrees from the George Washington University in Washington, DC and is pediatric board-certified. Her interest in pediatric environmental health has led her to work with the White House and the US Environmental Protection Agency.

**Penny M. Heaton, M.D.**

**Chief Executive Officer  
The Bill & Melinda Gates Medical Research  
Institute**

Dr. Penny Heaton is the Chief Executive Officer of the Bill & Melinda Gates Medical Research Institute (Gates MRI), a non-profit medical research institute that aims to accelerate translational science to combat diseases that disproportionately impact the poor in low- and middle-income countries.



Dr. Heaton leads the institute's work to capitalize on new strategies that could increase the identification, selection, and optimization of novel candidates for drugs, vaccines, and monoclonal antibodies that will help eradicate malaria, accelerate the end of the TB epidemic and prevent diarrheal deaths from occurring in children.

Prior to this role, Dr. Heaton served as director of the Bill & Melinda Gates Foundation's Vaccine Development and Surveillance team, where she led the foundation's vaccine development program against several diseases including HIV, tuberculosis, malaria, pneumonia, enteric diseases, and polio. She has more than 15 years of experience leading vaccine clinical research and development for companies like Novartis, Merck and Novavax.

Dr. Heaton began her career at the U.S. Centers for Disease Control and Prevention conducting diarrheal disease surveillance and investigating outbreaks of foodborne and diarrheal diseases, influencing her life-long passion for vaccine development. Notably, Dr. Heaton co-developed RotaTeq® during her time at Merck & Co., a rotavirus vaccine which has been licensed in more than 100 countries and universally recommended by the World Health Organization for infants worldwide.

A graduate of the University of Louisville School of Medicine in Kentucky, Dr. Heaton is board-certified in Pediatrics and Pediatric Infectious Diseases. She is a member of the Pediatric Infectious Diseases Society and a fellow of the American Academy of Pediatrics.

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**Kathrin U. Jansen, Ph.D.**

Senior Vice President and Head for Vaccine Research and Development at Pfizer Inc./ member of Pfizer's Worldwide Research and Development leadership team.

Dr. Jansen oversees a fully integrated, global vaccine research and development organization, with responsibilities ranging from discovery to registration and post-marketing commitments of first-in-class or best-in-class vaccines to prevent or treat diseases of significant unmet medical need. More recent accomplishments are the global licensures of Prev(e)nar13® to prevent pneumococcal diseases and the development and licensure of Trumenba®, the first vaccine licensed in the United States to prevent invasive disease caused by Neisseria meningitidis serogroup B. Before the Wyeth acquisition by Pfizer in 2009, Dr. Jansen served as Senior Vice President at Wyeth Pharmaceuticals and on Wyeth's R&D Executive Committee since 2006 and was responsible for vaccine discovery, early development and clinical testing operations.



Dr. Jansen also briefly worked at Vaxgen as Chief Scientific Officer and Senior Vice President for Research and Development with responsibility for the company's late stage development programs. Prior to joining Vaxgen, Dr. Jansen spent 12 years at Merck Research Laboratories where she directed or supported a number of vaccine efforts, including Merck's novel bacterial vaccine programs and viral vaccine programs (rotavirus, zoster and mumps, measles and rubella). Dr. Jansen initiated and led the development of Gardasil®, the world's first cervical cancer vaccine. Dr. Jansen received her doctoral degree in microbiology, biochemistry & genetics from Phillips University, Marburg, Germany, in 1984. Following completion of her formal training, she continued her postdoctoral training at Cornell University working on the structure/function of the acetylcholine receptor. She then joined the Glaxo Institute for Molecular Biology in Geneva, Switzerland, where she focused on basic studies of a receptor believed to be a drug target to treat allergies. Dr. Jansen has over 120 publications in peer reviewed journals and was appointed an Adjunct Professor at the University of Pennsylvania – School of Medicine in 2010.

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### **Gary Kobinger, Ph.D.**

Gary Kobinger obtained his Ph.D. from the University of Montreal in 1998 before completing a post-doctoral fellowship at the University of Pennsylvania. In March 2005, Gary was the Chief of the Special Pathogens Biosafety Level 4 program at the National Microbiology Laboratory where he worked for 11 years. He is now professor and the Director of the Infectious Disease Research Centre at the Université Laval and has an appointment of associate professor at the University of Manitoba and adjunct professor at the University of Pennsylvania.

Gary was granted several awards including scientists of the year award from Radio Canada (CBC), the Order of Manitoba in 2016 and the Meritorious Service Cross (civil division) of the Governor General of Canada also in 2016. Gary co-authored around 200 peer-reviewed scientific manuscripts, and gave numerous invited seminars in Universities, national and international funding agencies, departments of national defenses, the White House, Singapore NEA and the World Health Organization (WHO) concerning research on high consequence pathogens and the development of new public health policies and recommendations.

In 2013-2017, 60 minutes, National Geographic, BBC Horizon, NOVA, France 2, PBS, CBC, RC and others featured the leading work on successful treatment of Ebola infection that was developed by Gary and his team and the VSV-based Ebola vaccine to which he also contributed to bring to clinical trials including a Phase III efficacy study in Guinea.

**Doran L. Fink, M.D., Ph.D.**

Deputy Director for Clinical Review in the  
Division of Vaccines and Related Products Applications,  
Office of Vaccines Research and Review,  
Center for Biologics Evaluation and Research,  
US Food and Drug Administration

Dr. Fink has personal expertise in: Viral vaccines:  
Ebola, Smallpox, HPV, HIV, HSV, SMV, VZV,  
Japanese Encephalitis, Yellow Fever, Enterovirus 71,  
Adenovirus 4/7, Chikungunya, SARS, MERS, Zika.  
Bacterial vaccines: Staphylococcus aureus, Shigella spp.,  
TB. Parasitic vaccines: Malaria, Leishmania,  
Hookworm. Diagnostic skin test: PPD, Leishmania.  
Fecal Microbiota for transplantation.



Dr. Fink joined FDA as a Medical Officer in 2010 and has been responsible for primary and supervisory review of a broad portfolio of vaccines and related biological products. He currently oversees all clinical and toxicological review activities in the Division, which is responsible for the regulation of licensed and investigational vaccines for the prevention of infectious diseases, allergenic diagnostics and immunotherapy products, live biotherapeutic products (including fecal microbiota for transplantation) and bacteriophage therapies. Additionally, Dr. Fink contributes to the education of medical students, residents, and fellows in the Division and coordinates the FDA-CBER track of the CNMC Pediatric Infectious Diseases fellowship training program, in which fellows receive their clinical training at CNMC and pursue their scholarly activities as clinical reviewers in the Office of Vaccines at CBER.

Dr. Fink is board certified in Pediatrics and Pediatric Infectious Diseases. He received his undergraduate training at Stanford University and his MD and PhD (Molecular Microbiology and Microbial Pathogenesis) degrees in 2003 through the Medical Scientist Training Program at Washington University in St. Louis School of Medicine. Subsequently, Dr. Fink completed his residency and fellowship training in 2006 (pediatrics) and 2010 (Pediatric Infectious Diseases) at The Johns Hopkins University School of Medicine.

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**Dr. Meghna Alimchandani - FDA**

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**Dr. Nicole Brown - CDC**

Dr. Nicole Brown is an Epidemic Intelligence Service Officer in the Meningitis and Vaccine Preventable Diseases Branch in the National Center for Immunization and Respiratory Diseases at CDC. She earned her BA in Molecular Biology from William Jewell College and PhD in Molecular and Systems Pharmacology from Emory University. She has previously worked as a Health Scientist for CDC's Clinical Research Branch in clinical trials for novel drug regimens to treat tuberculosis. Since joining the Meningitis and Vaccine Preventable Diseases Branch, she has worked on surveillance related to meningococcal and Haemophilus influenzae disease, outbreak response to measles and Pneumococcal disease, and seroepidemiology of tetanus.

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**Gerald P. Linette**  
**University of Pennsylvania**

Gerald P. Linette, MD, PhD is a graduate of the Medical Scientist Training Program, Georgetown University School of Medicine. He completed training in Internal Medicine and Molecular Oncology at Washington University in St. Louis followed by fellowship in Hematology-Oncology at Massachusetts General Hospital/DFCI. Dr. Linette is currently Professor of Medicine and Medical Director, Sean Parker Institute of Cancer Immunotherapy at the Perelman School of Medicine, University of Pennsylvania. His primary interest is the development of cellular immunotherapies for melanoma and other solid tumors. His laboratory research is focused on human tumor neoantigen discovery. Dr. Linette is board certified in Internal Medicine and Medical Oncology and he maintains an active clinical practice at the University of Pennsylvania Abramson Cancer Center.

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**William C. (Bill) Gruber, Senior Vice President**

**Pfizer Vaccine Clinical Research and Development**

Bill is Senior Vice President of Pfizer Vaccine Clinical Research and Development, and responsible for global clinical development of vaccines. He has over 30 years of experience in vaccine development. Bill joined in 1999 as Vice President of Clinical Vaccine Research for Wyeth, now a wholly owned subsidiary of Pfizer. Other prior experience includes: Associate Professor of Pediatrics in the Division of Pediatric Infectious Diseases, Vanderbilt University School of Medicine, Director of the Diagnostic Virology Laboratory at Vanderbilt University Hospital.

Certification and credentials: Board certified in Pediatrics and Pediatric Infectious Diseases, Fellow of the American Academy of Pediatrics, member of the Society for Pediatric Research, Fellow of the Infectious Diseases Society of America, and member of the American Society for Microbiology.

Consultant/reviewer: NIAID, PATH, the Gates Foundation, and scientific journals.

Education: BA , Mathematical Sciences, Rice University, Houston, Texas, MD. Baylor College of Medicine, Houston, Texas, Pediatric residency, chief residency, and pediatric infectious disease fellowship, Baylor College of Medicine.

Authorship/co-authorship: 140 research articles and numerous invited articles and book chapters.

## Ruxandra Draghia, M.D., Ph.D.

### *Vice President, Public Health and Scientific Affairs*

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Ruxandra Draghia was appointed vice president of Public Health and Scientific Affairs – Global Vaccines in June 2017. Ruxandra is responsible for both developing and championing public health strategies that leverage innovations in vaccine science. She serves as a strategic partner, providing high-quality medical expertise to our Vaccines teams around the world and helping them differentiate our vaccines as innovative. Ruxandra maintains partnerships with the international scientific community and contributes to our mission of helping to improve public health in a collaborative, responsible and commercially successful manner.

Prior to her appointment in Global Vaccines, Ruxandra served as deputy director general for the thematic directorates in the area of Research & Innovation at the European Commission (EC). Prior to this assignment, Ruxandra was responsible for the strategic orientation and management of the Directorate for Health Research, establishing health-related research and innovation priorities, and providing support for policy issues. In these roles, Ruxandra worked with governmental and non-governmental organizations, patient organizations, and small and large industry, as well as working on novel funding programs. During her tenure with the EC, Ruxandra contributed considerably to the successes of the Directorate for Health Research.

Before joining the EC, Ruxandra worked in biotechnology companies as a vice president managing research programs in the areas of gene therapy and DNA vaccination and spent nearly 20 years as a medical doctor and researcher in Romania, France and the United States.

Ruxandra holds both M.D. and Ph.D. degrees in human genetics from the University Carol Davilla in Romania, and she participated in a fellowship program in the Genetics and Metabolic Pathology Department at René Descartes University in France. She completed her post-doctoral training in molecular biology at Baylor College of Medicine in the United States.