



EMERGING LEADERS IN BIOSECURITY CLASS OF 2012

This government funded initiative was launched in 2012 under the leadership of the program's Executive Steering Committee with support from the Center for Biosecurity of UPMC and CENTRA.

For more information, please visit www.emergingbioleaders.org

Contents

	Page
Welcome Statement from Andrew C. Weber, Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs	1
Building the Next Generation of Biosecurity Leaders <i>Ann Norwood, Program Manager, and Nidhi Bouri, Deputy Program Manager</i>	5
Class of 2012 Fellows	6
Executive Steering Committee	33
Center for Biosecurity of UPMC and CENTRA	34
Spring Meeting 2012: An Inside Look at Biosecurity Policy	38
Fall Meeting 2012: Putting Policy into Practice	43
Fellows' Perspectives on Practical Problems in Biosecurity	47
Behind the Scenes in Biosecurity with Leaders in the Field: <i>Interactive Seminars and Video Interviews</i>	60
A Great First Year <i>Tom Inglesby, Program Director, and Anita Cicero, Deputy Director</i>	62



“We must come together to prevent, detect, and fight every kind
of biological danger—whether it is a pandemic like H1N1,
a terrorist threat, or a treatable disease.”

President Obama, United Nations General Assembly, September 22, 2011

A UNIQUE AND INSPIRING EFFORT

This year, under the leadership of the Center for Biosecurity of UPMC, the Emerging Leaders in Biosecurity initiative was launched with outstanding success. The inaugural class of fellows selected for this program represent the best and the brightest. They have diverse experiences, hailing from institutions of learning, scientific laboratories, the federal government, local emergency response programs, and the private sector—backgrounds that will be crucial for building strong, effective capacity for global biosecurity in the years ahead.

This year, our fellows have had unprecedented opportunities to interact with senior leaders in public health, defense, homeland security, biopharma, think tanks, and beyond. They have walked the halls of the Pentagon, the US Capitol, and our premiere national laboratories to gain in-depth knowledge of US and global biosecurity efforts, and they have engaged the field with their own ideas.

I am confident the class of 2012 fellows will lead the way to a more secure future by implementing President Obama's vision under our *National Strategy for Countering Biological Threats*. This critical program will ensure that our next generation of leaders will be well-connected and prepared for this important work, which will make our world safer and more secure.

Moving forward, we are identifying our 2013 fellowship class, and we will ensure that alumni fellows will help shape and direct the program in the future. We expect that the fellows will remain closely in touch as they continue to develop their careers in the months and years ahead.

I am delighted to be a part of this unique and inspiring effort, and I look forward to remaining closely involved with the program as it grows.



ANDREW C. WEBER

*Assistant Secretary of Defense
for Nuclear, Chemical, and
Biological Defense Programs*

EMERGING LEADERS IN BIOSECURITY CLASS OF 2012









Building the Next Generation of Biosecurity Leaders

Ann Norwood, MD, Program Manager, and Nidhi Bouri, MPH, Deputy Program Manager

The Emerging Leaders in Biosecurity Initiative is a competitive program that was designed to create and sustain an energetic, multidisciplinary, and intergenerational community of motivated professionals in the field. In this inaugural year, 25 applicants who hailed from a wide variety of academic and professional disciplines were selected to participate as fellows.

Our goal was to create a rich array of experiences through which fellows would be able to deepen their expertise in biosecurity, expand their professional contacts, build leadership skills, and forge a network of lasting professional relationships. The response of the first-year fellows suggests that we succeeded.

As we look back on this inaugural year, we are impressed with the collective achievements of those chosen to be fellows—they brought a lot to the table—and we are grateful for the involvement and many contributions of the initiative's Executive Steering Committee members. The success of the first year reflects the enthusiasm of the fellows and the dedication of the Executive Steering Committee.

Through their participation at the spring meeting in Washington, DC, the fall meeting in San Francisco, and in the online forums, the fellows were exposed to new information,

professionals, and policy problems, and they eagerly contributed innovative ideas in their discussions with leaders. They also learned about a variety of professional pathways and opportunities to address important issues in biosecurity, and they exchanged ideas and resources with their peers. We think it is safe to say that all who participated in the program this year grew as a result of their experience.

The Executive Steering Committee members have been supportive from the start. Steering Committee members extended a warm welcome to the fellows by making themselves available for one-on-one talks, participating in the spring and fall meetings, and arranging tours of the Pentagon and Lawrence Livermore National Laboratory. The experiences they offered the fellows were invaluable, as was the guidance and insight they provided to us as we strove to develop a program that can help advance US biosecurity practice and policy.

This first year was deeply gratifying, and we enjoyed working with the fellows who were entirely new to the field and the seasoned professionals with whom we were privileged to collaborate throughout the year. We look forward to working with next year's class and the alumni, as we all strive to ensure that the rich field of biosecurity has a deep bench of leaders for the future.

JESSICA APPLER, PHD

Dr. Appler works for the Chemical and Biological Defense Division of the Department of Homeland Security's Science and Technology Directorate and is a Science and Technology Policy fellow with the American Association for the Advancement of Science (AAAS). Her fellowship is focused on developing the next generation of environmental biosurveillance technology. This includes supporting existing programs, participating in interagency work on biological detection technologies, and documenting critical requirements for environmental biosurveillance to lead to rapid response at the federal, state, and local levels. Her biosecurity interests include pandemic and infectious disease threat agents, all-hazards emergency response

and preparedness, synthetic biology and other dual-use research areas, and cutting-edge technology development, adaptation, and testing for biosecurity applications.

Prior to beginning her fellowship, Dr. Appler completed a short postdoctoral fellowship and earned her PhD in neurobiology at Harvard Medical School. Her research used molecular biology and systems-level genetic analysis to understand how the auditory system develops normally and how this pattern of development is disrupted in some hereditary deafness syndromes. She received a BS in biochemistry from the University of Southern California, with a minor in architecture.



“This program provided an excellent opportunity to build lasting relationships with the best and brightest future leaders in biosecurity. We also had the unique privilege of discussing our perspectives on how to address pressing biosecurity issues with the current leaders in the field.”



PATRICK AYSCUE, DVM

Dr. Ayscue graduated from Cornell University College of Veterinary Medicine in May 2012. His dissertation research involved mathematical modeling of transmission and propagation of zoonotic diseases, with an emphasis on indirectly transmitted pathogens. Dr. Ayscue then began a year's study to complete a PhD in epidemiology.

Dr. Ayscue earned his bachelor's degree in biology and environmental studies at Emory University, and then worked under the auspices of the Luce Scholars Program with the Wildlife Conservation Society in Cambodia. There, he studied

the impact of wild and domestic animal health on conservation efforts in the region and to established surveillance networks for avian influenza virus. He has also worked as a visiting scientist at the Pasteur Institute, studying a large hepatitis C epidemic in Egypt. Currently, he is completing a fellowship at the National Academy of Sciences in Science and Technology Policy. Mr. Ayscue anticipates applying his experience to a career in protecting the public's health and ensuring biosecurity.



STEFANIE BUMPUS, PHD

Dr. Bumpus is a science and technology policy fellow with the American Association for the Advancement of Science, and she works in the Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs at the US Department of Defense. She currently serves in the OASD/NCB-Office of Threat Reduction and Arms Control, supporting the DoD Cooperative Biological Engagement Program. In this role, Dr. Bumpus works in the area of global health security, with a regional focus on sub-Saharan Africa and India. Dr. Bumpus works with US government departments and agencies, international organizations, and partner country governments to strengthen human and animal health programs and ensure

partner countries are safe from biological threats, whether naturally occurring or of intentional release.

Dr. Bumpus received a BS in chemistry from the University of Louisville (KY) in 2005, graduating *summa cum laude*. Prior to beginning her fellowship, Dr. Bumpus earned a PhD in chemistry in December 2009 at the University of Illinois at Urbana-Champaign (IL), where she studied the biosynthesis of microbial natural products. She has published in the areas of biochemistry, microbiology, and analytical chemistry and has presented her research at multiple national and international meetings.

HILLARY CARTER, PHD

Dr. Carter is a program officer for the Biosecurity Engagement Program at the US Department of State. In this role, Dr. Carter oversees health security programs to reduce biological risks in South and Southeast Asia. Dr. Carter works closely with foreign counterparts, US government interagency, nongovernmental organizations, and international organizations to implement programs that strengthen global biosecurity.

Dr. Carter joined the State Department as a Science and Technology Policy fellow through the American Association for

the Advancement of Science. Before that, she received a PhD in cell and developmental biology at Vanderbilt University, where she studied intracellular transport during early development. She also holds a BS in neuroscience with a minor in Spanish from Vanderbilt. Dr. Carter's interests include international disease surveillance, science diplomacy, global health security, and dual-use technologies.



SHEANA CAVITT, MS

Ms. Cavitt is Senior Associate in PricewaterhouseCoopers' Washington Federal Practice Advisory group. Her primary area of expertise is biological attack response and recovery analysis for government and private sector clients. Her work has aided a number of clients in improving biological response processes through antibiotic prepositioning strategies, biodefense framework development, and end-to-end response and recovery planning. She has also been a thought leader in the area of biosurveillance and has an interest in improving intelligence and interdiction capabilities.

Ms. Cavitt has experience in the international public health and nonprofit sectors as well. Prior to joining PwC, she worked at Scitor Corporation, where she conducted a biosurveillance program review for a government agency and served as executive secretary for a panel on strategy to counter biological threats, and she studied human performance modification for the Office of the Secretary of Defense for Net Assessment.

Ms. Cavitt received a BS in biology from Furman University and a master's degree in biohazardous threat agents and emerging infectious diseases from Georgetown University.





ANGELA FOWLKES, MPH

Ms. Fowlkes joined the Emerging Leaders program as a graduate student at the University of Alabama at Birmingham School of Public Health, and she earned her MPH in May 2012. Her studies focused on emergency management and disaster preparedness policy in healthcare. She worked at Biolife Plasma Services, a division of Baxter Bioscience that focuses on providing life-saving therapies to patients with immune disorders. Ms. Fowlkes is an American Schools of Public Health fellow with the Department of Transportation.

Ms. Fowlkes earned a BS in biology from Alabama State University in 2007, where she was a Minority Access

to Research Careers (MARC/U*STAR) scholar. Her undergraduate research focused on characterization of myosin light chain kinase isoforms in intestinal epithelial cells and their role in bacterial infections. She won Alabama State University's Student of the Year award in the department of biological sciences (2002 to 2007).

Ms. Fowlkes was a Ronald E. McNair scholar at the University of Alabama at Birmingham in 2006, where she conducted research on a new method for dissection of virulence pathways by monitoring protein-protein interactions in *Mycobacterium tuberculosis*.



ASHLEY GRANT, PHD

Dr. Grant received her bachelor's degrees in chemistry and business economics and management from the California Institute of Technology in 2006. She graduated with a PhD in experimental pathology and an MPH in epidemiology from the University of Texas Medical Branch, where her studies focused on viral hemorrhagic fevers under the direction of Dr. CJ Peters. Dr. Grant conducts research in a biosafety level (BSL)-4 laboratory, the highest level of containment. She has also conducted field studies in remote locations in South America.

Dr. Grant is interested in biosecurity issues related to dual-use research and rules and regulations governing research with select agents.

“I think the most rewarding part of the Emerging Leaders in Biosecurity Initiative was meeting the other fellows. I learned about potential career paths and see most of them on a frequent basis at meetings, lectures, and activities surrounding biosecurity.”

HAROUN HABIB, MPH

Mr. Habib joined the Emerging Leaders program as an ASPH/ CDC Allan Rosenfield Global Health fellow with CDC Zambia, where he is focused on global program management. Prior to joining CDC Zambia, Mr. Habib worked as a policy support officer at the Office of the US Global AIDS Coordinator, US Department of State, as a communications specialist for an international development consulting firm, and as an analyst at a state public health nonprofit organization, where he supported public health preparedness and hospital preparedness policy initiatives and program activities.

Mr. Habib earned an MPH with a concentration in international health from Boston University School of Public Health in 2007, and a BS in health policy and administration from University of North Carolina Chapel Hill in 2004. He has experience with a diverse range of health policy issues on the local, state, national, and global levels, including HIV/AIDS, health disparities and minority health, injury prevention and control, and refugee health and human rights. This professional background has enabled Mr. Habib to develop an interest in exploring the synergy between global health and biosecurity, particularly in the policy arena.

“This program was important to me because it showed me the importance of the biosecurity aspects of the global health agenda such as disease surveillance and drug resistance and their broad effects in US efforts globally.”





“This fellowship was most beneficial in that it provided the opportunity to network with biosecurity professionals in a variety of stages of their careers. Even within the biosecurity field, there were clearly diverse interests, and I appreciated meeting professionals from different levels of government, academia, and the private sector. I hope to maintain and expand upon these contacts throughout my career.”

KATHARINE HAGEN, MS

Ms. Hagen works in the Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs on cooperative threat reduction oversight in the OASD (NCB)-Office of Threat Reduction and Arms Control. In addition to working on cooperative threat reduction, she is also involved with biosurveillance efforts.

Previously, Ms. Hagen was a presidential management fellow in the DHS Office of Program Analysis and Evaluation. She also served as an intern in the homeland security and counterterrorism program of the Center for Strategic and International Studies.

Ms. Hagen earned an MS in biohazardous threat agents and emerging infectious diseases from Georgetown University in 2010 and a BA in biochemistry from Occidental College in 2007. Before entering graduate school, she conducted laboratory research at City of Hope in Duarte, CA, and at the University of Leiden in the Netherlands, and she co-authored 5 peer-reviewed articles in biochemistry and molecular biology. Ms. Hagen is interested in a range of biosecurity topics, including international efforts to reduce the risk of infectious diseases, legal issues related to biosecurity, and the implications of advancements in synthetic biology.

CAROLYN HALL, PHD

Dr. Hall is a biodefense analyst with the Biodefense Knowledge Center at Lawrence Livermore National Laboratory (LLNL).

In that capacity, she researches, develops, and writes in-depth threat- and capability-based technical assessments and awareness bulletins that provide technical analyses of the dual-use potential of emerging biotechnologies.

Before joining the Biodefense Knowledge Center, Dr. Hall completed a postdoctoral fellowship at LLNL, during which she studied bioprospecting of an acid and heat tolerant bacterial

community for novel enzymes of industrial importance, including cellulases and lipases. In 2002, Dr. Hall was awarded a post-baccalaureate Intramural Research Training Award fellowship at the National Institutes of Health in Bethesda, MD.

She earned her PhD in microbiology and immunology from Stanford University in 2009, where she completed research that identified proteins involved in the invasion of host cells by the protozoan parasite, *Toxoplasma gondii*. Dr. Hall earned a BA in biology, with honors, from West Virginia University in 2002.





“This fellowship provided unique opportunities to meet and work with key biosecurity leaders and gain an understanding of the process for biosecurity policy formation that would have taken years to acquire outside of this fellowship.”

NICHOLAS KELLEY, PHD

Dr. Kelley is a research associate for the BioWatch program and is Preparedness Program Coordinator at the Center for Infectious Disease Research and Policy (CIDRAP) at the University of Minnesota. He researches, writes, and updates overviews on potential agents of bioterrorism and works on pandemic preparedness, concentrating his research on vaccines and on supply chain vulnerabilities. Dr. Kelley is passionate about preparing for emerging infectious disease threats and ensuring that the public health policy for those threats is evidence-based.

Before joining CIDRAP in his current position, Dr. Kelley was a research assistant and an assistant project director for the organization’s Comprehensive Influenza Vaccine Initiative.

He also is a member of the University of Minnesota’s Medical Reserve Corp.

Dr. Kelley earned both of his graduate degrees from the University of Minnesota. His 2011 PhD in environmental health followed completion of a thesis that evaluated the public health impact of influenza vaccines, and his 2008 MS in environmental health was awarded following completion of a thesis that examined the cascading effects of a severe pandemic on electrical power in the United States. He has a BA in biology from Luther College, where he researched the effect of calcium on the capsular polysaccharides levels of *Vibrio parahaemolyticus*.

LUIS MARTINEZ, MD, MPH

Dr. Martinez is president and CEO of Xyrion Medical, a biomedical consulting firm and provider of preventive, occupational, and travel medicine services in Puerto Rico. He is also a clinical instructor at the Ponce School of Medicine. As part of his clinical responsibilities, Dr. Martinez is actively involved in the tuberculosis and infectious diseases screening program headed by the Puerto Rico Health Department.

Dr. Martinez completed his residency in occupational and environmental medicine at the University of Pennsylvania.

He earned both his MD and MPH from the Ponce School of Medicine. He speaks 4 languages: English, Spanish, basic Mandarin, and Farsi.

In the realm of biosecurity, Dr. Martinez is particularly interested in technological advances, regulations, and accessibility of information that could grant hostile parties access to a wider array of biological weapons.



MICHAEL MONTAGUE, PHD

Dr. Montague is a staff scientist in the Department of Synthetic Biology and Bioenergy of J. Craig Venter Institute (JCVI). He works on several different projects, including application of proteomics to support the minimal-genome project, extension of methods used in the synthetic cell to nonmycoplasma, and application of synthetic biology techniques to drug discovery. Dr. Montague also worked on several aspects of the 2010 effort to create a synthetic cell, including quality control to confirm the sequences of various stages of assembly of the synthetic cell's genome. He also designed the watermarks that were encoded

into the synthetic genome and the system by which they were encoded.

Prior to joining JCVI in 2005, Dr. Montague earned his doctorate in the laboratory of Clyde A. Hutchison III, studying evolution and protein families, and completing a dissertation on functional phylogeny of protein families. He received a BS in biochemistry from the University of Dallas. Dr. Montague's interest in biosecurity stems from the confluence of his knowledge of the emerging field of synthetic biology and his long-time fascination with military history, strategy, and tactics.



“The chance to listen to and share ideas with members of the biosecurity community through this fellowship opened a cornucopia of professional opportunities to me. It has also dramatically evolved my understanding of the sheer scope of the topic of biosecurity. This evolved understanding is a result of the marvelous job that the Center for Biosecurity of UMPC does introducing the fellows to individuals from the amazingly diverse organizations that have an interest in the field of biosecurity, including the Diplomatic Corps, DoD, DHS, CDC, NIH, NAS, the intelligence community, several national labs, universities, think tanks, NGOs, and private firms. This diversity of perspectives, opinions, and experience spanning the worlds of science, policy, medicine, law, and defense all focused upon the subject of biosecurity is a resource that, likely, is not duplicated anywhere in the world. I feel privileged to have been a part of it, and I am certain that it has already changed my career and will continue to do so.”

“The Emerging Leaders in Biosecurity fellowship provided us with access to very competent, experienced individuals who are leaders in the field of biosecurity. We were able to engage them in informal settings, ask meaningful questions, and carry out thoughtful discussions. If the goal of this fellowship was to motivate us to contribute to the field of biosecurity or keep the issues on our mind as we advance in our careers, then it most definitely succeeded. Overall, this was a fantastic experience, and I know that I will embrace this new network for years to come.”



RAKESH RAGHUWANSHI, MPH

Mr. Raghuwanshi is an interdisciplinary scientist at the US Food and Drug Administration, where he helped launch the medical countermeasures (MCM) initiative. He currently manages the MCM regulatory science project portfolio, which incorporates novel scientific advances into the medical product review process to make product development more efficient and predictable.

Prior to joining FDA, Mr. Raghuwanshi studied taste sensation and adaptation in drosophila at the Johns Hopkins Center for Sensory Biology; he created a grant management system at the Baltimore City Health Department; and he conducted clinical

research at Premiere Oncology in southern California. He currently serves as a reviewer for the peer-reviewed journal *Diabetes Technology and Therapeutics*, and he has international field experience in improving rural communities' access to health care.

Mr. Raghuwanshi's interests in biosecurity include disaster preparedness and mitigation and leveraging innovative technologies to strengthen and speed up MCM development and approval.

Mr. Raghuwanshi received a BA in economics from UCLA in 2006 and an MPH from Johns Hopkins University in 2009.



PATRICK ROSE, PHD

Dr. Rose is a senior analyst at the Center for Health & Homeland Security, where he works on the Homeland Security Exercise and Evaluation Program. He also provides subject matter expertise for international delegations through the Senior Crisis Management Seminars in collaboration with the US Department of State, Office of Anti-Terrorism Assistance. Dr. Rose contributes expert analyses on public health-related issues and policy perspectives as an infectious disease expert. He also holds an adjunct assistant professor position at the University of Maryland School of Medicine, Department of Epidemiology and Public Health. Previously, Dr. Rose worked at the National Institutes of Health and the Los Alamos National

Laboratory. Most recently he was a National Research Service Award postdoctoral fellow at the University of Pennsylvania. His research focused on understanding the biology of insect-transmitted viruses, which contribute to morbidity and mortality worldwide and are a serious public health burden.

Fluent in German and French, Dr. Rose was named to the top 100 International Academics in 2011 by the German Scholars Organization and the President of Germany. He holds a BS in biological sciences from Clemson University, and a PhD in microbiology and immunology from Oregon Health & Sciences University.

SARA RUBIN, MA, MPH

Ms. Rubin is a program analyst at the National Association of County and City Health Officials (NACCHO). She serves as project lead and manages day-to-day duties for 2 projects—Alternative Methods for Antiviral Dispensing and the Nurse Triage Line—both of which are funded by CDC for exploration of various models for efficient and effective distribution of antivirals to the public during a pandemic.

Before joining NACCHO, Ms. Rubin was assistant director of research at the Bipartisan WMD Terrorism Research Center, where she collaborated with advisors to research and write sections of the Bio-Response Report Card. She gained policy and communications experience while at the Presidential Oil Spill Commission and the Commission on the Prevention of WMD Proliferation and Terrorism. She also worked at the

Federal Emergency Management Agency, where she focused on interagency planning to dispense medical countermeasures after an anthrax attack.

Ms. Rubin earned an MPH and an MA in international affairs in 2011 at George Washington University. She co-authored the manuscript “Effectiveness of mHealth Behavior Change Communication Interventions in Developing Countries: A Systematic Review of the Literature,” which was published June 2012 in the *Journal of Health Communication*. She received a BA/BS in political science and journalism, *magna cum laude*, from the University of Florida in 2009. In 2008, she served as a gubernatorial fellow at the Florida Division of Emergency Management. Ms. Rubin’s primary interest in biosecurity lies in public health preparedness and community resilience.

“This was a great opportunity to meet peers in the field who are interested in a broad array of specialties within biosecurity. I gained a greater network of professionals in my field, knowledge about many areas of biosecurity, and a renewed sense of belonging and continued interest in the field of biosecurity.”



YULIYA SELDINA, MPH

Yuliya Seldina is a doctoral candidate at Uniformed Services University of the Health Sciences, where she is investigating the in vivo progression of *Bacillus anthracis* in Dr. Alison O'Brien's laboratory.

Before she began her graduate studies, Ms. Seldina was an intern analyst for the Center for Biosecurity of UPMC, where she conducted research in support of Center projects.

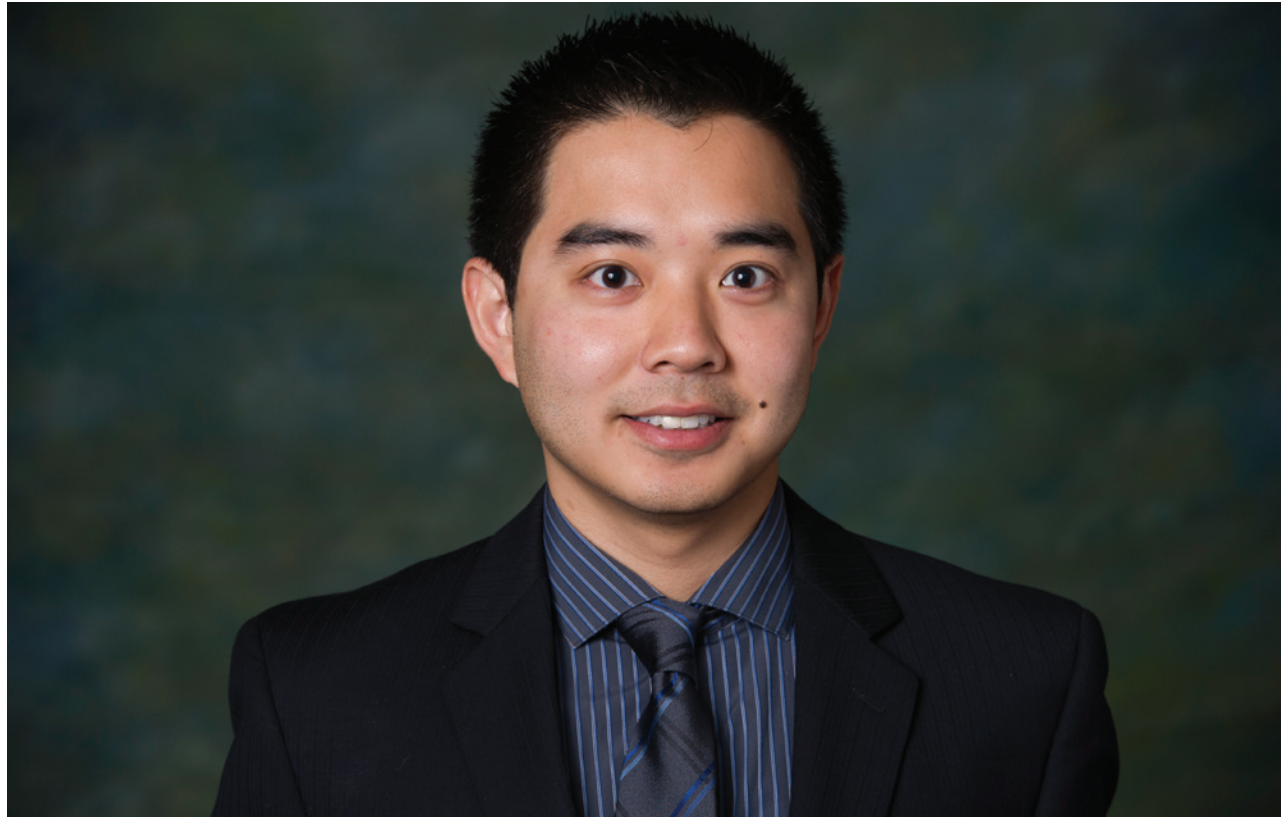
Ms. Seldina earned an MPH in infectious disease and microbiology at the University of Pittsburgh. Her thesis explored the effects of FDA-approved organic compounds on *Mycobacterium tuberculosis*, with a specific focus on the effect

of Epigallocatechin gallate and its potential therapeutic use. Ms. Seldina received a BS in microbiology from Wagner College in 2009, following completion of a thesis on the effect of oscillating magnetic/electrical fields on human pathogens. As a student, she was certified as a lead-based paint inspector and performed lead testing in New York City public schools.

Ms. Seldina emigrated from Lithuania to the United States in 2001. She is fluent in English, Russian, and Lithuanian. With her strong background in infectious disease and public health, Ms. Seldina would like to pursue work in intelligence and/or biosecurity policy and guidelines.



“I was not fully aware of the depth of the field of biosecurity before I joined this fellowship. The fellows I met come from different educational backgrounds and work for a variety of agencies throughout the government and other sectors. It was wonderful to be able to interact with such an amazing group of people who are more than willing to help me find my niche in the field.”



CALVIN SIOW, MS

Mr. Siow is a program coordinator for the department of international health at Georgetown University. He manages the Practical Experience Abroad Program, where he supervises undergraduate students conducting social science and policy-based international health research at health institutions around the world, and he coordinates logistical support with host institutions and collaborating researchers. Mr. Siow is also a research assistant concentrating on global health and international development, and a consultant for the World Bank, in which capacity he assists with review of a public-private global health program.

Mr. Siow is currently pursuing a master's degree in biohazardous threat agents and emerging infectious diseases at Georgetown University, where he is focusing on global health security, national biosecurity, and infectious disease agents. He earned his BS in international health from Georgetown University in 2009. As an undergraduate, he researched the health, socioeconomic, educational disparities, and other challenges faced by Aborigines living on Palm Island, and he presented culturally appropriate, sector-wide approaches to improve public health in the community as part of the Australian government-funded Palm Island Project.



“This fellowship program provided a stimulating forum to exchange and debate ideas, highlight different disciplinary approaches, and tackle present and future challenges in biosecurity. I also enjoyed the opportunity to interact with leaders in the field and to meet other young professionals interested in biosecurity.”

HALLEY SMITH, MS

Ms. Smith is a member of the technical staff in the International Biological Threat Reduction (IBTR) program at Sandia National Laboratories. There, she helps implement US cooperative threat reduction program initiatives within Southeast Asia, leads engagements with China and Indonesia, and is deputy of engagements in Malaysia and the Philippines. Ms. Smith manages IBTR’s internal database, and she is assisting the development of similar databases for the International Chemical Threat Reduction program and the International Nuclear Threat Reduction program. In this capacity, Ms. Smith facilitates

technological coordination between the databases and analytical projects and models within her purview. She is also involved with several laboratory-directed research and development proposals.

Ms. Smith earned a master’s degree in biohazardous threat agents and emerging infectious diseases from Georgetown University, and a bachelor’s degree in both Chinese language and art history from Williams College.

ANTHONY TREUBRODT, MS

Mr. Treubrodt is a science and technology analyst within the Weapons of Mass Destruction Directorate of the FBI, where he addresses issues in emerging biotechnologies and biosecurity. Mr. Treubrodt holds a master's degree in strategic intelligence from the National Intelligence University, where he completed a thesis that analyzed amateur biology groups as models for assessing broader biosecurity issues and biotechnology developments. Mr. Treubrodt also serves as a fellow within the Program for Emerging Leaders at the Center for the Study of WMD at National Defense University.

Prior to joining the FBI, Mr. Treubrodt worked as a contract toxicologist and consultant for the Environmental Protection Agency, where he assisted the risk assessment division within the Office of Pollution Prevention and Toxics. Mr. Treubrodt earned his first master's degree in biotechnology with a biodefense concentration in spring 2007 from Johns Hopkins University. He received a bachelor's degree in biophysics in 2005, also from Johns Hopkins. As an undergraduate Woodrow Wilson fellow, he researched and published on thermodynamics of protein-protein interactions within bacterial cell membranes.





RENEE D. WEGRZYN, PHD

Dr. Wegrzyn is a lead associate at Booz Allen Hamilton, where she founded and now leads a small team of PhD biologists who provide scientific and strategic support in the areas of biodefense, biosecurity, disruptive technologies, emerging infectious diseases, and synthetic biology to the Defense Advanced Research Projects Agency and other government clients.

Before joining Booz Allen, Dr. Wegrzyn developed multiplex immunoassays and peptide-based disease diagnostics for neurodegenerative diseases in the biotech industry, and she co-edited the forthcoming text *Alzheimer's Disease: Targets for New*

Clinical Diagnostic and Therapeutic Strategies. As an Alexander von Humboldt postdoctoral fellow in Heidelberg, Germany, she studied de novo protein folding at the ribosome, and she learned to speak German, earning the Zertifikat Deutsch.

Dr. Wegrzyn earned a PhD in applied biology with a minor in bioengineering in 2003 from Georgia Tech, where she studied the propagation of prion proteins.

STEPHEN WHITE, MS

Mr. White is Bioterrorism Defense Coordinator for the Miami Bureau of Laboratories, Florida Department of Health. As part of the Laboratory Response Network, the laboratory performs rapid and confirmatory testing for suspected agents of bioterrorism (clinical and environmental) in southern Florida. As part of his duties, Mr. White works with hospital sentinel laboratories, first responders, and law enforcement agencies to help ensure that the laboratory is prepared to respond to an act of bioterrorism in the region. Mr. White is also responsible for laboratory influenza surveillance, rapid screening for tuberculosis, and screening food for contamination with biothreat agents.

Before joining the bureau, Mr. White was a senior microbiologist with the South Dakota State Public Health Laboratory, where

he worked with molecular diagnostic assays, tuberculosis identification, and pulsed-field gel electrophoresis.

He earned a bachelor's degree in clinical laboratory science in 2009 and a master's degree in clinical practice management in 2011, both from Texas Tech University Health Sciences Center in Lubbock. Dr. White's interest in biosecurity lies in the realm of public health preparedness and response to incidents of bioterrorism or naturally occurring pandemics. Because of the unique nature of the public health laboratory, he is also interested in federal regulation and oversight of select agent laboratories.





“This fellowship has been a much richer experience than I could have ever imagined, and it was an absolute privilege to be an ELBI fellow. When I share my experiences with my colleagues and mention a few of the individuals that have shaped biosecurity during the past decades that the fellows have had the opportunity to interact with—the UPMC staff, D. A. Henderson, Richard Danzig, Andy Weber, Ken Bernard, Parney Albright, Tara O’Toole, Randy Larsen (the list goes on)—they hardly believe me! I was surprised to not only learn so much about the state of the art of biosecurity through the fellowship, but also the rich history of the origins of the field and major players. I look forward to a continued relationship with the staff of UPMC, the fellows, and hopefully fellows to come through the alumni network, and have encouraged several of my staff to apply next year.”

JAIME YASSIF, MA

Ms. Yassif is a doctoral candidate in the biophysics group at UC Berkeley. For her thesis, she is using fluorescence microscopy to study the nuclear pore complex, which controls the transport of materials between the cytoplasm and nucleus in eukaryotic cells.

Before starting her graduate studies, Ms. Yassif worked for several years in science and security policy at the Federation of American Scientists, where she helped write Congressional testimony on radiological weapons. She also worked at the Nuclear Threat Initiative, where she organized an international workshop on Global Best Practices in Nuclear Materials

Management. This was followed by a fellowship to study China’s nuclear posture at Tsinghua University in Beijing.

Ms. Yassif holds an MA in science and security from the War Studies Department at King’s College London, where she wrote her thesis on verification of the Biological Weapons Convention. She received a BA in biology from Swarthmore College. Ms. Yassif’s biosecurity interests include evaluation of microbial forensics as a tool for bioterrorism prevention and enhancing international biosecurity cooperation through work with practitioners in Asia. Ms. Yassif speaks Hebrew, Chinese, and French.

“The ELBI program provided me with greater insight into the perspectives of health professionals, scientists, and other non-attorneys both inside and outside government. As an attorney without experience in scientific research, I have found these perspectives to be extremely valuable to my biosecurity-related legal and policy work. In addition, the leaders of the program have been extremely generous with their time and advice, which I will always sincerely appreciate.”

DAVID AARON, JD

Mr. Aaron is an attorney in the US Department of Justice National Security Division, Office of Law and Policy. His responsibilities include biosecurity and security screening policy, among others.

Mr. Aaron has worked on a variety of legal and policy matters relating to national security operations, programs, and oversight, and he served as Special Assistant United States Attorney in the Eastern District of Virginia. Prior to joining the Department of Justice in 2005, Mr. Aaron was Assistant District Attorney in Manhattan.

Mr. Aaron received his JD in 2000 from Fordham University School of Law. As a law student, he published a student note focusing on prosecutorial ethics, served on the editorial board of the Law Review and Moot Court Board, and was a Stein Scholar in Public Interest Law and Ethics. He received his BA from the College of Social Studies at Wesleyan University in 1995.

BRENDAN THOMASON, PHD

Dr. Thomason is a senior analyst in the US Department of Defense. He works with a group that focuses broadly on emerging and disruptive medical technologies and countermeasures for important infectious diseases and CBRN agents. Previously, he was a scientist at the Naval Medical Research Center, where he studied genomics of biodefense-relevant pathogens in Dr. Timothy Read's group.

Dr. Thomason earned a PhD in microbiology and immunology in 2005 from the University of Michigan. His dissertation research was performed in the lab of Dr. Philip Hanna and focused on the pathogenesis of *Bacillus anthracis*. He received a BS in microbiology from Indiana University in 1999. Dr. Thomason's interest in biosecurity grew from his experiences with the Department of Defense's Cooperative Threat Reduction program, which led him to appreciate the potential rewards of science diplomacy. He looks forward to engaging on that issue along with public health in general in the future.

“For me, the best part of the Emerging Leaders in Biosecurity fellowship was forming new relationships—with both the Center staff and the fellows—with tremendously bright individuals who have vastly different backgrounds but care deeply about a truly significant issue. I think, sometimes, our day jobs can feel like an echo chamber, and this fellowship program has helped me break away from my own biases and think more broadly about what biosecurity means.”

“I wish ELBI existed when I entered the field. A program that enables the fellows to meet with the top leaders in government and industry, and develop strategic perspectives on the challenges and opportunities of biosecurity and a network that will last a lifetime makes this an extraordinary opportunity for the fellows and a great return on investment for the biosecurity community.”

*Col. Randall J. Larsen, USAF (Ret.),
Founding Director, WMD Center*







Randall J. Larsen



Luciana Borio



Bonnie Jenkins



John Grabenstein



Tara O'Toole



Parney Albright

Members of the Executive Steering Committee are senior leaders in US biosecurity and biodefense who collectively work or have worked in all branches of the US government, in private industry, and in academia. Their expertise and experience makes this body uniquely suited to offer guidance as we work to develop the nation's next generation of leaders in biosecurity.

EXECUTIVE STEERING COMMITTEE

Parney Albright, PhD, *Director, Lawrence Livermore National Laboratory*

RADM Kenneth W. Bernard, MD, USPHS (Ret.), *Special Assistant to the President for Homeland Security, Health, Security and Biodefense Affairs*

Luciana Borio, MD, *Assistant Commissioner for Counterterrorism Policy, FDA*

Richard Danzig, PhD, JD, *Chairman of the Board, Center for a New American Security*

David Franz, DVM, PhD, *Former Commander, USAMRIID*

John Grabenstein, PhD, COL, USA (Ret.), *Senior Medical Director for Adult Vaccines, Merck*

Jo L. Husbands, PhD, *Scholar/Senior Project Director, Board on Life Sciences of the US National Academy of Sciences*

Ambassador Bonnie Jenkins, PhD, JD, *Coordinator for Threat Reduction Programs, US Department of State*

Robert Kadlec, MD, *Former Special Assistant to the President for Homeland Security and Senior Director for Biological Defense Policy, Homeland Security Council, The White House*

Lawrence Kerr, PhD, *Deputy Director of Global Biological Threats, Office of the Director of National Intelligence*

RADM Ali Khan, (Ret.) MD, MPH, *Director, Office of Public Health Preparedness and Response, CDC*

Col. Randall J. Larsen, USAF (Ret.), *Founding Director, WMD Center*

Tara O'Toole, MD, MPH, *Under Secretary for Science & Technology, DHS*

James B. Petro, PhD, *Principal Director, Chemical and Biological Defense, OASD (NCB/CB)*

Alan Rudolph, PhD, MBA, *Director, Chemical and Biological Defense Directorate, Defense Threat Reduction Agency*

Andrew C. Weber, *Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs*

EX-OFFICIO MEMBERS:

William P. Hostyn, *Director, Advisory Committees and Programs Office, Defense Threat Reduction Agency*

William O'Donnell, *Director, Intelligence Plans and Resource Integration, Defense Threat Reduction Agency*

Stephen J. Polcheck, *Deputy, Advisory Committees and Programs Office, Defense Threat Reduction Agency*



Center for Biosecurity of UPMC

The Center for Biosecurity is an independent nonprofit organization of UPMC.

Our mission is to strengthen U.S. national security and resilience by reducing dangers posed by epidemics, biothreats, nuclear disasters, and other destabilizing events.

Our staff comprises experts in medicine, public health, national security, law, economics, the biological and social sciences, and global health.

Emerging Leaders in Biosecurity Program Staff

While several of us work on the Emerging Leaders in Biosecurity Initiative on a daily basis, virtually everyone in the Center has helped pitch in by providing ideas, contributing to meetings, reviewing papers, and advising fellows on their paper presentations.

Center for Biosecurity Program Staff

Program Director: Tom Inglesby, MD, *CEO and Director*

Anita Cicero, JD, *COO, Deputy Director*

Ann Norwood, MD, *Senior Associate*

Nidhi Bouri, MPH, *Senior Analyst*

Matt Watson, *Senior Analyst*

D. A. Henderson, MD, MPH, *Distinguished Scholar*

Gigi Kwik Gronvall, PhD, *Senior Associate*



CENTRA Technology, Inc.

CENTRA is a high-technology business providing security, analytic, technical, engineering, and management support to the government and private sectors. It has been delivering services to a wide range of customers in the security, defense, aerospace, and international communities since 1985.

CENTRA staff members have worked tirelessly to provide program support ranging from note-taking at conferences, videography, development of conference reports, hosting meetings, assisting in meeting management, and, in general, pitching in wherever it has been needed. Thanks, Team CENTRA.

CENTRA Program Staff

Program Manager: Rick Bogusky, *Senior Vice President*

Task Lead: Marybeth Davis, *Analytic Director*

Deborah Toy Lew, *Senior Research Analyst*

Monica Scott, *Senior Research Analyst*

Eileen M. O'Sullivan, *Comptroller*

Erika Van Erikson, *Subcontract Administrator*

Akar Bharadvaj, *Research Analyst*

Becky Dister, *Research Analyst*

Max Slaiman, *Research Analyst*

Jessica Zappia, *Research Analyst*

Albert Bjork, *Associate Research Analyst*

Dustin McCrae, *Associate Research Analyst*



Emerging Leaders in Biosecurity 2012 Events





Spring Meeting 2012: An Inside Look at Biosecurity Policy

Ann Norwood, Program Manager

The first important milestone of the fellowship was the spring meeting convened for the fellows in Washington, DC. We were impressed by the backgrounds of the 25 fellows chosen for the first class and were pleased that the initiative attracted high caliber applicants. The program received a great deal of support from current biosecurity leaders, especially those who readily agreed to serve on the Executive Steering Committee and network with the entering class.

The DC meeting was a success. The fellows actively participated in the many discussions held over the course of the day, and

they enthusiastically engaged with the many expert speakers. Senior leaders talked about their areas of focus and career trajectories with candor, fielded numerous questions, and talked at length with the fellows.

As part of the program, Senate staffers briefed the group of fellows on the types of biosecurity work they engaged in and talked about what it is like to work on the Hill. The day ended with a dinner that provided further opportunity for all of us to get to know one another. The program was off to a great start.



On the second day, the fellows attended the Center for Biosecurity's meeting Improving Epidemic Response: Building Bridges between the US and China. For the fellows interested in international work, this provided a valuable opportunity to observe how nations build reserves of good will through cooperation on such common interests as health, public health, and epidemic response. High level public health officials from both the US and China presented at the meeting. Fellows also attended the networking event immediately after this conference.

On the third day, the Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs invited

the fellows to the Pentagon for a briefing. A personal tour was also provided, during which we heard recollections of the 9/11 tragedy and its impact on the Pentagon. The tour was a fitting reminder of the importance of being able to use science in service to the good and to prevent malevolent use.

We ended the 3-day spring meeting impressed with the new fellows, and our initial impressions were only reinforced by our experiences with this fine group throughout the year.



Spring Meeting Program Agenda | May 14-16, 2012

May 14 | Inaugural Meeting of Emerging Leaders Fellows

- *Biological Threats: Past, Present, and Future:* Randall Larsen, Founding Director, WMD Center
- *Panel Discussion: Can Innovative Developments in Science and Technology Enhance Intelligence?*
 - Gigi Gronvall, Senior Associate, Center for Biosecurity of UPMC
 - Jason Matheny, Program Manager, Intelligence Advanced Research Projects Agency (IARPA)
 - Brad Smith, Homeland Security Advanced Research Projects Agency (HSARPA), Science and Technology Directorate, US Department of Homeland Security
 - Erik Prentice, Assistant Deputy Director for Global Biological Threats, National Counterproliferation Center, Office of the Director of National Intelligence
- *Leading DHS S&T—Challenges Ahead:* Tara O'Toole, Under Secretary for Science and Technology, US Department of Homeland Security
- *Panel Discussion: Biological Weapons Convention, Cooperative Threat Reduction, and International Engagement—Opportunities In Years Ahead*
 - Tom Inglesby, CEO and Director, Center for Biosecurity of UPMC
 - Ambassador Bonnie Jenkins, Coordinator for Threat Reduction Programs, US Department of State
 - James B. Petro, Principal Director, Chemical and Biological Defense, Office of the Assistant Secretary for Defense (NCB/CB), US Department of Defense
 - Jo Husbands, Scholar/Senior Project Director, Board

on Life Sciences, National Academy of Sciences

- *Panel Discussion: Developing Medical Countermeasures: How to Meet the Challenge*
 - Anita Cicero, COO and Deputy Director, Center for Biosecurity of UPMC
 - Luciana Borio, Assistant Commissioner for Counterterrorism Policy, US Food and Drug Administration
 - John Grabenstein, Senior Director for Adult Vaccines, Merck
 - Philip Russell, Former Senior Advisor, Office of the Assistant Secretary for Public Health Emergency Preparedness, US Department of Health and Human Services
- *Biosecurity—Past Adventures and Future Expectations:* D. A. Henderson, Distinguished Scholar, Center for Biosecurity of UPMC
- Capitol Hill Talk with Congressional Staffers

May 15 | Center for Biosecurity Conference

Improving Epidemic Response: Building Bridges between the US and China

May 16 | Pentagon Talk and Tour



Fall Meeting 2012: Putting Policy into Practice

Ann Norwood, MD, Program Manager

The fall meeting in San Francisco was designed to showcase the work of the fellows, expose them to additional leaders in the field, and give them the opportunity to tour the Lawrence Livermore National Laboratory (LLNL). We sponsored a writing competition and offered the winners an opportunity to present their papers at the fall meeting.

One of the fellows, Carolyn Hall, helped plan the group's day at LLNL, where she works. Formal presentations began with a panel on early career scientists' work at LLNL, which Carolyn had organized. Parney Albright, LLNL's director, gave a spellbinding presentation on the evolution of biosecurity following 9/11 and the anthrax attacks, offering his frontline view of policy development at the White House and DHS. In the afternoon, we attended presentations by senior scientists at LLNL, who discussed their work on environmental sensing of threat agents, computational drug design, and environmental decontamination following a bioterrorist attack. We also had an opportunity to tour the LLNL Computational Facility, which houses the world's fastest computer—able to process 20-million billion bytes of data per second.

On the second day, we met in San Francisco for a workshop that included presentation of the winning papers from the writing competition. Jessica Appler, Patrick Ayscue, Sheana Cavitt, Sara Rubin, Michael Montague, and Jaime Yassif gave compelling presentations and fielded questions from the audience.

The Honorable Andy Weber, Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs, shared his perspective on the emerging threat posed by bioagents. We were also fortunate to hear presentations from and discuss a variety of issues in biosecurity with a number of other experts, and then to participate in a brief tabletop exercise, *Viral Storm*, led by Randy Larsen. Colonel Larsen invited the fellows to sort through various policy choices in response to questions for which there were no good answers.

We were grateful for the opportunity to work with this fine group of first year fellows and hope they will be active members of the initiative's alumni network so the goals of the program can be fully realized. Next year's class will certainly benefit from the opportunity to meet and engage with this outgoing class of 2012.



Lawrence Livermore National Laboratory



Fall Program Agenda | September 13-14, 2012

September 13 | Lawrence Livermore National Laboratory

- *Panel Discussion: Early Career Scientists at LLNL*
 - *Developing a Career In Bioinformatics to Solve Problems In Biosecurity:* Jonathan Allen
 - *Distilling the Dualities of Biological Research for Policymakers:* Errett Hobbs
 - *Pursuing a Career in Biosecurity to Meet the Challenges of Emerging and Re-emerging Infectious Diseases:* Amy Rasley
- *The Role of National Labs in Supporting S&T Development for US Biosecurity:* Parney Albright, Laboratory Director, LLNL
- *Biodefense Knowledge Center:* Tom Bates, Director, Biodefense Knowledge Center, LLNL
- *Environmental Sensing of Threat Agents:* Crystal Jaing, Group Leader, Applied Genomics, LLNL
- *Computational Drug Design:* Felice Lightstone, Group Leader, Biosciences and Biotechnology Division, LLNL

Tour of Computation Facility

- *Decontamination After a Bioterrorist Event:* Ellen Raber, Deputy Program Director, Counterterrorism
- *International Scientific Engagement in Biosciences:* David J. Rakestraw, Program Manager, Sciences Program

September 14 | Fellows Seminar

- Fellows' Presentations Round 1

- *Bioforecasting: Incorporating Biosurveillance and Rapid Response:* Jessica Appler
- *Incentives to Revitalize Investment in Antibiotic Development:* Patrick Ayscue
- *Revamping the Bioterrorism State and Local Medical Countermeasure Response System by Engaging the Private Sector:* Sheana Cavitt
- *DIY Bio: What's in Your Garage?* Rob Carlson, Partner, Biodesic
- *Emerging Leaders to Address Emerging Threats:* Honorable Andrew C. Weber, Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs
- *Crossing the Line: Life Sciences Research of Concern in an Age of Revolution:* David A. Relman, Professor of Medicine, and of Microbiology and Immunology, Stanford University School of Medicine
- *Realpolitik of Federal Biodefense Policy:* Ken Bernard, former Special Assistant to the President or Biodefense; former Assistant Surgeon General
- Fellows' Presentations Round 2
 - *Local Use of mHealth Technology for Pandemic Preparedness:* Sara Rubin
 - *What We Don't Know Can Kill Us: Implications of Synthetic Biology to Biosecurity:* Michael Montague
 - *Microbial Forensics for Assessing BWC Compliance:* Jaime Yassif
- *Viral Storm: A Tabletop Exercise:* Randy Larsen, Founding Director, WMD Center

Fellows' Perspectives on Practical Problems in Biosecurity

One of the goals of the Emerging Leaders in Biosecurity Initiative is to elicit fellows' new ideas and proposals for overcoming current and future challenges in biosecurity. To this end, fellows were encouraged to write papers describing innovative approaches to solving as yet unsolved practical problems in the field.

Fellows' Perspectives on Practical Problems in Biosecurity: Paper Abstracts

Bioforecasting: Incorporating Biosurveillance and Rapid Response

Jessica Appler

Incentives to Revitalize Investment in Antibiotic Development

Patrick Ayscue

Revamping the Bioterrorism State and Local Medical Countermeasure Response System by Engaging the Private Sector

Sheana Cavitt

What We Don't Know Can Kill Us: Implications of Synthetic Biology to Biosecurity

Michael Montague

Local Use of mHealth Technology for Pandemic Preparedness

Sara Rubin

Microbial Forensics for Assessing BWC Compliance

Jaime Yassif

Enhancing Personnel Reliability of the Select Agent Program: A User's Perspective

Ashley Grant

Toward Effective Global Program Management of MDR/XTR TB HIV Co-Infection in Low-Income Countries: Implications for Global Health and Biosecurity

Haroun Habib

A Changing World and a New Paradigm for Biosecurity

Nicholas Kelley

Importance of Stopping Science Budget Cuts

Yuliya Seldina

Improving Biosurveillance Coordination and Information Exchange

Calvin Siow

Bioweapon Vaccine Development: Are the Opportunity Costs Too High?

Brendan Thomason

Challenges Facing Reference-level Laboratories Within the Laboratory Response Network

Stephen White

Providing Citizen Scientists the Tools for Self-governance Without Impeding Scientific Curiosity or Progress

Renee Wegrzyn

Bioforecasting: Incorporating Biosurveillance and Rapid Response

Jessica Appler

For more than ten years, substantial investments by the United States government have contributed to development of a national biosurveillance system to enable life-saving response to significant health threats. However, it has become clear that a faster, more nimble system will be needed as the nation moves into the future. In response to this need, the *National Strategy for Biosurveillance* puts forth a plan for an all-hazards, all-of-nation approach to save lives when facing any health incident of potential national significance. One core function of this plan is to promote national and local development and practice of bioforecasting. Bioforecasting is a fact-, model-, and experience-driven process of making informed decisions during uncertain health crisis situations.

Effectively incorporating bioforecasting into existing operations requires systematic changes in decision making standard operating procedures. Recommended changes to support development of bioforecasting capability within a fiscally constrained environment include: incorporating nontraditional information sources, delivering multimodal input in a cohesive manner, and pre-planning flexible decision structures that permit partial action. While bioforecasting can sound like science fiction, these and other changes can translate bioforecasting ideals into operationally useful tools that encourage the consideration of uncomfortable information when detecting, assessing, and rapidly reacting to a biological incident.

Incentives to Revitalize Investment in Antibiotic Development

Patrick Ayscue

Physicians are facing a rising shortage of effective antibiotics that threatens their ability to treat common infectious diseases. The cause of this shortage is two-fold: on one hand, bacterial resistance to current antibiotics is spreading around the globe, and on the other, there is a dramatic decrease in development of novel antibiotics.

Historically, major pharmaceutical companies have been responsible for most development of new antibiotics; however, most of these companies have drastically reduced or altogether eliminated their investments in antibiotic discovery. The reason given is unfavorable cost-benefit ratios,

especially as compared with other drug classes. There is general consensus in the scientific and health communities that interventions are necessary to correct the market failure to incentivize future development of novel therapeutics needed to protect the public's health. The form that these interventions should take has been a source of active debate.

Potential interventions should be carefully evaluated, and it is paramount that public health objectives be aligned with industry incentives in any approach to evaluation.

Revamping the Bioterrorism State and Local Medical Countermeasure Response System by Engaging the Private Sector

Sheana Cavitt

US policy invests state and local governments with primary responsibility for bioterrorism response. Distribution and dispensing of medical countermeasures is the responsibility of state and local public health departments. However, this responsibility is an add-on to the daily duties of US public health departments, which may not have the budgets or trained staff necessary to plan for or execute countermeasure distribution if called upon to do so.

The private sector is recognized as having existing infrastructure that could support these activities if needed. The government should create a structure in which responsibility for medical countermeasure

distribution and dispensing is vested in the private sector, and the US government provides oversight. State and local health departments should focus their efforts on reaching populations that the private sector cannot access, which tend to be the same populations that health departments focus on and reach daily. By removing barriers to private sector leadership in this area, the US government could achieve a unified, cost-effective response plan that may increase the possibility of success in bioterrorism response.

What We Don't Know Can Kill Us: The Implications of Synthetic Biology to Biosecurity

Michael Montague

Two facts ensure that biosecurity will remain an aspect of national defense for the foreseeable future. The first is synthetic biology. In the last decade, technologies that can be used to create and modify the biological properties of organisms have been revolutionized, giving rise to what is broadly referred to as synthetic biology. This revolution has already driven massive improvements in biological engineering by decreasing costs and increasing both ease and speed of engineering and implementing products. Small teams with limited training, conservative budgets, and universally available equipment now routinely use synthetic biology to easily, quickly, and cheaply produce designer organisms with novel characteristics for research purposes. Further, the synthetic biology revolution shows no sign of stopping; it will continue to exponentially accelerate scientific advancement for the foreseeable future. The second is the fact that, in

the United States and allied nations, most practical and empirical knowledge about biological warfare and bioterrorism predates the synthetic biology revolution (indeed, much of our knowledge predates the earliest uses of recombinant DNA technology).

The consequence of these two facts is that even experts in biosecurity and in synthetic biology are uncertain about what shape biological warfare or bioterrorism might take given today's capabilities and much less able to predict the directions biological warfare and bioterrorism will take in the future. This essay explores the danger and causes of this knowledge gap in its historical context. A solution is proposed to systematically improve predictive abilities by producing research that will provide empirical data (as opposed to theoretical speculation) to better understand and characterize modern, post synthetic biology, biological weapons.

Local Use of mHealth Technology for Pandemic Preparedness

Sara Rubin

The use of mobile health technologies, known as mHealth, by local health departments has the potential to improve the efficiency and effectiveness of communicating with the public and dispensing medical countermeasures during large-scale pandemics. Many definitions exist, but one way to describe mHealth is as a platform for use of mobile/wireless devices to improve health outcomes and health services. Such technologies could potentially reduce local preparedness capability gaps created by funding cuts, workforce shortages, and lack of community resilience support.

Emerging infectious diseases pose a strong health security threat to the United States, and the utilization of mHealth in the context of vaccination and immunization interventions has demonstrated potential for increased uptake of vaccine among diverse populations. The increased frequency with which Americans use smartphones coupled with their advanced capabilities provides an opportunity for communicating preparedness information.

Microbial Forensics to Assess BWC Compliance

Jaime Yassif

This paper explores the use of microbial forensics as a possible tool for assessing compliance with the Biological Weapons Convention (BWC), which lacks a verification protocol. Microbial forensics was initially developed as a means of identifying the source of a pathogen dispersed in a biological attack, with the aim of holding responsible parties accountable. However, this approach could be adapted to a variety of BWC inspection activities, including regular mandated inspections, voluntary site visits designed to increase transparency, and rare site visits to investigate allegations of biological weapons development.

This paper proposes a 4-step approach to evaluating the feasibility of using microbial forensics as part of on-site inspections: (1) design equipment to support inspections; (2) address technical challenges and identifying sources of uncertainty; (3) apply lessons learned from nuclear disarmament verification; and (4) assess the efficacy of microbial forensics under a range of inspection conditions.

Enhancing Personnel Reliability of the Select Agent Program: A User's Perspective

Ashley Grant

The National Science Advisory Board for Biosecurity (NSABB) has suggested several changes to the select agent program, including organizing agents into multiple tiers and enhancing personnel reliability. This article analyzes the impact that changes in rules and regulations may have on select agent research and will offer the unique perspective on the new rules—that of a current Biological Select Agent and Toxin (BSAT) user. Finally, suggestions will be made regarding action that could be taken to ensure a reasonable balance between security and the logistics of life science research.

Toward Effective Global Program Management of MDR/XDR Tuberculosis and HIV Co-Infection in Low-Income Countries: Implications for Global Health and Biosecurity

Haroun Habib

Multi-drug resistant tuberculosis (MDR-TB) and extensively drug resistant tuberculosis (XDR-TB), referred to as “Ebola on steroids” by some, collectively pose a significant threat to global health and biosecurity. To date, 77 countries have confirmed at least one case of MDR-TB and/or XDR-TB, and the global burden of MDR/XDR TB cases is sizeable. There is a pressing need to reinforce control, detection, and treatment strategies for this man-made problem. This is especially true for people with HIV/AIDS who are living in low-income countries, such as those in sub-Saharan Africa, where drug-resistant TB is becoming more widespread. The WHO has proposed a comprehensive management strategy it is calling “DOTS Plus,” but many low-income countries do not have the capacity to implement that strategy. When that is the case, global program management is required to provide the rapid detection, infection control, and effective treatment that will be required to meet the goal of eliminating TB by 2050 that has been put forth in the Millennium Development Goals and by the Stop TB partnership.

A Changing World and a New Paradigm for Biosecurity

Nicholas Kelley

In today's “flat world,” the global economy is sustained by just-in-time manufacturing, complex information systems, and global supply chains that enable product delivery to customers around the world at unprecedented speeds and minimal cost. This reality creates unique vulnerabilities, as local or regional natural disasters, pandemics, or political or social unrest that disrupt global supply chains can have significant implications for disaster preparedness and biosecurity.

For instance, many assume that the medical countermeasures (MCMs) necessary to respond to a biosecurity event will be available in sufficient numbers when needed. However, in this flat world there are several ways in which delivery of MCMs could be unintentionally or intentionally disrupted to an extent that could compromise response to a biosecurity event. Preparing in silos for a single extreme event is no longer sufficient. We need to expand preparedness to encompass multiple simultaneous disasters, such as disease outbreaks in which natural disasters and critical infrastructure failures occur at the same time. Biosecurity professionals are in unique roles to lead this effort due to the complexity of biosecurity challenges and the forward-looking, population-based approach to preparedness that drives this discipline.

Importance of Stopping Science Budget Cuts

Yuliya Seldina

Since the 2001 anthrax attacks in the United States, the threat of biological agents has come to the forefront as a major governmental and public health concern, and the importance of biosecurity and biodefense has been made clear. Many advances have been made toward the creation of a nation better prepared to deal with biological attacks, including establishment of the Strategic National Stockpile and enforcement of rapid response plans, but many gaps still remain. These gaps include, but are not limited to, the need for novel therapeutics in the age of antibiotic-resistant pathogens, rapid and efficient detection and diagnostic tools, and improved preventive measures (ie, vaccines).

The solution to most, if not all, of these shortcomings lies within scientific advancements. However, continuing federal budget cuts threaten the ability of the science community to carry out its ultimate mission in the pursuit of new knowledge and technologies. If the situation does not improve, the scientific field will lose efficiency in developing tools necessary in improving the nation's biosecurity capabilities as well as overall progress of the United States as a world leader. Changes must be made in the peer review and funding allocation processes and there is a need for an increased federal investment in the scientific infrastructure.

Improving Biosurveillance Coordination and Information Exchange

Calvin Siow

In July 2012, the United States released its first *National Strategy for Biosurveillance*. The strategy calls for an all-of-nation approach to support the goal of creating a well-integrated national biosurveillance enterprise that would allow for identification, detection,

and information gathering related to biological threats in order to prepare, respond, and mitigate against major biological events. One biosurveillance challenge that the US government has yet to overcome is creation of a federal coordinating entity to integrate the multiple biosurveillance activities across federal agencies and state, local, international, and private partners.

Addressing this challenge requires collaboration across multiple disciplines. Designing, developing, and operationalizing the right team will require careful consideration and planning. This paper addresses key concepts for a small, high-performance and interdisciplinary biosurveillance coordinating team that would provide for efficient exchange of information and provide strategic direction for biosurveillance research and development. A high-functioning team requires an agreed-upon purpose and approach to common performance goals; it should be composed of members with relevant complementary skills who are willing to defer to expertise in delegating responsibilities. Finally, an effective team will collect, consolidate, and share information according to standardized protocols and procedures that provide guidance for different disciplines. This offers guidance for convening and coordinating the activities of various biosurveillance stakeholders.

Bioweapon Vaccine Development: Are the Opportunity Costs Too High?

Brendan Thomason

Although the significance of vaccines in decreasing morbidity and mortality of debilitating illnesses cannot be overstated, their potential benefits for use in biodefense are far less clear. Given current fiscal restraints, it could be argued that vaccine utility is so questionable that diverting financial resources from more worthwhile programs only makes us less prepared for the biological weapons (BW) threat. Questions of utility are related to several key factors: (1) questionable ethics of conducting clinical trials with unknowable risk-benefit ratios; (2) limitations associated with time required to generate a protective immune response following vaccination; and (3) the very real possibility that the efficacy observed in animal models—satisfying regulatory requirements based on the Animal Rule—would fail to be replicated in people. Although the desire to have available biodefense vaccines is reasonable, it appears impractical on closer examination.

Given the uncertainty that would attend a BW event (identification of agent, time of release, etc.), it is not wise to dedicate our limited and diminishing financial resources to invest in solutions that are both agent-specific and timing-critical. Instead, we should focus on supporting capabilities that are far more likely to be used and useful. Specifically, we should increase investments

in intelligence collection and analysis, surveillance, detection, and public health preparedness. Doing so would not only improve our ability to mitigate the effects of a BW event, but also would improve our ability to predict and respond to any biological event. We can be better prepared for a biological attack if we change both our approach to preparedness and our funding priorities.

Challenges Facing Reference-level Laboratories Within the Laboratory Response Network

Stephen White

The Laboratory Response Network for Biological Terrorism comprises 3 levels of laboratories: sentinel, reference, and national. Each level plays a different role in the public health system's response to a potential bioterrorism attack. Reference-level laboratories, often located at the state or regional level, are uniquely situated to positively impact public health preparedness, response, and recovery activities. Reference laboratories are not without their challenges, however. As the years pass without a major bioterrorism event, federal and state funding diminishes to levels barely adequate to sustain current operations. This affects both the actual testing performed by the laboratory and its other critical responsibilities, such as training sentinel laboratories and first responders. Identifying these challenges is the first step to developing solutions to overcome them.

Providing Citizen Scientists the Tools for Self-governance Without Impeding Scientific Curiosity or Progress

Renee Wegrzyn

The emergent communities of citizen scientists, DIY garage biologists, and community labs are the product of unprecedented access to the genetic and molecular tools that enable biological manipulation for research, discovery, and even artistic expression. Decentralization of these tools from large commercial and academic labs into the hands of citizens offers exciting opportunities for learning and entrepreneurship, but it also introduces new vulnerabilities that could result in the accidental release of genetically engineered organisms into the environment. This report outlines the safety strategies implemented by 2 community DIY bio labs and proposes a pre-emptive rather than reactive strategy to engineer and provide the DIY communities with bacterial strains that will propagate only in user-defined, authorized lab conditions. Implementing such a system will significantly reduce the risk of unintentional release and will not hinder scientific curiosity or progress.



“Having worked in biosecurity and biodefense for nearly 20 years, I was truly excited about the young and talented fellows I met in the Emerging Leaders in Biosecurity Initiative. It is through this next generation of national security professionals that our country will be better protected, the people better served, and the skills of leadership successfully fostered both in and out of government. UPMC should be congratulated for promoting and developing this critical program.”

RADM Kenneth Bernard, MD, USPHS (Ret.)

BEHIND THE SCENES IN BIOSECURITY WITH LEADERS IN THE FIELD

Interactive Seminars

Fellows were invited to participate in two webinars, one with Dr. Richard Danzig, and the other with Dr. Ali Khan.



How Do We Prepare for What We Can't Predict?

Richard Danzig, PhD, JD, Chairman of the Board, Center for a New American Security

On August 20, 2012, Dr. Richard Danzig presented this 1-hour webinar in which he shared his conceptualization of the challenges associated with terrorists' use of bioweapons. Specifically, he described bioterrorism as comprising 3 kinds of problems: hard, harder, and hardest, based on the type of pathogen and the area affected by an attack. Dr. Danzig described hard problems as those we've been addressing for years that involve known pathogens. The harder and hardest problems are those of the near and more distant future that may involve unknown and/or synthesized pathogens that may produce limited or widespread disease outbreaks. Dr. Danzig also discussed the types of new solutions needed to address the increasingly complex problem of bioterrorism. After fielding questions and responses to his presentation, he encouraged the fellows to take active roles in solving the problems confronting the nation in biosecurity.



CDC's Office of Public Health Preparedness and Response (OPHPR)

RADM Ali Khan, (Ret.) MD, MPH, Director, OPHPR, CDC

On July 12, 2012, Dr. Ali Khan provided a 1-hour introduction to the role of CDC's OPHPR. Under the National Response Framework, CDC executes public health response activities, and Dr. Khan's office works at all levels of government to facilitate and improve the nation's emergency response infrastructure. Dr. Khan's career in national health security began in 1999, when he helped establish CDC's preparedness program. Dr. Khan also discussed innovations in public health preparedness at CDC.



Video Interviews

Our 2012 video interview series introduced the fellows to 4 senior leaders who offered their observations on basic research in biosecurity, pharmaceutical development and regulation, and preparedness and response policy. Each of the following experts also described how their respective organizations contribute to US biosecurity, and all noted that the interdisciplinary nature of civilian biosecurity and biodefense makes the ability to work collaboratively across multiple disciplines essential to leadership in the field.

Phyllis Arthur, *Senior Director, Vaccines, Immunotherapeutics and Diagnostics Policy, Biotechnology Industry Organization*

Luciana Borio, MD, *Director, Office of Counterterrorism and Emerging Threats, Food and Drug Administration*

Robert Kadlec, *Former Special Assistant to the President for Biodefense Policy*

Michael G. Kurilla, MD, PhD, *Director, Office of BioDefense Research Affairs, National Institute of Allergy and Infectious Diseases*

Video interviews with these distinguished experts are available on the Emerging Leaders in Biosecurity website: www.emergingbioleaders.org



A Great First Year

*Tom Inglesby, MD, Emerging Leaders in Biosecurity Program Director,
and Anita Cicero, JD, Deputy Director*

Over the last 14 years, the Center for Biosecurity has devoted itself to addressing many of the complex policy problems associated with the high-consequence, infrequent public health emergencies that can follow infectious disease outbreaks, bioterrorism, and natural disasters. We have learned through our experience that the best way to develop pragmatic policy solutions in the biosecurity sphere is to engage a diverse group of professionals from a wide range of disciplines to work together. The field of biosecurity demands this multidisciplinary approach. We were therefore honored to be entrusted with starting the Emerging Leaders in Biosecurity Initiative; we believe this kind of effort is long overdue.

When we set out to imagine the program, our hope was that the Emerging Leaders in Biosecurity Initiative would attract a select group of professionals with the potential to help shape and push the field forward in the years ahead. We knew we would seek the guidance of a steering committee comprising many of the most talented leaders now in the field. We would encourage fellows to offer their own ideas for biosecurity. We would bring them together with seasoned veterans to help them gain greater understanding of the problems, forces at play, programs and personalities that have built the field. We would expose them to science and knowledge about government that is difficult to attain elsewhere.

Now, at the end of the first year, we can see that our hopes for this program were realized and far exceeded. We had an extraordinary class of fellows, and a great first year. With the help of the first class—now the first alumni class—we will grow this network of biosecurity professionals and facilitate the career-long relationships that we hope will give rise to new leaders and creative engagement in the field of biosecurity for years to come. We look forward to many more great years.

Yearbook Credits

The Emerging Leaders in Biosecurity Class of 2012 Yearbook was written, edited, designed and produced by the Center for Biosecurity of UPMC.

Editors: *Ann Norwood, Nidhi Bouri, Matt Watson*

Design and Production: *Davia Lilly*

Printer: *Todd Allan, Beltsville, Maryland*

Photography:

Kaveh Sardari: pages 2-3, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 30-31, 32, 36-37, 61, 62

Gabriel Harber: pages 7, 15, 58

Concordia www.theconcordiasummit.org page 61 (Robert Kadlec)

Printed in the United States, January 2013