

Preserving National Security: The Growing Role of the Life Sciences

CONFERENCE REPORT

INTRODUCTION

The Center for Biosecurity's meeting *Preserving National Security: The Growing Role of the Life Sciences* (3/3/2011, Washington, DC) focused on the expanding and evolving connections between advances in the life sciences and U.S. national security.

Addressing the increasingly important and transformative role that the life sciences will play in the 21st century, distinguished speakers and panelists explored topics ranging from USG programs and priorities in the life sciences and biosecurity, to U.S. competitiveness in the global life science market, to the need for scientists to learn how to engage the public in meaningful discussion.

The summary that follows provides a brief synopsis of panel discussions and individual presentations. We invite you to explore the conference website, where you will find videos of the day's discussions as well as the conference agenda and other relevant materials.

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Conference Speakers

Parney Albright, Principal Associate Director, Global Security, Lawrence Livermore National Laboratory

Roger Breeze, President, Centaur Science Group

Robert Carlson, Principal, Biodesic

Gerald Epstein, Director, Center for Science, Technology & Security Policy, AAAS

David Franz, Vice President & Chief Biological Scientist, Midwest Research Institute

Margaret Hamburg, Commissioner, FDA

Catherine Hill-Herndon, Director, International Health & Biodefense, U.S. State Department

Franca Jones, Senior Policy Analyst, National Security & International Affairs Division, OSTP, The White House

Michael Kurilla, Director, Office of Biodefense Research Affairs, NIAID

Alan I. Leshner, CEO, AAAS; Executive Publisher, *Science*

Carol Linden, Principal Deputy Director, BARDA, Office of the Assistant Secretary for Preparedness & Response, HHS

Bernard Munos, Founder, Inno-Think; former Advisor, Corporate Strategy, Eli Lilly

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Life Sciences Rising

Conference goals. In his opening remarks, Dr. Inglesby established the goal of the conference—to discuss the impact of the life sciences on national security—and outlined recent



developments and challenges in the life sciences. He noted that the Obama Administration recognized the unparalleled period of advancements in life sciences in the National Strategy for

Countering Biological Threats (December 2009), which states that continued research and development in the life sciences is essential.

Importance of the life sciences to national security.

Dr. Inglesby said that for the purposes of this discussion, national security is the security, prosperity, and survival of the country through the use of military might, economic power, diplomacy, energy security, and emergency preparedness against terrorism and natural catastrophes. Life sciences play a key role in each of these endeavors.

Some of the breakthroughs of the past year give a sense of the fundamental discoveries emerging from the life sciences: self-replicating, genetically designed life; early diagnosis of Alzheimers; new rapid diagnosis of TB; faster and cheaper genome sequencing technologies; novel techniques to reprogram cells to perform new functions; depictions of the dark genome; and the unlocking of the microbiome.

The role of the life sciences in the American economy is expanding: 1.3 million Americans are employed in life science–related fields, and that number will only grow. As per Rob Carlson’s work: the biotechnology industry alone represents \$200-\$250 billion in annual revenue, 2% of the GDP, with 20% growth per year.

On the other hand, there are concerns about the U.S. ability to sustain its competitiveness in life sciences research and development and concerns about the increasing time it takes to develop and approve new medicines, especially in the face of impending cuts to the NIH budget in FY2011.

Key questions. Dr. Inglesby encouraged participants to consider several key questions, the answers to which, he suggested, should drive policy and action to clarify the role of the life sciences in preserving national security:

- What is the overall impact of the life sciences on national security?
- What are important trends in the life sciences and their impact on national security and the economy?
- What are the priorities of U.S. government programs in the life sciences field?
- What should the U.S. do to maintain competitiveness in the life sciences?
- What is the role of the life sciences in diplomatic efforts?
- What can the U.S. do to better realize the many contributions of the life sciences?



The Impact of Life Sciences on National Security

When Dr. Poste opened his talk, he told the audience that he intended to be provocative, and provocative he was.

Dr. Poste conveyed how the life sciences are intersecting with our security, from dangerous antibiotic-resistant pathogens that are now making the hospital “the most dangerous place on earth,” to convergent technologies that are making cognitive and genetic enhancement possible. Dr. Poste made the case that the national security landscape is changing because of vulnerabilities posed both by new life science technologies and by military applications of life technologies.

What is the role of the U.S. in this rapidly evolving future?

Dr. Poste said that while he still believes the U.S. is the greatest and most technologically advanced nation on earth, he is, for the first time in his 40 years in the U.S., worried about the nation’s ability to maintain dominance in the future.

He located his source of worry in several places, among them a concern that real progress is thwarted by adherence to the status quo in research and development, a sentiment echoed by speakers throughout the day. The danger of this, Dr. Poste suggested, is a lack of movement toward specific, meaningful deliverables and a lack of accountability.

We're avoiding the hard problems. Another concern is that we are not taking on the hard problems. We are choosing to ignore them, or addressing them with ineffectual reports or committees, or taking some simple but expensive actions—referred to by Dr. Poste as “salves”—that are not true solutions.

Dr. Poste argued, for instance, that the current U.S. government organization, with responsibility for life science research, regulation, and security spread across almost 20 departments and agencies, not only prevents the ability to form a coherent life sciences or security strategy, but makes analysis and decision making impossible.

Silos prevent coherent action. He cited dual-use technologies, health care, the environment, education, and energy as examples where silos prevent coherent action, where there are incomplete or archaic regulations, and where the government is not engaging with the private sectors that could provide necessary expertise. He cited BioWatch as a program that had been particularly concerning. Of course, the government could not possibly have all the expertise internally that is needed to solve a problem like the Gulf oil spill, and it should not try. Instead, it should serve a “concierge” function for the correct admittance of other technologies and companies, bringing experts from private industry to bear on the problem.

The answer, he asserted, is a coordinated and integrated strategy coupled with a demand for tangible results.

Risk aversity. Dr. Poste also argued that the USG has a tendency to avoid risk, and that risk aversion has prevented the USG from tackling in a meaningful way the large and complex problems of biosecurity. He offered that diagnostic tests could be “the single most important leverage point” to respond to natural or deliberate outbreaks, as they could determine who gets treatment, who is worried but well, and what disease a patient has—but the area has been profoundly neglected.

The status quo trumps innovation. In arguing that the time has come for a comprehensive strategy with clearly defined deliverables and accountability, Dr. Poste stressed that “the

preservation of the status quo trumps boldness and innovation,” and he suggested that programs that do not deliver should not be funded.

He asked if a catastrophe is the only thing that could mobilize us, and answered by suggesting that the USG should commit to finding solutions before catastrophes arise. He urged that we immediately tackle the problems and explore the opportunities that the life sciences present. While hopeful that such challenges can be met, Dr. Poste fears that the U.S. will waste “extravagant resources” until a cross-agency, cross-sector, systems approach is adopted.

KEY POINTS—IMPACT OF LIFE SCIENCES ON NATIONAL SECURITY

- The USG is not organized to tackle complex emerging problems that require life sciences expertise, including natural and deliberate epidemics, dual-use technologies, health care, the environment, education, and energy.
- Risk aversion and silos in government have prevented game-changing action on difficult problems like biodefense.
- A cross-sector (public/private), cross-agency approach is the only way to manage the risks and opportunities we face.

What's Next? Life Science Trends Worth Watching

Drs. Robert Carlson and Roger Breeze, with Gigi Kwik Gronvall as moderator, examined technological trends from the life sciences that affect national security and social trends that affect adoption of those technologies.



Panel L–R:
Gigi Kwik Gronvall,
Robert Carlson,
Roger Breeze

Distributed systems, technologies, and innovation.

Dr. Carlson focused on the rapidly changing structure of the life sciences from a centralized industry, dominated by large companies in industrialized nations to a geographically and demographically distributed industry. Another dramatic change he described is the growth in the number of small labs being set up in commercial spaces or even in homes, as exemplified

best by the “garage scientist” practicing DIY biology. Dr. Carlson located the source of this change in the move toward smaller and cheaper PCR machines, sequencers, and other equipment.

Dr. Carlson noted as well the worldwide distribution of innovation, with rapid growth following robust investments in the life sciences in China, India, Malaysia, Pakistan, and many other countries. He emphasized that no matter where in the world they are located, it is small companies and vastly expanded access to new technologies that are driving innovation to address demand from the health, agriculture, and industrial sectors. And with ever-increasing access to technologies that support, for instance, DNA and protein synthesis, computer-aided design, and 3-D printing, life sciences research will continue to expand rapidly and will decentralize to an even greater extent.

Regulatory structures outpaced by innovation. However, while the field may be poised for continuous and powerful innovation, Dr. Carlson argued that existing regulatory structures will not be able to support life science-based industries as these dramatic shifts occur. He suggested, for instance, that there is no regulatory framework in place for USG evaluation of the innovative technologies and products that smaller companies and independent labs are developing (a point later emphasized by FDA Commissioner Margaret Hamburg as well), particularly for those products that are not marketed as therapeutics or genetically modified organisms.

Synthetic biothreats difficult to monitor. Dr. Carlson also highlighted the increasing difficulty of monitoring potential synthetic biothreats—a problem that will only grow with continued rapid expansion of access to gene and protein synthesis technologies.

Intellectual property at risk. Finally, he pinpointed the problem of IP vulnerability in a centralized industry in which a company in one country may contract with a company in another country for cheap production of a protein or DNA. This transaction would require cross-border transfer of IP in the form of proprietary genes or proteins. Technology for protein and gene synthesis is, as a result, becoming more distributed as companies build in-house capacity to protect IP.

Vaccines are still not part of response to animal disease outbreaks. Dr. Breeze’s comments provided a stark counterpoint to Dr. Carlson’s overarching optimism about trends in the life sciences.

In general, Dr. Breeze lamented that the same impediments to progress are at play today as have been for the decades he has worked in the animal disease field. He argued that many useful technologies already exist, and have existed for a while, but they are not used. To drive his point home, he explained that the U.S. response to a foreign animal disease outbreak is, for all intents and purposes, the same today as it was in 1711: slaughter and quarantine. We do not use vaccine technologies available in Europe, because it was never seen as a priority to validate them in the U.S.

Available diagnostics are underutilized. Dr. Breeze also lamented the fact that, despite the availability of diagnostic tests for a number of animal diseases in other parts of the world, the USDA still does not have validated tests for more than 20 of the 33 select agent pathogens that the agency regulates. Samples still must be sent to the Plum Island laboratory for a confirmatory diagnosis—a step that can delay appropriate responses to a disease outbreak.

Response capabilities remain antiquated. Dr. Breeze described a 1946 outbreak of foot-and-mouth disease in Mexico that took the lives of 1 million cows and cost the U.S. \$200 million over 6 years, as the U.S. worked to prevent the disease from spreading across the border. He argued that we did not learn from this experience: slow adoption and implementation of the revolutionary new communications and diagnostics of the 1990s meant that response to recent foot-and-mouth disease outbreaks was about the same as the response of more than 65 years ago.

And the same problems persist. Dr. Breeze estimates that, in the end, the U.S. capacities and capabilities in responding to epidemics remain limited by the dearth of rapid diagnostics and countermeasures.

KEY POINTS—TRENDS WORTH WATCHING

- Access to life sciences technology has distributed research across the border to new global economies, small companies, and even individuals.
- Distribution of life science research will continue to give rise to regulatory challenges, security concerns, and IP issues.
- Currently available technologies are not being used as they should be, making response unnecessarily antiquated.

U.S. Government Programs & Priorities, Part 1

Drs. Parney Albright and Alan Rudolph discussed policies and priorities in the life sciences at the Lawrence Livermore National Laboratory (LLNL) and the Defense Threat Reduction



Panel L-R:
Thomas Inglesby,
Parney Albright,
Alan Rudolph

Agency's (DTRA) Chemical and Biological Technologies Directorate, respectively.

High performance computing power. In his presentation, Dr. Albright described how LLNL's high performance computing power is being harnessed to advance the life sciences. Computations that once would have taken days are now completed in minutes, enabling complex modeling of proteins in solution, for example, and other formerly impossible tasks.

One biodefense effort he highlighted is the development of large-format genomic and proteomic arrays for disease surveillance, clinical and laboratory diagnostics, and bioforensics. Dr. Albright anticipates that, in the future, new developments in high performance computing will lead to dramatic acceleration of the drug licensure process, ubiquitous deployment of large-format diagnostic arrays, and the development of triage platforms for large-scale events.

New developments cued by nature. Dr. Rudolph discussed new technologies offered by developments in the life sciences that may benefit both defense and civil society, and he highlighted several cases in which DTRA scientists are taking their cues in this effort from the natural world. For instance, DTRA is developing environmental sample collection systems using honeybees, which he called "electrostatic dust mops," and fish that "cough" more as water quality falls. He also discussed bioinspired and biomimetic systems, such as mechanical transport systems using dog-like legs, for defense applications.

USG attention needed to harness and apply power of new developments. Both speakers highlighted the need for significant government focus so that the life sciences may be properly harnessed to contribute to national security and to protect against emerging and deliberate disease threats.

Moonshot. Dr. Albright compared the level of effort needed to a Manhattan Project or a moonshot to emphasize his point that sustained government commitment and the collective focus of experts in many different fields are necessary to accomplish monumental tasks.

Dr. Rudolph concurred, adding that the USG is needed to develop an industrial base and to drive innovation. Dr. Rudolph also emphasized the need for extensive workforce development, noting that if the USG is going to invest in drug development, then there must be a skilled workforce in place to realize the benefits of that development.

KEY POINTS—USG PROGRAMS AND PRIORITIES

- New technologies such as high performance computing and developments based on living systems are changing the face of both civil and defense research.
- The public and private sectors will have to work together in a focused way to meet current challenges, exploit opportunities, and advance U.S. interests in the life sciences and national security.
- The convergence of different problem-solving disciplines will bring together new outlooks on pressing national security problems. Tremendous opportunity exists to move forward in national security using the life sciences.

Life Science Contributions to the 21st Century

The social context for life sciences. Dr. Leshner opened his talk by announcing that he had decided to change the title from "Life Science Contributions to the 21st Century" to "The Social Context for Life Sciences (Biosecurity) Research in the 21st Century."

He closed his talk with his favorite quote from President Abraham Lincoln: *Public*

*sentiment is everything. With public sentiment, nothing can fail. Without it, nothing can succeed.**



Speaker
Alan I. Leshner

Between the 2 points, Dr. Leshner made a compelling argument for the importance of engaging the public in meaningful dialogue about science, policy, and regulation of research activities.

Education not always the answer. Dr. Leshner observed that when faced with a lack of support for research or scientific findings, scientists (and policymakers) usually assume that the public is not knowledgeable enough to understand the findings. The assumption is that if the public had more science education, then they would be more inclined to accept scientific findings. This accepted wisdom is, Dr. Leshner asserted, demonstrably wrong.

Core values and beliefs always win. According to Dr. Leshner, people reject scientific findings when those findings conflict with their core values. Science may be able to, for instance, technically define when life begins. But if a person's core values are that life begins at the moment of conception, then no amount of scientific evidence will change the judgment that stem cell research entails taking lives. The person may understand the scientific fact, but his or her values will override that understanding.

Dr. Leshner acknowledged that research in synthetic biology, neuroscience, and many other fields may be scientifically exciting and filled with promise for future medical therapies, but for some, this research goes against the grain of core belief systems, fundamental values, and, in some cases, ideologies. And in those cases, Dr. Leshner argued, science will always lose. Education, therefore, is not the answer. Engaging the public is the answer, and that responsibility falls to scientists.

Don't harangue. Dr. Leshner called on scientists to avoid haranguing the public. He suggested that concerns must be heard, questions answered, and input solicited when decisions are being made regarding the application of scientific findings and regulation. (He strongly emphasized that community meetings are not the most effective forum for such discussions.)

Learn how to engage. Dr. Leshner confirmed that the ability to talk with the public about science and to engage nonscientists in meaningful dialogue is a learned skill, and he encouraged scientists to pursue training. AAAS has trained hundreds of scientists because they have recognized that this is a learned, not inherent, skill, and it is crucial.

Go "glocal." One of the most effective approaches to engaging the public is to go "glocal" by working with local opinion leaders to make a global issue meaningful on a local level. An example of

this is finding a way to address the issue of dual-use research, a global issue, so that it is meaningful at a local level.

Science investment and innovation are global. Finally, in confirming that life science research and production is increasingly globalized, Dr. Leshner's comments echoed those of Dr. Carlson. Like other speakers, he called for coherent and coordinated policies, practices, and norms that can support and encourage research, development, and innovation. He encouraged recognition of all types of investment in science, citing Rwanda as an example of a country with no natural resources that is, nevertheless, investing in what it has: brain power. The Rwandan government has been investing heavily in science education and research to cultivate talent.

As scientific capacity is increasingly recognized as essential to prosperity, Dr. Leshner reiterated the call for national policies that keep pace with innovation and promote excellence in science.

KEY POINTS—SOCIAL CONTEXT FOR BIOSECURITY RESEARCH

- Values often trump knowledge. Core values and ideologies have greater influence on acceptance of science than knowledge per se, which means that scientists must seek to engage the public in discussion and decision making.
- Scientists must engage the public in a meaningful and respectful dialogue. The skill of engagement is learned.
- The most effective national policies will be those that reflect the best science.
- Science is global; therefore, scientists must find ways to make global issues meaningful to local communities.

**Bryan WJ, ed. The World's Famous Orations. America: II. (1818-1865). Vol IX. General Books: 2010.*

Maintaining U.S. Competitiveness in the Life Sciences—What Will It Take?



Panel L–R:
Anita Cicero, Carrie Wolinetz, Gerald Epstein, Bernard Munos

The right innovation ecosystem? Citing widely expressed concerns that India and China may outcompete the U.S. in the life sciences, moderator Anita Cicero noted that while innovation is the cornerstone of national security, it is not clear how to best foster it. Open collaboration can catalyze new ideas, but it also bears the risk of information and technology falling into the wrong hands. Ms. Cicero then asked the panelists if the U.S. has the right innovation ecosystem to keep pace with other countries while keeping the nation secure.

Funding + the right regulation = competitiveness.

Carrie Wolinetz suggested that competitiveness in the life sciences is largely a matter of funding and regulation. While the NIH budget doubled between 1998 and 2003, there has been little additional funding since.

Dr. Wolinetz cited burdensome regulation as another factor affecting competitiveness. She noted that before beginning a project, scientists may first have to ensure that they are in compliance with rules and regulations stipulated by their institutional review boards (IRBs), the Association for the Accreditation of Human Research Protection Programs (AAHRPP), institutional biosafety committees (IBCs), Embryonic Stem Cell Research Oversight Committees (ESCRO), and a host of others. Streamlining regulations could ease this burden.

Open participation, open communication. Gerald Epstein warned that to maintain competitiveness, the U.S. must avoid reflexive reactions to dual-use research—that is, research intended for beneficent purposes but with the potential for misapplication. For the scientific community to prosper, it needs: (1) open participation, because talented people are everywhere; and (2) open communication to build on and extend research.

Dr. Epstein acknowledged that the security agenda can often

impinge on the sciences as the security community seeks to keep people and information out of dangerous hands. Inevitably, imposing security measures will incur a cost on the development of the life sciences. The question to be addressed then is: what costs are the U.S. willing to tolerate? The U.S. is increasingly dependent on foreign-born scientists in the life sciences, but resistant to offering them full citizenship.

Windows, not walls. Export control systems have been effective in limiting the proliferation of American-made weapons, but it is not clear how these rules should apply to life science products. Noting that “security comes from windows not walls,” Dr. Epstein suggested it would be unwise to do away with controls, but he also noted that the presumption of openness in science is essential for fostering an innovative environment.

Essential disruption of the status quo. Bernard Munos emphasized that the biomedical community is experiencing an innovation crisis and that large pharmaceutical companies are settling for incremental advances and marginal innovation that pose lower risks to investors.

He urged the audience to consider the examples of Microsoft, Apple, Twitter, Facebook, Ebay, Amazon—all companies that were created by 20-year-olds who set out to disrupt the status quo. He asked the audience to imagine what might have happened had Sergey Brin and Larry Page taken a job at AT&T instead of founding Google, or if Bill Gates had embarked on a career at IBM instead of founding Microsoft. He noted that they might still be climbing the ranks, or they might have been dismissed entirely for being mavericks. Surely, he suggested, they would not have been as successful innovating in a system bogged down by bureaucracy.

Cut funding. To foster an innovation ecosystem, Dr. Munos suggested that the U.S. enable platforms of so-called “disruption.” He argued that industry and government must cut funding to status quo development mechanisms and create enough financial restraint to force scientists beyond the status quo, to a point at which they must reconceptualize their processes and innovate.

KEY POINTS—MAINTAINING U.S. COMPETITIVENESS

- Maintaining competitiveness in the life sciences requires a higher level of funding.
- The U.S. should engage globally. Only then will we know where innovative potential and security threats lie.

- Disruption of the status quo is the key to innovation. The U.S. must foster an environment that encourages disruption.

U.S. Government Programs & Priorities, Part 2

This series of discussions gave 3 leaders in the federal government an opportunity to share their perspectives and priorities regarding the use of the life sciences to strengthen national security, specifically in the context of defending against biological threats.

NIAID’s Concept Acceleration Program (CAP). Michael Kurilla noted that the recently released Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Review emphasizes the identification and removal of “roadblocks” in the research and development process. To this end, NIAID has



launched CAP to identify promising findings early in basic development and facilitate their translation into products suitable for

advanced development and manufacturing. Dr. Kurilla then described the 3 components of CAP:

- Tech watch to identify candidate products
- Targeted solicitation program in which NIAID personnel work directly with investigators to inform and guide enrollment of candidate products
- Facilitation teams that help shepherd candidate products through the research and development process

Finally, Dr. Kurilla identified the development of platform technologies to expedite the development of medical countermeasures to biological threats as a critical need.

Intelligence community outreach. Erik Prentice gave an overview of the intelligence community’s activities and interests in this field. In 2007, the National Counterproliferation Center within the ODNI released the National Intelligence Strategy for Countering Biological Threats. Dr. Prentice reported that a major pillar of that strategy is outreach to a broad range of stakeholders in the scientific community, and that progress to date has been

very encouraging. He also noted that an updated strategy document would be released in April 2011.

New BARDA initiatives. Carol Linden described the impact of the PHEMCE Review on BARDA’s programs and priorities. She began with a quote from Secretary Kathleen Sebelius: *Our nation must have a system that is nimble and flexible enough to produce medical countermeasures quickly in the face of any attack or threat, whether it’s a threat we know about today or a new one.**

In support of this vision, BARDA has undertaken a number of initiatives. First, to energize the product pipeline for broad-spectrum antibiotics, the agency has approached industry stakeholders to inform them that both biodefense and routine indications would be supported by federal funds, which is a novel strategic approach.

Second, BARDA will be establishing Centers for Innovation in Advanced Development and Manufacturing, which will be operated as public-private partnerships intended to marry the development expertise of large pharmaceutical companies with the innovative advantage of smaller biotechnology firms. In addition to expediting the availability of medical countermeasures (MCM) for a broad range of biological threats, including pandemic influenza, these facilities would also foster workforce development in this critical field.

Finally, Dr. Linden described the advances made in improving the manufacturing process for influenza vaccines. BARDA is currently supporting the following research initiatives:

- Construction of a cell-based influenza vaccine manufacturing facility
- Application of recombinant DNA technology to influenza vaccine research
- Use of adjuvants to improve vaccine efficacy
- Development of a broadly protective universal flu vaccine

As seen during the 2009 H1N1 influenza pandemic, bringing vaccine to market rapidly will be critical. To reduce the production timeline, BARDA is conducting research on the following: optimization of seed virus production, more efficient potency assays, and rapid sterility tests.

KEY POINTS—USG PRIORITIES

- NIAID is proactively identifying promising early stage discoveries and working with investigators to realize the practical benefits of their work.

- Members of the IC are actively monitoring trends in the life sciences, formulating strategy to prevent scientific misuse, and engaging with practitioners to foster a common understanding of risks.
- The PHEMCE Review has altered government’s approach to MCM development: BARDA is now reviewing its priorities and investments in order to expedite countermeasure development.

*Sebilius K. *Public Health Emergency Medical Countermeasures Enterprise Review*. August 19, 2010. <http://www.phe.gov/preparedness/mcm/enterprisereview/pages/default.aspx>. Accessed 3/7/10.

Science Diplomacy for Global Security: Current Initiatives & Future Possibilities

Dr. Henderson introduced this panel discussion by describing the current public, private, and academic interest in the fields of public health and global health. He believes an opportune environment exists for resolving significant foreign policy dilemmas, especially those involving issues of global health, because of the hopefulness, interest, and energy he now perceives.

State Department efforts. Ms. Hill-Herndon described the State Department’s efforts in science diplomacy as crucial to the attainment of U.S. foreign policy goals and outlined 3 areas of focus:



Panel L–R:
D. A. Henderson, David Franz, Catherine Hill-Herndon

1. Using diplomacy to push health goals
2. Linking diplomatic health and science goals
3. Using health diplomacy to support foreign policy goals

Ms. Hill-Herndon described the State Department’s role as that of supporting and facilitating development assistance, public-private partnerships, academic partnerships, and the Biological and Toxin Weapons Convention (BWC). She spoke of a need to balance the competing interests of companies with private IP and countries with health and humanitarian needs.

Ms. Hill-Herndon described the State Department’s role as that of facilitating use of science as a common ground on which

countries with little else in common can engage and build partnerships. To that end, the State Department supports life sciences research abroad, builds health security, and supports and facilitates development assistance by leveraging public-private partnerships, academic and industrial expertise, and the BWC.

Social, ethical, and technical solutions to the threat of biological weapons. Dr. Franz spoke about his experiences during a long career of public service to make the case that science engagement is security engagement. He also argued for social and ethical solutions that can work in tandem with technical solutions to address the threat of biological weapons.

Interpersonal connections undergird international diplomacy. Dr. Franz offered several anecdotes from his experience in the DoD and the NAS Committee on International Security and Arms Control to illustrate how he came to believe that the foundation of science diplomacy is the interpersonal connections among scientific colleagues in partner countries. He observed, for instance, that his relationship with Russian scientists, cemented through discussions of families and children and common scientific interests, helped in the process of negotiating scientific details of an agreement with the Ministry of Foreign Affairs in Moscow. The professional and personal connections built during that visit proved invaluable in the 15 years that followed, as communication and collaboration with the Russians expanded and improved after the decline of the Soviet Union.

Force protection vs. civilian protection. Dr. Franz joined the chorus of other speakers who stressed the complexity and enormity of the threat of biological weapons. He located a significant source of this complexity in the 1990s shift to a focus on protecting civilian populations, arguing that while it is relatively easy to protect military forces, it is exceedingly difficult to protect the U.S. civilian population.

Science diplomacy in the post-proliferation world. Dr. Franz went on to assert that proliferation of equipment and the knowledge needed to make bioweapons is already broadly disseminated. Technology in the life sciences is readily available worldwide. As a result, he observed, it is the intent to use biological weapons that is the biggest part of the threat today. Science diplomacy, or collaboration among nations to solve difficult common problems, is the best solution for global security. It provides transparency, depth of knowledge, and perhaps even early warning of disease outbreaks or attacks, and therefore serves 4 critical purposes:

1. Reduce the impact of natural disease
2. Improve knowledge and understanding of the world and events around us
3. Undermine support for intentional misuse of biology and traditional forms of terrorism
4. Reduce the likelihood of terrorism and use of bioterrorism.

To build the partnerships on which effective science diplomacy depends, Dr. Franz reiterated the need for the right people with the skills and longevity to build relationships. He warned that the current reliance on short-term contractors undermines achievement of long-term goals and cementing of the long-term relationships essential to effective science diplomacy. In the end, Dr. Franz described trust as “the Holy Grail” for science diplomacy, which, he reminded, should be measured in human relationships.

KEY POINTS—SCIENCE DIPLOMACY FOR GLOBAL SECURITY

- Science and health are key to accomplishing the U.S. foreign policy goals.
- Science is a common ground on which countries can work toward mutual prosperity and security.
- Interpersonal relationships are the foundation of science diplomacy.

FDA Strategy for Medicines & Vaccines of Importance to National Security

MCM review as catalyst for change. Dr. Hamburg spoke to the importance of the life sciences to national security, and the essential role the FDA will play in assuring the safety and quality of innovative biomedical products. She began her talk by citing the recent MCM review as a catalyst for significant change within the FDA, noting that the review both emphasized the need for agile countermeasures platforms for rapid response to unknown and unprecedented threats and highlighted that the FDA is an

underappreciated but key player in that effort. She also stressed that the Obama Administration considers the new, mandated MCM platform a priority.



Speaker
Margaret Hamburg

New FDA approach. Dr. Hamburg described a 3-pronged response: First, the FDA will grant MCMs priority over noncountermeasure products along the regulatory pathway. With early and frequent meetings with developers, Dr. Hamburg expects that the FDA will be able to anticipate needs and give advice that will shorten the regulatory approval process.

To this end, the FDA has already established an MOU with the Defense Advanced Research Projects Agency (DARPA) to stipulate the approval process and timeline for countermeasure development.

Second, the FDA is reevaluating the regulatory legal framework to identify policies that may impede effective and rapid MCM development and deployment.

Third, the FDA intends to strengthen its internal science capacity and build partnerships with government, academia, and industry to advance regulatory science, an effort that should enhance the agency’s capacity to evaluate candidate MCMs.

Dr. Hamburg is optimistic about this new approach. She offered as an example of its success the recent emergency use authorization (EUA) of intravenous peramavir during the 2009 H1N1 pandemic. The peramavir EUA was the product of a new FDA modeling approach for dosage safety evaluation that was developed through the regulatory science initiative.

Recent successes. Responding to an inquiry about the FDA’s recent international initiatives, Dr. Hamburg urged the audience to consider the complex networks that underlie product development and production in today’s global economy. Because many components of biomedical products, and often the finished products themselves, are manufactured overseas, it is essential that the FDA engage with partners abroad. Dr. Hamburg discussed the development of a new, longer-lasting meningitis vaccine as a real public health success in Africa, which was developed in a cooperative arrangement with the Serum Institute of India to safely scale up production. Today, nearly 20 million people in Africa have received the vaccine.

Just the beginning of many advances to come. While noting that the meningitis vaccine and peramavir examples are positive indicators of progress in the FDA, Dr. Hamburg recognized that they are just the beginning of the advances she is pursuing. She stressed a fundamental need for the life sciences community to coalesce in unprecedented ways with a multidisciplinary, multisectoral plan based on a common goal of taking all possible action today to secure our nation and globe tomorrow.

Dr. Hamburg ended by assuring the audience that the FDA is eager and committed to embracing the unprecedented opportunities now presenting themselves.

KEY POINTS—FDA STRATEGY

- FDA is taking clear steps to advancement: The FDA has acted to boost the science of regulation through enhancement of their own internal capacity and by reaching out to partners in government, industry, and academia.
- Early successes have been realized: Dr. Hamburg cited the meningitis vaccine and the EUA of intravenous peramavir as successful examples of their new initiative being effective.