Executive Summary

As the Manhattan Project and World War II wound together to mutually dependent ends, a small group of technically trained researchers found themselves standing astride the suddenly unclear borders of US science and security policy. Their contributions, and the federal commitment to continuing the productive association of industry, academia, and the Department of Defense into peacetime, created the template for an enduring (if not always cordial) relationship between science advisers and policymakers. Scientific and technological developments have since become integrated into every facet of diplomacy, defense, and daily life, making dependable systems for delivering useful scientific advice to decision makers even more critical to good governance. Over the last decade, many thoughtful reports have mapped possible paths between every level of political organization and credible, accessible sources of scientific and technical analysis. Nonetheless, determining when and how to incorporate science, technology, and health (STH) expertise into government decision-making remains a challenge, a particularly pressing one for the agencies involved in the national security policy process.

The dichotomous nature of scientific progress, with its ability to yield new weapons and new shields – sometimes based on the same technologies – vaulted into the public consciousness again following the terrorist events of September 11, 2001, and the subsequent anthrax assaults. Policymakers and the public found themselves confronted with the suddenly evident threat of biological terrorism and warnings of a sadly eroded public health infrastructure almost simultaneously. The U.S. Congress and the Executive branch have responded with dramatically increased funding and a raft of laws, regulations, directives, and new programs for biological defense and security. Despite this evidence of current political will, the public health, bioscience, intelligence, law enforcement, and security communities still face many challenges in working together to develop a long-term, effective commitment to preventing the proliferation and use of biological weapons. These diverse communities must develop a shared vocabulary as well as a seamless strategy; their success will rely heavily on the integration of appropriate STH expertise at every level of biological security policy development and implementation.

In order to capitalize on current enthusiasm for stronger ties between the security and bioscience communities, those familiar with both must find ways to match the demand for STH expertise in Congress and the Executive branch, including relevant regulatory agencies, with the most appropriate sources. This report attempts to identify strategies for, and obstacles to, successfully completing this task. Its findings rely heavily upon the knowledge and experiences described by a group of technical experts, decision makers, and science policy professionals during a series of roundtable discussions on "Science,

Technology, and Health Expertise in the National Biological Security Policy Process," hosted by the Henry L. Stimson Center with the support of the Carnegie Corporation of New York. Participants met in sessions intended to concentrate on the perspectives of three distinct communities: 1) the governmental and non-governmental organizations that serve in advisory capacities to government bodies, providing technical analysis, science policy guidance, or resident science and technology fellows; 2) homeland security, disaster response, and domestic law enforcement; and 3) intelligence, defense, and foreign relations. Participants (see Acknowledgements and Preface) brought a wealth of experiences to the table, frequently wearing the multiple hats of their past and current roles in each discussion. Each group was asked to consider the same series of central questions, in addition to potential case studies and questions tailored to the group's specific interests:

1. What science, technology and health (STH) data and resources do the Federal entities that formulate biosecurity policy, and experts within them, identify as essential to the policy process?
2. Where and how do these entities consistently seek STH expertise deemed necessary?
3. How much internal STH expertise resides in agencies with operational security missions, and how is it used in both technical and general policy processes?
4. How have various offices/agencies "engineered the science into the system" – do personal relationships between resident science advisors suffice?
5. Given infinite resources, what would the "wish list" for STH expertise available to the agencies charged with biological security look like?

BIOLOGICAL SECURITY IN THE POLICY LANDSCAPE

New efforts to incorporate STH expertise into the national biological security policy take place against the broader background of science policy and politics. The low level of science literacy in the U.S presents a serious problem in communicating science and technology issues to policymakers and the public. Individual leaders in the executive and legislative branches have placed varying degrees of value on S&T policy advice as part of the political decision-making process, both reflecting and exacerbating occasional tensions between the political, science policy, and science communities. The influence and status of S&T advisors to the presidents have varied with each administration's distinct priorities, most dramatically in 1973 when President Nixon abolished the President's Science Advisory Committee out of frustration with perceived political disloyalty. The Office of Technology Assessment (OTA) provided Congress with nonpartisan, unbiased S&T policy analyses on the range of increasingly complex technical issues facing legislators from 1972 until it closed, a victim of budget politics, in 1995.

The legacies of such decisions and the current science policy climate affect decision-makers' openness and access to science policy advice. Although both the President's Council and OTA enjoyed high levels of credibility among technical experts and receptive policymakers, their well-merited reputations for offering politically neutral and competent S&T advice did not prove sufficient to save them during times of budget, organizational, and political turmoil. Conflicts between groups of scientists and political leaders, such as those recently played out publicly between science advocates and the Bush administration, can affect the receptivity of executive branch decision-makers to analyses that might be critical. The demise of OTA also left a vacuum that can be detected not only in uneven access to S&T analysis among members of Congress, but in the changing demands on remaining governmental and non-governmental policy analysis organizations. Legislators and their staffs depend increasingly on S&T experts within the NGO community, who may have different backgrounds, different sources of information, and possibly different organizational stakes in various issues.

The population of professionals who are "bilingual" in the vocabularies of research culture and government policy continues to evolve with the increasing number of fellowship opportunities and academic programs. The American Association for the Advancement of Science (AAAS) S&T Fellowship programs alone now counts about 1700 alumnae, with approximately one-third of each year's AAAS fellowship class electing to remain within the policymaking and policy analysis communities. S&T fellows, former fellows, and other scientists seeking what are often labeled "alternative careers" in policy have changed the baseline level of technical sophistication in the policymaking and policy analysis communities. Despite increased training opportunities, scientists willing to leave the laboratory bench for policy work still remain the exception rather than the norm, and may experience tacit or explicit disapproval from leaders in their academic institutions and fields. Although a relatively minor burden for tenured or otherwise senior researchers, the lack of career incentives for even more limited public service may discourage researchers earlier in their careers from volunteering to serve as technical experts.

WHAT DOES STH EXPERTISE LOOK LIKE?

Scientific expertise can take various forms, all of which fulfill the general task of providing an interface between the scientific community and decision-makers. These currently accepted forms for providing STH expertise in the national biological security policy process strongly influence when and how science policy information can be supplied. Such forms include:

- Standing advisory bodies to Congress, including the Government Accountability Office (GAO, formerly the General Accounting Office) and the Congressional Research Service (CRS), which have taken on an increasing number of technology-based studies with the demise of OTA;

- Standing advisory bodies to security and regulatory agencies, such as the Defense Advisory Board, the recently launched FBI Science and Technology Advisory Board, and the Department of Homeland Security (DHS) Homeland Security Science and Technology Advisory Committee**;**

- Issue-specific or ad hoc advisory bodies to security and regulatory agencies, which may be statutorily required by Congress, such as the Secretary's Council on Public Health Preparedness at the Department of Health and Human Services (HHS), or convened by the agencies themselves to gather information on a specific topic quickly;

- Professional societies, representing those who share specific technical training or working areas, have become a growing source of information on biodefense and biosecurity issues in the past three years;

- Non-profit, non-governmental policy organizations, which provide an increasing amount of biological security expertise to decision-makers through publications, briefings, testimony, and personal relationships with policymakers and their staffs, or to agencies through contracts;

- S&T fellowship programs, which introduce technical expertise directly into Congressional or Executive branch agency offices, simultaneously providing fellows with hands-on public policy experiences and government offices with resident scientists;

- The National Academies, the nation's premier source of independent S&T analyses, which convene workshops, administer fellowship programs, conduct educational outreach, and, most significantly carry out science policy studies (largely at the request of federal agencies, although the Academies can carry out self-driven studies); and

- Science advisors and in-house expertise, including those officially styled as S&T advisors (such as the new Senior Science and Technology Adviser to the Secretary of State, and technically trained professionals within Congressional offices and regulatory or security agencies whose roles includes providing S&T policy advice as part of a more complex job description.

THE DISTINCTIVE CHALLENGES OF BIOSECURITY

With increased scrutiny on and funding for bioterrorism prevention in the US, the number of individuals newly immersed in related preparedness and research efforts has ballooned concomitantly. Biodefense and biosecurity mandates command an increasing amount of time, attention, and resources from professionals in fields where such issues until recently remained peripheral, including public health, health care, biological and biomedical sciences, and agricultural and food safety. Reliance on a public health infrastructure composed largely of state and local assets has necessitated STH expertise at every level of government. Organizations that represent health professionals at the state and local level, professional societies representing researchers, and research universities have become stakeholders in biodefense and biosecurity issues.

The roles of the various Federal agencies charged with aspects of biodefense and biosecurity have also evolved since 2001 as a result of both major legislation (including the Bioterrorism Prevention Act) and a series of executive directives and agreements. Programs within the Departments of Defense and State have changed little, while increased funding has translated to a dramatic expansion of programs and offices within HHS. The Department of Agriculture has increased research, oversight, and security responsibilities, and the Environmental Protection Agency (EPA) has gained new responsibilities (with little budget accompaniment) for water security and remediation of contaminated buildings. The largest change of all included the 2002 creation of the Department of Homeland Security (DHS), which oversees operational, research and development, and policy missions related to biodefense and biosecurity within its Emergency Preparedness and its Science and Technology Directorates.

The legacies of heavily politicized nuclear threat issues and years of massive government-funded research projects fostered interaction between various groups of physicists, security policy analysts, and policymakers at every level. In contrast, many of the now-key players in biological security and defense have received a relatively recent introduction to the security concepts. Until quite recently, the community of biologists with any experience in studying biological weapons or defense against biological attacks, or who claimed strong ties to government policies in any way other than grant-making, remained fairly small. This historical schism between security issues, including those involving biological weapons, and the life sciences pervaded the policy analysis community as well.

Attitudes toward biosecurity issues in the biological research community may have been influenced by worries about visa issues, and – for those most intimately connected with biodefense research – the impact of the "select agent rules." Researchers who study pathogens now classed as select

agents and their institutions have experienced uncertainty about the scope of the new rules, frustration with bureaucratic backlogs in processing registrations for laboratories and security risk assessments for individuals, and fears that criminal penalties might result from unintended compliance failures. Many select agent researchers also harbor concerns about self- or government-imposed controls on open publication in peer-reviewed journals of techniques that might prove useful in designing biological weapons, an extremely difficult set of criteria to define when almost all biological research falls into the inherently dual-use category. Although new biodefense research grants continue to draw researchers to the field, countering warnings that the logistics of compliance would have a chilling effect on all biodefense research, this influx has itself created a wave of new experts with varying degrees of experience in handling different pathogens.

STH ADVICE IN BIOLOGICAL SECURITY: THE CURRENT DEMAND

Experts necessary to providing sound science and science policy advice can be classified in three general tiers:

- Technical experts have scientific or professional training in a biological or biomedical discipline, including current acquaintance with cutting-edge research and real-world conditions. These subject matter experts can serve on advisory committees (such as the standing advisory boards, ad-hoc or issue-specific committees, or National Academies panels), or be recruited to address specific questions by government agencies or programs, but most likely serve as advisors briefly before returning to the research environment.

- Technical policy advisors with specific expertise have technical training as well as practical experience in a specific biological or biomedical field. These (mostly mid-career) scientists rely upon their research expertise and experience in providing guidance for operational and analytical missions within government agencies, as well as intra- or inter-agency planning. Technical policy advisors sometimes have greater policy leverage as scientifically credible liaisons to interagency working groups than they do as available sources of expertise within home agencies, where they may be somewhat isolated by a stove-piped organizational structure.

- Science policy professionals have technical training and credentials which confer credibility among both researchers and government decision-makers, but focus on broader science and science policy issues. They may rarely (or never) rely upon their original areas of narrow technical expertise, but rather make use of their dual familiarity with researchers and research

culture and the policy environment and its demands to connect decision-makers with the most appropriate types of STH expertise when needed, in an accessible and useable form.

Identifying technical experts in biodefense and biosecurity often proves more difficult than simply seeking a distinguished publication record or academic reputation -- a scientist may be a world expert on the natural history of a specific pathogen but have little or no knowledge of existing data on that pathogen's behavior in weaponized form (such as a deliberately released aerosol). "Expert exhaustion" can pose a problem, especially during a crisis or a period of intense policy debate, when the number of technical experts with reliable credentials and adequate free time can prove unequal to the demand. Although both technical experts and technical policy advisors should obviously have specific expertise in the programs that they guide, participants acknowledged that this is not always the case, and that the decision-makers who rely upon them may not distinguish between scientific disciplines at all.

INCORPORATING STH EXPERTISE INTO DECISION-MAKING

Reports or publications in which science and science policy advice are presented can take several forms: specific technical analysis or broad science policy, open or closed (produced for use within a specific organization with no outside distribution), anticipatory or reactive, self-driven by an organization or solicited by request, and evidence-based or estimate-based – that is, relying upon incomplete evidence and past experiences to draw "best guesses."

Integration of STH expertise in most agencies and organizations may depend upon informal personal networks rather than a systemized approach. The likelihood that STH expertise enters the process through a more formal mechanism may reflect the value that high-level administrators place on science policy advice, the history of advisory mechanisms within the organization, or a combination of both. In-house S&T expertise does exist in intelligence and federal law enforcement agencies, but the organizational components of the programs with a technical or research and development focus tend to be segregated from the offices that make decisions on broader policy issues. Getting scientists "out of the ghetto and into the main office" requires placing a small core of science policy professionals at multiple levels throughout the organization, rather than just within programs or offices that concentrate on technical or research issues; ensuring that at least some of these science policy professionals are integrated into the staff that fulfills policy and planning functions in a systemized way; creating credible scientific leadership within the agency, with adequate resources and authority stemming directly from the head of the program or organization; and educating senior decision-makers to recognize the relevance and value of STH expertise early in the decision-making process through internal and external outreach.

The National Science Advisory Board for Biosecurity (NSABB) offers a potentially successful model for incorporating policy recommendations made by STH experts into the national biological security policy process. The National Academies initiated a study called Biotechnology Research in an Age of Terrorism (also known as the "Fink Report" after its chair, Dr. Gerald Fink), a self-driven, anticipatory, largely evidence-based open report on broad science policy issues, prior to the anthrax assaults of fall 2001 with the support of the Sloan Foundation and NTI. The resulting report outlined several steps in a new system for overseeing inherently dual-use biotechnology research (which might result in knowledge or tools that could be applied equally to legitimate research and development or the production of biological weapons). One recommendation included creating the NSABB, which was realized when the Secretary of HHS announced the charter of the NSABB in March 2004. Although decision-makers did not adopt every recommendation of the Fink report, they did charge the NSABB specifically with addressing most of its recommendations. Thus, a comprehensive anticipatory report's operational recommendations on science policy have been translated into at least the launch of a structure intended to ensure that appropriate STH expertise goes into development of particular regulatory and oversight structures, based on a set of policy recommendations that outlined specific courses of action.

SURMOUNTING THE BARRIERS

A constant influx of fresh perspectives, born of active communication between technical experts, science policy professionals, and experts in security and law enforcement issues will be required to prevent the first reactions to a domestic biological attack from becoming entrenched and unyielding dogma. Although some decision-makers, STH technical policy advisors, and science policy professionals have developed personal networks to exchange STH information, whether many of these fairly new S&T advisory mechanisms for biodefense and biosecurity issues will prove robust enough to survive the comings and goings of individual personalities remains unclear in a still-evolving policy environment.

Classification and secrecy issues

A barrier with both practical and conceptual aspects facing the S&T policy community lies in access to classified materials and potential application of classification (or the vague "sensitive but unclassified" label) to basic research publications, stemming from a relatively small population of bioscientists accustomed to secrecy issues and cultural differences between the bioscience and intelligence and law enforcement communities on the desirability of open information. A relatively easily accomplished task involves increasing accurate perceptions of the nature of classification and secrecy in

science and science policy analyses within the community of potential biodefense experts. The converse involves enabling STH experts to push back against reflexive rather than productive classification by the intelligence community, a more challenging task. Accomplishing this task would require outreach within the S&T community as well as to the intelligence and law enforcement agencies to establish a clear message on when classification of biodefense and biosecurity information might prove counter-productive, and to provide willing expertise where possible to help make informed decisions on restricting information. Approaches include creating formal channels for continuing feedback between scientists and policy or intelligence analysts after workshops or studies have been concluded, rather than relying on groups of academic experts who "operate in a vacuum, present ideas, and then go away."

Deepening the Pool of Experts

A lack of encouragement or mentoring for those interested in science policy options, especially for professionals considering a policy career but not yet ready to "leave the fold," and the nature of tenure demands for those scientists who would like to contribute time to public service without leaving their laboratories for a prolonged period can limit the pool of technically trained science professionals both interested and willing to participate in the national biological security policy process to either quite senior scientists or those who have given up professional recognition within their disciplines for the less tangible rewards of a science policy career. Further investigation is needed to characterize the demand for career development programs for scientists with an interest in public service and science policy who might not be ready for or interested in a year-long fellowship commitment, and to seek methods to make short-term commitments to public service a "career builder" for academic researchers. A potential method for introducing researchers interested in public service, but not necessarily eager to leave the laboratory entirely, to policy concepts could come in the form of a curriculum to develop non-technical communications skills. Finally, attention should be paid to reforming the categories of post-training career choices deemed as indicators of successful service for former recipients of federal pre-doctoral or post-doctoral training grants, and to encourage accurate estimates of the population of S&T policy professionals by encouraging professional societies and government organizations that examine career choices within the larger community of S&T research professionals to include science policy career options among the choices available.

Reliance on Interagency Expertise

One aspect of providing STH expertise articulated by some participants reflected a bias that might not be intuitive to policy analysts in the NGO community: a tendency for government decision-makers to seek technical information, when necessary, from other government sources. Successful intra- and

interagency exchange of STH expertise can result from formal mechanisms for consulting on particular issues, or as a result of the "Rolodex Effect," in which science policy professionals or technical science advisors deliberately cultivate relationships with decision-makers in order to provide an obvious source of STH expertise when necessary. Building a strong core of internal STH expertise depends, in part, upon the availability of professionals with the appropriate skills and knowledge, and the commitment of the organization's leadership to fostering integration of S&T professionals into the decision-making process. Lessons in determining the most effective methods of encouraging interagency sharing of appropriate STH expertise may be drawn from the examples of interagency working groups, temporary assignments of employees from one agency to another, and "virtual committees" of experts representing different programs and agencies that have been favored by the intelligence community. A growing body of STH expertise on biodefense and biosecurity issues now resides in the NGO community; for it to be accessed, such organizations must build trust with government decision-makers, possibly through adopting a reliable system for quality assurance in technical reports.

Building a Better Study

Core expertise in biodefense and biosecurity studies – those who study pathogens, infectious diseases, and potential countermeasures – is critical but not enough to provide relevant STH advice. Cross-disciplinary working groups and advisory committees that include experts in sociology, anthropology, political science, and other social sciences in addition to biology and security allow decision-makers to consider biosecurity issues in a richer context. The demise of OTA has left significant gaps in two specific areas: reports designed to provide insights on (sometimes politically controversial) technical issues for a public constituency, and anticipatory reports allowed the luxury of taking the long view. The previously cited Fink Report on dual-use biotechnologies provides one example of an anticipatory study conducted by the National Academies; only about 20% of the projects conducted through the National Academies receive funding from a non-federal source. Financial resources are needed to help policy analysis organizations, including the National Academies, produce studies that can anticipate, rather than merely respond to, serious biodefense and biosecurity policy issues before political pressures or events demand immediate actions.

Cementing Scientific Leadership

Developing and supporting scientific leadership within government agencies and programs, ideally in the form of a senior science advisor, constitutes a critical step in securing both adequate in-house expertise and institutional receptivity to STH advice. Without authority, permanence, and sufficient resources, the science advisor can end up being "a cheerleader for science," whose most

effective possible role is "trying to connect disparate agencies and perspectives as opposed to being an advisor and influencing how science is driven." Lessons might be drawn from early successes in establishing a senior science advisor at the State Department, from failures where they have occurred, and from analyzing whether agencies with security missions have functioned differently when policymakers with science or technical expertise served at the highest levels.

The likelihood that STH expertise can be successfully incorporated into the decision-making process at every level of the national biosecurity policy process depends not only on institutional structures, but on continued outreach among the bioscience research, science policy, security, law enforcement, and intelligence communities to develop a shared vocabulary, increase mutual understanding, and identify the problems that STH expertise can and cannot solve.