Chapter 3

The Distinctive Challenges of Biosecurity

The challenges of integrating appropriate STH expertise into the national biological security policy process surpass the struggles to identify enduring channels for effective communication that permeate the whole intersection of science and policy. One of the first obstacles lies in the simple novelty of national security issues to many central stakeholders in the burgeoning fields of biodefense and biosecurity.[1] One roundtable participant pointed out that some researchers with expertise in the biology of *Bacillus anthracis* and other potential weapons agents encountered security issues for the first time in the wake of the 2001 anthrax assaults, when they found themselves in the novel position of being both experts and suspects to the same government agencies. 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:

- health care providers, ranging from the caregivers themselves to the entire infrastructure of healthcare administration;
- public health professionals, encompassing epidemiologists, laboratory technicians, microbiologists, and many other specialists who work together in an interdependent network (including public and private clinical laboratories) at the local, state, and national levels to detect and control communicable diseases;
- biological and biomedical researchers, especially in the field of infectious diseases; and
- agricultural and food safety researchers and inspection/enforcement officers.

While broad priorities for biodefense research and response programs have been set at the Federal level, inherent reliance on a public health infrastructure composed largely of state and local assets (and Congressional mandates to allocate laboratory and hospital preparedness funding directly to states) have necessitated STH expertise at every level of government. This involvement has engaged organizations that represent health professionals at the state and local level, such as the Association of Public Health

[1] In the context of the roundtable discussions and this report, the term "biodefense" refers to all strategies designed to prevent the effective use of biological weapons, including technologies and public health, veterinary, and agricultural practices to protect human, animal, and plant health and safety. "Biosecurity," a broader and still evolving term, encompasses strategies to prevent the deliberate or natural introduction of pathogens into a community or ecosystem, and includes efforts to prevent malicious use of biological agents, skills, tools, and knowledge.

Laboratories, the Association of State and Territorial Health Officials, the National Association of City and County Health Officials, and the American Public Health Association. These have become not only vocal stakeholders in biodefense and biosecurity issues on behalf of their constituencies, but have served as conduits to convey STH expertise and policy guidance from the local and state levels to the federal level, and vice versa. Universities have received research funding from both DHS and NIAID through grants to individual researchers or consortia of laboratories, as well as larger awards to create regional homeland security and biodefense "centers of excellence," high-level biological containment laboratories, and physical or virtual centers to study specific questions or produce biodefense research resources.[2],[3] Organizations representing the academic community have thus become engaged in biosecurity and biodefense issues, as have professional societies, such as the American Society for Microbiology, that both represent researchers' interests and provide forums for the propagation of technical information through meetings and publications.

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. In fact, successive laws and agreements have moved the responsibilities for specific biodefense programs between agencies more than once within a span of years. For some executive branch agencies, the biodefense mission has changed little; DOD continues to focus mostly on military needs and force health protection. The State Department's overall biological weapons non-proliferation mission has remained fairly constant, complemented by increased attention on biosecurity issues within the Office of Counterterrorism. For agencies such as HHS (including budgets within CDC, HRSA, NIH, the Food and Drug Administration, and the office of the Secretary), increased funding has translated to a dramatic expansion of programs and offices created prior to the fall 2001 terrorist attacks as well as new responsibilities. CDC and HRSA now administer millions of dollars annually in state preparedness agreements, and NIAID's budget for biodefense research leapt from $53 million in FY 2001 to more than $1.4 billion in FY 2004.[4] USDA's biodefense responsibilities have expanded to include new research responsibilities, as well as several new food safety and biosecurity initiatives. The Environmental Protection Agency (EPA) has gained new responsibilities (with little budget accompaniment) for water security and decontamination of buildings, with its first foray into novel technologies for remediation of a structure following a biological attack demonstrated in the Senate

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[2] "NIAID Launches Biodefense Resources and Opportunities," Supplement to *NIAID Council News* (28 November 2003), http://www.niaid.nih.gov/ncn/newsletters/nl112803/nl112803_n08.htm (accessed August 2004).

[3] "Fact Sheet: Partnering with the Nation's Universities," Press Release, Department of Homeland Security, (27 April 2004), http://www.dhs.gov/dhspublic/display?content=3517 (accessed August 2004).

[4] Ari Schuler, "Billions for Biodefense."

Hart Building and other portions of the Capitol complex in 2001. The largest change of all, of course, came in 2002 with the creation of the new agency, DHS, charged with leading national homeland security efforts. DHS oversees operational, research and development, and policy missions related to biodefense and biosecurity within its Emergency Preparedness and its Science and Technology Directorates. Four major offices within the latter (Programs, Plans, and Budgets; the Office of Research and Development [ORD]; the Homeland Security Advanced Research Projects Agency [HSARPA]; and Systems Engineering and Development) steer programs intended to assess biological threats, foster development of countermeasures, and encourage specific biodefense research strategies in the national laboratories, universities, and industry.

In this rapidly changing landscape, technical experts in bioscience, public health, and medicine and their counterparts in intelligence, security, and law enforcement have been forced to seek a shared vocabulary quickly, while struggling with new missions and the sudden realization of a biological threat. Roundtable participants related several anecdotes illustrating how a lack of basic mutual understanding can lead to poor communication and confusion. As an example, the term "surveillance" evokes very different images for specialists from different communities; the term may conjure disease detection and tracking systems for an epidemiologist, aerial photography for an intelligence analyst, and wire-tapping for a law enforcement expert, with each envisioning a different set of resources, tasks, and responses. Without progress on shared frames of reference, current enthusiasm for building stronger ties between these communities with vastly disparate missions may dissipate as a result of major or minor frictions.

THE SCHISM OF SECURITY AND THE LIFE SCIENCES

In the wake of World War II, the majority of scientists who became deeply engaged in science and security issues arrived from the field of physics, partly as a result of the sense of social responsibility instilled in the Manhattan Project generation, and partly because of the pressing technological issues of the Cold War and space race. As Vannevar Bush, Director of the Office of Scientific Research and Development that coordinated wartime scientific research for Presidents Roosevelt and Truman among many other roles in science policy, stated in a post-war article on the future of science:

> This has not been a scientist's war; it has been a war in which all have had a part. The scientists, burying their old professional competition in the demand of a common cause, have shared greatly and learned much. It has been exhilarating to work in effective partnership. Now, for many, this appears to be approaching an end. What are the scientists to do next?

> For the biologists, and particularly for the medical scientists, there can be little indecision, for their war work has hardly required them to leave the old paths. Many indeed have been able to carry on their war research in their familiar peacetime laboratories. Their objectives remain much the same.[5]

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. As summarized by a participant, there is a "profound difference in the level of experience and engagement of the life sciences community in security issues relevant to others, at least since the Biological Weapons Convention and the US got out of the offensive [biological weapons] business."

This historical schism between security issues, including those involving biological weapons, and the life sciences pervaded the policy analysis community as well, as described by participants familiar with various organizations. Although the National Academies continued to conduct studies on security topics that encompassed biological weapons issues (such as Cooperative Threat Reduction efforts) following the classified studies of the World War II era, most relied heavily on experts in security and defense rather than biology well into the 1980's and early 1990's. A major NRC report on the flow of science and technology information and national security, which heavily influenced the Reagan-era decision to refrain from classifying basic scientific research to the maximum extent possible, focused on the technology paradigm of energy research rather than the information-driven model of the life sciences.[6] Within OTA, the security program conducted studies of defense technology and arms control issues, encompassing nuclear threats, while biological and health issues fell into the separate division of life sciences. Not until the early 1990s did the security program turn to studying technologies underlying biological weapons;[7] the security staff relied largely on the advisory panels (rather than in-house life

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[5] Vannevar Bush, "As We May Think," *The Atlantic Monthly* (July 1945). Available at http://www.cs.sfu.ca/CC/365/mark/material/notes/Chap1/VBushArticle/ (accessed August 2004).

[6] Panel on Scientific Communication and National Security, *Scientific Communication and National Security*, (Washington, DC: National Academies Press, 1982). This report is frequently called "the Corson Report" after the study chair. In 1985, President Reagan adopted the central recommendations of the Corson Report in National Security Decision Directive-189, which specified that a) "to the maximum extent possible, the products of fundamental research remain unrestricted," and b) "the mechanism for control of information generated during federally-funded fundamental research in science, technology and engineering at colleges, universities and laboratories is classification ."

[7] US Congress, Office of Technology Assessment. *Technologies Underlying Weapons of Mass Destruction,* (Washington, DC: US Government Printing Office, 1993).

sciences specialists) to provide technical expertise in biology. Although many NGOs provided analysis on biological weapons non-proliferation regimes, the vast majority of these did not rely on technically trained bioscientists, and only a handful considered biodefense issues prior to the escalation in public awareness of the late 1990's. Analyses frequently paired biological and chemical weapons as an inseparable duo despite profound technical differences between the two classes of threats, and many enfolded the "Chem-Bio" chimera further into a combined "chemical-biological-radiological-nuclear" or "weapons of mass destruction (WMD)" whole.[8] This one-label approach may have contributed to an inaccurate impression among policymakers that a security paradigm developed for nuclear threats, the clearest-cut of the WMD non-proliferation strategies, would serve equally well for all WMD threats.

Finally, in addition to a lack of traditional ties to the national security policy process, many in the biological research community experienced an abrupt and somewhat discomforting introduction to security concepts during the development and implementation of policies formulated in response to the attacks of fall 2001. Like many scientists and engineers in the US, bioscientists have encountered the direct and indirect effects of new visa requirements for foreign scientists and graduate students on their institutions, their laboratories, and their professional societies. The presidents of the three branches of the National Academies summarized some of these concerns in a December 2002 open statement:

> The evidence we have collected from the US scientific community reveals that ongoing research collaborations have been hampered; that outstanding young scientists, engineers, and health researchers have been prevented from or delayed in entering this country; that important international conferences have been canceled or negatively impacted; and that such conferences will be moved out of the United States in the future if the situation is not corrected.[9]

Although recent indications suggest that new State Department actions have eased the visa backlogs that accumulated in late 2001 and 2002 as a result of new policies, many researchers fear that changed perceptions of US receptiveness to foreign students and visiting scientists may affect graduate education and research for years to come.[10]

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[8] The "Chem-Bio" label endures for convenience as well as program recognition reasons, even as experts in the fields of non-proliferation and security have begun to address the issues separately. Federal agencies, including the division still known as the Federal Emergency Management Agency within DHS, still produce informational materials combining advice on "Chem-Bio" preparedness and response.

[9] Bruce Alberts, Harold Fineburg, and William Wulf, "Statement on the Impact of Current US Visa Restrictions on Science and Engineering," December 13, 2002. Can be found at http://www4.nationalacademies.org/news.nsf/0a254cd9b53e0bc585256777004e74d3/e061a6d4c13ed9ec85256ca70072dce5?OpenDocument (accessed August 2004).

[10] Michael Arnone, "Security at Home Creates Insecurity Abroad," *The Chronicle of Higher Education* (12 March 2003).

In addition to sharing worries about visa issues with the rest of the US science community, the researchers most intimately connected with biodefense research have encountered specific security mandates in the form of the recently implemented select agent rules, as described briefly in the Introduction to this report. With the rapid development and implementation of regulations based on the Bioterrorism Prevention Act and Patriot Act, researchers who study pathogens now classed as select agents and their institutions experienced first uncertainty about the scope of the new rules, and then frustration with bureaucratic backlogs in processing registrations for laboratories and security risk assessments for individuals.[11],[12] The rules have imposed what some scientists have deemed an onerous paperwork burden, complicated by potential criminal penalties that can result from compliance failures. The well-publicized prosecutions of graduate student Tomas Foral under the Patriot Act for retaining two vials of anthrax-infected tissue in a university freezer, Dr. Thomas Butler (acquitted of lying to the FBI and smuggling plague samples but convicted of improperly shipping samples and 46 additional counts of fraud unrelated to the original charges), and art professor Steven Kurtz and genetics professor Robert Ferrell for mail and wire fraud after the FBI confirmed that the non-pathogenic agents procured by the latter for the former's performance art project did not fall under any bioterrorism laws, sent what many researchers have found to be a clear message about the Justice Department's zeal in prosecuting violations whether or not terrorist intent is suspected.[13],[14] Some institutions have destroyed pathogen collections, and some scientists discontinued select agent research projects, rather than risk an unintended breach of the new rules.[15]

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 scientists involved in various disciplines of energy, computer sciences, and cryptography research have contended with information and technology control regimes for many years, most biological and biomedical researchers and the journals in which they publish their findings began truly wrestling with the issues only after 2001. Many journals have taken steps to screen submitted manuscripts for potentially worrisome data or techniques, but questions of how

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[11] Peg Brickley, "New Antiterrorism Tenets Trouble Scientists," *The Scientist* No. 16(21), (28 October 2002), p. 49.

[12] Ted Agres, "Researchers Bemoan Bioterror Bureacracy," *The Scientist* (24 September 2003).

[13] Jonathan B. Tucker, "Research on Biodefense Can Get Generous Funds, but With Strings Attached," *The Chronicle of Higher Education* No. 50(26), 5 March 2004.

[14] Jennifer Couzin, "US Prosecutes Professors for Shipping Microbes," *Science* No. 305 (9 July 2004), p. 159.

[15] Joanne Chan, "Issue Brief: Select Agent Rules (updated)."

to identify and censor such information without unduly inhibiting scientific progress or undermining the scientific process associated with peer review, and whether scientists and editors considering such data should work through classification and clearance processes, await resolution.[16] Despite reassurances that the 1982 National Security Decision Directive 189 (keeping basic research findings as open as possible and resorting to classification only if necessary) still stands, many bioscientists fear both heavy-handed use of classification and possible imposition of the poorly defined "sensitive but unclassified" label.[17] Few biological researchers have had experience with secrecy requirements apart from proprietary protections in the pharmaceutical and biotechnology industries, and many regard the security clearance and classification processes that are second-nature to the intelligence community with deep suspicion.[18]

New NIAID 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. As participants pointed out, this influx has created a wave of new experts with varying degrees of experience in handling different pathogens, as well as biosafety and security concerns borne of propagating new select agent research programs. Obviously, many bioscientists have decided to endure the requirements imposed by the new US biosecurity regime in order to carry out their work, but the degree to which US researchers have accepted the biological threat paradigm adopted by the intelligence and security communities still remains unclear. Whether or not philosophical differences on secrecy, the actual threat posed by domestic select agent research, and the effectiveness of current biosecurity regimes will affect the willingness of technical experts from the academic community to engage with the policy analysis and policymaking communities on biodefense and biosecurity strategies also remains to be seen.

STH ADVICE IN BIOLOGICAL SECURITY: THE CURRENT DEMAND

The demand for STH expertise in the biological security policy process has changed since the surge of interest in the late 1990's, and many times more since fall 2001. During the Clinton presidency, the National Security Council acquired its first special advisor on health and security matters with a medical background; now, most federal advisory councils and working groups on homeland security

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[16] Ronald M. Atlas, "Public Health: National Security and the Biological Research Community," *Science* No. 298, (25 October 2002), p. 753.

[17] Ryan Ricks, "Issue Brief: Sensitive but Unclassified Information (updated)."

[18] In one extreme example, a controversial initial announcement that the CIA intended to issue a classified report on an unclassified session on scientific openness, convened by the NRC to bring prominent microbiologists together with the CIA's strategic assessments group, drew subsequent public criticism and reprisals from some participants, ending with figuratively ruffled feathers on both sides and doing little to promote mutual trust between the two communities. See Peg Brickley, "CIA openness report to be classified?" *The Scientist* (7 April 2003).

issues boast at least one member, and frequently more, with life sciences training. Biological weapons are now recognized as threats technically distinct from chemical weapons, even if old labels remain. Nonetheless, as several participants highlighted, the understanding that biological weapons issues have attained a more prominent place in the security landscape does not translate into automatic inclusion of STH expertise in the early stages of decision-making processes. Nor, as all three discussions emphasized, do researchers trained in the biological sciences – or even pathogen research – necessarily have a full picture of the technologies and biological weapons capabilities upon which they may offer advice.

In attempting to capture the essence of the current demand for STH expertise in the national biological security policy process, participants in all three roundtable discussions identified basic characteristics of *experts* necessary to providing sound science and science policy advice. These experts can be classified in three general tiers, with myriad organizational models for connecting the advice that they provide to the decision-making process.

Technical Experts

Technical experts have scientific or professional training in a biological or biomedical discipline closely related to issues at hand, including reasonably recent experience in the laboratory, field, or clinic that grants 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

These scientists have technical training as well as practical experience in a specific biological or biomedical field, but have chosen to forego a typical research career (temporarily or permanently) to work within a government agency or program. This group consists of mostly mid-career scientists who rely upon their research expertise and experience in providing guidance for operational and analytical missions, as well as intra- or inter-agency planning. For example, a technical science policy advisor might direct a program to meet national security objectives through funding particular lines of research and development, or to oversee the deployment of particular countermeasures. Participants agreed that these technical policy advisors (as well as the science policy professionals described below) 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

The relatively small core of actively engaged 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. These professionals often serve as science policy advisors within legislative or executive branch organizations, or as policy analysts in government or non-government organizations.

Science policy professionals require a diverse set of skills and accomplishments that allow them to communicate productively and credibly as liaisons between the scientific community and decision-makers. As one participant explained, “There is a relatively small cadre of individuals that can fit the nexus between all of those domains, operational policy, analytical and scientific.” Although S&T fellowship programs provide one avenue for grooming technically trained researchers for policy careers, participants emphasized that the career development of individuals with the right personality and skills cannot be taken for granted. “You need people like that, and there are a few folks around, but it’s by accident that they develop that way as opposed to purposefully,” explained one participant. Participants generally agreed that short-term training courses designed to give scientists a brief introduction to policy and security issues probably served well in helping researchers understand the implications of their work, but did not replace immersion in the policy-making/analysis communities as a training regimen for new science policy professionals. No participant agreed with the idea that graduate training programs in the biological and biomedical sciences should deliberately train students for careers unrelated to science or science policy (citing costs as well as the degree of commitment required to succeed in research), but most expressed support for mentoring programs to help scientists with an interest in public service understand the necessary skills and available options. The discussions proved less conclusive on the roles of graduates with degrees in hybrid fields, such as masters’ degrees in science and security; some participants felt that these individuals lacked sufficient knowledge of and credibility with researchers to serve as effective policy liaisons, while others felt that the requisite communication skills, accompanied by some technical background, would meet the requirements of most policymakers.

Participants agreed that, for all three categories, scientists must establish and maintain credibility to have a positive impact. For a technical expert to serve as a "trusted skeptic," he or she must have not only impeccable research credentials, but enough distance from the government organizations soliciting advice to maintain an outsider's clear viewpoint and uninhibited ability to voice potentially unwelcome opinions. A participant with substantial security and research experience emphasized that identifying technical experts in biodefense 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), information that may be limited to a small subset of mostly government biodefense researchers. "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. As one participant remarked, pointing out the number of individual technical experts who had served on multiple advisory panels, "If it is a fairly finite community, that group is going to be very heavily tapped, and given that most of them are stretched, because they are technical experts running laboratories…we're going to be limited to people who are semi-retired or older, very senior."

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. Due to the high ratio of physicists to biologists with policy experience, and the enfolding of biological weapons issues with nuclear issues, the "technical experts" in various biodefense and biosecurity policy programs have sometimes been physicists with informally acquired knowledge of biological weapons technologies. The degree to which this proves a problem depends largely on the circumstances. As one participant pointed out, the researchers who get into these positions are "smart and capable," and can function perfectly well as cross-disciplinary technical advisors by calling in specific expertise to complement their own knowledge. Another cautioned that those with a veneer of expertise in biological sciences laid atop a science background in another field could miss critical biosecurity details. "In particular, it makes a difference when you create programs in a climate of great suspicion, when it's very easy to make technical claims and charges and you don't have anybody on the inside saying, 'No, that isn't how it actually works. It isn't how it operates.'"

Above all, participants emphasized in all three roundtable sessions, science advisors of all sorts have to remember both their strengths and their limitations when speaking to issues outside of their technical training. Very few, if any, policy decisions depend on scientific evidence alone, and scientists new to serving as technical experts or policy advisors frequently become frustrated with the failure of policymakers to act upon what appears to be obvious evidence. Conversely, scientists who provide technical advice on issues with which they have little familiarity, or who offer value-driven opinions with the full weight of their credentials behind them, risk jeopardizing not only their own credibility but that of their colleagues. As one participant remarked, "Science professionals maintain their credibility if they stay in their lanes….You get physicists trying to do biology. But they go beyond that. You now get physicists telling people how to do intelligence. Their contributions to science are empirical, but you get over that and it becomes damaging."

Forms of science policy recommendations: describing reports

In addition to identifying the types of STH experts currently providing various forms of policy advice, participants discussed at length the various forms of reports or publications in which science and science policy advice can be presented. In doing so, they defined five broad categories for such reports, with each category divided into two opposing types, as described in the table below. Defining these categories allowed for a more fruitful discussion of criteria for forms of STH expertise found particularly useful. Any given policy report can fall into a pattern definable within all five areas. As an example, according to these criteria, the NAS report called *Making the Nation Safer* released in response to the 2001 terrorist attacks, described in Chapter 2, could be described as a self-driven, reactive, largely evidence-based open report on broad science policy issues.[19]

[19] *Making the Nation Safer*, 2002..

Table 1: Forms of STH Expertise

Specific technical analysis	**Broad science policy**
Draws on technical information and STH expertise to address a particular technical subject in detail that may range from a fairly broad review to a narrow assessment.	Draws on technical information and STH expertise to outline the implications of certain actions or policies, and may provide recommendations or options to guide decision-makers.
Open	**Closed**
Published for a general audience, with dissemination allowed or encouraged beyond the organization that requested the analysis.	Produced for use within a specific organization or program, with no intention of distribution outside of those circles. (Classified reports would represent one specialized subset of closed reports.)
Anticipatory	**Reactive**
Initiated by policy analysts and/or technical experts who foresee that an issue might become important in the future, and wish to consider that issue in depth before a crisis arises.	Initiated in response to a specific event or incident, or in response to an agency request driven by external influences or program needs.
Self-driven	**Solicited**
Conducted as a self-tasking by a policy analyst or analysis organization, in the absence of any specific external request or event, to study an issue based on interest, available expertise, or other opportunities. (Funding organizations, as well as internal interest, may shape such studies.)	Conducted in response to a specific request by a policymaker, program, or agency.
Evidence-based	**Estimate-based**
Relies upon the preponderance of existing data and STH expertise to determine the most probable correct answers to science or science policy questions, in order to aid in selecting between possible courses of action.	Relies upon available evidence and past experiences of STH experts to extrapolate the most probable answers when existing data is incomplete or nonexistent, in order to provide "best guesses."

INCORPORATING STH EXPERTISE INTO THE DECISION-MAKING PROCESS

In all three roundtable sessions, participants dedicated considerable time to discussing the integration of STH expertise in government decision-making, and factors that had – in their experiences – improved the odds that science policy advice would be weighed in the biological security policy process. First, participants cautioned that such integration of STH expertise, in most agencies and organizations, often depends on 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. As summarized by a participant,

> How do agencies or those interested identify, tap into the expertise that exists? Obviously, there are lots of different models. When I came from [a Federal agency], it really until recently didn't have a fixed model they would go to, rather it was an informal network that was set up usually by somebody's Rolodex; actually part of my Rolodex got it started. But then you have standing bodies like the [Defense] Science Board that have a fixed population with identified government advisors that come in and work on problems….Ultimately, if you look at an agency that's very operational and like the one I came from, part of this dimension of seeking out, tasking and then identifying and accessing [STH expertise] has to do with trust building. 'I'm going to give you something I can understand, use, and has value to me.'[20]

Based on these and similar observations, participants discussed various agencies' and programs' successes and failures in setting up formal channels for ensuring access to STH expertise at various stages in the decision-making process. As several participants pointed out, the Manhattan project, subsequent nuclear arms development, and the space race endowed DOD with a legacy of relying on scientific expertise that has endured for more than 60 years. In that time, the department has established well-defined channels for soliciting S&T advice through its standing advisory boards and FFRDCs, and its leaders have shown an appreciation for the contribution of STH expertise in guiding research and development strategies, acquisitions plans, and red-teaming. Although more attention has been paid to energy and conventional weapons than biosecurity and biodefense issues, policymakers within DOD remain receptive to seeking S&T advice when necessary, a trait that stems largely from an appreciation of the very tangible advantage that S&T advances give to forces. Participants pointed out that this receptiveness often allows S&T advice to influence budget decisions, and therefore to influence policy decisions indirectly or directly. In addition, DOD – working through a program commissioned by the

[20] The name of the Federal agency in question has been omitted to preserve confidentiality of participants, as agreed upon in the conditions of the roundtable sessions.

Defense Advanced Research Projects Agency (DARPA) and administered by the Institute for Defense Analyses, an FFRDC – has sought to cultivate the interest of emerging academic researchers in science and technology through its Defense Science Study Group. These researchers spend 22 days over two academic years learning about issues and policies related to national security.[21] As described by a participant, this investment in teaching researchers about S&T applications and security policies in real-world settings can foster a new generation of potential S&T policy advisors, or simply increase researchers' interests in DOD-funded science and engineering projects; the ongoing involvement of program alumnae in various capacities indicates some degree of success. Another participant cautioned that this program, although successful for DOD, may have less allure for other agencies. The success of the Defense Science Study Group depends to a great extent on the "glamour" of, and the lure of grants to study, new technologies. Despite these caveats, some participants felt that specific aspects of this program, particularly its emphasis on introducing scientists to the operational contexts for S&T developments and policy recommendations and its sensitivities to the academic life cycle, provide a template for engaging research professionals in biosecurity or biodefense programs within other agencies.

With tremendous in-house biological and biomedical expertise in the CDC, NIH, and its other programs, HHS can depend largely on internal science advisors with the assistance of its issue-specific advisory committees. Other agencies involved in the national biological security policy process have much shorter records in incorporating STH expertise. The State Department has no external S&T advisory panels, although its resources include the Senior S&T Advisor and a cadre of S&T fellows to supplement its finite in-house expertise. The senior scientific leadership at DHS, given the opportunity to start "from scratch," appears to have found at least initial success in creating a strong Science and Technology Directorate with a system for cultivating coordination between S&T portfolio managers and decision-makers in the other directorates. The S&T Directorate now boasts a strong in-house expertise (including an increasing number of biologists to supplement the initial core of physicists), and an S&T fellowship program and an external S&T advisory committee that arose nearly simultaneously with the department itself. Despite this promising start, most participants agreed that the agency itself remains too new to draw many lessons-learned, or conclusions about whether S&T policy advice channels have surpassed individual personalities to remain systemized in the long-term.

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. As described by one

[21] Information on the program can be found at http://dssg.ida.org/ (accessed August 2004).

participant, the various programs tend to be "neighboring tribes, at best." In addition, the intelligence and law enforcement communities have less experience incorporating STH expertise as a driver of policy decisions than in turning to S&T programs as a source of "unique tools of the trade…the gizmos that nobody else has that help us collect intelligence."

The FBI has just launched new efforts to include STH expertise in the biological security policy process; the agency's small size and fairly flexible organizational structure can lend themselves to relatively quick change, given sufficient support from high-level leadership. The opportunity does exist for more management cohesiveness in science issues within the Department of Justice (DOJ) as a whole. DOJ has a senior science advisor to the Director, although at the time of the roundtable sessions, participants cautioned that this position remains mostly symbolic in the absence of sufficient resources or authority. Several participants cautioned that the many reform initiatives being considered by and for the intelligence community will create an upheaval that may create new opportunities for incorporating STH expertise into decision-making processes in the long run, but will probably not be hospitable to new institutions in the near term. Various parts of the intelligence community have successfully gleaned STH expertise from issue-specific committees, consultants, and "red-teaming" groups, and the Central Intelligence Agency has increased its efforts to engage bioscientists through National Academies-facilitated workshops and studies with some success.

An issue that affects the ability to communicate STH expertise to policymakers in general, but one that particularly affects the intelligence community, is that reports to policymakers may be derived from many months of in-depth analysis under the aegis of various entities. As one participant pointed out, what started out as a six-month long, highly technical study may be boiled down into one paragraph for the report that actually goes to decision-makers.

> I think we do a lot of taking the 50-page papers and turning them into a paragraph. A paragraph would be generous. A memo to the Secretary of State is one page maximum, that is it. One page. So we're taking a lot of disparate data and distilling it for the policymaker's recommendations. I don't know if it's underrepresented or that they'd say oh, this must have been done in 20 minutes because it's only one page. They are not aware that there is this back story, if you will.

The first step to incorporating STH expertise successfully and consistently, participants agreed, lies in getting scientists "out of the ghetto and into the main office." Even agencies that house significant in-house STH expertise are unlikely to integrate those experts into decision-making beyond their specific technical realms if they remain lodged within organizational structures that promote the "neighboring tribes" mentality. Participants suggested that lessons can be learned from some successes at DOD and

State, as well as less-than-sterling attempts to encourage incorporation of STH expertise, about changing an agency's or program's culture so that policymakers become accustomed to considering STH advice throughout all stages of decision-making relies. Keys to success include:

- Placing a small core of science policy professionals, with appropriate cross-disciplinary skills to contribute to non-technical as well as S&T issues, 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, such as a senior S&T advisor, with adequate resources and authority supported directly and visibly by the head of the program or organization; and
- Educating senior decision-makers to promote recognition of the relevance and value of STH expertise incorporated early in the decision-making process through both internal and external outreach.

Once adequate scientific leadership has been established, the agencies can find themselves in far better position to make use of both STH expertise (in the form of technical reports and science policy recommendations) and experts (such as fellows, outside technical advisors, and technical policy advisors). Another step that increases the likelihood that STH advice will be incorporated into the decision-making process, participants with experience in security and federal law enforcement emphasized, is the inclusion of operational suggestions or at least concrete policy recommendations in the reports produced by policy analysis organizations. Whether or not reports on S&T issues find use within various agencies and programs frequently relies upon the actions of science policy professionals who can act as "translators" to link technical findings into potential actions for policy-makers. If such science policy professionals have not yet been firmly established within an agency, even excellent recommendations may go ignored by decision-makers in the target audience.

As an example of a successful model for incorporating policy recommendations made by STH experts into the national biological security policy process, these participants emphasized the value of the founding of the National Science Advisory Board for Biosecurity (NSABB) as a case study. As described previously in this report, the National Academies initiated a study on 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 study committee consisted of experts in a range of biological and biomedical disciplines, as well as international law and defense security issues, who set about assessing the "capacity of advanced biological research activities to cause disruption or harm, potentially on a catastrophic scale," through either the theft or diversion of pathogens or the creation of novel threat agents.[22] During the course of this study, the biosecurity regulatory regime in the US changed profoundly, and the committee considered the impact and adequacy of the new regulations among its other charges. In its report, published in fall 2003, the Committee outlined 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). Recommendations included systems for educating scientists, categorizing and reviewing "Experiments of Concern" and unexpected results at several levels, sustaining communication between the life sciences and security communities, improving biosafety, promoting international harmonization of biosecurity regulations, and creating the NSABB. In March 2004, the Secretary of HHS announced the charter of the NSABB, a board designed to advise all federal agencies that support life sciences research on overseeing such dual-use biological research, "taking into consideration both national security concerns and the needs of the research community."[23]

The charter states that the NSABB will be composed of outside experts in a variety of relevant biological, biomedical, health, legal, and security fields, plus ex officio members from the represented Federal agencies, and HHS has already set about hiring S&T experts to head the committee staff. 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 a structure intended to ensure that appropriate STH expertise goes into development of particular regulatory and oversight structures, providing an amalgam of community expertise and top-down authority. Although participants emphasized that this model had not achieved perfection (given the initial two-year lifespan of the Board, some confusion about the authorities of the various agencies involved, what seems like an overwhelming workload for a Board scheduled to meet four time per year, and the obvious omission of classified and industry research from the Board's scope), they did suggest that it provided a relatively satisfactory solution to a biosecurity dilemma that could have resulted in stringent, top-down, and possibly counter-productive regulation of biological and biomedical research. The keys to this success, they believed, lay

[22] *Biotechnology Research in an Age of Terrorism,* 2003.

[23] Charter, National Science Advisory Board for Biosecurity (4 March 2004), available at http://www.biosecurityboard.gov/SIGNED%20NSABB%20Charter.pdf (accessed August 2004).

in the strengths of the science policy report and recommendations, which offered a mix of comprehensive, comprehensible background information and a set of policy recommendations that outlined specific courses of action.