

The Interagency Challenge of

Biosecurity

in Dual-Use Research

by Matthew J. Moakler

On October 17, 2014, the White House Office of Science and Technology Policy announced a funding pause for “gain-of-function” research (i.e., research that increases an organism’s ability to cause disease) in order to conduct a study to develop a new federal research policy.¹ This announcement is the latest in a long history of U.S. policies intended to mitigate the risk of advancements in the life sciences contributing unwittingly to a biological weapon (BW) program. While the intention to protect U.S. citizens from a BW attack may be noble, biosecurity policies and regulations appear to be implemented as reactions to discreet events without a comprehensive strategy to address potential future threats. This latest decision raises many questions about what must inform a discussion of the interagency’s biosecurity task:

- Who can best determine whether specific biological research can contribute to BW development?
- What is the balance between advancing life-saving techniques and protecting the population from a BW attack?
- How do different biosecurity stakeholders interact with each other?
- Who gets the final say on allowing research to go forward?
- What measures should be taken to prevent the misuse of life science research?
- Who should have the responsibility to enforce such measures?

The urgency of these and similar questions becomes apparent in view of the fact that the pace of advancement in the life sciences is expected to increase not only in the realm of existing

U.S. Army Lieutenant Colonel Matthew J. Moakler serves at the International Security and Nonproliferation Bureau, Department of State. He holds a M.S. degree in biodefense and is a Countering WMD Graduate Fellow at National Defense University.

technologies, but also with the introduction of new technology, techniques, and venues for conducting research—including experiments conducted by do-it-yourself researchers in home laboratories.² In light of these expectations, it seems clear that those most familiar with the advancements in the life sciences should play a larger, more formal role in the indispensable allied task of biosecurity. Neither life science professionals nor security professionals fully possess the wide range of tools necessary to protect the nation from the threat of BW. Hence, life science, when viewed as a profession, should play a larger role in the task of biosecurity. Understanding the extent of the life science profession’s role in the task of biosecurity will lead to more informed interagency discussion about ways to mitigate the risks of misuse of biology.

The idea of a “profession” itself involves having specially qualified practitioners who can deal in concrete ways with an abstract body of knowledge essential for accomplishing a specific task for the good of society. Additionally, the jurisdiction of a profession does not always have clear lines of separation from other professions that have a stake in the same task. This is especially true in the case of disciplines, like biosecurity, whose very name suggests competing jurisdictional claims. Moreover, biosecurity is a term that has different meanings depending on the community using the term.³ It can refer to very specific threats, such as protection for “plant and animal health” and “biodiversity”; protection against bioterrorism; and “oversight of dual-use research.”⁴ Conversely, it can refer, as the National Academy of Sciences (NAS) defines it, to “security against the inadvertent, inappropriate, or intentional malicious or malevolent use of potentially dangerous biological agents or biotechnology, including the development, production, stockpiling, or use of biological weapons as well as natural outbreaks of newly

emergent and epidemic diseases.”⁵ Underlying all of these definitions, however, is the problem posed by “dual-use research,” namely research “intended for civilian application that can also be used for military purposes.”⁶

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The following analysis focuses on the division of professional labor as it applies to the task of biosecurity in dual-use research. The task of biosecurity is caught between the competing professions of national security and life science research. For the purposes of this discussion, the relevant security professionals are composed of U.S. government policymakers on the White House Staff, administrators at the National Institutes of Health, and law enforcement professionals who have roles in regulating biological research. The life science profession, as it applies to the task of biosecurity, is composed of principal investigators, university administrators, and academics that are at the cutting edge of research intended to exploit the natural processes of living organisms for the benefit of society—many of them recipients of federal research grants from throughout the interagency.

The Current Biosecurity Management Approach

For the past several decades, the U.S. government security profession has primarily claimed the task of biosecurity by imposing a series of regulations. With the pace of advancement in the life sciences, government regulations characteristically lack the flexibility

to anticipate whether potential threats may develop as the science matures. Current legislation and the related regulations should balance protection from the threat without being “overly restrictive given the critical role that the development of effective vaccines, diagnostics, therapeutics, and detection systems, along with a responsive public health system, will play in providing protection against bioterrorism—and other serious health threats.”⁷ As Robert Carlson observes:

There are currently calls to limit research in the United States on the basic biology of many pathogens to preempt their use as bioweapons, and the possession and transport of many pathogens was legislated into criminality by the Patriot Act. The main difficulty with this approach is not that it assumes the basic biology of pathogens is static—which because of either natural variation or human intervention it is not—but rather that it assumes we have already catalogued all possible natural pathogens, that we already know how to detect and defeat known and unknown pathogens, and that rogue elements will not be able to learn how to manipulate pathogens and toxins on their own.⁸

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Given that there are too many unknowns—both natural and man-made—government regulations alone cannot provide full protection from the potential misuse of dual-use research. In fact, the current U.S. strategy and government-commissioned studies concede this point. The “National Strategy for Countering Biological Threats” states that “life scientists

are best positioned to develop, document, and reinforce norms regarding the beneficial intent of their contribution to the global community as well as those activities that are fundamentally intolerable.”⁹ In a 2003 report “Biotechnology Research in an Age of Terrorism,” the recommended system of governance over dual-use research “relies heavily on a mix of voluntary self-governance by the scientific community and expansion of an existing regulatory process that itself grew out of an earlier response by the scientific community to the perceived risk associated with gene-splicing research.”¹⁰ A 2006 NAS report “Globalization, Biosecurity, and the Future of the Life Sciences” states that the U.S. security community has “been unable to establish and maintain the breadth, depth, and currency of knowledge and subject matter expertise in the life sciences and related technologies that are needed” to anticipate future biological threats.¹¹

However, despite the acknowledgement that the life science community must have a larger role in the regulation of dual-use research, the practice of the U.S. government has been to enact regulations with only the advice of the life sciences. This amounts to a weak relationship in which the life science profession is only allowed the “legitimate right to interpret, buffer, or partially modify actions”¹² that are within the full jurisdiction of U.S. security professionals.

The government regulation of scientific research in the U.S. has evolved along with the perception of the threat. Each regulation was developed in response to a specific perceived threat. For example, the original “NIH Guidelines for Research Involving Recombinant DNA Molecules” were developed in response to the perceived public-health threat posed by recombinant DNA research.¹³ Unfortunately, a study of the effect of a reactionary approach to biosecurity policies developed almost exclusively by the security portion of the interagency apparatus reveals (not

surprisingly) both a decrease in motivation for self-governance from the science community and an increase in the amount of time required to issue policies and regulations after the threat is identified.

Bioterrorism and Dual-Use Research

The deliberate spread of anthrax through the mail in October 2001 caused both security and life science professionals to give renewed emphasis to the threat of bioterrorism. After the National Commission on Terrorism released a report in 2000 recommending that biological physical security standards “should be as rigorous as the physical protection and security measures applicable to critical nuclear material,”¹⁴ the NAS Committee on International Security and Arms Control became concerned about how Congress might seek to implement this recommendation. Hence, it established its own committee to “review current U.S. mechanisms to prevent the destructive application of biotechnology research and to recommend improvements to those mechanisms that would still permit legitimate research to proceed.”¹⁵ In effect, the committee’s work was an effort by the life sciences profession to preempt legislation that could further hinder scientific advancement. The committee’s work, known popularly as the Fink Report, contained several recommendations that are still being addressed in policy recommendations over a decade after it was published in 2003. The overall tenor of the recommendations was to leave evaluation of the biosecurity risk in the hands of the life science community. The report identified seven “experiments of concern” to focus the discussion of whether an experiment should be conducted in the first place and, if conducted, whether the results should be published in the open literature.¹⁶ Since the NIH Guidelines already provided a mechanism for evaluating research risk through its Institutional Biosafety Committee (IBC), the Fink Report recommended

expanding the IBC role to include dual-use research.¹⁷ Another important recommendation was the establishment of the National Science Advisory Board for Biodefense (NSABB). This board was to be composed of both science and security representatives to provide a strategic forum for science and security dialogue and a resource for advice on specific experiments being carried out at research institutions.¹⁸

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After nine years, the U.S. government released the “United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern” in 2012. This policy requires federal departments and agencies to submit a biannual risk assessment for all experiments they conduct or fund as defined in seven categories. These categories are slight variations of the “experiments of concern” described in the Fink Report, but are now referred to as “dual-use research of concern” (DURC). After over two additional years of deliberation and development, the U.S. government issued an additional policy, “United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern,” in 2014. This newest policy maintains all of the requirements for federal departments and agencies that fund DURC and adds additional responsibilities for the principal investigators—the lead scientists conducting an experiment—and the institution where the research is being conducted, regardless of whether the institution is receiving federal funding. The 2014 policy requires research

institutions to assign an institutional contact for dual-use research (ICUDR) and to establish a review committee that can evaluate the risk of misuse of a particular experiment. Institutions may use an existing IBC, create a new review committee, or use an IBC from a neighboring research institution.¹⁹

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Responding to the threat of bioterrorism and the potential misuse of DURC is a process, and research institutions have until September 2015 to develop relevant compliance procedures. However, it is still possible to discern the similarities between previous reactions to science security concerns and this one. First, the life science profession was the first to initiate a study on how to address the risk of potentially dangerous technology being made available to terrorists. It was, in fact, the science community—not the U.S. government—that established the initial recommendations for regulation, stressing the desire to retain the predominant jurisdiction with the scientists. Second, two government regulations emerged in response to the risk of DURC. The policies on oversight of DURC—both government and institutional—require researchers to define the scope of the research addressed and require institutions to create an internal review board. However, they retain the ultimate control of the biosecurity task within the government security profession. The most recent policies even use the same IBCs as options for institutions to evaluate the new threat.

To further complicate matters, the time that security professionals take between identifying the threat and issuing a policy is trending longer.

It took at least nine years to determine how to control the DURC threat. At the same time, the pace of advancement in the life sciences is increasing, limiting the effect that published policies may have on the problem. Now is an opportune time for the interagency to reevaluate the relationship between the security and life science professions.

A Model for Conducting the Needed Reevaluation

The general bureaucratic model that has been followed thus far in regulating potential for misuse of life science research has been to identify the risk, consult the life science community, and develop government regulations to mitigate the risk.

This model assumes that U.S. government security professionals are uniquely qualified to be entitled to practically full jurisdiction over the task of biosecurity as it pertains to dual-use research. While the most recent policy regulations state the intention to reevaluate and update policies “as warranted,” history has shown that new policies only add additional requirements on top of old ones, resulting in a perpetuation of the same relationship between professions. In situations like this one, it is useful to apply a different method of evaluating the problem to see if it may provide a more useful result.

In his seminal work *The System of Professions: An Essay on the Division of Labor*, sociologist Andrew Abbot describes what constitutes a “profession” and how professions relate to each other when confronted with the requirement to determine the extent of shared jurisdiction over a task. In doing so, he moves beyond the typical professional literature that focuses on “structures of operational control,” such as “licenses, schools, journals, [and] associations.”²⁰ Two aspects of Abbot’s model that are pertinent to the discussion of the life science profession are his description of what

constitutes “professional work”²¹ and his discussion of the legitimate and rational grounds for claims of professional “jurisdiction.”²² The first, as applied to the present subject, addresses the requirement for a profession to assume the task of biosecurity; the second addresses the issue of which profession should carry out which tasks associated with overlapping jurisdictional claims and to what extent.

Abbot argues that all professional work is composed of “human problems amenable to expert service.”²³ These problems contain both objective and subjective properties that contribute to solving the task at hand. Objective properties are “given by natural or technological imperatives,” while subjective ones are “imposed by the present and past of a culture itself.”²⁴ When these properties are applied to the threat of biological weapons, one can easily establish that a threat exists, and that there is a need for an expert service to minimize that threat. The objective nature of the biological weapons threat is well documented. Both the U.S. and the Soviet Union amassed stockpiles of biological weapons during the Cold War. The 1972 Biological Weapons Convention had a great deal of success in establishing an international norm against state production, stockpiling, and use of biological weapons. However, a non-state threat remains. For example, in 1984, the Rajneeshees cult contaminated salad bars with salmonella in an effort to reduce voter turn-out and skew the results of a local election.²⁵ The Japanese cult Aum Shinrikyo attempted to disperse anthrax spores in Tokyo.²⁶ There is also evidence that al Qaeda attempted to develop an anthrax weapon with the assistance of Pakistani and Malaysian scientists.²⁷ Perhaps the most well-known act of bioterrorism occurred in 2001 when anthrax filled envelopes were sent to several locations in the U.S. through the mail.²⁸ Based on these examples, there should be no disagreement that, objectively, the threat of bioterrorism exists, and

that by extension, a rational claim can be made to the effect that some societal organ is best positioned from among competing alternatives to assume jurisdiction in addressing the threat.

Subjective properties of a problem provide the arena where different professions may compete for jurisdiction of the task. Abbott divides subjective qualities into three parts: diagnosis, inference, and treatment. Diagnosis is the process of collecting information about a problem and then classifying it into a category for which there are treatments. Inference occurs “when the connection between diagnosis and treatment is obscure” and requires the most expertise in a given field in order to bridge the gap between diagnosis and treatment. Treatment is the prescription of a solution to the problem.²⁹ As these generic terms from Abbot’s theory are applied to the problem of biosecurity in dual-use research, their usefulness quickly becomes apparent.

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Based on the three examples above, it is clear that both the life science and security communities have a stake in achieving the right diagnosis. Abbott contends that diagnosis “not only seeks the right professional category for the client, but also removes the client’s extraneous qualities.”³⁰ The difficulty in diagnosing the task of biosecurity lies in the fact that the clients are not only the researchers working in the field, but also the American public, whose concerns are not strictly the same as those of scientific researchers. Hence, security professionals cannot, or perhaps should not, attempt to remove from their calculus what they may consider to be “extraneous qualities” like fear, politics, and limited government resources from

the diagnosis. This fact, however, admittedly makes it harder to classify the resulting picture into a “dictionary of legitimate problems.”³¹ For when this happens, the result is a diagnosis of the problem that has to take into account every possible outcome, no matter how remote the chance.

After diagnosing the threats from DURC, NAS conducted a study to draw on the knowledge of the science community in order to bridge the gap between diagnosis and treatment. However, the two professions interpret inference differently. Once again, Abbot’s analysis provides a perspective that assists in determining the overlap in jurisdictional claims. He delineates two types of inference: exclusion and construction. “Exclusion” assumes that a profession will get multiple attempts to apply treatment. If a treatment is not successful, the professional can apply different treatments in succession to solve the problem.³² This type of inference is most closely related to the trial-and-error conducted by researchers in the life science profession. Professionals are able to conduct their experiments in a controlled environment (i.e., the laboratory) before arriving at their desired result. When developing a new medical

biological weapons attack would amount to a biosecurity failure from the perspective of the American public. Security professionals are not afforded the controlled environment of a laboratory. Security professionals appear to be using inference by exclusion when inference by construction is required based on the nature of their profession. This is apparent by the compounding treatments that are applied to the threat of misuse of scientific research. An understanding of the different types of inference and which is most appropriate for the competing professions will help to define the primary clients of each profession (discussed below).

The final attribute of professional work is treatment. Where diagnosis removes the personal qualities of the problem, treatment needs to reintegrate them so that a treatment will be effective to the clients. Abbott calls this “the process of prescription.”³⁴ Prescriptions that have been discussed thus far have come in the form of policies and regulations. Security professionals have retained the right to prescribe security classifications and institutional review boards on scientific research in order to make the treatment effective for the American public. However, the clients of biosecurity are not just the American public; they are also the researchers and institutions themselves. The security profession’s prescription does not adequately take this additional constituency into account. Conversely, prescriptions from the life science profession, when it has been given the ability to prescribe, tend to lean more toward the researcher clients and tend to omit adequate consideration of the larger society.

Diagnosis, inference, and treatment provide a lexicon that allows the analysis of how different professions may establish relative jurisdiction within a given task. In the previous discussion, examples illustrated the different perspectives of security and life science professions within this lexicon. The following discussion will focus on how these professions,

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treatment for anthrax, for example, the researcher must first test the drug on animal models, then a controlled group of human subjects, before the drug is ready for administration to the public. “Construction,” on the other hand, assumes that the profession will only get one chance to solve the problem, requiring it to develop a more comprehensive treatment.³³ Security professionals are faced with the biosecurity challenge of preventing all misuse—one

as a whole, relate to each other.

Claim of Jurisdiction

Abbott provides a useful method that can be applied to analyze the relationship between security and life science professionals. Both have a stake in ensuring that life science research is conducted safely within the lab and that the results of the research cannot be easily misused by those that wish to do harm. Jurisdictional claims are at the heart of what constitutes a profession. Abbott explains:

A jurisdictional claim made before the public is generally a claim for legitimate control of a particular kind of work. This control means first and foremost a right to perform the work as professionals see fit. Along with the right to perform the work as it wishes, a profession normally also claims rights to exclude other workers as deemed necessary, to dominate public definition of the tasks concerned, and indeed to impose professional definitions of the task on competing professions. Public jurisdiction, in short, is a claim of both social and cultural authority.³⁵

Since tasks frequently fall within the jurisdictional claim of multiple professions, those professions must establish a relationship that is accepted by the public and reinforced in laws. Abbott describes five relationships or “settlements of a jurisdictional dispute” ranging along a spectrum of “full,” “subordinate,” “intellectual,” “divided,” and “advisory.”³⁶ Based on the cases described above, security professionals appear to claim “full” jurisdiction over biosecurity. This is demonstrated by the fact that the prescription of treatments comes in the form of policies and regulations that are imposed upon the life science profession. In the past, even when the life science profession has attempted to prescribe its own treatment, security professionals have imposed additional

regulations.

Currently, the life science profession can best be described as claiming an “advisory” jurisdiction on the task of biosecurity. Abbot

Both [security and life science professionals]...have a stake in ensuring that life science research is conducted safely...

describes this jurisdictional relationship as “a weak relation, in which one profession seeks a legitimate right to interpret, buffer, or partially modify actions another takes within its own full jurisdiction.”³⁷ This advisory role is manifest in NAS committees and the NSABB. However, some have questioned the continued relevance of the NSABB, the main component of the life science profession’s already limited role in biosecurity. The NIH stripped the NSABB of its oversight role in 2012, and the NSABB currently meets less frequently than called for in its charter.³⁸

Several examples illustrate the current advisory role of life science professionals in relation to security professionals. In the past, the science community took the lead in initiating moratoria on experiments that caused it concern, such as experiments with recombinant DNA. In contrast, today the Office of Science and Technology Policy and the Department of Health and Human Services—the bureaucratic institution—pauses funding for certain experiments until it—and not the scientific community—can conduct a “deliberative process to assess the potential risks and benefits associated with a subset of life science research.”³⁹ In another example, The Cambridge Working Group, a group concerned about “potential pandemic pathogen” research, called for a pause in research similar to the one that introduced this article; however, the group appears to support the security

profession's claim of jurisdiction by posting the government's research pause announcement at the top of its website without any disclaimer whatsoever.⁴⁰ What little claim that an advisory jurisdiction provides to the life sciences over the task of biosecurity appears to be dwindling.

Abbott states that advisory jurisdiction is "sometimes a leading edge of invasion, sometimes the trailing edge of defeat."⁴¹ If the life science profession intends to assert a claim on biosecurity, it must work its way up Abbott's spectrum of settlements to gain public legitimacy. The next level of settlement on Abbott's spectrum is "division of labor." This is a "division of the jurisdiction into functionally interdependent but structurally equal parts."⁴² A step up to settlement by division of labor may improve the task of biosecurity by leveraging the life scientists' knowledge, maintaining the benefit of the profession's inference, and prescribing treatments that benefit both types of client—the public and the research institutions.

Benefits of Division of Labor

In order to remain relevant in the task of biosecurity, the life science profession needs to expand its jurisdiction to assume a larger claim on diagnosis and treatment of the task. The profession should do this to protect

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its own researchers and institutions from overregulation, but also to avoid the indirect consequences on the public. After the release of the March 2012 DURC Policy, the Federal Bureau of Investigation (FBI) Weapons of Mass Destruction (WMD) Directorate, the American Association for the Advancement of Science,

the Association of American Universities, and the Association of Public and Land-grant Universities hosted a series of meetings with academic scientists and research administrators. Representatives from both the security and life science professions discussed the security profession's techniques of implementing oversight regulation requirements and its effects on conducting research. Among researchers' concerns was the potential that "overly restrictive" government policies and regulations could deter research institutions from working with the regulated agents and experiments. Abandonment of this type of research "could have negative repercussions on biodefense preparedness, health, and agriculture, and possibly result in increased vulnerability to biological threats."⁴³ This observation demonstrates that overregulation by a security profession that has sole jurisdiction of biosecurity could create consequences for the American public as well.

The Obama Administration has affirmed a need for the contributions of the life sciences in achieving protection from biological threats.⁴⁴ The Fink Committee highlighted the importance of government regulations in conducting experiments of concern. Refinement is needed in determining where division of labor should occur. Abbott's model for professional work provides a lexicon that may be used to analyze the boundaries of this relationship between professions.

As discussed above, diagnosis of the DURC risk differs between the two professions depending on their predominant clients. The security profession could draw on the objectivity of the life science profession, releasing some of its claim in order to scope the problem correctly. A more accurate diagnosis of the threat would lead to better prescriptions for both the public and the researchers. If all DURC is deemed suspect until it is proven otherwise, the inevitable delay will only lead to more

funding pauses and “deliberate” analysis. In the meantime, less research will be conducted to protect the population from certain germs—and to protect the population from possible biological weapon threats.

“Inference” is an area of work where more collaboration can occur. In the examples given above, after the threat was identified, inference occurred in series—first in a NAS committee, then in the security professional’s evaluation of the recommendations. Both professions could benefit from combining their respective bodies of knowledge in a collaborative inference exercise to address both security and research concerns in parallel, thereby addressing the needs of both types of client—the American public and the professional researcher.

Finally, “prescription of treatment” is an area where the life sciences could play a much larger role. Abbott argues that “measurability of results” can contribute to the relative vulnerability in a jurisdictional claim.⁴⁵ Hence, simply stating that a bioterrorism attack has not occurred as the result of published results of DURC, as some may cite in defense of full jurisdiction for the security profession, is not an accurate measurement of success. Success should be determined by the demonstrated functioning of an oversight system. As revealed by the Sunshine Project surveys in 2004 and 2006, the NIH Guidelines IBC requirements for evaluating the research at issue were not accurately measured by the security professionals that imposed them. Life science researchers with experience in laboratories can more accurately assess the capacity for their institutions to conduct a DURC review. Starting with the existing capacity, the life science profession can work with the security profession to build that capacity over time. This security-life science collaboration is already occurring in certain fields. For example, the FBI WMD Directorate creates partnerships between its own WMD coordinators and academia, institutions,

industry contacts, and other organizations.⁴⁶ The intent of these partnerships is to change the attitude within the research community from a code of ethics for “safeguarding science” to developing a “not on my watch” attitude among life science professionals.⁴⁷ Partnerships like these will help develop capacity to conduct DURC risk analysis over the long term and should lead to a culture change within the life science profession that will help to validate its increased claim on the jurisdiction of biosecurity.

Conclusion

The life science profession is losing what little jurisdictional claim it had on the task of biosecurity. Government policies and regulations have replaced the life sciences’ self-imposed moratoria and guidelines on research

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of the past. Leaving biosecurity within the full jurisdiction of security professionals, while it may provide improved protection to American citizens from a bioterrorism attack, imposes an increasing burden on the other clients of biosecurity—the researchers. A jurisdictional settlement that involves a division of labor between security and life science professions could improve the results of biosecurity for both professions’ predominant clients.

Most discussion about biosecurity for DURC has been about trying to find the proper balance between security and an open and collaborative scientific community. Some have interpreted the increase in security regulations

as an imposition on the life science community. This article argues that, by taking a cue from Abbot's sociological model, it is possible to change the method of analysis that currently impedes, rather than facilitates, the teleological aim of biosecurity—an aim that transcends professional boundaries and speaks to the greater societal good. Once one can identify the type of relationship that currently exists between the life sciences and the security professions, it is possible to discuss the benefits of adjusting that relationship. Jurisdictional claims are an ever-changing competition between professions that desire to control a specific task. In the case of biosecurity, the life science practitioners that are most associated with DURC must now shape the discussion and justify an increased ability to self-regulate, especially in the attributes of diagnosis and treatment. **IAJ**

NOTES

1 The White House, "Doing Diligence to Assess the Risks and Benefits of Life Sciences Gain-of-Function Research," <<http://www.whitehouse.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research>>, accessed on October 28, 2014; Francis S. Collins, "Statement on Funding Pause on Certain Types of Gain-of-Function Research," The NIH Director-National Institutes of Health (NIH), <http://www.nih.gov/about/director/10172014_statement_gof.htm>, accessed on October 28, 2014.

2 Robert Carlson, "The Pace and Proliferation of Biological Technologies," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, Vol. 1, No. 3, September 1, 2003, pp. 203–209.

3 Gregory D. Koblentz, "Biosecurity Reconsidered: Calibrating Biological Threats and Responses," *International Security*, Vol. 34, No. 4, March 17, 2010, pp. 104–107. The rise of globalization, the emergence of new diseases, and the changing nature of conflict have increased the risks posed by naturally occurring and man-made biological threats. A growing acceptance of a broader definition of security since the end of the Cold War has facilitated the rise of biosecurity issues on the international security agenda. Developing strategies to counter biological threats is complicated by the lack of agreement on the definition of biosecurity, the diverse range of biological threats, and competing perspectives on the most pressing biological threats. A comprehensive definition of biosecurity that encompasses naturally occurring, accidental, and deliberate disease outbreaks can help to further research, analysis, and policymaking. Operationalizing this broad conception of biosecurity requires a taxonomy of biological threats based on a levels-of-analysis approach that identifies which types of actors are potential sources of biological threats and the groups most at risk from these threats. A biosecurity taxonomy can provide a common framework for the multidisciplinary research and analysis necessary to assess and manage these risks. It also has implications for how to prevent and respond to biological threats, as well as for the future of biosecurity research." "DOI": "10.1162/isec.2010.34.4.96", "ISSN": "0162-2889", "shortTitle": "Biosecurity Reconsidered", "journalAbbreviation": "International Security", "author": [{"family": "Koblentz", "given": "Gregory D."}], "issued": {"date-parts": [{"2010", 3, 17}]}, "accessed": {"date-parts": [{"2014", 7, 11}]}, "locator": "104-107", "schema": "https://github.com/citation-style-language/schema/raw/master/csl-citation.json"

4 *Ibid.*, pp. 105–106. The rise of globalization, the emergence of new diseases, and the changing nature of conflict have increased the risks posed by naturally occurring and man-made biological threats. A growing acceptance of a broader definition of security since the end of the Cold War has facilitated the rise of biosecurity issues on the international security agenda. Developing strategies to counter biological threats is complicated by the lack of agreement on the definition of biosecurity, the diverse range of biological threats, and competing perspectives on the most pressing biological threats. A comprehensive definition of biosecurity that encompasses naturally occurring, accidental, and deliberate disease outbreaks can help to further research, analysis, and policymaking. Operationalizing this broad conception of biosecurity requires a taxonomy of biological threats based on a levels-of-analysis approach that identifies which types of actors

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5 Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats, National Research Council, Globalization, Biosecurity, and the Future of the Life Sciences, The National Academies Press, Washington, 2006, p. 32, <http://www.nap.edu/download.php?record_id=11567>, accessed on August 27, 2014.

6 Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology, Biotechnology Research in an Age of Terrorism, National Academies Press, Washington, 2004, p. 18.

7 Ibid., pp. 2–3.

8 Carlson, p. 210.

9 The White House, “National Strategy for Countering Biological Threats,” November 23, 2009, p. 8.

10 Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology, p. 3.

11 Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats, p. 9.

12 Andrew Abbott, *The System of Profession: An Essay on the Division of Expert Labor*, University of Chicago Press, Chicago, 1988, p. 75.

13 Gerald L. Epstein, “Preventing Biological Weapon Development Through the Governance of Research,” *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, Vol. 10, Issue 1, March 28, 2012, p. 19. and Science”, ”page”:"17-37", ”volume”:"10", ”issue”:"1", ”source”:"online.liebertpub.com.mutex.gmu.edu (Atypon

14 National Commission on Terrorism, “Countering the Changing Threat of International Terrorism,” <<http://fas.org/irp/threat/commission.html>>, accessed on November 13, 2014.

15 Epstein, p. 20. and Science”, ”page”:"17-37", ”volume”:"10", ”issue”:"1", ”source”:"online.liebertpub.com.mutex.gmu.edu (Atypon

16 Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology, p. 5.

17 Ibid., pp. 6–7.

18 Ibid., p. 9.

19 Office of Science and Technology Policy, “United States Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern,” February 22, 2013, <<http://www.phe.gov/s3/dualuse/Documents/oversight-durc.pdf>>, accessed on May 3, 2014.

20 Abbott, pp. 315–316.

21 Ibid., pp. 35–58.

22 Ibid., pp. 59–85.

23 Ibid., p. 35.

24 Ibid., p. 36.

25 World at Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism,

Vintage Books, 2008, p. 10.

26 Ibid.

27 Ibid.

28 Ibid., pp. 9–11.

29 Abbott, pp. 40–52.

30 Ibid., p. 41.

31 Ibid.

32 Abbott, p. 49.

33 Ibid.

34 Ibid., p. 46.

35 Ibid., p. 60.

36 Ibid., pp. 69–79.

37 Ibid., p. 75.

38 Gregory Koblentz, “Is the NSABB Still Relevant to Today’s Biosecurity Challenges?” The Pandora Report, <<http://pandorareport.org/2014/07/16/is-the-nsabb-still-relevant-to-todays-biosecurity-challenges>>, accessed on August 9, 2014.

39 The White House, “Doing Diligence to Assess the Risks and Benefits of Life Sciences Gain-of-Function Research.”

40 “The Cambridge Working Group,” <<http://www.cambridgeworkinggroup.org>>, accessed November 3, 2014.

41 Abbott, p. 76.

42 Ibid., p. 73.

43 Pete Kelly et al., “Bridging Science and Security for Biological Research: A Discussion about Dual Use Review and Oversight at Research Institutions,” American Association for the Advancement of Science Meeting Report, Washington, SMichell ZappaepSeptember 13–14, 2012, p. 22.

44 The White House, “National Strategy for Countering Biological Threats,” p. 3.

45 Abbott, p. 46.

46 Federal Bureau of Investigation, “Inside the Biological Countermeasures Unit, Part 1,” February 21, 2012, <http://www.fbi.gov/news/stories/2012/february/wmd_022112/wmd_022112>, accessed on February 7, 2014.

47 Supervisory Special Agent Edward You, personal conversation, September 2014.