



Publishing Scientific Papers with Potential Security Risks: Issues for Congress

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Summary

The federal government generally supports the publication of federally funded research results because wide dissemination may drive innovation, job creation, technology development, and the advance of science. However, some research results could also be used for malicious purposes. Congress, the Administration, and other stakeholders are considering whether current policies concerning publishing such research results sufficiently balances the potential benefits with the potential harms. The current issues under debate cut across traditional policy areas, involving simultaneous consideration of security, science, health, export, and international policy. Because of the complexity of these issues, analysis according to one set of policy priorities may adversely affect other policy priorities. For example, maximizing security may lead to detriments in public health and scientific advancement, while maximizing scientific advancement may lead to security risks. Accounting for such trade-offs may allow policymakers to establish regulatory frameworks that more effectively maximize the benefits from such “dual-use,” i.e., potentially beneficial and also potentially harmful, research while mitigating its potential risks.

The issue of balancing scientific publication with security concerns has a long historical context, but the current consideration began in late 2011, when two groups of U.S. government-funded scientists submitted papers to academic journals detailing genetic modifications that increase the transmissibility of a deadly influenza strain. Although these research results may improve pandemic influenza preparedness and response, they may also increase the probability that a highly contagious and deadly influenza strain will be introduced, either accidentally or deliberately, into the human population. Stakeholders, including the Department of Health and Human Services, the World Health Organization, journal publishers, and scientists, debated whether the possible benefits of publication outweighed the potential harms. The editors of the scientific journals decided to publish modified versions of both papers.

The controversy surrounding the publication of these influenza experiments revealed weaknesses in the existing federal mechanisms to identify and balance potential benefits of life science research and security trade-offs. Responding to these cases, the Administration released new government-wide policies to address some of these flaws. These new policies establish roles for federal funding agencies, institutions, and scientists to regularly review life science research portfolios and develop methods to mitigate security risks.

It is not clear whether the 113th Congress will agree with the Administration that the new policies sufficiently address all of the dual-use issues brought to light by this recent controversy. Congress could decide to allow the new policies to be fully implemented before evaluating them. Alternatively, Congress could require agencies to implement new, different processes to identify potential research of concern prior to funding; require federal prepublication review of all potential research of concern to establish appropriate limits on the distribution of the research results; require federal licensing of researchers permitted to conduct such experiments and access results; and limit such research to the most safe and secure laboratories. All of these options might, however, reduce the number and quality of research studies undertaken.

This report describes the underlying controversy, the potential benefits and harms of publishing these manuscripts, the actions taken by domestic and international stakeholders, and options that may improve the way research is handled to minimize security concerns.

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Introduction

The federal government generally supports the open publication of unclassified, federally funded research results. It does so because wide dissemination may drive innovation, job creation, technology development, and the advance of science. Many federal grants and contracts supporting scientific research urge the publication of research results. Only in cases where security concerns rise to the level of classification does the federal government bar publication of fundamental research. This current federal policy, established in National Security Decision Directive 189, is that fundamental research results should be widely available, and that in the rare case where it is necessary to restrict access, classification is the appropriate mechanism.¹

Advances in technology that have lowered technical barriers in modern biological sciences, making it easier for people, including potential adversaries, to reproduce biological experiments raise questions whether the use of classification as the standard for determining the tradeoff between dissemination and security.

Recent events regarding influenza research serve as a case study of the challenges the federal government faces in balancing funding scientific discovery with limiting security concerns. In late 2011, two groups of researchers receiving federal funding separately sought to publish manuscripts in scientific journals describing their successful attempts to increase the transmissibility of a highly pathogenic strain of influenza. This strain of influenza, H5N1, is sometimes referred to as avian or bird flu in the popular press. It causes severe disease in humans, but is not highly contagious between humans. The federal government moved first to restrict publication of the manuscripts. Following additional discussions and deliberations, the federal government recommended publishing modified versions of the manuscripts. Some stakeholders believe the research results should not have been published. They assert that broad dissemination of such research results increases the likelihood that a highly contagious form of the virus will be introduced, either accidentally or deliberately, into the human population. Others state that the public health benefits from such research outweigh concerns regarding malicious use.

The H5N1 influenza research case study highlights the general tensions among stakeholders and the ramifications of various federal actions and policies. The controversy surrounding the decisions to publish these manuscripts highlights deficiencies in the federal decision-making processes related to dual-use life science research.² In addition, the debate about the publication of scientific research with potential security implications cuts across multiple policy issues. These include federal support of research, maintenance of homeland security, and the flow of research information, and may require simultaneous consideration of security, science, health, export, and international policy. Because of the complexity of these issues, analysis according to one set of policy priorities may adversely affect other policy priorities. In addition, the controversy surrounding the decision to publish these experiments has demonstrated flaws in the existing mechanisms to identify and balance the potential public benefits and security trade-offs.

¹ White House, Executive Office of the President, “National Policy on the Transfer of Scientific, Technical, and Engineering Information,” *National Security Decision Directive-189*, 1985. For non-fundamental research, additional mechanisms may be used to restrict dissemination, such as contract clauses related to release of information and export controls.

² For a historical perspective on the development of current policy framework, see Gerald L. Epstein, “Preventing Biological Weapon Development Through the Governance of Life Science Research,” *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, vol. 10, no. 1 (2012).

Congress has acted in the past to restrict access to pathogens where it deemed the potential risk of their misuse posed a greater threat than the benefits arising from unrestricted access.

Congressional policymakers may decide that research results in some areas pose similar risks and may move to impose similar limits through a variety of mechanisms. Conversely, congressional policymakers may assess the risks of information exchange to not require additional regulation.

This report describes the underlying controversy, the potential benefits and harms of publishing these manuscripts, the actions taken by domestic and international stakeholders, and options to improve the way research is handled to minimize security concerns.

Case Study: H5N1 Influenza Research

The ongoing controversy regarding the appropriateness of funding research on (and publishing the results of) H5N1 influenza transmissibility serves as a case study for the broader challenges of balancing the potential benefits and potential harms from such research. This section outlines the presence of H5N1 influenza in nature; describes and discusses the transmissibility experiments that led to the current policy debate; outlines the potential benefits and harms arising from the conduct and publication of such research; and outlines the various recommendations and actions from various governmental and non-governmental stakeholders.

H5N1 Influenza in Nature

Influenza is a virus that circulates through both human and animal populations. The form of the influenza virus changes frequently. These changes produce various strains with differing properties, including host species, levels of contagiousness, and severity of disease. Strains harmless in one host may be deadly in another. Scientists and public health officials often refer to different influenza virus strains through abbreviation. Influenza viruses have two specific disease-related proteins (H for hemagglutinin and N for neuraminidase), each of which have several varieties denoted by different numbers. For example, the H1N1 influenza virus caused the 2007 “swine flu” human pandemic.

A different strain, the H5N1 influenza virus, commonly known as avian or bird flu, began infecting people in China in 1997. This highly pathogenic strain had previously infected only birds. In the initial outbreak, the virus infected 18 people, 6 of whom died.³ Since then, the virus has spread internationally, infecting humans in at least 15 countries. As of February 2013, the World Health Organization (WHO) has confirmed 615 human cases and 364 deaths from this H5N1 influenza strain.⁴

Although highly contagious among birds, the H5N1 influenza virus does not pass easily between people. Nearly all of the known human infections resulted from close contact with infected poultry. However, because viruses constantly change, future versions of H5N1 influenza virus might be more contagious among humans. If the virus did become more contagious among

³ World Health Organization, *H5N1 Avian Influenza: Timeline of Major Events*, December 17, 2012; http://www.who.int/influenza/H5N1_avian_influenza_update_20121217b.pdf.

⁴ World Health Organization, *Cumulative Number of Confirmed Human Cases for Avian Influenza A (H5N1) Reported to WHO, 2003-2013*, February 1, 2013. For the most current data available, see http://www.who.int/influenza/human_animal_interface/H5N1_cumulative_table_archives/en/index.html.

humans and also kept its disease-causing characteristics, a human pandemic with serious disruptions in services and social order might occur. These potential consequences drive federal investments in influenza pandemic preparedness activities, including research on various influenza strains.

H5N1 Influenza Experiments Under Debate

While scientists know that H5N1 influenza strains naturally change over time, they do not yet understand in detail how these specific changes lead to new viral properties. Gaps in our current scientific understanding limit our ability to determine the likelihood of increased human-to-human transmission.⁵ This likelihood could have important public health policy ramifications. For instance, if these changes are likely to occur, then policymakers might increase H5N1 influenza-related countermeasure development efforts. Conversely, if such changes are unlikely or impossible, then policymakers might decrease such efforts or divert federal efforts into more pressing threats.

The National Institute for Allergy and Infectious Disease (NIAID) funded multiple researchers to determine the genetic changes that would cause H5N1 strains to become more transmissible among humans. Dr. Yoshihiro Kawaoka, based at the University of Wisconsin-Madison, and Dr. Ron Fouchier, based at the Erasmus Medical Center in Rotterdam, the Netherlands, each led research groups that successfully determined such changes. Both groups used ferret-to-ferret transmission to model human-to-human transmission.⁶ Independently, and using different methods, each group found specific genetic changes to the H5N1 influenza virus that make it transmissible through the air between ferrets in separate cages.

Dr. Kawaoka's group used standard molecular biological techniques to create a ferret-to-ferret transmissible H5N1 virus. The scientists took the H1N1 virus that caused the 2009 human pandemic and replaced the H1 portion with a genetically modified version of the H5 portion from an H5N1 strain. This hybrid version passed between ferrets housed in separate cages. However, this new virus, unlike the naturally occurring H5N1 virus, did not kill the ferrets. Additionally, his group found that current vaccines and antiviral medications are effective against this new hybrid strain.⁷

Dr. Fouchier's group directly infected ferrets with a genetically modified H5N1 virus. After the ferret became sick, virus from the sick ferret was used to directly infect another ferret. After multiple iterations, the H5N1 virus had changed sufficiently to become transmissible between

⁵ Li-Mei Chen, Ola Blixt, and James Stevens et al., "In Vitro Evolution of H5N1 Avian Influenza Virus Toward Human-Type Receptor Specificity," *Virology*, vol. 422 (November 5, 2011), pp. 105-113; and Martin Enserink, "Controversial Studies Give Deadly Flu Virus Wings," *Science*, vol. 334 (December 2, 2011), p. 1192.

⁶ Most scientists agree that ferrets are an appropriate animal model for such studies; however, the new viruses may act differently in humans. They may have different transmissibility or disease severity in humans than they do in ferrets. See Anthony S. Fauci and Francis S. Collins, "Benefits and Risks of Influenza Research: Lessons Learned," *Science*, vol. 336 (June 22, 2012), pp. 1522-1523.

⁷ Yoshihiro Kawaoka, "Flu Transmission Work Is Urgent," *Nature*, published online January 25, 2012, <http://www.nature.com/nature/journal/vaop/ncurrent/full/nature10884.html>; and Masaki Imai, Tokiko Watanabe, Masato Hatta et al., "Experimental Adaptation of an Influenza H5 HA Confers Respiratory Droplet Transmission to a Reassortant H5 HA/H1N1 Virus in Ferrets," *Nature*, published online May 2, 2012, <http://www.nature.com/nature/journal/vaop/ncurrent/full/nature10831.html>.

ferrets in separate cages.⁸ The scientists determined five specific genetic changes were sufficient to convey airborne transmissibility among ferrets. They found that this new strain of H5N1 virus was less transmissible and caused a less severe disease than naturally occurring seasonal influenza. Additionally, ferrets previously exposed to seasonal flu were immune to infection with the new H5N1 virus.⁹

The two groups submitted manuscripts to different scholarly journals. In both cases, the submission was to a publisher not based in the country where the experiments were performed. Dr. Kawaoka submitted his research conducted in the United States to the United Kingdom journal, *Nature*. Dr. Fouchier submitted his research conducted in the Netherlands to the U.S. journal, *Science*.

Dual-Use Results

The Department of Health and Human Services (HHS) deemed the manuscripts from these two groups as the results of “dual-use” research. In this context, this term describes information or technologies that have the potential to both help and harm society.¹⁰ The HHS defines dual-use biological research as “biological research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security.”¹¹

Balancing Potential Benefits and Harms

Policymakers and stakeholders face difficult calculations when trying to balance the potential benefits of this research against potential harms. Most public health experts agree that an influenza pandemic, of some nature, will occur at some indeterminate time in the future. Research on the influenza virus may provide ways to mitigate the effects of such a pandemic. However, most experts also agree that such research also increases the risk that an influenza pandemic could occur through accidental or deliberate release of a modified virus.¹² The disagreement among experts largely lies in the relative probabilities of these events. No universally accepted method exists to precisely determine these probabilities, and analysts may arrive at different, but equally valid, conclusions.

⁸ Sander Herfst, Eefje J.A. Schrauwen, and Martin Linster et al., “Airborne Transmission of Influenza A/H5N1 Virus between Ferrets,” *Science*, vol. 336 (June 22, 2012), pp. 1534-1541.

⁹ Ron Fouchier, “H5N1 Research Discussion,” Panel discussion at the American Society for Microbiology Biodefense and Emerging Infectious Disease Research Meeting, Washington, DC, February 29, 2012, <http://www.asmbiodefense.org/index.php/program-information/nsabbs-recommendations-for-h5n1-research>; and Sander Herfst, Eefje J.A. Schrauwen, and Martin Linster et al., “Airborne Transmission of Influenza A/H5N1 Virus Between Ferrets,” *Science*, vol. 336 (June 22, 2012), pp. 1534-1541.

¹⁰ Historically, the term “dual-use” has referred to technologies that have both a military and a civilian application.

¹¹ Department of Health and Human Services, National Science Advisory Board for Biosecurity Charter, March 4, 2004.

¹² Declan Butler, “Fears Grow over Lab-bred Flu,” *Nature*, vol. 480 (December 22, 2011), pp. 421-422; and Marc Lipsitch, Joshua B. Plotkin, and Lone Simonsen et al., “Evolution, Safety, and Highly Pathogenic Influenza Viruses,” *Science*, vol. 336 (June 22, 2012), pp. 1529-1531.

Possible Benefits

These H5N1 influenza research results provided previously unknown scientific information. In particular, this research identified some of the genes involved in transmitting the disease between mammals. Future experiments may build upon these results to further scientific understanding of how influenza virus causes disease in different animals. Such experiments could create new approaches to treating and preventing the disease.¹³ Prior to this work, scientists did not know whether H5N1 virus could ever become easily transmissible between humans, and if so, how likely it would be to occur.¹⁴ As discussed above, both groups found that some H5N1 viruses are transmitted through the air between ferrets.

Additionally, the five genetic changes that Dr. Fouchier's group found sufficient to cause mammalian transmissibility have each been identified in naturally occurring H5N1 viruses.¹⁵ This suggests the possibility that all five could appear in the same strain through natural processes. This observation has led some experts to suggest that looking for these five genetic changes together in nature may provide advanced warning of a coming pandemic.¹⁶ Other experts suggest that current surveillance efforts are inadequate for this task. Additionally, focusing specifically on these genetic changes may cause researchers to miss other genetic changes that would also cause the virus to become transmissible between humans.¹⁷ Dr. Kawaoka suggested a slightly different strategy, "rather than watching for specific genetic changes, it is more important to scan for the traits they bestow."¹⁸ That type of surveillance might identify strains with human pandemic potential without relying on a list of known genetic changes associated with human transmission. Current surveillance efforts might require enhancement to perform such activity.

Possible Harms

Some observers believe that the H5N1 influenza research could create new threats to public health and homeland security. These threats might arise from accidental or deliberate release of H5N1 virus from a laboratory or use of the information in the published manuscripts for malicious purposes.

Possible harm from conducting these types of experiments could come from several different mechanisms. Some observers worry that modified H5N1 virus might escape from laboratories causing a human pandemic.¹⁹ Some of these experts assert that research that increases

¹³ Ron A.M. Fouchier, Sander Herfst, and Albert D.M.E. Osterhaus, "Restricted Data on Influenza H5N1 Virus Transmission," *Science*, vol. 335 (February 10, 2012), pp. 662-663; and Masaki Imai, Tokiko Watanabe, Masato Hatta et al., "Experimental Adaptation of an Influenza H5 HA Confers Respiratory Droplet Transmission to a Reassortant H5 HA/H1N1 Virus in Ferrets," *Nature*, published online May 2, 2012, <http://www.nature.com/nature/journal/vaop/ncurrent/full/nature10831.html>.

¹⁴ National Science Advisory Board for Biosecurity, "Policy: Adaptations of Avian Flu Virus Are a Cause for Concern," *Nature*, vol. 482 (January 31, 2012), pp. 153-154.

¹⁵ Declan Butler, "Caution Urged for Mutant Flu Work," *Nature*, vol. 481 (January 25, 2012), pp. 421-422; and Sander Herfst, Eefje J.A. Schrauwen, and Martin Linster et al., "Airborne Transmission of Influenza A/H5N1 Virus Between Ferrets," *Science*, vol. 336 (June 22, 2012), pp. 1534-1541.

¹⁶ Declan Butler, "Caution Urged for Mutant Flu Work," *Nature*, vol. 481 (January 25, 2012), pp. 421-422.

¹⁷ Paul S. Keim, "Q&A: Reasons for Proposed Redaction of Flu Paper," *Nature*, published online January 31, 2012, <http://www.nature.com/nature/journal/vaop/ncurrent/full/482156a.html>.

¹⁸ Ed Yong, "Mutant-flu Paper Published," *Nature*, vol. 485 (May 3, 2012), pp. 13-14.

¹⁹ Lynn Klotz and Ed Sylvester, "Worry About Lab Infections," *Nature*, vol. 481 (January 15, 2012), pp. 257-259; (continued...)



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contagiousness or disease severity should not be done because of the danger posed by possible release. Although it is not possible to accurately predict how a modified virus would affect humans, some analysts warn that the 1918 influenza pandemic, which had devastating social effects, was caused by a virus with a lower fatality rate than unmodified H5N1. They assert that the potential harm from a pandemic outweighs any possible benefits from the research.²⁰ Other observers assert that this work can be safely conducted using appropriate precautions. For example, Dr. Fouchier and Dr. Kawaoka performed these experiments following widely accepted guidelines established by the National Institutes of Health (NIH) for working with potentially dangerous pathogens. However, even laboratories licensed by the Centers for Disease Control and Prevention for work with “select agents,” dangerous regulated pathogens, have known accidental releases.²¹

Other potential harms could come from adversaries. Experts on a federal biosecurity advisory board highlight the possibility that published research could provide adversaries a “roadmap” to create a bioweapon.²² In general, scientific publication provides enough information so that the experiments can be replicated. Such independent verification is a cornerstone of modern science. However, experiments could be replicated for malicious purposes by those lacking sufficient skill or experience to perform the original research. It is difficult to assess the risks posed by publishing dual-use research results in general. In the present case of the H5N1 influenza manuscripts, modifying the virus independently would require additional technical knowledge and skill even with publication of experimental methods. In addition, the transmissibility and severity of the disease from the modified H5N1 virus is unknown. On the other hand, if the modified virus were highly transmissible between people and caused severe disease, it could cause a pandemic with devastating societal effects. Given the potential effects, it is conceivable that some adversary might attempt to use these research results for malicious purposes.

Stakeholder Recommendations

As information about the modified H5N1 influenza research results spread, various stakeholders debated the merits of their publication. Domestic and international groups deliberated ethical, scientific, and security issues and made recommendations concerning publication. The National Science Advisory Board for Biosecurity (NSABB) issued recommendations adopted by HHS. The World Health Organization (WHO) also issued recommendations. *Science* magazine, published by the American Association for the Advancement of Science (AAAS), issued statements and agreed to consider recommendations from other stakeholders. The U.K. magazine *Nature* agreed to consider other stakeholder recommendations prior to publication. Many

(...continued)

Thomas Inglesby, “Engineered H5N1: A Rare Time for Restraint in Science,” *Annals of Internal Medicine*, vol. 156 (March 20, 2012), pp. 460-462; and Marc Lipsitch, Joshua B. Plotkin, and Lone Simonsen et al., “Evolution, Safety, and Highly Pathogenic Influenza Viruses,” *Science*, vol. 336 (June 22, 2012), pp. 1529-1531.

²⁰ Thomas Inglesby, “Engineered H5N1: A Rare Time for Restraint in Science,” *Annals of Internal Medicine*, vol. 156 (March 20, 2012), pp. 460-462; Lynn Klotz and Ed Sylvester, “Worry About Lab Infections,” *Nature*, vol. 481 (January 15, 2012), pp. 257-259.

²¹ For more information, see Richard D. Henkel, Thomas Miller, and Robbin S. Weyant, “Monitoring Select Agent Theft, Loss and Release Reports in the United States—2004-2010,” *Applied Biosafety*, Vol. 17, No. 4, 2012, pp. 171-180.

²² National Science Advisory Board for Biosecurity, “Policy: Adaptations of Avian Flu Virus Are a Cause for Concern,” *Nature*, vol. 482 (January 31, 2012), pp. 153-154.

prominent international influenza scientists agreed to temporarily suspend certain influenza research to provide public policymakers time to consider issues raised by this research.²³ The following section summarizes various stakeholder position and concerns.

National Science Advisory Board for Biosecurity (NSABB)

The NSABB is the primary federal scientific board with responsibility for issues of biosecurity. It consists of experts in biological sciences, law, security, and other areas. Federal officials representing agencies that fund life science research serve as non-voting members. Its responsibilities include advising the Secretary of Health and Human Services and providing guidance to life scientists on dual-use research and other biosecurity issues.²⁴

Prior to the debate about the H5N1 influenza research results, the NSABB recommended a framework to help the federal government develop a comprehensive system for the “responsible identification, review, conduct, and communication of dual-use research.”²⁵ It established certain categories of research that should draw additional attention and review. It termed this research “dual-use research of concern.” The NSABB provided guidance on how to identify dual-use research of concern, recommended that individual researchers and institutions evaluate research projects for potential dual-use aspects, and identified possible ways to reduce potential harmful results of their research. However, when the H5N1 influenza research manuscripts neared publication, the federal government had yet to develop and implement a comprehensive, effective system for oversight of dual-use research of concern. As part of its advisory duties, the NSABB reviewed the submitted manuscripts and issued recommendations.

First Review

In October 2011, the NSABB initially reviewed the manuscripts. It found “that there was significant potential for harm in fully publishing these results and that the harm exceeded the benefits of publication.”²⁶ The NSABB recommended that HHS ask the manuscript authors and the journal editors to redact certain portions of the manuscripts. Due to the importance of the findings to the public health and research communities, the NSABB recommended publishing the general conclusions but excluding the methodological and other details that could enable replication of the experiments. The NSABB also recommended adding to the manuscripts additional explanation of the goals and potential public health benefits of the research and the extensive safety and security measures taken to protect laboratory workers and the public. Also, the NSABB recommended that the U.S. government develop a mechanism for providing select access to the redacted information, stating “In order to manage the risks posed by communicating

²³ Ron A. M. Fouchier, Adolfo Garcia-Sastre, and Yoshihiro Kawaoka et al., “Pause on Avian Flu Transmission Studies,” *Nature*, vol. 481 (January 26, 2012), p. 443; and World Health Organization, *Report on Technical Consultation on H5N1 Research Issues*, February 16, 2012, p.4, http://www.who.int/influenza/human_animal_interface/mtg_report_h5n1.pdf.

²⁴ For more information on the NSABB responsibilities, see Department of Health and Human Services, *Charter of the National Science Advisory Board for Biosecurity*, April 4, 2012, http://oba.od.nih.gov/biosecurity/PDF/NSABB-Charter_Signed_2012.pdf.

²⁵ National Science Advisory Board for Biosecurity, “Proposed Framework for the Oversight of Dual-Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information,” June 2007.

²⁶ National Science Advisory Board for Biosecurity, “Policy: Adaptations of Avian Flu Virus Are a Cause for Concern,” *Nature*, vol. 482 (January 31, 2012), pp. 153–154.

future cases of dual-use research of concern, the Board strongly urges the U.S. Government to develop in an expeditious manner a practical and secure mechanism for sharing sensitive scientific information in order to support public health, safety, and security efforts.”²⁷ In such a manner, those scientists requiring access to the sensitive portions of the manuscripts might gain access, while the broader public and scientific community would be excluded.

Following weeks of debate among other stakeholders, including the World Health Organization (see “World Health Organization” below), it became apparent that other stakeholders did not share the NSABB view. Also, practical concerns regarding the ability to establish a limited distribution network for methodological details and the ramifications of such a structure on obligations to share information derived from international influenza virus samples spurred an additional review by the NSABB. The NIH requested that the manuscript authors submit revised manuscripts reflecting additional information presented during the evolving stakeholder debate to the NSABB.

Second Review

In April 2012, following a second review of the manuscripts, the NSABB reversed its earlier position, recommending the publication of both manuscripts. The members of the NSABB unanimously supported the full publication of the Kawaoka manuscript. The panel also recommended the publication of a revised version of the Fouchier manuscript on a 12-6 vote. The panel stated that it reversed its earlier recommendations on the basis of “additional information in the revised manuscripts, new non-public epidemiological information, and security information ... presented in a classified briefing.”²⁸ The majority of the panel concluded that the data would not immediately threaten public health or national security, the data may benefit public health and surveillance efforts, and the research was conducted under appropriate biosafety conditions. Factors the NSABB considered during the second review included how a decision not to fully publish would affect pandemic preparedness activities,²⁹ influenza research, and international relations.³⁰ The NSABB did not state the relative importance of these factors in reaching its decision.

One of the members who disagreed with the majority opinion on the Fouchier manuscript decision outlined his dissent in a letter to National Institutes of Health Office of Science Policy.³¹

²⁷ National Science Advisory Board for Biosecurity, *Findings and Recommendations*, March 29-30, 2012, p. 6, http://www.nih.gov/about/director/03302012_NSABB_Recommendations.pdf.

²⁸ National Science Advisory Board for Biosecurity, *Findings and Recommendations*, March 29-30, 2012, p. 2, http://www.nih.gov/about/director/03302012_NSABB_Recommendations.pdf.

²⁹ Robert Webster, “Case Study: H5N1 Avian Influenza,” Presentation at National Academies of Science Workshop “Issues Raised, Lessons Learned, and Paths Forward for Dual-Use Research in the Life Sciences: The H5N1 Controversy,” Washington, DC, May 1, 2012, <http://sites.nationalacademies.org/PGA/stl/H5N1/index.htm>.

³⁰ Testimony of Paul S. Keim, Ph.D., Acting Chairman, National Science Advisory Board for Biosecurity, National Institutes of Health, U.S. Department of Health and Human Services, before the Senate Committee on Homeland Security and Governmental Affairs, April 26, 2012.

³¹ Letter from Michael T. Osterholm, Director of the Center for Infectious Disease Research and Policy, to Amy P. Patterson, Associate Director for Science Policy, National Institutes of Health, April 12, 2012, http://news.sciencemag.org/scienceinsider/NSABB%20letter%20final%2041212_3.pdf.

He believes that a flawed NSABB review process produced flawed decisions. The NIH wrote a letter to respond to his assertions.³²

World Health Organization

The World Health Organization (WHO) is the primary international forum for coordinating worldwide influenza pandemic preparedness efforts. In February 2012, after the first NSABB review but before the second, the WHO convened a small group of public health and influenza experts to discuss the publication of the H5N1 influenza manuscripts. This group of experts determined that the potential benefits of publishing the results outweighed the risks. This panel recommended publishing the results without redaction but advocated for the development of a focused communications plan. This plan would aim to increase public awareness and understanding of the significance of the H5N1 influenza studies, the rationale for their publication, and their essential biosafety and biosecurity aspects.³³

Like the NSABB, the WHO panel discussed the concept of publishing redacted manuscripts with a mechanism for providing the restricted information to legitimate recipients. However, the WHO panel identified complications with the creation of such a mechanism due to international agreements and national legislation.³⁴ One germane international agreement is the Pandemic Influenza Preparedness (PIP) Framework. This agreement links international access to influenza virus samples with sharing the benefits from research done with those samples. Some donor countries might interpret efforts to restrict access to research results as counter to the PIP Framework, possibly decreasing those countries' willingness to share virus strains.

Department of Health and Human Services

The HHS charters and oversees the NSABB and adopted both sets of NSABB recommendations. Because the recommendations of the NSABB evolved over time, the actions and positions taken by HHS also changed. Even though HHS, through NIH, had funded the H5N1 influenza research, HHS actions were in response to the proposed publication of the research results by domestic and foreign publishers. The HHS has no authority over publisher activities, and a previous attempt by HHS to discourage a scientific journal from publishing a manuscript with security concerns had been unsuccessful.³⁵

The HHS endorsed the NSABB recommendations following the first review and issued them to both the manuscript authors and the journal editors. The HHS also stated that the U.S. government would work “to establish a mechanism to allow secure access to the information to those with a legitimate need in order to achieve important public health goals. The U.S.

³² Letter from Amy P. Patterson, Associate Director for Science Policy, National Institutes of Health, to Michael T. Osterholm, Director of the Center for Infectious Disease Research and Policy, April 25, 2012, <http://blogs.nature.com/news/files/2012/05/Response-to-Dr-Osterholm-04-25-2012.pdf>.

³³ World Health Organization, *Report on Technical Consultation on H5N1 Research Issues*, February 16, 2012, p.3, http://www.who.int/influenza/human_animal_interface/mtg_report_h5n1.pdf.

³⁴ World Health Organization, *Report on Technical Consultation on H5N1 Research Issues*, February 16, 2012, p.4, http://www.who.int/influenza/human_animal_interface/mtg_report_h5n1.pdf.

³⁵ Jocelyn Kaiser, “PNAS Publishes Botulinum Paper,” *Science*, vol. 309, July 1, 2005, p. 31.

government is also developing a proposed oversight policy that would augment existing approaches to evaluating research that has the potential to be misused for harmful purposes.”³⁶

As the debate on the H5N1 influenza manuscripts progressed, HHS continued to respond to developments. When scientists declared a temporary moratorium on H5N1 influenza research (see “Scientific Community” below), HHS announced that U.S. government agencies that conduct or fund such research would also abide by this moratorium.³⁷ Following the February 2012 WHO meeting, in which HHS representatives participated, HHS continued “to stand by the December 2011 recommendations of the National Science Advisory Board for Biosecurity (NSABB) but we intend to consider carefully the information discussed during the WHO-hosted meeting.”³⁸

According to NIH, the WHO-hosted meeting revealed additional information about the manuscripts. This led NIH to request that the authors submit to the NSABB revised manuscripts reflecting this information. When the NSABB recommendation changed from withholding at least part of the manuscripts to publishing the manuscripts, the HHS recommendations also changed. The HHS concurred with the new NSABB recommendation that the information in the manuscripts be communicated fully. The HHS Secretary and the NIH Director conveyed this concurrence to the journals.³⁹

In addition, the White House Office of Science and Technology Policy (OSTP) released through HHS a new policy on dual-use life sciences research (see “Overseeing Dual-Use Life Science Research” below). The HHS stated that

the recently released Federal policy on dual-use research of concern is an important step in enhancing the oversight of federally funded life sciences research going forward. Through implementation of this policy, the U.S. Government aims to preserve the benefits of vitally important life sciences research that holds the promise of enhancing quality of life for all of us, while minimizing the possibility that the knowledge, information, products, or technologies provided by such research could be misused for harm.⁴⁰

In addition, HHS developed a new policy framework that will guide its funding decisions for research proposals that may create H5N1 influenza virus strains that may be airborne transmissible between mammals.⁴¹

³⁶ National Institutes of Health, Department of Health and Human Services, *Press Statement on the NSABB Review of H5N1 Research*, December 20, 2011.

³⁷ Francis S. Collins, Director, National Institutes of Health, Department of Health and Human Services, and Anthony S. Fauci, Director, National Institute of Allergy and Infectious Diseases, Department of Health and Human Services, *NIH Statement on H5N1*, January 20, 2012.

³⁸ Francis S. Collins, Director, National Institutes of Health, Department of Health and Human Services, *NIH Statement on H5N1 and the World Health Organization Meeting*, February 17, 2012.

³⁹ Francis S. Collins, Director, National Institutes of Health, Department of Health and Human Services, *Statement by NIH Director Francis Collins, M.D., Ph.D. on the NSABB Review of Revised H5N1 Manuscripts*, April 20, 2012.

⁴⁰ Francis S. Collins, Director, National Institutes of Health, Department of Health and Human Services, *Statement by NIH Director Francis Collins, M.D., Ph.D. on the NSABB Review of Revised H5N1 Manuscripts*, April 20, 2012.

⁴¹ U.S. Department of Health and Human Services, *A Framework for Guiding U.S. Department of Health and Human Services Funding Decisions About Research Proposals with the Potential for Generating Highly Pathogenic Avian Influenza H5N1 Viruses That Are Transmissible Among Mammals by Respiratory Droplets*, February 2013, <http://www.phe.gov/s3/dualuse/Documents/funding-hpai-h5n1.pdf>; Amy P. Patterson, Lawrence A. Tabak, and Anthony S. Fauci, et al., “A Framework for Decisions About Research with HPAI H5N1 Viruses,” *Science*, vol. 339 (continued...)

Scholarly Publishers

As previously noted, Dr. Kawaoka and Dr. Fouchier submitted their manuscripts to the journals *Nature* and *Science* respectively. Both publishers of these journals voluntarily delayed publication of the submitted manuscripts while discussion and debate occurred. Neither journal publisher was under a mandate not to publish; the recommendations of government bodies were not binding. Both journals published the manuscripts after the NSABB changed its recommendation.⁴²

Since 2003, many journal editors and publishers have voluntarily adopted the responsibility of weighing the dual-use implications of submitted manuscripts.⁴³ These journal editors screen, review, and potentially reject manuscripts on the basis of their weapons potential. The editors developed this policy during an earlier dual-use research result publication controversy; this occurred while the federal government was considering imposing new requirements through legislation or regulation.

The voluntary nature of the publisher review and the ability of a publisher to ignore non-binding government recommendations may raise questions about the efficacy of such a process. For example, the editors of *Nature* emphasized that although they voluntarily delayed publication while NSABB and WHO considered the manuscripts, they were not bound by any external recommendations. Rather, their decision to publish or not was based on internal considerations. The journal commissioned an independent risk and benefit assessment that concluded the paper should be published in full. Furthermore, the editors concluded that they will not consider redacting key details from any paper or limiting access to select recipients in the future.⁴⁴

Relying on an editor-based effort, such as the *Nature* example above, might not sufficiently address the federal government's security concerns. Even a consensus protocol for handling dual-use research results that addresses the U.S. government's national security concerns may not stop such information from entering the open literature. The competitive, international nature of scientific publishing may lead foreign journals that lack such a protocol to legally acquire and publish material prohibited from domestic publication. Finally, with the growing ability to disseminate scientific information to a wide audience online without resorting to formal publication, the effectiveness of a publisher-based policy in restricting the dissemination of contentious research is an open question.

Scientific Community

The scientific community split over the decision whether to publish the H5N1 influenza manuscripts. Some scientists supported publishing redacted versions. Others argued for full and

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(March 1, 2013), pp. 1036-1037; and David Malakoff and Martin Enserink, "New U.S. Rules Increase Oversight of H5N1 Studies, Other Risky Science," *Science*, vol. 339 (March 1, 2013), p. 1025.

⁴² Masaki Imai, Tokiko Watanabe, Masato Hatta et al., "Experimental Adaptation of an Influenza H5 HA Confers Respiratory Droplet Transmission to a Reassortant H5 HA/H1N1 Virus in Ferrets," *Nature*, published online May 2, 2012; and Sander Herfst, Eefje J.A. Schrauwen, and Martin Linster et al., "Airborne Transmission of Influenza A/H5N1 Virus Between Ferrets," *Science*, vol. 336 (June 22, 2012), pp. 1534-1541.

⁴³ Journal Editors and Authors Group, "Uncensored Exchange of Scientific Results," *Proceedings of the National Academy of Science*, vol. 100, February 18, 2003, p. 1464.

⁴⁴ Editorial, "Publishing Risky Research," *Nature*, published online May 2, 2012.

open publication. Many prominent influenza researchers, including those that conducted the experiments in question, agreed to a voluntary moratorium on research into modified H5N1 influenza transmission to allow some discussion of the policy issues.⁴⁵ This moratorium ended in January 2013.⁴⁶

Some experts view this moratorium as similar to that enacted in the 1970s over genetic engineering and recombination.⁴⁷ At that time, scientists responded to criticism and public pressure by establishing a voluntary moratorium on such research. In 1975, at the Asilomar conference center in Pacific Grove, CA, scientists developed a consensus statement regarding a voluntary moratorium on some types of recombinant DNA research and an increase in security and containment requirements for other research areas. The statement and accompanying moratorium successfully allayed many, but not all, public concerns and provided a uniform framework to address such issues. This consensus statement became the starting point for research rules developed by the National Institutes of Health Recombinant DNA Advisory Committee, which was formed to oversee such research.⁴⁸ With respect to H5N1 influenza transmissibility research though, all stakeholders have not reached consensus regarding appropriate controls, emerging government policy notwithstanding.⁴⁹

Issues for Congress

The H5N1 influenza research case study highlights the general tensions among stakeholders and the ramifications of various federal actions and policies. The controversy surrounding the decisions to publish these manuscripts highlights deficiencies in the federal decision-making processes related to dual-use life science research.⁵⁰ Congressional policymakers may face many issues when considering research with potential security risks, especially in the life sciences. These issues include the appropriate federal government role in overseeing, funding, and publishing dual-use research activities.

⁴⁵ Ron A. M. Fouchier, Adolfo García-Sastre, and Yoshihiro Kawaoka et al., “Pause on Avian Flu Transmission Studies,” *Nature*, vol. 481 (January 26, 2012), p. 443; and World Health Organization, *Report on Technical Consultation on H5N1 Research Issues*, February 16, 2012, p.4, http://www.who.int/influenza/human_animal_interface/mtg_report_h5n1.pdf.

⁴⁶ Ron A. M. Fouchier, Adolfo García-Sastre, Yoshihiro Kawaoka, et al., “Transmission Studies Resume for Avian Flu,” *Science*, Vol. 339 (February 1, 2013), pp. 520-52; and Ron A. M. Fouchier, Adolfo García-Sastre, Yoshihiro Kawaoka, et al., “H5N1 Virus: Transmission Studies Resume for Avian Flu,” *Nature*, Vol. 493 (January 31, 2013), p. 609.

⁴⁷ Paul S. Keim, “Q&A: Reasons for Proposed Redaction of Flu Paper,” *Nature*, published online January 31, 2012, <http://www.nature.com/nature/journal/v482/n7384/full/482156a.html>.

⁴⁸ An overview of the Asilomar conference can be read in Donald S. Fredrickson’s “Asilomar and Recombinant DNA: The End of the Beginning,” found in *Biomedical Politics* (Washington, DC: National Academy Press), 1991, pp. 258-298.

⁴⁹ Editorial, “Vigilance Needed: Experiments That Make Deadly Pathogens More Dangerous Demand the Utmost Scrutiny,” *Nature*, vol. 493 (January 24, 2013), pp. 451-452.

⁵⁰ For a historical perspective on the development of current policy framework, see Gerald L. Epstein, “Preventing Biological Weapon Development Through the Governance of Life Science Research,” *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, vol. 10, no. 1 (2012).

Overseeing Dual-Use Life Science Research

The federal government funds a variety of life science research activities. The private sector performs much of these activities, which are funded via contracts and grants. It performs oversight of these activities through standard procedures and protocols generally identified as contract or grant terms and conditions. Examples of such terms and conditions include regularly issuing technical and business reports to program managers regarding the expenditure of federal funds and complying with generally accepted best practices.

Federal agencies funding life science research do not systematically review all research-related activities, such as publication, for dual-use ramifications. To review all such activities for all federally supported life science research would place enormous burdens on the research community and the federal government. However, the current controversy highlights the flaws in the current processes to identify and mitigate potential security risks associated with performing some research. Even though both H5N1 influenza researchers received federal funding, NIH, the funding agency, was unaware of the dual-use nature of the actual results until the manuscripts were submitted for publication.

To help correct perceived flaws in agency process, the Administration issued new policy for federal agencies titled “United States Government Policy for Oversight of Life Sciences Dual-Use Research of Concern” on March 28, 2012.⁵¹ This new policy aims to

establish regular review of United States Government funded or conducted research with certain high-consequence pathogens and toxins for its potential to be dual-use research of concern (DURC) in order to: (a) mitigate risks where appropriate; and (b) collect information needed to inform the development of an updated policy, as needed, for the oversight of DURC. The fundamental aim of this oversight is to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.⁵²

This new policy for federal agencies defines “dual-use research of concern” as specified types of experiments using specified pathogens or toxins that “can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, material or national security.”⁵³ Seven types of experiments are subject to this policy, and the pathogens and toxins covered by this policy are also regulated as select agents.⁵⁴

This new policy requires every federal department and agency to review all sponsored life science research projects and identify those that meet the dual-use research of concern criteria. The sponsoring agency must “assess the risks and benefits of such projects, including how research methodologies may generate risks and/or whether open access to the knowledge, information,

⁵¹ *United States Government Policy for Oversight of Life Sciences Dual-Use Research of Concern*, March 28, 2012. http://oba.od.nih.gov/oba/biosecurity/pdf/united_states_government_policy_for_oversight_of_durc_final_version_032812.pdf.

⁵² Ibid.

⁵³ Ibid.

⁵⁴ The possession, use, and transfer of all of the pathogens and toxins covered by this policy are also subject to the select agent regulations (see 7 C.F.R. 331, 9 C.F.R. 121, 42 C.F.R. 72, and 42 C.F.R. 73).

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products, or technologies generates risk.”⁵⁵ This policy directed departments and agencies to report the results of their reviews to the Assistant to the President for Homeland Security and Counterterrorism within 90 days and then biannually.

Based on this assessment, and in collaboration with the institution or researcher, the agency must develop a risk mitigation plan. When appropriate, the agency is to incorporate the risk mitigation plan into the grant, contract, or work agreement with the researcher. For existing projects, the agency should consider modifying the existing agreement or seek voluntary implementation of the risk mitigation plan. For proposed projects that have not yet been funded, the agency is to consider incorporating a risk mitigation plan into the grant, contract, or agreement. The policy does not require specific risk mitigation procedures, but contains examples, such as modifying the design or conduct of the research; performing periodic progress reviews by the agency; and determining how the results will be published or otherwise communicated. If the agency determines that risk mitigation efforts prove insufficient, the agency is to consider requesting voluntary redaction of any publication or communication; classifying the research; or terminating project funding.⁵⁶

In accordance with the new policy, NIH conducted its review and found 381 extramural and 404 intramural projects using pathogens or toxins covered by the new policy. Of these projects, NIH designated 10 extramural and no intramural projects as dual-use research of concern. Seven of the designated dual-use research of concern projects use influenza virus, while one project each uses the pathogens that cause anthrax, plague, and botulism.⁵⁷ The NIH determined appropriate risk mitigation steps with researchers in each case.⁵⁸

Once fully implemented, this policy might address some of the deficiencies highlighted by the recent publishing controversy. Reviews of proposed research and periodic reviews of funded research might alert the funding agency of potentially challenging results early enough for agencies to mitigate their potential harmful effects. However, some of the risk mitigation steps in this policy, including the use of prepublication manuscript review and the possibility of limiting distribution of research results, raise additional issues, such as compliance with export control regulations, that likely complicate implementation of this policy.

While NIH has performed the requisite reviews, guidance for grantees is still under development. This may raise challenges to proper implementation of risk mitigation steps if grantees lack knowledge of their responsibilities and the potential consequences of compliance and non-compliance.

On February 22, 2013, the White House Office of Science and Technology Policy released for public comment the proposed policy “United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern.”⁵⁹ This proposed policy describes the

⁵⁵ *United States Government Policy for Oversight of Life Sciences Dual-Use Research of Concern*, March 28, 2012, http://oba.od.nih.gov/oba/biosecurity/pdf/united_states_government_policy_for_oversight_of_durc_final_version_032812.pdf.

⁵⁶ Classified research results are not published in generally accessible scientific journals.

⁵⁷ Testimony of Anthony S. Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health, U.S. Department of Health and Human Services, before the Senate Committee on Homeland Security and Governmental Affairs, April 26, 2012.

⁵⁸ *Ibid.*

⁵⁹ Office of Science and Technology Policy, “United States Government Policy for Institutional Oversight of Life (continued...) ”

responsibilities of researchers and institutions that receive federal funding to perform research that may qualify as DURC.⁶⁰

Publishing Dual-Use Research Results

The federal government generally supports the open publication of unclassified, federally funded research results. Many federal grants and contracts supporting scientific research urge the publication of research results. The current federal policy, as described in National Security Decision Directive 189, is that access to fundamental research results should remain unrestricted with respect to dissemination, and that in the rare case where it is necessary to restrict access to such information, classification is the appropriate mechanism.⁶¹ For non-fundamental research, additional mechanisms may be used to restrict dissemination, such as contract clauses related to release of information and export controls. Implementation of the new dual-use research of concern policy may create significant exceptions to this general policy.⁶²

Prepublication Review and Export Control

The Department of Commerce regulates the export of some dual-use technologies and research results through administration of the Export Administration Regulations (EAR), which apply to technologies (and technical information) listed on the Commerce Control List (CCL).⁶³ The CCL includes the pathogens and toxins covered by the new federal dual-use research of concern policy. Noncompliance with export controls can result in fines and imprisonment.

Research that qualifies as “fundamental research” is exempt from export controls.⁶⁴ To qualify as “fundamental research,” research activities must be ordinarily published and shared broadly within the scientific community. They must also be free of prepublication review, except for purposes of determining whether proprietary information is being divulged or patent rights are being compromised. Thus, information resulting from government-sponsored research where the government has required prepublication review for national security reasons is not “fundamental research.” Research funded with such prepublication agreements would be subject to export regulation and potential control.

The concept of “deemed export” further complicates this issue. A deemed export is the transfer of information, not physical items, to a foreign national within the United States.⁶⁵ Deemed exports

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Sciences Dual Use Research of Concern,” 78 *Federal Register* 12369-12372, February 22, 2013; and <http://www.phe.gov/s3/dualuse/Documents/oversight-durc.pdf>.

⁶⁰ David Malakoff and Martin Enserink, “New U.S. Rules Increase Oversight of H5N1 Studies, Other Risky Science,” *Science*, vol. 339 (March 1, 2013), p. 1025.

⁶¹ White House, Executive Office of the President, “National Policy on the Transfer of Scientific, Technical and Engineering Information,” *National Security Decision Directive-189*, 1985.

⁶² Mark S. Frankel, “Regulating the Boundaries of Dual-Use Research,” *Science*, vol. 336 (June 22, 2012), pp. 1523-1525.

⁶³ For more on export controls, see CRS Report R41916, *The U.S. Export Control System and the President’s Reform Initiative*, by Ian F. Fergusson and Paul K. Kerr.

⁶⁴ 15 C.F.R. 734.3(b)(3)(ii).

⁶⁵ For more on deemed export issues, see the Department of Commerce Bureau of Industry and Security’s Deemed Export FAQ at <http://www.bis.doc.gov/deemedexports/deemedexportsfaqs.html>.

are treated the same as other exports. Thus, foreign nationals may require export licenses or be completely prohibited from performing some research if the contract or grant contains prepublication review provisions, since these would disqualify it for the fundamental research exemption. In contrast, equivalent research conducted under a grant or contract without prepublication review provisions would likely qualify as “fundamental research,” would not require an export license, and would not raise deemed export issues.

Limited Access to Research Results

In order to address the security challenges presented by the H5N1 influenza manuscripts, the NSABB recommended that the government develop a mechanism to provide controlled access to sensitive scientific information:

the Board also recognizes that research findings will likely emerge in the very near future that should not be widely disseminated because of a high risk of misuse but that nevertheless should be made available to certain researchers and public health officials around the world who have a legitimate need to know. The need for an effective, practical, and feasible mechanism for selectively sharing sensitive scientific information has never been more apparent. In order to manage the risks posed by communicating future cases of dual-use research of concern, the Board strongly urges the U.S. Government to develop in an expeditious manner a practical and secure mechanism for sharing sensitive scientific information in order to support public health, safety, and security efforts.⁶⁶

The Department of Health and Human Services initially endorsed this approach and began exploring how to establish such a mechanism, but HHS ultimately rejected this option as infeasible for the two H5N1 influenza manuscripts.

Limiting general access to research results has several challenges. These challenges include formalizing the criteria for identifying this information; the need to identify what entity would establish the infrastructure to store and retain control of the restricted information; how access to the restricted information can be assessed for current and future researchers; what penalties or other mechanism would be invoked to limit secondary dissemination of the information (either through subsequent publication of research building on the restricted information or through more informal information exchange); and how to facilitate restricted information exchange across international borders in order to meet treaty and other obligations.

Experts have questioned whether such controls would be effective.⁶⁷ Scientists and other professionals regularly exchange preliminary information through seminars, conferences, and other informal gatherings. If, at a later date, federal government deems such information should be restricted, it may be difficult or impossible for the government to prevent its spread. Similarly, publishers of scientific research generally distribute information, not restrict information, and may lack the infrastructure or inclination to compartmentalize information with respect to their subscribers. For example, the editors of *Nature* have stated that they will not consider limiting distribution of any data that have been submitted to them.⁶⁸ The editors of *Science* support the

⁶⁶ National Science Advisory Board for Biosecurity, *Findings and Recommendations*, March 29-30, 2012, p. 6, http://www.nih.gov/about/director/03302012_NSABB_Recommendations.pdf.

⁶⁷ Bruce Schneier, “Securing Medical Research: A Cybersecurity Point of View,” *Science*, vol. 336 (June 22, 2012), pp. 1527-1529.

⁶⁸ Editorial, “Publishing Risky Research,” *Nature*, published online May 2, 2012.

development of an international system to provide access to information deemed not openly publishable to those with a “need to know.”⁶⁹

International ramifications of a limited access approach may be significant. The WHO determined that controlling the distribution of influenza research results would likely damage worldwide pandemic influenza preparedness by reducing the willingness of countries to share samples of influenza virus. In addition, other countries’ export regulations might or might not limit dissemination of information restricted by another country, requiring further harmonization with treaty obligations and mechanisms to determine scientific credentials.⁷⁰

These challenges may be surmountable with sufficient federal investment. The federal government maintains information with access restrictions, has cataloged publications and best practices, and oversees a credentialing system for researchers who wish physical access to certain pathogens known as select agents. While these systems do not currently serve the purpose of limiting access to dual-use research results, they may provide a potential model for developing necessary systems. However, it remains unclear whether policymakers would deem increasing the federal role in this manner an appropriate response to address this issue.

Funding Dual-Use Research

A key component of the OSTP policy on dual-use life sciences research of concern is the identification of the dual-use nature of research programs when they begin. The federal government historically has funded a wide array of research including that with dual-use implications. The prevailing rationale for supporting such research is the belief that the benefits from dual-use research outweigh the potential risks of misuse since many more people will use it for beneficial purposes than for malicious ends.

The OSTP policy requires each funding agency to review its existing and future research portfolios and identify those research activities that are potential dual-use research of concern. This new policy raises several challenges, including the completeness of such a review, the mechanism and criteria for identifying research projects, and the mechanism and criteria for assessing risk and its mitigation. While this policy initially may identify some dual-use research of concern, it also may not identify all dual-use research of concern. In some cases, the research results that might qualify as dual-use research of concern arise unexpectedly out of the research activities. Periodic review of ongoing research projects could identify these unforeseen results, but may create its own set of challenges.

The effort to review existing and future research activities may require clear guidance and oversight. Federal agencies often fund dual-use research, only some of which reaches the higher threshold of being “of concern.” Thus, those program managers or other officials reviewing research projects could spend most of their reviews identifying activities that are not dual-use research of concern. This may affect the accuracy of review if program managers develop expectations regarding their research portfolio based on past reviews.

⁶⁹ Bruce Alberts, “H5N1,” *Science*, vol. 336 (June 22, 2012), p. 1524.

⁷⁰ Ron A.M. Fouchier, Sander Herfst, and Albert D.M.E. Osterhaus, “Restricted Data on Influenza H5N1 Virus Transmission,” *Science*, vol. 335 (February 10, 2012), pp. 662-663.

In addition, some experts have argued that the dual-use implications of a research activity vary depending on an analyst's perspective. Some analysts, for example, question whether the risks of performing federal biodefense research activities outweigh the potential benefits.⁷¹ The experience and expertise of officials or scientists performing the risk and benefit assessment may vary between or within agencies, which could lead to inconsistent appreciation of risks or benefits both of performing the research and in publishing its results.

The NIH efforts to develop policy for NIH-funded H5N1 influenza transmissibility research highlights the challenges of addressing dual-use research funding. While the NIH intentionally established a narrow scope to its policy deliberation, it has not achieved stakeholder consensus on the details of its policy. Efforts to broaden the approach taken by NIH regarding the specific H5N1 influenza transmissibility research policy may be even more difficult because of the expanded stakeholder base and diversity of research activity. On the other hand, the NIH process may serve as a template and provide lessons learned for future efforts to develop similar policies in other life-science areas, research fields, or funding agencies.

Scope

Concomitant with the other policy considerations is the issue of how broadly to apply new federal dual-use policies. The new dual-use research of concern policy discussed above is limited to government-sponsored life science research using a few specific organisms and toxins for defined types of experiments. This policy does not encompass other research or technologies outside this scope which may pose equivalent risk and benefit trade-offs.

Once fully implemented, the new policies may not identify all government-sponsored life science research with potentially significant national security concerns. The list of covered organisms and toxins does not include all those that have been deemed by the federal government to pose a significant potential threat to national security or public health in other contexts, such as under the select agent regulations⁷² or included as NIAID Category A, B, and C priority pathogens. Thus, research on such pathogens that increases their harmful effects or decreases their response to countermeasures would not be identified by this policy.

Additionally, research on unlisted pathogens that could also apply to related covered pathogens may not be identified by this policy. In 2001, researchers serendipitously discovered modifications to mousepox virus that rendered mousepox vaccination in mice ineffective. This raised fears that similar modification to the closely related smallpox virus would render smallpox vaccination in humans ineffective.⁷³ It is not clear that the new dual-use research of concern policies would identify this type of research.

Another challenge may come from emerging technologies. Non-life science research may produce enabling technologies that increase the risk of malicious use of the pathogens and toxins

⁷¹ Malcolm Dando, *The United States National Institute of Allergy and Infectious Diseases (NIAID) Research Programme on Biodefense: A Summary and Review of Varying Assessments*, Bradford Disarmament Research Center (Bradford, UK), July 2004.

⁷² 42 C.F.R. 73, 7 C.F.R. 331, and 9 C.F.R. 121.

⁷³ Ronald J. Jackson, Alistair J. Ramsay, Carina D. Christensen et al., "Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox," *Journal of Virology*, vol. 75 (February 2001), pp. 1205-1210.

covered by the dual-use research of concern policy. For example, advances in encapsulation or aerosolization technologies could significantly increase the effectiveness of the malicious use of one of the listed pathogens. Such research, although possibly directly applicable to increasing the risk of bioterrorism, appears unlikely to be identified by this new dual-use research of concern policy.

The OSTP has also proposed additional policies for oversight of dual use research of concern. The “United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern” would establish institutional review and oversight requirements for certain categories of federally funded life sciences research. The OSTP acknowledges that its scope is limited, but states that it may be broadened in the future to cover additional pathogens or types of experiments. It grants research institutions discretion to consider other types of life sciences research under its proposed DURC framework.⁷⁴

Stakeholders may also note that this proposed policy applies only to federal-government-sponsored research. The government only funds about 53% of basic research and 39% of applied research conducted domestically.⁷⁵ Research not sponsored by the government is not covered by this new dual-use research of concern policy. However, research institutions that do not receive federal life science funding are “strongly encouraged to implement similar oversight procedures consistent with the culture of shared responsibility underpinning this Policy.”⁷⁶

Broadening the scope of the OSTP policies on federal oversight of dual-use research of concern may address many of these potential shortcomings. However, such broadening will likely increase the administrative burden on both the research community and government agencies. Additionally, extending oversight to include non-government-sponsored research will likely raise additional issues such as appropriate enforcement mechanisms and possible decrease in international competitiveness.

Options for Congress

Congressional policymakers have a variety of options before them. They may decide that the current policy framework serves as a good starting point and allow the executive branch to further develop and implement the proposed policies. Alternatively congressional policymakers might increase oversight activities and direct the Administration, either through hearings, report language, or legislation, to take specific actions to address scientific or security concerns.

⁷⁴ Office of Science and Technology Policy, “United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern,” February 22, 2013, p.3, <http://www.phe.gov/s3/dualuse/Documents/oversight-durc.pdf>.

⁷⁵ Percentages presented for 2011, the most recent available data. Mark Boroush, National Science Foundation, *U.S. R&D Spending Resumes Growth in 2010 and 2011 but Still Lags Behind the Pace of Expansion of the National Economy*, NSF 13-313, January 2013.

⁷⁶ Office of Science and Technology Policy, “United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern,” February 22, 2013, p.7, <http://www.phe.gov/s3/dualuse/Documents/oversight-durc.pdf>.

Allow Current Policy Framework to Develop

Policymakers may choose to continue to allow the executive branch to address dual-use research concerns through the NSABB, voluntary advisory processes with publishers, and the new government-wide dual-use research of concern policy. Federal agencies are currently developing rules and procedures to implement the new dual-use research of concern policy. Congress could decide to wait to act until agencies complete implementation before determining whether the new policies adequately address the challenges highlighted by the recent H5N1 influenza manuscripts. Alternatively, Congress could decide to more closely monitor the development and implementation of these policies through oversight activities such as requests for information from the Administration or additional oversight hearings.⁷⁷

Change Current Policy Framework

Rather than rely solely on executive branch action, congressional policymakers might choose to increase oversight activities or introduce legislation to provide greater direction or focus to the relevant executive branch agencies, or to directly address perceived policy gaps. Alternatively, Congress could agree with the overall policy direction but decide that codifying the policies in statute would more effectively address the issues.

Early Identification of Dual-Use Research of Concern

Congressional policymakers interested in the extent of dual-use research funded by the federal government might direct funding agencies to identify and tabulate prospective dual-use concerns prior to funding the research. Since the federal government lacks a fully implemented framework to assess or value such dual-use research concerns currently, congressional policymakers likely would need to formalize the criteria against which such research would be measured. Measures developed by the NSABB and the dual-use research of concern policy might apply. The current policy is narrowly focused and affects a relatively small portion of federally funded research. Assessment of all research activities might require significant investment by executive branch agencies, due to the large number of research grants and contracts awarded by the federal government annually. Such concerns might be weighed against the prospective benefits to assess the dual-use impact of the research investment and risk mitigation measures used to manage the risk and benefit relationship.

Voluntary or mandatory prepublication review for federally funded research or the development of new funding opportunities containing prepublication review as a condition of acceptance may improve the government's ability to identify and mitigate dual-use concerns of particular results. Individual funding vehicles have been offered to universities which would provide the funding agency with access to research results prior to publication.⁷⁸

⁷⁷ For examples, see Letter from Congressman F. James Sensenbrenner, Jr., Vice-Chairman House Committee on Science, Space and Technology, to John D. Holdren, Director of the White House Office of Science and Technology Policy, March 1, 2012, http://sensenbrenner.house.gov/UploadedFiles/Letter_to_John_Holdren.pdf; and U.S. Congress, Senate Committee on Homeland Security and Governmental Affairs, *Biological Security: The Risk of Dual-Use Research*, 112th Cong., 2nd sess., April 26, 2012.

⁷⁸ Examples of contracts containing prepublication review being offered by federal funding agencies is found in Peg Brickley, "Contract Conflicts," *The Scientist*, January 7, 2003; D. Malakoff, "Universities Review Policies for Onsite (continued...)"

Opponents of this approach cite the general unwillingness that universities have towards restricted research funding.⁷⁹ Some universities have explicit policies barring acceptance of federal funding requiring prepublication review. Also, scientists may not be as willing to work in research areas where publication is not allowed as in areas where publication is encouraged.⁸⁰ As a consequence, the pool of eligible scientists competing for federal funding might decrease, potentially lowering the quality of research and development performed in these areas. Additionally, determining at the funding stage whether research will lead to sensitive results is considered difficult. For example, the previously cited mousepox experiments were part of a fertility research program aimed at techniques for pest control, and the results of the experiment were unexpected.⁸¹

Alternatively, congressional policymakers might identify the recipients of research funding as more appropriate to perform the review. In such an approach, federal agencies might require contract and grant recipients to identify when their research activities either have, or might be expected to produce, dual-use ramifications. Again, the criteria against which recipients would judge their research activities would have to be identified. As with the federal review option, a framework and guidance would need to be established.⁸²

Prepublication Review of Dual-Use Results

Congressional policymakers might increase federal oversight by mandating federal funding agencies perform prepublication review of dual-use research results and identify those publications with security concerns. The NSABB recommended the government develop mechanisms for limiting distribution.⁸³ If combined with credentialing scientists able to receive such information, potentially in a manner similar to select agent registration, this approach could allow scientists with appropriate credentials or need-to-know access to such scientific literature, but would bar others' access. Access to such information might be controlled by the federal government or by the publisher through secure, password-controlled websites.⁸⁴ Other options might include dissemination of such material via professional societies.

(...continued)

Classified Research," *Science*, Vol. 295 (February 22, 2002) pp. 1438-1439; and Andy Fell, "Homeland Security Goals Create Impact: Campus Responds To Satisfy Range of New Terrorism Laws," *Dateline UC Davis*, November 22, 2002. See also American Association of Universities/Council on Government Relations, *Restrictions on Research Awards: Troublesome Clauses*, April 8, 2004.

⁷⁹ See, for example, AAU/COGR/NASULGC Letter to OSTP Director on Scientific Openness, found online at <http://www.aau.edu/research/Ltr1.31.03.pdf>.

⁸⁰ Philip Cohen, "Recipes For Bioterror: Censoring Science," *NewScientist.com*, January 18, 2003; Paul Elias, "Academic Freedoms Said Hindered by 9/11," *Washington Post*, September 11, 2003; and Gerald L. Epstein, "Preventing Biological Weapon Development Through the Governance of Life Science Research," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, vol. 10, no. 1 (2012).

⁸¹ "Biowarfare Warning," *Journal of the American Medical Association*, Vol. 285, No. 6 (February 14, 2001), p. 725.

⁸² Gerald L. Epstein, "Preventing Biological Weapon Development Through the Governance of Life Science Research," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, vol. 10, no. 1 (2012), p. 30.

⁸³ National Science Advisory Board for Biosecurity, *Findings and Recommendations*, March 29-30, 2012, p. 6, http://www.nih.gov/about/director/03302012_NSABB_Recommendations.pdf.

⁸⁴ R.A. Zilinskas and J.B. Tucker, "Limiting the Contribution of the Open Scientific Literature to the Biological Weapons Threat," *Journal of Homeland Security*, (December 2002).

Opponents of such an approach cite the logistical difficulties in determining those scientists with a *bona fide* reason for access to this information; determining how and in what manner application the dual-use label would be implemented; and determining how such material would be disseminated to those scientists eligible to receive it. Additionally, some scientists or universities might choose not to participate in a process which would determine access eligibility, especially if the process lacked transparency or was viewed as potentially arbitrary.⁸⁵

Another concern is the effectiveness of such a federally based review. The federal government funds about 31% of the total research and development efforts in the United States. In terms of basic and applied research, the federal government funds 53% and 39% respectively.⁸⁶ If prepublication review resides within the federal government, in contrast to a voluntary submission to professional societies or an ethical or moral statement developed and overseen by journal publishers, then all basic and applied research would not be reviewed.

Many members of the scientific community strongly believe that all unclassified scientific results including all information necessary to reproduce an experiment should be shared widely.⁸⁷ Some observers believe that efforts to restrict access to the data will be impractical or ineffective.⁸⁸ However, in contrast, some prominent members of the scientific community support developing such a system.⁸⁹

Finally, some universities may fear that federal prepublication review to determine whether the results pose a security risk would invalidate the fundamental research exemption that such research results normally enjoy. As a consequence, university research done in an export-controlled subject area might not be excluded from export control regulations (see “Prepublication Review and Export Control”), potentially exposing the institution and researchers to significant penalties if such regulations were violated.

Federal Licensing of Research

Congressional policymakers might believe that the role of the federal government should be expanded beyond a gatekeeping role when considering dual-use biological research. Since much research that has potential terrorism concerns also may play a role in biodefense, it has been suggested that such research should continue, but only performed by select researchers at specific facilities. For example, a national federal authority might license qualified researchers and research facilities and oversee research by licensed researchers in licensed facilities.⁹⁰ Some scientists have asserted that licensing researchers, facilities, or experiments would have a strong,

⁸⁵ Massachusetts Institute of Technology, *In the Public Interest. Report of the Ad Hoc Faculty Committee on Access to and Disclosure of Scientific Information*, June 2002.

⁸⁶ Percentages presented for 2011, the most recent available data. Mark Boroush, National Science Foundation, *U.S. R&D Spending Resumes Growth in 2010 and 2011 but Still Lags Behind the Pace of Expansion of the National Economy*, NSF 13-313, January 2013.

⁸⁷ Carrie Wolinetz, “Implementing the New U.S. Dual-Use Policy,” *Science*, vol. 336 (June 22, 2012), pp. 1525-1527.

⁸⁸ Bruce Schneier, “Securing Medical Research: A Cybersecurity Point of View,” *Science*, vol. 336 (June 22, 2012), pp. 1527-1529. Carrie Wolinetz, “Implementing the New U.S. Dual-Use Policy,” *Science*, vol. 336 (June 22, 2012), pp. 1525-1527.

⁸⁹ Bruce Alberts, “H5N1,” *Science*, vol. 336 (June 22, 2012), p. 1524.

⁹⁰ John Steinbruner, Elisa D. Harris, and Nancy Gallagher et al., *Controlling Dangerous Pathogens: A Prototype Protective Oversight System*, The Center for International and Security Studies at Maryland, the University of Maryland, College Park, MD, March 2007, http://www.cissm.umd.edu/papers/files/pathogens_project_monograph.pdf.

negative impact on scientific productivity in those areas.⁹¹ However, the registration of life scientists wishing to work with select agents has shown that many scientists are willing to engage in such licensed research.⁹² Such a licensing approach might limit the rate of advance of scientific discovery due to the lessened amount of discussion and degree of research diversity. Additionally, in influenza research this approach may be incompatible with international agreements and increase the difficulty of obtaining viral samples from countries with endemic influenza.

Increase Biosafety Level

An alternative approach to addressing concerns raised by specific research might be to mandate increased biosafety for those activities. For example, such an approach might allow for a tailored response to emerging concerns while not adversely impacting similar research with, for example, other pathogens or techniques. Conversely, this approach might undercut biosafety best practices by creating a patchwork of biosafety requirements based on criteria unrelated to pathogen safety, such as national security concerns.

In the case of H5N1 influenza transmissibility research, Canada has increased the required biosafety level from BSL 3 to BSL 4 following a review of the various risks.⁹³ Some experts assert requiring such research to be conducted only at the highest level of biosafety containment and under the most secure conditions would effectively reduce the possibility of an accidental release or a deliberate release by a disgruntled or disturbed laboratory worker.⁹⁴ Current U.S. requirements for H5N1 influenza research require research activities to be done at the BSL 3 level. Many laboratories meet the BSL 3 standards. In contrast, the number of BSL 4 laboratories, built to a much more stringent—and expensive—standard, is significantly smaller, even though the number of BSL 4 laboratories has increased since 2001. Increasing the required biosafety level would limit the number of locations where the research could be performed and the number of researchers with access.

While increasing the biosafety level might limit the risks of an unintentional release due to biocontainment failure, it would also likely limit the rate of scientific advance. Such limitations could arise, for example, from logistical issues, such as insufficient research space for the number of interested researchers; and cost issues, due to the higher overhead cost for performing work in a BSL 4 laboratory. As a consequence, congressional policymakers may wish to balance both the potential outcomes and the potential likelihood of events. For example, increasing near-term biosafety may make it less likely that a release of transmissible H5N1 virus occurs due to a laboratory accident, but at the potential cost of not having important research results to mitigate potentially more likely naturally occurring outbreak of transmissible H5N1 influenza.

⁹¹ Peg Brickley, “Science Police Needed?” *The Scientist*, April 8, 2003.

⁹² For more information on the Select Agent Program, see online at <http://www.cdc.gov/od/sap/>.

⁹³ Public Health Agency of Canada, “Biosafety Advisory: Efficiently Transmissible Engineered Influenza A H5N1 Viruses,” February 1, 2012, <http://www.phac-aspc.gc.ca/lab-bio/res/advi-avis/sbn-asb-2012-01-31-eng.php>.

⁹⁴ Richard H. Ebright, “Mitigate the risks of release,” *Nature*, vol. 481 (January 15, 2012), pp. 257-259.

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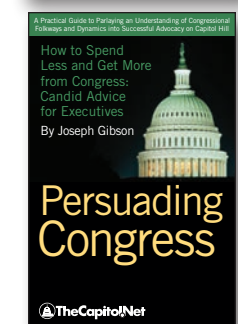
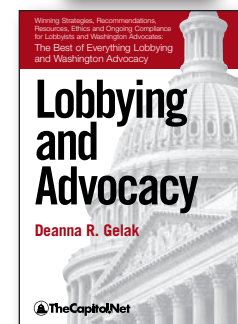
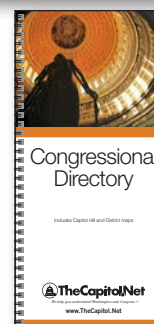
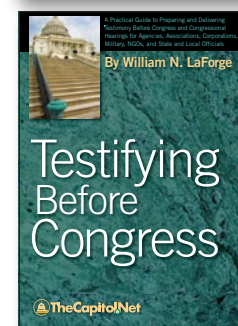
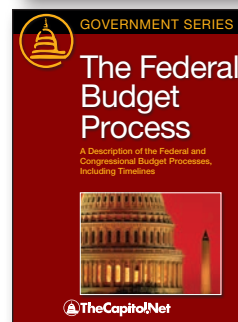
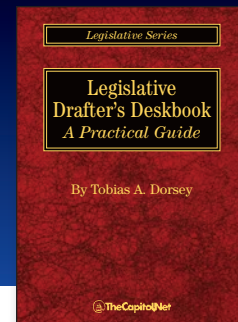
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Conclusion

Policymakers faced with assessing dual-use issues are particularly challenged by the multi-disciplinary nature of dual-use activities. Dual-use issues cut across traditional policy areas, involving simultaneous consideration of security, scientific, health, export, and international policy. Because of the complexity of dual-use issues, analysis of a topic according to one set of policy priorities may lead to unforeseen complications due to its intersection with other policy priorities. For example, maximizing security may lead to detriments in public health and scientific advancement, while maximizing scientific advancement may lead to security risks. Accounting for such trade-offs may allow policymakers to establish regulatory frameworks that more effectively maximize the benefits from dual-use research while mitigating its potential risks.

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