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# Balancing Scientific Publication and National Security Concerns: Issues for Congress

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Dana A. Shea
Specialist in Science and Technology Policy
Resources, Science, and Industry Division

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# Balancing Scientific Publication and National Security Concerns: Issues for Congress


## Summary

The federal government has historically supported the open publication of federally funded research results. In cases where such results presented a challenge to national security concerns, several mechanisms have been employed. For fundamental research results, the federal policy has been to use classification to limit dissemination. For advanced technology and technological information, a combination of classification and export and arms trafficking regulation has been used to inhibit its spread. The terrorist attacks of 2001 have increased scrutiny of nonconventional weapons, including weapons of mass destruction, and publication of some research results have increased concerns over whether publication of federally funded extramural research results could threaten national security.

The current federal policy, as described in National Security Decision Directive 189, is that fundamental research should remain unrestricted and that in the rare case where it is necessary to restrict such information, classification is the appropriate mechanism. Other mechanisms restrict international information flow, such as Export Administration Regulations (EAR) and International Traffic in Arms Regulations (ITAR) that control export of items and technical information on specific lists. Both EAR and ITAR do not apply to sharing fundamental research results, so long as they are not subject to any governmental prepublication review.

The areas where export regulation and classification have predominantly occurred have been in mathematical, engineering, and physical sciences. Other contentious research areas, such as genetic engineering and manipulation, have been overseen through scientists' self-regulation and monitoring. The 1975 Asilomar conference produced a consensus statement on recombinant DNA research that formed the basis for the National Institutes of Health Recombinant DNA Advisory Committee. Recent research publications that have raised national security concerns have fallen outside of the areas traditionally regulated through classification and export control, and it is unclear whether these mechanisms will be equally effective. The National Science Advisory Board for Biosecurity is being established to aid in determining whether proposed federally funded research presents a biosecurity threat.

Stakeholders do not agree on the best method of balancing scientific publishing and national security. Some believe that the current method of selective classification of research results is the most appropriate. They assert that imposing new restrictions will only hurt scientific progress, and that the usefulness of research results to terrorist groups is limited. Others believe that self-regulation by scientists, using an "Asilomar-like" process to develop a consensus statement, is a better approach. They believe that, through inclusion of scientists, policymakers, and security personnel in the development phase, a process acceptable to all will be found. Relying on publishers to scrutinize articles for information which might potentially have security ramifications is third option. Finally, mandatory review by federal funding agencies, either before funding or publication, is seen as a potential federally based alternative. This report will be updated as events warrant.

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# Balancing Scientific Publication and National Security Concerns: Issues for Congress

## Introduction

Publication of scientific research results that might be used by terrorist groups has led some policymakers to question whether the method used to control scientific research results, namely classification, should be revisited. The Administration, legislators, and scientific professional societies are reexamining policies relating to scientific information that might threaten national[1] or homeland[2] security. In March 2002, executive branch agencies were instructed by Assistant to the President and Chief of Staff Andrew Card to determine if government-owned information, especially that regarding weapons of mass destruction, was being inappropriately disclosed. Also in March 2002, the Department of Defense (DOD) promulgated a draft regulation expanding information controls to basic and applied science research and development.[3] Scientific professional societies are engaged in developing self-regulatory mechanisms to address the concerns of the national security community. In 2003, at the annual meeting of the American Association for the Advancement of Science, 32 editors of leading scientific journals issued a policy statement regarding publication of research results that could be misused. Additionally that year, the National Academy of Sciences held a meeting discussing whether current publication policies and practices in the life sciences could lead to the inadvertent disclosure of "sensitive" information to those who might misuse it. In 2004, the National Research Council issued a report, *Biotechnology Research in an Age of Terrorism*, which recommended an oversight structure, based on institutional biosafety committees, for research in select areas of concern. Following some of the recommendations

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[1] National security is defined in Executive Order 12356 as "the national defense or foreign relations of the United States." Both broader and narrower definitions of national security have been suggested as well. For a discussion on this topic, see Arvin S. Quist, *Security Classification of Information. Volume 2. Principles for Classification of Information (K/CG-1077/V2)*, (Oak Ridge, TN: Oak Ridge National Laboratory), September 1989, Chapter 5.

[2] Homeland security is a concerted national effort to prevent terrorist attacks within the United States, reduce America's vulnerability to terrorism, and minimize the damage and recover from attacks that do occur. Office of Homeland Security, *National Strategy for Homeland Security*, The White House, July 2002.

[3] Basic research is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view. Applied research is also original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific practical aim or objective. Organisation for Economic Co-operation and Development, *Frascati Manual*, (OECD), 2002, p. 30.

presented in the National Academies' report, the Department of Health and Human Services established in 2004 the National Science Advisory Board for Biosecurity to, among other things, advise the federal government on biosecurity matters. Policymakers may wish to determine what changes, if any, should be made to current government policy regarding publication of federally funded research results, and whether the options currently under consideration adequately balance the concerns and needs of the security and scientific communities.

Since the 1950s, the United States has developed an established policy of identifying, prior to publication, areas of basic and applied research where information controls may be required. This research, typically related to weapon systems or nuclear technologies, may be designated classified and have strict information controls placed upon it. When fundamental research is not classified, the government generally does not place other information controls on it.

This policy remained essentially unchanged until the 1970s when controls were developed on the export of domestically developed, advanced, dual-use technologies and technological information.[4] Under export control regulations, even if a technology is barred from export, the fundamental, basic science underlying the technology is generally exempt from controls and can be published in the open literature.

In the early 1980s, foreign student and scientist access to technological information that might fall under export control regulations became the focus of a Department of Defense effort to restrict such information presented in classrooms and conferences. In 1985, following a report from the National Academy of Sciences asserting that openness in science leads to stronger long-term security,[5] President Reagan issued National Security Decision Directive 189 (NSDD-189), reiterating that fundamental research results were to be controlled only through classification. NSDD-189 continues to define federal policy on restricting the dissemination of fundamental research results.[6]

Since that time, the conduct of science and the composition of the scientific community have become increasingly international, and there have been growing concerns about the effectiveness of export control regulations. The international spread and independent development of dual-use technologies has made the United States less often a sole technology source. Concern that export control regulation is negatively impacting domestic business prosperity has led to attempts to lower the trade barriers erected by export control. Additionally, the presence of foreign students and scientists in the United States has increased the availability of education

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[4] Dual-use technologies are those technologies that have both a legitimate civilian and military use.

[5] National Academy of Sciences, *Scientific Communication and National Security*, (Washington DC: National Academy Press), 1982.

[6] Assistant to the President for National Security Affairs Condoleezza Rice, letter to Dr. Harold Brown, co-Chairman, Center for Strategic and International Studies, November 1, 2001.

and training in basic skills which may be transferred to other countries upon the return of those individuals to their home countries.

Since the terrorist events of 2001, concern that open publication of scientific and technological results may provide unwitting assistance to other nations or terrorist groups in developing weapons of mass destruction has resurged. Scientific research is conducted in many disparate areas, and historically the areas where the balance between scientific openness and national security required consideration have been centered in the mathematical and physical sciences and their applications, such as aerospace engineering, advanced computer technology, and cryptography. Research in biology – such as the origins of virulence, development of vaccines, and the genetic manipulation of biological agents – has recently emerged as an area of concern because of its potential relevance to biological weapons of mass destruction. Whether the current method of only using classification to limit the dissemination of fundamental research results is the best or most effective method of maintaining national security is an open question. It is unclear whether classification will be effective when applied to research areas that have not historically been classified, nor is it clear that a system of classified research will be embraced by scientists working in these areas.

Several competing proposals regarding how to control federally funded research results have been proposed, ranging from strict information control on all federally funded research to maintaining the status quo. Some scientific professional societies have suggested that self-regulation, either by scientists themselves or through the editors of scientific journals, would be an appropriate mechanism for limiting the publication of research results that might aid terrorist groups. Others have advocated more formal government oversight of potentially contentious research. The development of a new category of "sensitive, but unclassified" information to protect information which does not require classification, but may still have the potential to damage national security, might encompass such research results.[7] The potential impact of these options raises much concern and debate.

A fundamental trade-off between scientific progress and security concerns is the crux of the policy debate. The scientific enterprise is based upon open and full exchange of information and thrives on the ability of scientists to collaborate and communicate their results. On the other hand, this very openness provides potential enemies with information that may allow them to harm U.S. interests. The technological advances arising from scientific breakthroughs contribute to economic prosperity, but the openness required to continue this process creates risks, which may be perceived as more acute since September 11, 2001. What level of risk caused via publication of scientific advances is acceptable in the eyes of policymakers and the public? How will controlling the publication of federally funded research results increase safety? If policymakers determine that more control of these sorts of

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[7] This report does not address the development of federal standards of usage for "sensitive, but unclassified" material. For more information on federal government use of "sensitive, but unclassified" and efforts regarding standardization, see CRS Report RL31845, *"Sensitive But Unclassified" and Other Federal Security Controls on Scientific and Technical Information: History and Current Controversy*, by Genevieve J. Knezo.

research results is warranted, what possible mechanisms could be used to oversee these results?

This report presents examples of scientific research results whose publication raised concern regarding the threat they potentially pose to national security. Past and current information control mechanisms are discussed, along with current federal policy concerning dissemination of fundamental research results through the open literature. Recent policy actions regarding dissemination of federal information and federally funded research results are outlined, along with the responses these actions have evoked from various professional societies and publishers. The advantages and disadvantages to potential policy actions addressing classification and other controls over open publication of federally funded research results are also described.

## Examples of Research Results of Concern

The publication of several scientific articles reignited concerns that information published in the open literature may aid terrorist groups in developing weapons of mass destruction. Presented below is a selection of some more highly publicized examples of such scientific articles.

In 2000, researchers at the Co-operative Research Centre for the Biological Control of Pest Animals (CRC) in Australia genetically modified mousepox virus while conducting rodent fertility research. This modification unintentionally enabled the virus to infect mice that had been previously vaccinated against mousepox.[8] The publication of this result was greeted with criticism due to its weapons potential.[9] This experiment was repeated in 2003 by Dr. Mark Buller at the University of St. Louis using funding supplied by the National Institute of Allergy and Infectious Diseases.[10]

Another article widely viewed as having bioweapon potential was published in July 2002. Researchers at the State University of New York at Stony Brook assembled functional poliovirus from chemical sequences ordered from a scientific mail-order firm.[11] Dr. Eckard Wimmer, the lead scientist, described the experiment

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[8] R.J. Jackson, A.J. Ramsay, C.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 (2001), pp. 1205-1210.

[9] J. Stephenson, "Biowarfare Warning," *Journal of the American Medical Association*, Vol. 285, No. 6 (2001), p. 725.

[10] Robert Roos, "Scientists Research Antidotes to Super Mousepox Virus," *CIDRAP News*, November 6, 2003.

[11] J. Cello, A.V. Paul, and E. Wimmer, "Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template," *Science*, Vol. 297 (August 9, 2002) pp. 1016-1018.

as graphic proof that bioterror agents can be made without a terrorist ever having access to dangerous microbes.[12, 13]

Other scientific publications have been viewed as potentially aiding terrorist groups or countries. Publication of successes in "reverse genetics" has led some to believe that other viruses could be constructed in the laboratory without having access to actual virus ahead of time.[14] In October 2001, the full genome of *Yersinia pestis*, the bacteria which causes bubonic and pneumonic plague, was published in the journal *Nature*.[15] Simultaneous with the release of this article was the publication of an accompanying news article in *Nature Science Update* that highlighted the existence of "a debate about whether releasing genomic information for virulent diseases, such as plague or smallpox, might aid malicious science."[16] The full genome sequence of *Coxiella burnetii*, the causative agent of Q fever, was published in *Proceedings of the National Academies of Science of the United States of America* (PNAS) in April 2003,[17] and the annotated genome of *Bacillus anthracis*, the causative agent of anthrax, was published in *Nature*.[18]

Researchers at the University of Pittsburgh identified key proteins which provide *Variola major*, the causative virus of smallpox, with high virulence.[19] Accompanying this article was a commentary explaining how "the work is far more likely to stimulate advances in vaccinology or viral therapy than it is to become a threat to biosecurity."[20] Researchers published in the *Journal of Clinical*

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[12] Rick Weiss, "Polio-Causing Virus Created in N.Y. Lab: Made-From-Scratch Pathogen Prompts Concerns About Bioethics, Terrorism," *The Washington Post*, July 12, 2002.

[13] For an overview of the policy implications of the successful synthesis of poliovirus, see CRS Report RS21369 *Synthetic Poliovirus: Bioterrorism and Science Policy Implications*, by Frank Gottron.

[14] Sylvia Pagan Westphal, "Ebola Virus Could Be Synthesised," *New Scientist*, July 17, 2002, accessed online at [http://www.newscientist.com/news/news.jsp?id=ns99992555]

[15] J. Parkhill, B.W. Wren, N.R. Thomson, et al., "Genome Sequence of *Yersinia pestis*, The Causative Agent of Plague," *Nature*, Vol. 413 (October 4, 2001) pp. 523-527.

[16] J. Whitfield, "Black Death's DNA," *Nature Science Update*, October 4, 2001.

[17] R. Seshadri, I.T. Paulsen, J.A. Eisen, *et al.*, "Complete Genome Sequence of the Q-fever Pathogen *Coxiella burnetii*," *Proc. Natl. Acad. Sci. USA*, Vol. 100 (April 9, 2003) pp. 5455-5460.

[18] T.D. Read, S.N. Peterson, N. Tourasse, et al., "The Genome Sequence of *Bacillus anthracis* Ames and Comparison to Closely Related Bacteria," *Nature*, Vol. 423, 2003, pp. 81-86.

[19] A.M. Rosengard, Y. Liu, Z. Nie, and R. Jimenez, "Variola Virus Immune Evasion Design: Expression of a Highly Efficient Inhibitor of Human Complement," *Proceedings of the National Academy of Sciences of the United States of America*, Vol. 99 (June 25, 2002) pp. 8808-8813.

[20] P.J. Lachmann, "Microbial Subversion of the Immune Response," *Proceedings of the National Academy of Sciences of the United States of America*, Vol. 99 (2002) pp. 8461-8462.

*Microbiology* a potential cause of enhanced virulence for some strains of anthrax.[21] The assessment of antibiotic resistance in select *Bacillus anthracis* isolates was also identified as an article of potential concern.[22]

These articles have led some to question the wisdom of openly publishing information that could be used to threaten national security. An editorial in *New Scientist* stated:

> That this mind-boggling quantity of information is going to transform medicine and biology is beyond doubt. But could some of it, in the wrong hands, be a recipe for terror and mayhem?[23]

Bioethicist Arthur Caplan from the University of Pennsylvania was reported as saying:

> We have to get away from the ethos that knowledge is good, knowledge should be publicly available, that information will liberate us. ... Information will kill us in the techno-terrorist age, and I think it's nuts to put that stuff on Web sites.[24]

Stewart Simonson, Assistant Secretary for Public Health Emergency Preparedness for the Department of Health and Human Services (HHS), when discussing the decision of the *Proceedings of the National Academy of Sciences of the United States of America* to publish an article on vulnerabilities of the milk supply chain, reportedly stated through a spokesman that he regretted the journal's decision to publish the paper:

> We recognize, of course, that this is an issue about which good and reasonable people disagree. But I must say that if the Academy is wrong, the consequences could be dire and it will be HHS–not the Academy–which will have to deal with it.[25]

## Past and Current Controls on Information

Past examples of research excluded from publication in the open literature have focused on military applications such as cryptography and nuclear weapons. Prior to U.S. entry into World War II, physicists in the private sector doing research on

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[21] P.R. Coker, K.L. Smith, P.F. Fellows, *et al.*, "*Bacillus anthracis* Virulence in Guinea Pigs Vaccinated with Anthrax Vaccine Adsorbed Is Linked to Plasmid Quantities and Clonality," *Journal of Clinical Microbiology*, Vol. 41 (March 2003) pp. 1212-1218.

[22] A. Athamna, M. Athamna, N. Abu-Rashed, *et al.*, "Selection of *Bacillus anthracis* Isolates Resistant to Antibiotics," *J. Antimicrob. Chemother.*, Vol. 54 (2004) pp. 424-428.

[23] "Surfing for a Satan Bug. Why Are We Making Life So Easy for Would-be Terrorists?" *New Scientist*, July 20, 2002, p. 5.

[24] Eric Lichtblau, "Response to Terror; Rising Fears That What We Do Know Can Hurt Us," *Los Angeles Times*, November 18, 2001, p. A1.

[25] Alison McCook, "PNAS Publishes Bioterror Paper, After All," *The Scientist*, 6(1), June 29, 2005.

nuclear fission voluntarily stopped publishing results in scientific journals, fearing that they would provide crucial information to Germany's nuclear bomb project.[26] A joint National Academy of Sciences–National Research Council Advisory Committee on Scientific Publications was established to restrict publication on nuclear fission. While the United States was involved in World War II, this committee secured the cooperation of scientific journals in restricting the transfer of select scientific information within the United States.[27]

Nuclear power is another area where information controls have been instituted. Private industry was permitted to explore applications of nuclear power under the Atomic Energy Act of 1954. Prior to this act, nuclear energy activities were protected by the federal government with security and secrecy programs. The federal government retains authority over results which relate to atomic weapons, production of special nuclear material, and use of special nuclear material in the production of energy.[28] Information developed in those areas, even if developed privately without federal government aid, is regarded as "born classified."

Genetic engineering and recombinant species were an area of great contention in the 1970s, and there were calls for regulation of the methods for manipulating DNA and of experiments containing genetically engineered species. In response to criticism and public pressure, a voluntary moratorium on such research was set. In 1975, at the Asilomar conference center in Pacific Grove, California, discussion on how scientists could self-regulate such research was held. A consensus statement regarding a voluntary moratorium on some types of recombinant research and an increase in security and containment requirements for other research areas successfully allayed many public concerns, and provided a uniform framework to address such issues. This consensus statement formed the starting point for research rules developed by the National Institutes of Health Recombinant DNA Advisory Committee, which was formed to oversee such research.[29]

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[26] Peter J. Westwick, "In the Beginning: The Origin of Nuclear Secrecy," *Bulletin of the Atomic Scientists*, Vol. 56, (November/December 2000), pp. 43-49.

[27] Rexmond C. Cochrane, *The National Academy of Sciences: The First Hundred Years, 1863-1963*, (Washington, DC: National Academy of Sciences), 1978, pp. 385-387.

[28] Harold Relyea, *Silencing Science: National Security Controls and Scientific Communication*, (Norwood, New Jersey: Ablex Publishing Corporation), 1994, pp. 94-96.

[29] 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.

## Current Federal Policy on Scientific Publication

In the United States, there has long been support for a policy of not restricting publication of federally supported extramural and intramural research results, except where classified for national security reasons. This position was restated in 1985 by President Ronald Reagan in National Security Decision Directive 189, which said:

> It is the policy of this Administration that, to the maximum extent possible, the products of fundamental research remain unrestricted. It is also the policy of this Administration that, where the national security requires control, the mechanism for control of information generated during federally-funded fundamental research in science, technology and engineering at colleges, universities and laboratories is classification. Each federal government agency is responsible for: a) determining whether classification is appropriate prior to the award of a research grant, contract, or cooperative agreement and, if so, controlling the research results through standard classification procedures; b) periodically reviewing all research grants, contracts, or cooperative agreements for potential classification. No restrictions may be placed upon the conduct or reporting of federally-funded fundamental research that has not received national security classification, except as provided in applicable U.S. Statutes.[30]

Fundamental research is also defined within NSDD-189:

> 'Fundamental research' means basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community, as distinguished from proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons.[31]

NSDD-189 has not been superceded and continues to be the government policy regarding controls on federally-funded research results. In the wake of the terrorist attacks of September 2001, then-Assistant to the President for National Security Affairs Condoleezza Rice reaffirmed this position in a letter to the Center for Strategic and International Studies, by stating,

> ...this Administration will review and update as appropriate the export control policies that affect basic research in the United States. In the interim, the policy on the transfer of scientific, technical, and engineering information set forth in NSDD-189 shall remain in effect...[32]

Executive branch agencies have followed this general policy by requiring that the results of agency-funded extramural research be published promptly and with

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[30] White House, Office of the President, *National Security Decision Directive-189*, 1985.

[31] *Ibid.*

[32] Assistant to the President for National Security Affairs Condoleezza Rice, letter to Dr. Harold Brown, co-Chairman, Center for Strategic and International Studies, November 1, 2001.

wide dissemination. For example, the National Science Foundation research policy states:

> NSF expects significant findings from research and education activities it supports to be promptly submitted for publication, with authorship that accurately reflects the contributions of those involved. It expects investigators to share with other researchers, at no more than incremental cost and within a reasonable time, the data, samples, physical collections and other supporting materials created or gathered in the course of the work.[33]

Research performed with National Institutes of Health funding is also to be disseminated to the public:

> It is NIH policy to make available to the public the results and accomplishments of the activities that it funds. Therefore, PIs [principal investigators] and grantee organizations are expected to make the results and accomplishments of their activities available to the research community and to the public at large, and to effect their timely transfer to industry for commercialization.[34]

The Department of Defense also encourages the publication of research it funds. For example, Office of Naval Research policy states:

> Publication of results of the research project in appropriate professional journals is encouraged as an important method of recording and reporting scientific information.[35]

In general, federal agencies appear to agree that there should be open publication of research results when the research has been funded by taxpayer dollars. The exception is when research is classified. Classified research projects, even those performed by scientists outside of government laboratories, are not published in the open literature, with information being transferred only between those who obtain requisite clearance.[36] Some classified research areas are later declassified, and the advances developed in these programs used more generally.[37]

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[33] The National Science Foundation, *National Science Foundation (NSF) Grant General Conditions (GC-1)*, July 1, 2002, p. 17.

[34] National Institutes of Health, *NIH Grants Policy Statement (Rev. 03/01)*, U.S. Department of Health and Human Services, March, 2001, p. 122.

[35] Office of Naval Research, *Educational Institutions, Nonprofit Institutions, and For-profit Organizations: Research Grant Terms and Conditions*, U.S. Department of Defense, July, 2001, p. 6.

[36] Some classified research is contracted to private industry or academic groups.

[37] An example would be adaptive optics technology, which was declassified in 1991 and now is used in astronomical telescopes.

# Mechanisms of Governmental Control

Current mechanisms for federal agencies to control the publication of federally funded extramural research results include classification, export and arms trafficking regulations, and specifications in federal contracts, such as prepublication review.

## Classification

Generally, classification is to be used when it is necessary to control scientific information.[38] The advent of classified extramural research led most universities to clarify their positions on acceptance of funding for classified research. Significant debate exists over the propriety of conducting classified research in an academic setting.[39] Some universities elect to not perform classified research on campus, espousing that this is contrary to the founding beliefs of the university or their university charters. For example, Kansas State University maintains:

> ...[T]he policy of the university is that classified research may not be carried out under university auspices by any faculty member, unclassified professional member, student, or other university personnel.[40]

Universities that perform classified research typically establish research facilities specifically to handle classified materials and research. These research facilities are often located off-campus. Examples of such universities include the Massachusetts Institute of Technology and the Johns Hopkins University.[41] Some universities have developed mechanisms by which classified research may be approved on a case-by-case basis.[42]

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[38] In addition to NSDD-189, Executive Order 12958, which was issued on April 17, 1995, describes the general classification policy of the federal government. This Order was amended on March 25, 2003 via Executive Order 13292. Section 1.4e states that scientific, technological, or economic matters relating to the national security, which includes defense against transnational terrorism, may be classified, and, in section 1.7b, reiterates that basic scientific research information not clearly related to the national security may not be classified.

[39] See, for example, Steven Aftergood, "Classified Research on Campus," *Secrecy News*, September 26, 2003, for a discussion of the debate occurring at the University of Alaska, Fairbanks, regarding classified research.

[40] Office of Academic Services, *University Handbook*, Kansas State University, June, 2001, Section G.

[41] D. Malakoff, "Universities Review Policies for Onsite Classified Research," *Science*, Vol. 295 (February 22, 2002) pp. 1438-1439.

[42] For example, University of North Carolina at Chapel Hill, University of Colorado, University of Virginia, and University of Michigan have each established mechanisms for faculty members who wish to engage in classified research to apply to for permission from the university administration on a case-by-case basis.

## Export Controls

**Export of Technologies.** Another federal control mechanism for private research results occurs through export control and arms trafficking regulations. The Department of Commerce implements Export Administration Regulations (EAR) which bar the export of items, technology, and technological information found on the Commerce Control List to foreign countries without appropriate export license.[43] The Department of State implements the International Traffic in Arms Regulations (ITAR) which regulate the export of items, technology, and technological information maintained on the Munitions Control List.[44]

Export control laws primarily constrain the flow of technology and technical information from the United States to other nations. The EAR covers the transfer of dual-use commercial goods, while ITAR is focused on armaments and military technologies. These regulations exist to prohibit the proliferation of certain specific technologies for either national security or trade reasons.

Because of the technological breadth of EAR and ITAR, private researchers, using private funds, sometimes perform research in areas that fall within these regulations. For example, research relating to aerospace technology or cryptography would fall under export regulation. Universities performing basic research are sometimes uncertain whether the research being performed at the institution falls under EAR or ITAR restrictions.

Both EAR and ITAR possess exemptions for "fundamental research." Fundamental research is defined under ITAR as:

> ... basic and applied research in science and engineering where the resulting information is ordinarily published and shared broadly within the scientific community, as distinguished from research the results of which are restricted for proprietary reasons or specific U.S. Government access and dissemination controls. University research will not be considered fundamental research if:
> (i) The University or its researchers accept other restrictions on publication of scientific and technical information resulting from the project or activity, or
> (ii) The research is funded by the U.S. Government and specific access and dissemination controls protecting information resulting from the research are applicable.[45]

Universities generally rely on the fundamental research exclusion to exempt the research performed there from export control. If the university research is not exempt through the fundamental research exclusion, export licensing must be

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[43] The Commerce Control List for Export Administration Regulation can be found online at [http://www.access.gpo.gov/bis/index.html].

[44] The Munitions Control List for the International Traffic in Arms Regulations can be found online at [http://www.access.gpo.gov/nara/cfr/waisidx_01/22cfr121_01.html].

[45] The definition given here is from 22 CFR 120.11. It varies slightly from the definition given in NSDD-189 and from the definition given in 15 CFR 734.8.

obtained and information controls with respect to foreigners performed. Failure to obtain such a license can result in prosecution and large fines.

**Export of Information.** A further complication to export regulation is the concept of a "deemed export." A deemed export is transfer of information, not physical items, to a foreign national from select countries without first obtaining an export license for that technology. This provision has been especially troubling for universities, as foreign students and researchers who attend graduate-level classes may be exposed to information relating to technology which falls under export controls.

There have been cases where export control of information and scientific research have coincided. In the 1980s, research papers were removed by the Department of Defense from a scientific convention because foreign nationals ineligible for export licenses would be attending, and other conventions were held in private session, to avoid violation of the deemed export aspect of these regulations.[46] Some universities have reported problems in collaborations with foreign researchers, and cited, as an example, difficulty in transferring some technologies developed by foreign graduate students to industry.[47]

The Export Administration Act of 1979 (P.L. 96-72) has not been reauthorized. As a consequence, President George W. Bush invoked the International Economic Emergency Powers Act (P.L. 95-223) to maintain export administration regulation. While the International Economic Emergency Powers Act continues export administration regulation, the penalties for violating this act and the enforcement authority granted under this act are less than those under the Export Administration Act of 1979.[48]

The USA PATRIOT Act (P.L. 107-56) created another mechanism to block certain foreign nationals from obtaining specific information. Access to or information about biological and toxin agents on the "select agent" list[49] is barred to individuals, including students, originating from countries which support terrorism. Under the USA PATRIOT Act, universities are charged with improving security and access controls to select agents, and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) requires sites with select

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[46] For example, in 1984, the 25th Structures, Structural Dynamics and Materials Conference closed two proceedings sessions to foreign nationals. For other examples, see Harold Relyea, *Silencing Science: National Security Controls and Scientific Communication,* (Norwood, New Jersey: Ablex Publishing Corporation), 1994, pp. 125-126.

[47] Testimony by the Association of American Universities before the Senate Committee on Foreign Relations, Subcommittee on International Economic Policy, Export, and Trade Promotion, June 15, 2000.

[48] For more information on the reauthorization of the Export Administration Act of 1979, see CRS Report RL31832 *The Export Administration Act: Evolution, Provisions, and Debate,* by Ian F. Fergusson.

[49] The select agent list consists of viruses, bacteria, rickettsiae, fungi, and toxins and is determined by the Secretary of Health and Human Services. Agents on the select agent list are considered to have the potential to pose a severe threat to public health and safety.

agents to keep a current inventory of those agents and register their possession with the Department of Health and Human Services or with the Department of Agriculture, depending on the nature of the select agent.

Most universities generally reconcile their dual roles, that of providing educational and research opportunities to their students while simultaneously remaining in compliance with the limits of export regulations, by relying on the fundamental research exclusion. Some universities affirm their role as disseminators of knowledge and do not identify the nationality of students attending classes, citing the incompatibility of closed classrooms with their academic charter.[50]

## Prepublication Review

Some federal funding agencies, for example, the U.S. Army Research Laboratory, Army Corps of Engineers, the Department of Energy, and the Federal Aviation Administration, occasionally incorporate publication restrictions in the terms and conditions of their research contracts when the area of research either may have potential defense applications or contain sensitive material.[51] In general, these restrictions have not been applied to entire research fields, but, instead, have been targeted at research considered to be of import or relevance to national defense or where portions of a contract may contain classified information. An example would be an instance at the University of Minnesota where a prepublication review clause was required in a sub-contract performed by the university. Even though no classified information was handled by the University of Minnesota, classified material was present in the main contract, and prepublication review to determine no classified material appeared in any open publication was required.[52]

University administrators have been reportedly uneasy about such prepublication review clauses within funding vehicles. Officials at Duke University reportedly renegotiated and rejected contracts that had prepublication clauses inserted into them by the Department of Defense.[53] Administrators at the Massachusetts Institute of Technology have refused contracts including prepublication review

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[50] For example, access to classrooms, libraries, laboratories, and specialized research facilities of the University of California is open, without regard to citizenship, residency status, or visa category. Questions regarding citizenship status may not be asked of those entering such facilities unless a special exception has been granted. Office of the President, University of California, *Operating Guidance Memo No. 00-05*, October 30, 2000. Such guidance does not hinder the Universisty's compliance with legal obligations under federal law.

[51] Anne Marie Borrego, "Colleges See More Federal Limits on Research," *Chronicle of Higher Education*, November 1, 2002, p. 24 and Connie Cass, "Science Community Struggles With Terror-Wary Feds," *Associated Press*, January 2, 2003.

[52] As related in the minutes of the University of Minnesota Senate on April 25, 2002, found online at [http://www1.umn.edu/usenate/usen/020425sen.html].

[53] David Malakoff, "Universities Review Policies for Onsite Classified Research," *Science*, Vol. 295 (February 22, 2002) pp. 1438-1439.

language.[54] While prepublication review clauses within Department of Defense funding vehicles have caused concern among the academic community that they may violate NSDD-189, the Director of the Office of Science and Technology Policy (OSTP), Dr. John Marburger, has stated that the Department of Defense use of prepublication clauses in contracts has been consistent with prior policy.[55] Dr. Marburger requested that the academic community provide OSTP with examples of such clauses. The Council on Government Relations and the American Association of Universities prepared a joint report submitted to OSTP documenting 103 prepublication clauses presented over a six month period to a sample of 20 universities.[56]

# Policy Actions

The catastrophic terrorist attacks of 2001 led to an executive branch reevaluation of the treatment of government-owned information. In the wake of these events, many government agencies evaluated information which was available to the public through government websites and began to reassess documents that had recently been declassified.[57]

## The Card Memorandum

This process was marked by a memorandum on March 19, 2002 sent by Assistant to the President and Chief of Staff Andrew Card to executive branch departments and agencies.[58] This memorandum became known as the "Card memo." It cautioned that information possessed by the federal government which could be reasonably expected to assist in weapons of mass destruction development or use should not be inappropriately disclosed. Additionally, the guidance contained within the Card memo reinforced the need to protect "sensitive, but unclassified" information related to homeland security.

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[54] Anne Marie Borrego, "Colleges See More Federal Limits on Research," *Chronicle of Higher Education*, November 1, 2002, p. 24.

[55] Remarks of Dr. John Marburger, Director, Office of Science and Technology Policy, at the National Academies of Science Roundtable on Scientific Communication and National Security, June 19, 2003.

[56] American Association of Universities/Council on Government Relations, *Restrictions on Research Awards: Troublesome Clauses*, April 8, 2004.

[57] William J. Broad, "Nation Challenged: Domestic Security: U.S. Is Tightening Rules On Keeping Scientific Secrets," *The New York Times*, February 17, 2002.

[58] The Card memo contained guidance from the Acting Director of the Information Security Oversight Office, National Archives and Records Administration, and the Co-Directors of the Office of Information and Privacy, Department of Justice. A copy of this memo is available at [http://www.fas.org/sgp/bush/wh031902.html].

The term "sensitive, but unclassified" was not defined in the memorandum and it is not clear how sweepingly construed this category might be.[59] Further guidance regarding the use of this category is found within the memo itself:

> The need to protect such sensitive information from inappropriate disclosure should be carefully considered, on a case-by-case basis, together with the benefits that result from the open and efficient exchange of scientific, technical, and like information.[60]

Several comparable, but still dissimilar, definitions of "sensitive, but unclassified" are in use at different agencies. The Department of State describes "sensitive, but unclassified" information as:

> ...information which warrants a degree of protection and administrative control that meets the criteria for exemption from public disclosure set forth under Sections 552 and 552a of Title 5, United States Code: the Freedom of Information Act and the Privacy Act.[61]

The Department of Energy's use of "sensitive, but unclassified" is described as:

> Information for which disclosure, misuse, alteration or destruction could adversely affect national security or government interests. National security interests are those unclassified matters that relate to the national defense or foreign relations of the Federal Government. Governmental interests are those related, but not limited to, the wide range of government or government-derived economic, human, financial, industrial, agricultural, technological, and law enforcement information, as well as the privacy or confidentiality of personal information provided to the Federal Government by its citizens.[62]

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[59] For more information on "sensitive, but unclassified" information, see CRS Report RL31845, *'Sensitive But Unclassified' and Other Federal Security Controls on Scientific and Technical Information: History and Current Controversy*, by Genevieve J. Knezo.

[60] *Ibid.*

[61] Definition taken from the U.S. Department of State, *Foreign Affairs Manual*, located at 12 FAM 541.

[62] Definition taken from Office of Security Affairs, *Safeguards and Security Glossary of Terms*, U.S. Department of Energy, December 18, 1995, as cited in Commission on Science and Security, *Science and Security in the 21st Century: A Report to the Secretary of Energy on the Department of Energy Laboratories*, The Center for Strategic and International Studies, April, 2002.

The Department of Defense maintains several types of controlled, unclassified information. The Department of State category of "sensitive, but unclassified" is a document designation comparable to For Official Use Only.[63] The criteria for allowing access to For Official Use Only and "sensitive, but unclassified" information are the same. The Department of Defense describes For Official Use Only as:

> ... a designation that is applied to unclassified information that may be exempt from mandatory release to the public under the Freedom of Information Act (FOIA).[64]

## The Department of Defense Draft Directive

The Department of Defense requires a developed and documented plan for the protection of information important to prolonging the effectiveness and lifetime of acquired weapons systems for each acquisition program. Under current policy, basic and applied research funded by DOD is not required to have these information protection plans. Coincident with the issuance of the Card memo, DOD presented new draft regulations in March 2002 for protecting research and technology within the DOD.[65] The DOD draft regulation proposed to extend the requirement for acquisition programs to basic and applied research, both intra- and extramural, and would include the possibility of prepublication review of all research results funded by DOD.

The academic community, as well as some personnel from the Department of Defense, were highly critical of these draft regulations.[66] One criticism forwarded was that, since any research, even basic and applied fundamental research, performed under Department of Defense auspices might be expected to have an impact on some weapon system's performance, all research results obtained would be categorized as sensitive, unclassified information.[67] As a result, all research funded by the Department of Defense would require prepublication review. Another criticism was that, if plans for prepublication review of research results were developed, they could undercut established policy regarding fundamental research as developed in NSDD-189. Some suggested that it would become possible to be held criminally liable for

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[63] As reported on the Defense Security Service website at [http://www.dss.mil/search-dir/training/csg/security/S2unclas/Intro.htm].

[64] Department of Defense, "Information Security Program," Department of Defense Directive 5200.1-R, January 1997.

[65] U.S. Department of Defense, *Mandatory Procedures for Research and Technology Protection Within the DoD - Draft Regulations*, March 2002, found online at [http://www.fas.org/sgp/news/2002/04/dod5200_39r_dr.html].

[66] Ron Southwick, "Pentagon Backs Away From Strict Controls on Basic Research," *The Chronicle of Higher Education*, May 31, 2002, p. 21.

[67] Don J. DeYoung, White Paper on "Proposed Security Controls On Defense Research," April 2, 2002, found online at [http://www.fas.org/sgp/othergov/deyoung.html].

publishing unclassified research results as a consequence of the proposed regulation.[68] In the wake of such criticisms, the draft proposal was removed.

## Congressional Action

Following the publication of the poliovirus research results, Representative Dave Weldon introduced H.Res. 514 into the 107th Congress, which criticized the publishing of research potentially compromising national security. Subsequently, the House of Representatives' Committee on Science held a hearing on October 10, 2002, titled "Conducting Research During the War on Terrorism: Balancing Openness and Security" where testimony related to methods to control dissemination of sensitive scientific results was provided. There Dr. Marburger stated that the White House was revisiting treatment of sensitive homeland security information primarily for application to critical infrastructure and law enforcement information, rather than scientific results. Dr. Marburger said:

> I'm aware that there is an impression that the administration is considering a policy of pre-publication review of sensitive federally-funded research. This is incorrect–this is not the thrust of the considerations, and it's important to note that this process is in the formative stage.[69]

Additionally, Dr. Ronald Atlas, President of the American Society for Microbiology, stated that some information which might prove valuable for new drug therapies or vaccines could also be used maliciously to increase the danger of a pathogen.[70] Dr. Atlas voiced his support for a self-imposed code of conduct and oversight.[71] Dr. Atlas said:

> If policy measures to prevent terrorists from acquiring pathogens, equipment, and technical information are not crafted with great care, they may have a significantly adverse effect upon critically important research activities.[72]

The Homeland Security Act (P.L. 107-296) created the Department of Homeland Security, within which many research and development functions relating to homeland security were aggregated under a Science and Technology directorate. The Science and Technology directorate is responsible for researching, developing, and deploying biological, chemical, nuclear, and radiological countermeasures. It

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[68] Ron Southwick, "Pentagon Considers Tighter Control of Academic Research," *The Chronicle of Higher Education*, May 3, 2002, p. 24.

[69] Oral testimony from John Marburger, Director, Office of Science and Technology Policy, before the House of Representatives Committee on Science, October 10, 2002.

[70] An example of this dual nature is found in a research report showing genetically modified anthrax is a potent anti-tumor agent. S. Liu, *et al.*, "Potent Antitumor Activity of a Urokinase-Activated Engineered Anthrax Toxin," *Proc. Natl. Acad. Sci. USA*, (January 13, 2003).

[71] "Too Much Bioterrorism Research Censorship More Dangerous Than Not Enough, ASM's Atlas Testifies," *Washington Fax*, October 11, 2002.

[72] Written testimony from Ronald M. Atlas, President, American Society for Microbiology, before the House of Representatives Committee on Science, October 10, 2002.

also has management of the Homeland Security Advanced Research Projects Agency, which funds extramural homeland security research.

How homeland security information shall be handled by the Department of Homeland Security is further described in the Homeland Security Act. While to the greatest extent practicable, the results of research funded by the Department of Homeland Security are to be unclassified,[73] the President is also instructed to:

> prescribe and implement procedures under which relevant Federal agencies ... identify and safeguard homeland security information that is sensitive but unclassified. ... The President shall ensure that such procedures apply to all agencies of the Federal Government.[74]

Congress has held many hearings to perform oversight of the Department of Homeland Security. Issues raised in these hearings indicate that some policies are not yet in their final form. Since extramural scientific research funded by the Department of Homeland Security might be reasonably expected to also have security ramifications, an explicit policy relating to publication of such sensitive but unclassified information will likely be needed.

## Response of Professional Societies

Scientists are divided about how to balance scientific openness and national security concerns. While recognizing that security concerns are valid, some scientists assert that the value of publication of research results is greater than the potential risks. Others state that publication of select research results is troublesome and that mechanisms for determining which research results fall into this category and addressing publication of these results need to be determined.

The American Association for the Advancement of Science, the professional organization which publishes *Science*, has implemented a formal policy on how to deal with potentially dangerous reports.[75] The American Society for Microbiology, a professional organization which publishes many scientific journals, including the *Journal of Virology* in which the mousepox article was printed, has received requests by authors to be allowed to omit certain information from their submissions.[76] By omitting such information, the experiments described in the article would be much more difficult to reproduce, perhaps impossibly so.

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[73] P.L. 107-296, Section 306.

[74] P.L. 107-296, Section 892(a).

[75] The new policy for potentially dangerous reports is described in Information for Contributors, *Science*, January 3, 2003.

[76] Andrew Moesel, "Scientists Call For Withholding Sensitive Data," *University Wire*, August 12, 2002.

The American Society for Microbiology has adopted the position that all information necessary to reproduce an experiment must be included in any submission for publication. Former American Society for Microbiology president, Dr. Ronald Atlas, testified:

> Omission of materials and methods from scientific literature would compromise the scientific process and could lead to abuses as well as the perpetuation of errors. Independent reproducibility is the heart of the scientific process. Even within the context of heightened scrutiny, research articles must be published intact. If scientists cannot assess and replicate the work of their colleagues, the very foundation of science is eroded.[77]

Recognizing as valid the concern that scientific information in journals might be inappropriately used, the American Society for Microbiology has developed and established new policy guidelines for reviewers and editors of their journals. These new guidelines establish a procedure for special review of submissions concerning select agents and for those submissions which reviewers feel may possess the potential for inappropriate use.[78] In July 2002, Dr. Atlas requested that the National Academy of Sciences convene a meeting of journal editors to address the developing situation.[79]

The Presidents of the National Academies released a joint statement and background paper which avers that the federal government should continue its current practice of classification and not further develop a less well-defined category to encompass sensitive research results.[80] They asserted that scientific creativity and national security would both be lessened if clear distinctions are not drawn between areas where open publication is acceptable or not. They also emphasized that wide dissemination of research results and peer review are important aspects of research science.[81]

A meeting entitled "Scientific Openness and National Security" was held at the National Academy of Sciences on January 9, 2003.[82] It addressed some aspects of the debate regarding scientific publication and national security. Members of the academic scientific community, the non-profit community, and the federal

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[77] Written testimony from Ronald M. Atlas, President, American Society for Microbiology, before the House of Representatives Committee on Science, October 10, 2002.

[78] The guidelines developed by the American Society for Microbiology for authors, editors, publishers, and reviewers are found online at [http://www.journals.asm.org/misc/Pathogens_and_Toxins.shtml].

[79] Lila Guterman, "Academy Plans Debate on Publication of Papers That Withhold Data to Avoid Helping Terrorists," *The Chronicle of Higher Education*, July 29, 2002.

[80] Statement on Science and Security in an Age of Terrorism from Bruce Alberts, Wm. A. Wulf, and Harvey Fineberg, Presidents of the National Academies, October 18, 2002.

[81] *Background Paper on Science and Security in an Age of Terrorism*, National Academies of Science.

[82] This meeting was co-hosted by the National Academy of Sciences and the Center for Strategic and International Studies.

government met for a day-long symposium identifying the significant contentious issues.

At this meeting, Dr. Marburger reiterated that NSDD-189 continues to define policy for publication of federally funded research results. He suggested that research should be designated as classified prior to awarding a federal grant or contract, and that the need for deviation from this policy should be uncommon. He also stated that previous precedents of control in the physical sciences may not provide adequate guidance for bioterrorism.[83] Dr. Penrose Albright, then of the Office of Science and Technology Policy and the Office of Homeland Security, also stated that an articulated and defensible criteria for inappropriate research, able to distinguish dangerous and benign research results, combined with a mechanism for identifying articles containing dangerous but valuable information would be well received by the Executive Branch.[84]

While consensus was not achieved among the attendees regarding the potential solutions, there was general agreement that a growing dialogue between the scientific and security communities would aid in satisfying community members' concerns. Towards this goal, the National Academy of Sciences and the Center for Strategic and International Studies convened a two year, joint Roundtable on Scientific Communication and National Security. Both the scientific and security community were invited to informally discuss, and potentially develop, solutions to the tension over publication.[85] This led to the formation of a Commission on Scientific Communication and National Security by the Center for Strategic and International Studies. This Commission published a white paper in 2005, recommending that the federal government maintain NSDD-189 and that research institutions establish mechanisms to ensure informed compliance with applicable regulations regarding dissemination of scientific information.[86]

Journal editors described the new procedures put in place for *Science* and American Society for Microbiology journals and cited the relatively small percentage of articles that were considered potentially dangerous.[87] Dr. Donald Kennedy, editor of *Science*, suggested the identification of an informal group of qualified security

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[83] "NAS Forum on Scientific Openness Considers National Security Concerns," *Washington Fax*, January 10, 2003.

[84] Public comments, Penrose Albright at "Scientific Openness and National Security," National Academy of Sciences, January 9, 2003.

[85] "National Security, Scientific Openness," Center for Strategic and International Studies Press Release, March 14, 2003.

[86] Commission on Scientific Communication and National Security, *Security Controls on Scientific Information and the Conduct of Scientific Research*, June 2005.

[87] For example, the American Society for Microbiology has reported that only a small fraction of submitted manuscripts have been flagged as being of potential concern. Shirley Haley, "Statement on Scientific Publication and Security Asks Journal Editors to Exercise Responsible Constraint," *Washington Fax*, February 19, 2003.

representatives that would advise journal editors upon their request.[88] Dr. Nick Cozzarelli, editor for *Proceeding of the National Academies of Science of the United States of America*, described the difficulties in identifying published research results for which security concerns would override their scientific value.

At the American Association for the Advancement of Science's 2003 Annual Meeting in February 2003, 32 journal editors and scientist-authors issued a statement calling for renewed vigilance and personal responsibility for potentially dangerous research presented to them for publication.[89] This joint statement, which evolved from meetings following the National Academies' meeting, provided the base for subsequent announcements in *Science*, *Proceeding of the National Academies of Science of the United States of America*, and the British journal *Nature* affirming editorial policy to both deal responsibly and effectively with security issues while maintaining the integrity of the scientific publishing process.[90] It has been asserted that the joint statement should be understood as augmenting, but not supplanting, existing editorial policy at the signatory journals.[91]

The American Society of Microbiology's guidelines for publishing potentially contentious research have been tested with the publication of a manuscript in March, 2003 in the journal *Infection and Immunity*. This paper described the effects of proteins that accompany botulinum toxin during natural production and assessed the proteins' effects when inhaled. Upon receipt of the manuscript, editors requested that some portions of the paper be modified, in order to allay the editors' security concerns.[92]

The National Academy of Sciences issued a report which recommended that the policies of NSDD-189 be continued and that other mechanisms should be developed to address the difficulties of assessing and responding to contentious research.[93] The report identified seven research areas where results might pose a security concern, and advocated that proposed research in these areas be reviewed, and potentially rejected, by a committee, specifically the institutional biosafety committee within each research institution, before the research is performed. Thus, research of concern

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[88] Public comments, Dr. Donald Kennedy at "Scientific Openness and National Security," National Academy of Sciences, January 9, 2003.

[89] Lila Guterman, "Journal Editors and Scientists Call for More Caution in Publishing Potentially Dangerous Research," *The Chronicle of Higher Education*, February 17, 2003.

[90] Journal Editors and Authors Group, "Uncensored Exchange of Scientific Results," *Proceedings of the National Academy of Sciences of the United States of America*, Vol. 100, No. 4, (February 18, 2003) 1464. "Statement on Scientific Publication," *Science*, Vol. 300, (February 21, 2003) 1149. "Statement on the Consideration of Biodefence and Biosecurity," *Nature*, Vol. 421, (February 20, 2003) 771.

[91] See, for example, William Schulz, "Journal Editors Deal With Security Issues," *Chemical and Engineering News*, February 17, 2003, p. 15.

[92] Nell Boyce, "Keeping Details From the Devil," *U.S. News & World Report*, March 10, 2003.

[93] National Research Council, *Biotechnology Research in an Age of Terrorism*, (Washington, DC: National Academies Press), October, 2003.

could be identified and weighed before results were generated. Editors and publishers would continue to exercise their professional judgement in the publishing of manuscripts, without federal review or requirements.

Response to this proposal has been mixed. While many in the scientific community have supported this framework as an appropriate balance of scientific self-regulation and federal advisory oversight, others have criticized the proposal for not being legally binding or requiring such review of government or industrial research.[94] As an example of the limitations of the National Academies proposal, critics refer to the open discussion of mousepox research results by Dr. Buller at a biosecurity convention in Geneva, Switzerland.[95]

## Department of Homeland Security

The Department of Homeland Security has not, as of this writing, developed the methods by which potentially contentious extramural research results will be identified and handled or publicly disseminated policies regarding these results. Secretary Ridge, in remarks to the Association of American Universities in April 2003, has stated that the federal government continues to uphold NSDD-189, and that he does not plan to apply sensitive but unclassified or sensitive homeland security information guidelines to federally funded research. Instead, sensitive homeland security information and sensitive but unclassified information would only be information that the federal government already possesses.[96]

The Undersecretary for Science and Technology Charles McQueary has reportedly voiced his views on the treatment of scientific research results. At the American Association for the Advancement of Science Colloquium on Science and Technology Policy in April 2003, Undersecretary McQueary reportedly told the audience that scientific organizations should establish their own criteria for prepublication review of risky research articles and that scientists and journal publishers should set the bar for themselves.[97]

It has been reported that the Homeland Security Advanced Research Projects Agency follows a Department of Defense model for quasi-classified broad agency announcements. Jane Alexander, deputy director of the Homeland Security Advanced Research Projects Agency reportedly said that in some circumstances information may be held back from broad agency announcements in order to avoid

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[94] See, for example, John Dudley Miller, "National Academy Proposes Scientists Self-Police," *The Scientist Online*, October 9, 2003.

[95] See, for example, John D. Steinbruner and Elisa D. Harris, "When Science Breeds Nightmares," *International Herald Tribune*, December 3, 2003.

[96] Remarks by Secretary Tom Ridge to the Association of American Universities, Washington, DC, April 14, 2003.

[97] Shirley Haley, "Scientists Should Decide For Themselves What Research Is Too Risky To Publish, DHS S&T Chief Says," *Washington Fax*, April 15, 2003.

revealing vulnerabilities.[98] The criteria for these circumstances has not been made publicly available. Whether research results arising from such broad agency announcements could be freely published has not been made clear.

### Department of Health and Human Services

Following the publication of *Biotechnology Research in an Age of Terrorism*, the Department of Health and Human Services announced the establishment of a National Science Advisory Board for Biodefense (NSABB), building on several of the National Academies' recommendations.[99] The NSABB is, among other duties, to provide advice, guidance, and leadership regarding biosecurity oversight of dual-use research.[100] While the NSABB is managed and supported by the National Institutes of Health (NIH), it is to advise the Secretary of HHS, the Director of NIH, and the heads of all federal departments and agencies that conduct or support life sciences research.

The NSABB is composed of not more than 25 non-federal voting members appointed by the Secretary of Health and Human Services in consultation with the heads of other federal departments and agencies conducting life sciences research. It also contains non-voting *ex officio* federal members who represent agencies and departments that conduct or support life sciences research.[101]

## Policy Options

The balance between publication of federally-funded research results and protecting national security raises numerous questions, such as: Should there be regulation of the publication of federally-funded research results? Is the potential impact on scientific quality, productivity, and advancement resulting from publication controls worth the added potential security gained through such controls? How might relevant policy be uniformly employed by all agencies of the federal government? Should such policy vary by scientific and technical disciplines? At what stage, if any, of the civilian research process might regulation or restriction occur? How much authority, if any, does the federal government have over the publishing of research results developed through private funding? How might development or implementation of such authority introduce first amendment conflicts? Since science is an increasingly international discipline, how would

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[98] Judi Hasson, "Research Arm Puts Lid on Contracts," *Federal Computer Week*, August 14, 2003.

[99] Department of Health and Human Services, "HHS Will Lead Government-wide Effort to Enhance Biosecurity in "Dual Use" Research," *Press Release*, March 4, 2004.

[100] Dual-use research is defined as biolgoical research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security. Department of Health and Human Services, *National Science Advisory Board for Biosecurity Charter*, March 4, 2004.

[101] For more information on the National Science Advisory Board for Biosecurity, see online at [http://www.biosecurityboard.gov/].

national security concerns regarding federally funded research results be implemented in a global context? How might the federal government encourage scientists to develop guidelines for self-regulation? Given the international nature of scientific publication, might self-regulation by domestic publishers cause sensitive research results to be published in international journals rather than domestic journals? How might Congress provide oversight of this issue with respect to extramural research and development funded by the Department of Homeland Security?

## Maintaining the Status Quo

Some in the scientific community advocate that the status quo, where the mechanism for blocking publication of federally-funded research results is classification, should remain the federal government's policy on controlling research. They assert that this mechanism has been sufficient in the past, and that the vigor of scientific research could be unduly, and perhaps seriously, impeded if new controls were developed and added. Advocates of classification assert that, with the addition of the Secretary of Health and Human Services,[102] the Secretary of Agriculture,[103] and the Administrator of the Environmental Protection Agency[104] to the list of those persons authorized to classify information, the federal government has greater capacity to identify information for classification. They assert that, in line with NSDD-189, information which is not classified should be freely publishable and distributable. Advocates of this position claim that areas of proscribed research should be well defined and protected by strong barriers, such as those provided under classification.

Advocates of retaining the status quo also cite substantial concern about the impact of publication controls on science, especially in biological sciences.[105] Some have claimed that there would be a flow of scientists out of contentious research areas into areas where there is less concern about the legal ramifications of their work.[106] Others have spoken of a general slowdown and decline in scientific endeavor as the collaborative aspect of research becomes impeded.[107]

Additionally, some scientists believe that an unimpeded flow of scientific information is important to maintaining national security. They assert that national security will be increased if many researchers have access to information that may

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[102] 66 Fed. Reg. 64345 (December 12, 2001).

[103] 67 Fed. Reg. 61,463 (September 30, 2002).

[104] 67 Fed. Reg. 31,109 (May 9, 2002).

[105] Charles Vest, "Response and Responsibility. Balancing Security and Openness in Research and Education," *Report of the President for the Academic Year 2001-2002*, Massachusetts Institute of Technology, September 2002.

[106] For example, see Mark Clayton, "Academia Becomes Target for New Security Laws," *The Christian Science Monitor*, September 24, 2002, p. 11.

[107] D.J. Galas and H. Riggs, "Global Science and U.S. Security," *Science*, Vol. 300, (June 20, 2003) 1847.

lead to new vaccines, detectors, and treatments, or conversely, that impeded access may limit the development of countermeasures.[108] Dr. Paul Keim, a scientist at Northern Arizona University, stated:

> If the *Bacillus anthracis* genome had not been released, we would not have been able to develop the high-resolution system that is currently so important [to the investigation of the anthrax attacks].[109]

On the other hand, advocates for changing the current system contend that scientists are currently making available to terrorist groups information that can be used to harm the populace. Classification is not applied to information already published in the open literature and research results that threaten national security may arise from normally unclassified fields. Advocates of changing the current system assert that classification is insufficient to stop dissemination of such information. These proponents claim that the continued publication of such information will harm national security, and that changes should be made so that such federally funded research results can be classified before it is distributed. Some policymakers have also asserted that the current classification system may not be appropriate for all sciences. They emphasize the difficulties in clearly defining what aspects of biological research should be subject to regulation,[110] and that, unlike other classified research areas, much of microbiology is performed outside of the federal government.[111] They suggest that classifying basic biological research might be necessary for homeland security, but also might unduly restrict future applied research. Thus, they claim a different method for handling such results may be necessary.[112]

Advocates for adjusting the current system also assert that information published in scientific journals may undermine biodefense efforts. For example, publishing which portion of a pathogen's genome is used in a new biodetection device could inform terrorists how to create a pathogen which would avoid detection by that method.[113, 114]

The development of export control regulation may be indicative of ways that science and security measures can be developed in a mutually acceptable approach.

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[108] Daniel J. Kevles, "Biotech's Big Chill," *Technology Review*, July/August 2003, pp. 41-49.

[109] Debora MacKenzie and Sylvia Pagan Westphal, "Should the Genetic Sequences of Deadly Diseases Be Kept Secret?" *New Scientist*, July 20, 2002, p7.

[110] Gigi Kwik, "Biosecurity: Science in the Balance," *Biodefense Quarterly*, (Winter 2003).

[111] Peg Brickley, "CIA Openness Report To Be Classified?" *The Scientist*, April 7, 2003.

[112] D. Malakoff, "Researchers Urged to Self-Censor Sensitive Data," *Science*, Vol. 299, (January 17, 2003) 321.

[113] Nicholas Wade, "Traces of Terror: Bioterrorism; Scientists Worry Journals May Aid Terrorists," *The New York Times*, July 26, 2002, p. A19.

[114] Richard Monastersky, "Publish and Perish? As the Nation Fights Terrorists, Scientists Weigh the Risks of Releasing Sensitive Information," *The Chronicle of Higher Education*, October 11, 2002, p. A16.

In these areas, the concerns of national security are met while simultaneously allowing research to continue.

## Self-Regulation by Scientists

While many individual scientists may identify reasonable and valid concerns regarding the potential inappropriate use of information in scientific journals, opinions vary about how to best address these concerns. Some have advocated a self-policing framework where scientists regulate themselves through a combination of ethical agreements and publishing oversight.[115] They claim that scientists are in the best position to determine the threshold for responsible science and to respond to new scientific developments. As was shown through the experience of the National Institutes of Health Recombinant DNA Advisory Committee, amendment or adjustment of regulation and rules related to science is often needed, as the subject matter continues to evolve and progress.

Several mechanisms are possible within a self-regulating framework. One might involve review boards within institutions to assess research results. Much research involving human subjects, for example, is governed by local institutional review boards. A board's purview generally extends to all human research at the institution, irrespective of funding source. Although required by the Public Health Service Act and the Federal Food, Drug and Cosmetic Act for certain human experimentation, the boards at extramural research institutions are not federal entities.[116] These institutional review boards have the ability and authority to approve, require modifications within, or disapprove research projects. Similar review boards established within research facilities could be given the role of screening manuscripts in a formal or informal manner prior to their publication.

Another possibility would be to convene a new "Asilomar-like" conference, where members of the scientific and national intelligence communities, along with public input, come together and craft codes of conduct which will satisfy the varying needs of these disparate groups.[117] By doing so, a framework could be developed to identify sensitive research results and provide alternate dissemination routes.[118]

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[115] See for example Joseph G. Perpich, "The Recombinant–DNA Debate and Bioterrorism," *The Chronicle of Higher Education*, March 15, 2002, p. 20.

[116] More information about institutional review boards can be found online at [http://www.fda.gov/oc/ohrt/irbs/faqs.html].

[117] Ronald M. Atlas, "National Security and the Biological Research Community," *Science* Vol. 298, (October 25, 2002) pp.753-754.

[118] For example, see Letter to the Editor, "Science Publishing and Security Concerns," *Science*, Vol. 300, (May 2, 2003) p. 737.

NIH National Institute of Allergy and Infectious Diseases Director Anthony Fauci has voiced support for the above proposals. During an address at the World Medical Association meeting in October 2002, he suggested the formation of a panel to determine the appropriateness of certain types of biomedical research and stated:

> There should be a committee – a combination of academics and societies and perhaps journal editors – to discuss [publication], so if there is a question in the mind of someone, you can bring it to a body who can, in an unbiased way, give you an idea about whether or not you should [publish].[119]

Whether scientific researchers would be able to properly weigh the security concerns of research results is uncertain as well. For example, Dr. Stephen Morse, in endorsing the idea of an Asilomar-like conference, pointed out:

> Scientists are not in the age of innocence anymore. And they should be aware of the moral implications of what they're doing.[120]

Some have maintained that the natural inclination of scientists is to err on the side of openness and publication,[121] while others posit that since the science and security communities are separated, trust in the actions of the opposing community is difficult to develop.[122] Other complications to self-regulation exist as well. As scientific research has become more international in scope, it would be necessary for such a self-regulatory framework to be adhered to on an international basis. Without the agreement of international scientists to maintain similar codes of conduct, contentious research results generated by international scientists would continue to enter the open literature.

The NIH guidelines developed out of the Asilomar conference are generally followed on an international level, but the scientific community is much larger now than in the 1970s, and developing agreement among such a community may be more difficult to achieve.[123] Genetically modified foods and stem cell research are examples of biological research areas around which a community-wide, international consensus has not evolved.

The National Research Council report *Biotechnology Research in an Age of Terrorism* provides recommendations for a potential self-regulatory mechanism. It identifies seven areas where "experiments of concern" might exist, and recommends that experiments within these areas be reviewed by an institutional biosafety

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[119] Anthony Fauci, quoted in "Security Exceptions to Transparency in Publishing NIH-funded Research Will Be Rare, Fauci Says," *Washington Fax*, October 11, 2002.

[120] Laurie Garrett, "Scientists Advocate Greater Security," *Newsday*, October 14, 2001, p. A5.

[121] M. Mechanic, "Publish and Perish?" *East Bay Express*, September 11, 2002.

[122] D. Kennedy, "Two Cultures," *Science*, Vol. 299, (February 21, 2003) p. 1148.

[123] See G.L. Epstein, "Controlling Biological Warfare Threats: Resolving Potential Tensions Among the Research Community, Industry, and the National Security Community," *Critical Reviews in Microbiology*, Vol. 27, No. 4, (2001) pp. 321-354.

committee to determine whether the experiment presented some degree of concern. The institutional biosafety committees would thus provide an initial review of proposed experiments. If further review or consultation was needed to determine whether an experiment was of concern, then the experiment could be referred to an expanded Recombinant DNA Advisory Committee or to a higher authority for adjudication.[124] The establishment of the National Science Advisory Board for Biosecurity may be interpreted by some to fulfill this role and function, but issues regarding the authority and scope of the NSABB have yet to be fully resolved.

## Regulation by Publishers

The newly implemented editorial guidelines, either those developed by the American Society for Microbiology or others announced at American Association for the Advancement of Science meeting, for handling the results of potentially sensitive research may be models for other publishing houses to adhere to in the face of potential legislation or federal regulation. By empowering journal editors to screen, review, and reject research papers on the basis of their weapons potential, advocates hope to avoid new laws or regulations that might constrain the research process and scientific productivity. The revelation that some journal papers have been modified because of ethical concerns raised through the editorial process has been seen as a success for this style of oversight.[125]

Still, some cite the opinions of the editor of *Science* and chief executive of the American Association for the Advancement of Science initially expressed regarding the need for open publication[126] as indicative that the publishing community is not unified in perspective, and that an editor-based effort might yield unsatisfactory results. Even if domestic publishers develop a consensus protocol for handling research results which might threaten national security, it is unclear if this would 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 that is prohibited from publication in domestic journals. Finally, with the growing ability to disseminate scientific information to a wide audience without resorting to formal publication, it has been questioned whether a publisher-based policy will be effective in restricting the dissemination of contentious research.[127]

The National Research Council report *Biotechnology Research in an Age of Terrorism* recommends that journal editors continue to assess whether potentially contentious manuscripts should be published. It asserts that a voluntary approach,

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[124] National Research Council, *Biotechnology Research in an Age of Terrorism*, (Washington, DC: National Academies Press), October, 2003.

[125] Shaoni Bhattacharya, "Bioterrorist Fears Prompt Journal Paper Censorship," *NewScientist.com*, February 17, 2003.

[126] J. Couzin, "A Call for Restraint on Biological Data," *Science*, Vol. 297, (August 2, 2002) pp. 749-751.

[127] Steven Aftergood, "Science Journals Will Screen Papers For Hazards," *Secrecy News*, February 18, 2003.

where scientists and editors can continue to refine and respond to criticism or other input, is essential to the credibility of such a system within the research community.[128] Without such credibility it is believed that scientists may not take part in potentially contentious biodefense research.

## Federal Regulation

**Prepublication Review of Sensitive, But Unclassified Results.** An option viewed as potentially imminent by some in the scientific community is the imposition by the federal government of sensitive, but unclassified status, such as that being weighed by the Office of Management and Budget and discussed in the Card memo, and subsequent prepublication review of scientific research resulting from federal government sponsorship or funding. Application of this standard would likely allow scientists with appropriate credentials or need-to-know access to such scientific literature, but would bar others' access. Advocates of such a standard point out that such information could be transferred among scientists with fewer controls than classified information. It has been suggested that access to sensitive, but unclassified research results could be controlled by the publisher through secure, password-controlled websites.[129] Other options might include dissemination of such material via professional societies or directly from the federal government.

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 of such a label would be implemented; and determining how such sensitive, but unclassified material would be disseminated to those scientists eligible to receive it. A further complication is that the categorization of what information might be sensitive, but unclassified is still not clear or uniformly codified across all federal scientific funding agencies.[130] Additionally, some scientists or universities might choose not to participate in a process which would determine access eligibility. A Massachusetts Institute of Technology report rejects such security reviews as potentially becoming arbitrary.[131]

Another concern is the effectiveness of such a federally based review. The federal government funds about 26% of the total research and development efforts in the United States. In terms of basic and applied research, the federal government

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[128] National Research Council, *Biotechnology Research in an Age of Terrorism*, (Washington, DC: National Academies Press), October, 2003.

[129] 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).

[130] Potential new regulations regarding the definition of sensitive, but unclassified information being studied by the Office of Management and Budget may address these issues.

[131] 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.

funds 49% and 26% respectively.[132] 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 less than half of all basic and applied research would be so reviewed.

A strong sentiment held by many members of the scientific community is that all unclassified scientific results should be shared widely. Results are sometimes construed to include actual samples of research materials and all information necessary to reproduce an experiment. For example, the National Academy of Sciences' Board on Life Sciences has recommended that authors of scientific papers allow unrestricted access to data and supporting materials related to published findings.[133] Such a position indicates a potential lack of support within the science community for any credential system barring access to research results.

Lastly, universities fear that federal prepublication review to determine the sensitive, but unclassified status of material in a publication might invalidate the fundamental research exemption that such research results normally enjoy. As a consequence, university research done in an export-controlled area would no longer be excluded from export control regulations.[134]

**Security Review at the Funding Stage.** Another suggestion to addressing research with security implications is to categorize such research at the funding stage, rather than at the publication stage.[135] Including voluntary or mandatory prepublication review for federally-funded research or the development of new funding opportunities containing prepublication review as a condition of acceptance are potential remedies. Individual funding vehicles have been offered to universities which would provide the funding agency with access to research results prior to publication.[136]

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[132] Percentages calculated in constant 1996 dollars. Total research and development funding information taken from National Science Foundation, *National Patterns of R&D Resources: 2000 Data Update*, Table 1B. Basic research funding information taken from National Science Foundation, *National Patterns of R&D Resources: 2000 Data Update*, Table 2B. Basic research funding information taken from National Science Foundation, *National Patterns of R&D Resources: 2000 Data Update*, Table 3B.

[133] National Research Council, *Sharing Publication-Related Data and Materials: Responsibilities of Authorship in the Life Sciences*, (Washington, DC: National Academies Press) 2003.

[134] Eugene B. Skolnikoff, "Protecting University Research Amid National-Security Fears," *The Chronicle of Higher Education*, May 10, 2002, pp. B10-B12.

[135] For example, see Joan Lowy, "Debate Flares on Bioterror Research," *Scripps Howard News Service*, October 2, 2002.

[136] 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 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 UCDavis*, November 22, 2002. See also American Association of Universities/Council on (continued...)

Opponents of this approach cite the general unwillingness that universities have towards restricted research funding.[137] Some universities have a policy barring acceptance of federal funding requiring prepublication review. Also, it is questioned whether scientists are as willing to work in research areas where publication is not allowed as in areas where publication is encouraged.[138] As a consequence, the pool of eligible scientists competing for federal funding would likely decrease, potentially lowering the quality of research and development performed in these areas. Additionally, it is considered difficult to determine at the funding stage whether research will lead to sensitive results. For example, the often cited mousepox experiments were part of a fertility research program aimed at techniques for pest control, and the results of the experiment were unexpected.[139]

**Federal Licensing of Research.** Some experts have suggested that the role of the federal government should be expanded beyond a gatekeeping role when considering 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, Dr. John Steinbruner has suggested, as part of a Biological Research Security System, that a national federal authority be established to license qualified researchers and research facilities and oversee research by licensed researchers in licensed facilities.[140] Some scientists have asserted that licensing researchers, facilities, or experiments would have a strong, negative impact on scientific productivity in those areas.[141]

## Oversight of Homeland Security-Related Research

Congress may continue to oversee development of policies relating to publication of extramural research results funded by the Department of Homeland Security's Science and Technology directorate. Whether the Department of Homeland Security should adopt a currently existing policy on extramural research or create a new policy; how this policy might be implemented; and the degree to

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[136] (...continued)
Government Relations, *Restrictions on Research Awards: Troublesome Clauses*, April 8, 2004.

[137] 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].

[138] Philip Cohen, "Recipes For Bioterror: Censoring Science," *NewScientist.com*, January 18, 2003 and Paul Elias, "Academic Freedoms Said Hindered by 9/11," *Washington Post*, September 11, 2003.

[139] "Biowarfare Warning," *Journal of the American Medical Association*, Vol. 285, No. 6 February 14, 2001, p. 725.

[140] An initial local level of review and an international review agency are also established as part of the Biological Research Security System. J.D. Steinbruner and E.D. Harris, "Controlling Dangerous Pathogens," *Issues in Science and Technology*, Vol. 19, Spring 2003. For a regularly revised version of this system, see online at [http://www.cissm.umd.edu/documents/pathogensmonograph.pdf].

[141] Peg Brickley, "Science Police Needed?", *The Scientist*, April 8, 2003.

which extramural research funded by the Department of Homeland Security might present security concerns may be areas where further congressional direction occurs.

Additional oversight may focus on the activities underway in the Department of Health and Human Services, where the National Science Advisory Board for Biosecurity has been established. The charter of the NSABB is broad and recommendations brought forth from the body may impact much federally funded, homeland security-related research. The degree of impact, the comprehensiveness of such recommendations, and their ramifications may be areas of congressional interest. Alternately, should the NSABB be unable to provide practical recommendations, the difficulties and barriers encountered by the board may draw attention.

## Concluding Observations

Developing policy in this area balances many concerns, some of which may be more difficult to address than others. How would a federal policy that encouraged self-regulation of manuscript submissions, either by journal publishers or scientists, be enforced? How would the concerns of security officials regarding national security be met if scientists are relied upon to review articles? Conversely, how would the concerns of scientists regarding scientific openness and academic freedom be met if security officials review articles? A policy involving review of research may require the cooperation of members of both the scientific and security community, two communities that generally have limited interaction. Finally, how would the success of a program controlling scientific research results be measured? Some aspects of such a program, like the economic costs involved in processing the articles, might be directly measurable, while others, such as the success in blocking terrorist group access to this information, might not be so easily measured.