Regulation of Biological Research in the Terrorism Era

Barry Kellman
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I. INTRODUCTION

Perhaps no discipline has made (and continues to make) such a profound contribution to humanity as biological science. Unquestionably, the pace and significance of that contribution has steadily accelerated, all the more so in recent years. Most experts believe that revolutionary leaps are yet to come but not far off. Not to be overlooked is that this progress has come with nary a “dark side” – Cassandra prophecies of rampaging mutants have, as yet, not materialized.

A widely-held view within the biological community is that progress is a function of minimal government regulation. Indeed, there is an apparent correlation between the pace of scientific discovery and the freedom of scientists to pursue ideas according to their own experience and creativity without bureaucratic intrusion; whether there a causal relationship or mere coincidence is debatable.

It is reasonable to ask, therefore, why policy makers are insisting on greater control over biological science. The answer has to do with terrorism and proliferation, of course, but that answer disguises more than it illuminates. Sophisticated and malevolent groups can use biological means to draw attention to their misconceived political objectives, but this potentiality is not dependent on leading edge research. Making a biological weapon is not trivial, but neither does it demand the dedicated services of the discipline’s elites. The argument for regulating biological research in order to prevent biological terrorism is somewhat simplistic.

A subtler, and better, answer focuses on three concerns of the relationship between biological research and bio-terrorism. First and most obvious, while terrorists of exceptional training and resources might be able to make and disseminate a biological weapon, the difficulties of doing so may be substantially reduced with ready access to

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unique and highly refined pathogens, to advanced equipment, and to innovative procedures. Second and somewhat related is that while making a crude weapon may be pedestrian, biological research is increasingly raising possibilities that an individual or small group could develop a disease of such devastation that civilization itself would be fundamentally maimed with attendant risks of economic collapse and political upheaval. Third and quite distinct is biological research offers the potential to uncover the underlying principles of pathogenicity and develop vaccines and other protective measures against a bioterrorist event; would the net gain would be greater in suppressing information that might conceivably be used malevolently, or in disseminating that information to allow legitimate research into underlying biological phenomenon.¹

Two unrelated events since Sept. 11th have brought these concerns into sharper relief. First were the anthrax-laden mailings to various political leaders. Although anthrax is readily available in nature, this powder was extraordinarily refined, suggesting that its production was the work of a remarkably advanced laboratory process. Second was the re-creation of the polio virus in a laboratory (discussed infra). A crippling disease that has been thought to be eradicated from most of the world and due to be extinguished has suddenly re-arisen, not by natural outbreak, but by scientists' intentional design.

These events have provoked various political initiatives, three of which are the subject of this discussion. First, under the recently enacted Public Health Security and Bioterrorism Preparedness and Response Act, the scope of regulatory oversight of pathogens has been substantially expanded from what earlier law had provided. Second, an initiative is currently under consideration to shift critical elements of biological regulation from the Department of Health and Human Services to the to-be-formed Department of Homeland Security, suggesting a shift of regulatory emphasis from the promotion of social welfare to the protection of national security. Third, new regulations from various agencies are raising a specter of governmental restraint on the free dissemination of knowledge in the biological sciences.

II. REGULATORY OVERSIGHT OF PATHOGENS

As recently as 1995, few legal restrictions applied to domestic transfers of lethal pathogens. The experience of Larry Wayne Harris as well as rising fears of terrorist access to biological weapons precursors provoked passage of the Antiterrorism and Effective Death Penalty Act in 1996. The Act authorized the Centers for Disease Control (CDC) to regulate transfers of pathogens of unique interest in terms of their capacity to be used as weapons (the select agents list). Accordingly, the CDC required that laboratories transferring select agents be registered; a registered laboratory could legally transfer select agents only to another registered laboratory; transfers to non-registered laboratories were prohibited. Registration under that Act, however, was principally a matter of notification: a laboratory was obligated to notify relevant authorities of a transfer to another registered facility and that the transfer itself complied with applicable safety standards. Specific information about particular pathogens that the facility possessed did not have to be reported, not even if they were the subjects of extensive research, so long as they were not transferred. This was not intended to be a strict licensing system but merely a way of overseeing the traffic (slight though it may be) in lethal pathogens.

Although it is still not known (as of this writing) whether a domestic laboratory was the source of the deadly anthrax attacks in 2001, a burgeoning concern over the risks associated with biological terrorism led to enactment of the Public Health Security and Bioterrorism Preparedness Response Act. The "Act authorizes $1.6 billion to implement state plans and conduct additional preparedness activities, [and it] addresses other related public health security issues [such as] additional safety and security measures affecting the nation’s food and drug supply, additional safety and security measures affecting the nation’s drinking water, [and] measures affecting the Strategic National Stockpile and development of priority countermeasures to bioterrorism."
HEALTH MATRIX

A. Enhanced Reporting Obligations

Title II of the new Act, Enhanced Controls of Dangerous Biological Agents & Toxins, substantially broadens the regulatory obligations for laboratories working with select agents. Indeed, its objective far exceeds oversight of the movements of pathogens; its objective is to establish a national database for dangerous pathogens and to monitor their distribution and use.

The new law requires any entity possessing select pathogens$^6$ to report to the Secretary of HHS the names and locations of relevant facilities, the select agents they possess, use or transfer, and information about the characteristics of the select agents.$^7$ Approximately 190,000 research and diagnostic laboratories, scientists and manufacturers must notify federal authorities whether they have any of 36 listed pathogens that can be used to make biological weapons or components of them that control virulence or toxicity. The new legislation also authorizes the US Department of Agriculture (USDA) to develop a list of agriculturally significant biological agents and toxins and, consistent and cooperatively with the HHS, regulate possession, use or transfer of listed biological agents and toxins that threaten plant or animal health or their products.$^8$ It is expected that the USDA will soon add 24 more livestock diseases and possibly more plant pathogens as potential sources for biological weapons.$^9$

$^6$ Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Secretary must establish and “maintain a list [which may be updated when necessary] of each biological agent and toxin that has the potential to pose a severe threat to public health and safety.” The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-88, § 351A(a)(1)(A), 116 Stat. 594, 637 (2002). In deciding which agents or toxins shall be included, the Secretary must consider:

(I) the effect on human health of exposure to the agent or toxin;
(II) the degree of contagiousness of the agent or toxin and the method by which it is transferred to humans;
(III) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent illness resulting from the infection; and
(IV) any other criteria including the needs of children and other vulnerable populations. The list may be updated when necessary.

$^7$ Id. at § 351A(a)(1)(B)(i)(I)-(IV).

$^8$ Id. at § 351A(d).

Under the new laws, only researchers with a "legitimate need" may have access to the materials, which will be barred to students or researchers from countries considered sponsors of terrorism and to people with felony or drug convictions or with histories of mental illness.\(^\text{10}\) The necessary implication is that unreported possession of select agents is an offense and punishable by up to five years imprisonment.\(^\text{11}\)

The obligation to report applies from 90 days following enactment of the bill based on guidance issued by the Secretary within 30 days of enactment and the issuance of a final rule with requirements for registration of facilities in 180 days of enactment; the final rule will take effect after 60 days of the final rule.\(^\text{12}\)

Because innocent breach of this obligation is not a defense, every laboratory must scour through its freezers and other storage sites for such items lest they materialize unexpectedly. For many laboratories, notably associated with universities, collections of pathogens are improperly labeled, complicating the task of conducting a complete inventory. Even those laboratories that are not working with one of the agents or toxins on the list have to file a notification to the Secretary.\(^\text{13}\) This alone signifies a substantial regulatory change for facilities engaged in biological research: before the new act, only a conscious decision to transfer a select agent provoked a regulatory obligation; now, obligations apply to every research facility without regard to any current choice to engage in regulated activity.

Even clinical or diagnostic laboratory that might come into possession of a select pathogen temporarily only in order for specimen diagnosis, verification or proficiency testing must report that item unless it promptly either destroys the sample on site or transfers it to a registered facility.\(^\text{14}\) Congress explicitly rejected any broad exclusion...
of these facilities. The Secretary may, in his/her discretion, exempt products that are used in investigational or clinical trials authorized under federal laws, with attention to the time sensitivity of such trials.

B. Enhanced Safety and Security

The Secretary must also provide for the establishment and enforcement of safety procedures, including: (1) proper training and appropriate skills to handle such agents and toxins; (2) proper laboratory facilities to contain and dispose of such agents and toxins; (3) measures to prevent access to such agents and toxins for use in domestic or international terrorism or for any criminal purpose; (4) procedures to protect the public safety in the event of a violation of the safety or security measures; and (5) appropriate availability of biological agents and toxins for research, education, and other legitimate purposes. The Secretary may inspect facilities subject to regulations to ensure their compliance with such regulations, including prohibitions on restricted persons.

The Secretary and appropriate federal, state and local law enforcement agencies must be promptly notified in the event of a theft or loss of listed agents and toxins or in the event of a release of agents outside the proper bio-containment area. If the Secretary finds that the release poses a threat to public health or safety, s/he must take appropriate action to notify authorized emergency response authorities. On an annual basis, the Secretary will report to Congress the

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15 H.R. REP. No. 107-481, at 122 (2002). See Notice of OMB Approval of Data Collection, 67 Fed. Reg. 51058 (Aug. 6, 2002) ("Congress permits exemption of such clinical and diagnostic laboratories from registration requirements, ... only if they report the identification of select agents to the Secretary and either promptly transfer the agent to a registered person or destroy the agent on site in accordance with regulations established by the Secretary").

16 Exemptions are provided consistent with the current select agent transfer rule for products that are or contain select agents and are approved under specific federal laws unless the Secretary determines that additional regulation is necessary for a specific product to ensure protection to public health and safety. The legislation mandates a prompt determination by the Secretary of an exemption within 14 days after the applicant has submitted a complete exemption request and has notified the Secretary that the investigation may proceed as authorized under federal law. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-88, § 351(A), 116 Stat. 594, 642 (2002).

number and nature of notifications received relating to theft or loss
and to releases.\textsuperscript{18}

C. Enhanced Restrictions on Access

Entities having registered facilities must limit access to select
agents; only persons that the entity determines to have a legitimate
need to handle or use select agents may have access. An even more
overt imposition of law enforcement concerns is the Act’s require-
ment that the entity submit such individuals’ names to the HHS and
the Attorney General who will check relevant criminal, immigration,
national security and other electronic databases as to whether the in-
dividual is a restricted person as defined in section 175b of Title 18 of
the US Code or is reasonably suspected by any federal law enforce-
ment or intelligence agency of committing a crime, knowing involve-
ment with domestic or international terrorism or crime, or being an
agent of a foreign power.\textsuperscript{19} The Attorney General must promptly no-
tify the HHS Secretary who, in turn, must notify the entity about
whether an individual is granted or denied access. Denial of access
privileges may be appealed pursuant to a stipulated review process
that includes provisions to ensure that classified or sensitive law en-
forcement information is not compromised during those reviews.

D. Regulation of Information

The Secretary must maintain a national database that includes the
names and locations of registered persons, the listed agents and toxins
such persons are possessing, using, or transferring, and information
regarding the characterization of such agents and toxins. The Attor-
ney General will have access to the database.\textsuperscript{20}

Nondisclosure obligations apply to reported information concern-
ing

(1) [T]he possession, use, or transfer of a listed agent;

\textsuperscript{18} See The Public Health Security and Bioterrorism Preparedness and Re-

\textsuperscript{19} Section 175b was enacted on 26 October 2001 in the Patriot Act (PL
107-56) and prohibits restricted persons from possessing, using or transferring select
agents and includes individuals with criminal felony records, fugitives from justice,
aliens illegally in the United States, foreign nationals from terrorism-sponsoring na-
tions, individuals dishonorably discharged from the Armed Services, and individuals
adjudicated as mentally defective.

\textsuperscript{20} The Public Health Security and Bioterrorism Preparedness and Response
(2) [t]he national database;
(3) safeguard and security measures . . . to prevent unauthorized access;
(4) notification of any release, theft or loss of a listed agent,
(5) an inspection of a registered facility.\textsuperscript{21}

All relevant federal agencies and departments are bound by the nondisclosure obligation.

\textbf{III. OVERSIGHT OF BIOLOGICAL RESEARCH}

Of different but no less impact to the conduct of biological activities is the question of what government authority is responsible for oversight. Arguably, the favored answer here among many in the biological community is “none of the above.” That option being politically unacceptable, however, most of that community has a distinct preference to be regulated by agencies that share its fundamental objectives and philosophy. For many years, regulation of biological activities has been within the domain of the Department of Health and Human Services (HHS); regulation of especially dangerous pathogens has been within the domain of the CDC which itself is within HHS’ domain. A certain comfort level has been established both because of long familiarity and because HHS’ mission is to promote health—a mission that is obviously in accord with the work of most biological scientists.

Precisely because of this mission, HHS is ill-suited to be the federal agency primarily responsible for preventing terrorist misuse of biological agents. That is primarily a national security or law enforcement function. Its principal motifs entail circumscribing unfettered freedom of action in certain spheres while increasing the government’s access to and control of information—motifs that are substantially at odds with a mission of promoting basic scientific research to the goal of improving human health and welfare. To address this mismatch, it may be appropriate either to transfer some of HHS’ responsibilities to a different department that is better suited to pursue national security or to authorize such a department to establish national priorities and policies while leaving HHS to implement those policies.

In this context, the President’s proposal for a Department of Homeland Security has raised a troubling issue for the biological community. It is not that the creation of this new federal authority is viewed as unnecessary or inappropriate; concerns have arisen as to the

\textsuperscript{21} \textit{Id.} at §§ 351A(h)(1)(A)-(E).
transfer of responsibilities from Health and Human Services to the Department of Homeland Security. Under current law, The CDC and the National Institutes of Health (NIH), both part of HHS, now administer most biodefense programs, including support for state and local public health preparedness and research on threats to human health.\textsuperscript{22} Under the new proposal, for some public health and medical activities, "DHS would assume [direct] responsibility; [for other activities,] DHS would [be] responsible for setting goals and providing strategic direction but would rely upon HHS to implement and operate the activities on a day-to-day basis."\textsuperscript{23}

Given that the new Department will have important intelligence, threat, and vulnerability-related information necessary for the identification of program priorities, it has been argued that the new Department should develop our national strategic plan for bioterrorism activities and identify our most urgent national priorities, including priorities for programs at HHS.\textsuperscript{24} Some of the functions that the President proposes be transferred to DHS include: oversight of select agents and enforcement of controls, responsibilities relating to emergency preparedness and response, and oversight of biological research.\textsuperscript{25} This proposal has generated concerns that transferring bioterrorism preparedness planning and research to the new department would undermine efforts to strengthen the public health system.\textsuperscript{26}

A. Select Agent Registration and Enforcement Program

As discussed above, the recently enacted Public Health Security and Bioterrorism Preparedness and Response Act has authorized HHS to promulgate and enforce regulations concerning the possession,


\textsuperscript{23} \textit{DHHS and the Dep't of Homeland Security before the House Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations}, (June 25, 2002) (statement of Claude A. Allen, Deputy Secretary, Dep't of Health and Human Services).


\textsuperscript{25} Allen, supra note 23.

transfer and use of select agents. From the perspective of averting the threat of misuse of those agents by terrorists, the HHS and the CDC are arguably not designed to exercise the level of oversight that might be appropriate to the objective of preventing malevolent use of lethal pathogens. Accordingly, the President’s bill proposes to transfer to the Secretary of Homeland Security the responsibility to administer the select agents program with the HHS Secretary in a consultative role: HHS will provide DHS with scientific expertise and other technical assistance and make key medical and scientific decisions.

B. Emergency Preparedness and Response

1. The Office of the Assistant Secretary for Public Health Emergency Preparedness

Among its many initiatives, the 2002 Bioterrorism Act created the HHS Office of the Assistant Secretary for Public Health Emergency Preparedness with responsibility for supervising the Office of Emergency Preparedness, the National Disaster Medical System, the Metropolitan Medical Response Systems, and related HHS emergency management functions. This office was designed and intended to serve as the central coordinator of consequence management activities in the event of a biological attack or act of bio-terrorism. In such an event, it will be imperative to mobilize substantial medical resources, most likely involving specialized expertise. It may also be necessary to exercise special authority with regard to issues such as commandeering of private resources and implementation of quarantines. The question arises as to whether this is a “public health” function or a “national security” function.

In proposing the establishment of the DHS, the Administration asserted that, on balance, it would be preferable to maintain a “seamless integration of national public health and medical emergency management assets with the Nation’s new preparedness and response infrastructure at DHS.” This proposal was not submitted critically of HHS but to reflect the need for coordination among diverse consequence management responsibilities.

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28 Allen, supra note 23.
29 Id.
30 Id.
31 Id.
2. Certain Public Health-Related Activities

The President’s proposal provides that the new Department shall—unless otherwise directed by the President—carry out through HHS certain public health related activities (such as programs to enhance the bioterrorism preparedness of state and local governments and non-federal public and private health care facilities and providers). The object of this provision is to continue the HHS’ role in assisting state and local governments and the hospital and public health community in preparing for and responding to large scale public health emergencies. “As with the research program, the Secretary of [DHS,] in consultation with the Secretary of [HHS], will establish the Nation’s anti-terrorism preparedness and response program and priorities, but implementation of the public health components of that program will be carried out largely through HHS.”

3. The Strategic National Stockpile

In order to provide medicines rapidly if there is a catastrophe, whether natural or man-made, the CDC operates “12 ‘push packages’ of pharmaceutical and medical supplies and equipment strategically located around the United States; additional lots of pharmaceuticals and caches of medical materiel are maintained by manufacturers under special contractual arrangements with CDC.” The proposal to shift authority over this pharmaceutical stockpile to DHS is based on the professed need to integrate it with other national emergency preparedness and response assets at DHS. Under the proposal, “the Secretary of [DHS] will assume responsibility for continued development, maintenance, and deployment of the Stockpile—making it an integral part of the larger suite of federal response assets managed by FEMA and other future DHS components—while the Secretary of HHS will continue to determine its contents.”

C. Biological, Biomedical and Infectious Disease Defense Research and Development

The President’s proposal provides that, in regard to civilian human health-related biological, biomedical, and infectious disease defense research and development, the Secretary of Homeland Security,
in consultation with the Secretary of DHS, will have the authority to establish the research and development program that will be implemented through HHS. Thus, as the agency responsible for assessing threats to the homeland, DHS, in consultation with the HHS Secretary, will provide strategic direction regarding the nation’s biological and biomedical countermeasure research priorities. Moreover, while if the DHS conducts or authorizes biological research it must collaborate with HHS, it need not do it under HHS’ supervision. The proposal is silent on what happens if DHS and HHS are unable to arrive at a joint strategic prioritization agreement or if DHS finds that research designed by HHS does not ensure achievement of a joint agreement.

In general, the issue here is whether it is feasible to separate authority from responsibility, or to separate the officials charged with administering those responsibilities from the personnel required to do so. Some members of the biological research community have voiced concerns that HHS, a scientific health agency, is best qualified to prioritize and conduct federal research on human health-related biological, biomedical, and infectious diseases, and to identify scientific opportunities and research approaches for meeting biodefense needs. The response to bioterrorism will require the long-term dedication of financial resources and scientific talent; HHS/NIH has already demonstrated its capacity for such service. Transfer of primary responsibility for the prioritization and/or design of human biodefense research to DHS would create unpredictability for research programs and would not be the optimum way to obtain the integrated work of the best scientific minds, including the ability to rapidly mobilize the scientific community with the appropriate expertise. Other difficult questions arise, such as whether HHS would retain authority, pursuant to the Public Health Service Act, to declare public health emergencies or issue quarantines.

Perhaps the most important controversy here involves funding. The President’s proposal allocates to the DHS Secretary primary au-

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37 See Testimony of W.J. “Billy” Tauzin, supra note 24 (stating need for collaboration between agencies).
38 Id.
39 Id.
42 Id.
authority over the $1.9 billion in NIH research grants relating to pathogens and countermeasures and the $1.5 billion in public health emergency grants to state and local public health departments included in recently enacted bioterrorism legislation.\footnote{See Testimony of W.J. "Billy" Tauzin, supra note 24 (showing authority over funding decisions to counter bioterror).} A concern here is that much of the terrorism-related research currently being performed through NIH and CDC is dual-purpose in nature – serving the priorities and needs of both counter terrorism and traditional public health. Similarly, the grants to state and local public health departments and hospitals are not just to prepare for the possibility of bioterrorism, but for building up basic infrastructures such as surveillance and communication systems to improve response to all sorts of public health emergencies, whether intentionally caused or naturally occurring.

A few specific provisions illustrate the controversy.

- All research supported by funding appropriated to NIH for bioterrorism research must be conducted under “joint strategic prioritization agreements” with DHS.
- Regarding joint strategic prioritization agreements, the DHS will have the authority to establish general research priorities that will be embodied in the joint strategic prioritization agreements. DHS need not consult with HHS in establishing priorities; it will have full authority to establish human health-related bioterrorism research priorities.
- Once a joint strategic prioritization agreement is reached, HHS should develop the specific scientific research agenda to implement the agreement. However, HHS is expressly required to consult with DHS in setting the research agenda.
- DHS is permitted to transfer funds to HHS in connection with joint strategic prioritization agreements, enabling it to wield the power of the purse regarding bioterrorism research.\footnote{See Am. Soc'y for Microbiology, at http://www.asmusa.org/pasrc/liebermanltr.htm.}

IV. RESTRICTIONS ON EXCHANGES, PUBLICATION OF BIOLOGICAL RESEARCH INFORMATION

From a terrorist’s perspective, culturing crude pathogens is not an insurmountable barrier nor is obtaining rudimentary equipment for its dissemination. But to make a truly catastrophic weapon, advanced
knowledge of biological science can be helpful if not essential. If the
goal is to create a weapon that is uniquely dangerous, access to recent
and cutting-edge research might be key to success. Thus, broad pub-
lication of the results of legitimate biological research activities might
enable a scientifically-sophisticated terrorist to develop new agents or
refine existing agents. New research could also enhance a terrorist’s
ability to weaponize agents, either by rendering them capable of mass
dissemination, increasing the range of their applicability and effec-
tiveness, or rendering them less susceptible to immunization or treat-
ment. Accordingly, unfettered biological activity and communication
may provide opportunities for persons who would threaten our secu-

A policy to restrict the dissemination of scientific information,
however, raises serious objections. First, there is the basic issue of
freedom of speech, reinforced by scientists’ strong belief that free
exchange of ideas is compulsory for progress. A second objection
relates to how information would be restricted. Classified research is
not at issue here; restrictions would be imposed upon the completion
of research that is otherwise in the public domain because of a gov-
ernment official’s determination that the information is too dangerous
to be released. Notably, a scientist could spend considerable time and
professional resources in the pursuit of break-through information
which, upon reaching that goal, could be banned from publication,
with attendant consequences for his/her career. A third objection re-
lates to enforcing the restriction. Publication in a domestic journal
could, conceivably, be restricted, but it is far harder to prevent a report
from leaping to a foreign outlet or to the internet. Moreover, scientists
routinely exchange information through less monitorable communica-
tions at conferences and otherwise.

These objections notwithstanding, there is reason for con-
cern. According to George Poste, a leading expert on these ques-
tions:

Training in genetics, microbiology and biotechnology is now
offered in college courses around the world. Huge volumes
of information pertinent to bioterrorism are available in non-
classified scientific journals and on the internet. The number
of trained personnel capable of undertaking sophisticated ge-
netic manipulations has expanded substantially, including in
ations viewed as potential sponsors of terrorism. Techno-
logical advances allow the cultivation and harvesting of large
quantities of virulent micro-organisms virtually anywhere and
at minimal expense. A survey of 1,400 US academic institu-
tions revealed that 16% had stocks of pathogens listed in the
draft Biological Weapons Convention, 11% had high-level microbiological containment facilities and 3% had large volume bioreactors. Over 2000 new biotechnology companies have been formed in the US and 1,500 in Europe during the last 20 years, together with a parallel expansion of expertise in genetics and molecular biology within the pharmaceutical sector.\textsuperscript{46}

A. Applicable Law

Current policy reflects the preference for unfettered dissemination of information unless classified. National Security Decision Directive 189, formulated in 1985 and upheld last November by National Security Advisor Condoleeza Rice as this administration’s policy, establishes that research ought to remain as unrestricted as possible, and that the only authorized way to restrict scientific information is through classification; no research will be restricted unless it is classified. Specifically, the directive provides that:

\textit{[W]here 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 conduct or reporting of federally-funded fundamental research that has not received national security classification.}\textsuperscript{47}

At this time, the following statutory provisions relate to the applicability of the policy set forth in National Security Decision Directive 189:

\textsuperscript{46} George Poste, \textit{Biotechnology and Terrorism}, at www.prospect-magazine.co.uk...asp?accessible=yes&p_Article=11341

• **The Espionage and Sabotage Act of 1954** is designed to prevent military secrets from being transmitted to foreign agents. This statute could apply to biotechnology under a broad interpretation of what constitutes “information relating to the national defense.” A key element of an offense under the act is proof of intentional dissemination of the information with a desire to willfully harm the United States.

• **The Export Administration Act of 1979** allows control of the nation’s exports as necessary for national security. The Secretary of Commerce, acting with the Secretary of Defense, must establish a comprehensive list of all goods and technologies that should be subject to export controls. The regulations then require that to export such items requires the grant of a license by the Secretary of Commerce.

• **Arms Export Act** sets forth a list of materials that may not be exported without a license. The Act encompasses technologies that are both classified and unclassified; information which is in the public domain is not included under the Act.

• **The US Patent System** The Commissioner of the US Patent and Trademark Office has the power to initiate a process whereby inventions that may be detrimental to the national security may be kept secret, thereby obligating the applicant to not disclose the invention to others. Failure to obey the order results in abandonment of the patent application and in extreme cases can result in a fine and imprisonment.

B. Recent Developments

The tension between the need to prevent widespread dissemination of potentially dangerous information and the need for scientific freedom was recently highlighted by the publication in Scientific

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50 18 U.S.C. § 794 (2000) ("[w]hoever, with intent or reason to believe that it is to be used to the injury of the United States or to the advantage of a foreign nation, communicate . . . ")
51 Parrett, supra note 49, at 161.
52 Id.
53 Id. at 167-70.
Magazine Online of July 11, 2002, of a paper, “Chemical Synthesis of Poliovirus DNA: Generation of Infectious Virus in the Absence of Natural Template.” The paper presented a detailed description of how to assemble a human polio virus by using DNA stretches obtained by mail from a specialty reagent supplier. Nature Medicine Magazine published another controversial study that pinpoints a mutation in an influenza A virus gene that may explain the virulence of the influenza outbreak in Hong Kong in 1997.

Thus, what had been an abstract concern has suddenly become demonstrably realistic, raising concerns that the public availability of information might enhance threats to homeland security. Immediately upon the publication of the polio paper, Representative Weldon along with seven other members of Congress filed House Resolution 514, criticizing the American Association for the Advancement of Science (“AAAS”) for having published what he described as “a blueprint for creating a polio virus and other harmful pathogens that could be released on the population of the United States.” The Resolution called for the scientific community to develop ethical standards for preventing published materials from aiding terrorists in the development of agents of bioterrorism. Of far greater concern to the scientific community, the Resolution instructed the Executive Branch to “examine all policies, including national security directives, relevant to the classification or publication of federally funded research to ensure that, although the free exchange of information is encouraged, information that could be useful in the development of chemical, biological, or nuclear weapons is not made accessible to terrorists or countries of proliferation concern.”

In response, members of the scientific community have asserted that public dissemination of such controversial information spurs research efforts, that the fear that information in such publications may be abused is far outweighed by the benefits it may provide. “Many microbiologists say that they see no threat to national security in the

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55 Id.
56 See Sang Heui Seo et al., Lethal HSN1 Influenza Viruses Escape Host Anti-Viral Cytokine Responses, 8 NATURE MED. 950 (Sept. 2002), (explaining experiments that detected a genetic mutation that makes the strain of influenza resistant to regular anti-viral treatments) available at http://www.nature.com.
57 House Resolution 514
58 Id.
59 Id.
60 Id.
polio [case] because the DNA sequence [of the virus] is available over the Internet and techniques for building [the virus] have long been known. Accordingly, the American Society for Microbiology ("ASM") has recently released guidelines for handling research manuscripts dealing with pathogenic agents that have potential bioterrorism applications. Primarily, the new guidelines ask all reviewers to advise their editors "if, in their opinion, the manuscript under review describes misuses of microbiology or of information derived from microbiology." A second question is if you are going to publish a paper, should information be withheld to prevent that information from being publicly available to terrorists. If the answer to either question is "yes", then "appropriate action will be taken in consultation with the Board of publication." The new policy allows the editors to serve as screeners who may block publication of any research that may aid terrorists.

A committee of the National Research Council, the operating arm of the National Academies is currently conducting a study which will:

- Review current rules regulations and institutional arrangements and processes in the US that provide oversight of research on dangerous biological pathogens, including government laboratories, universities and other research institutions and industry. The review will focus on how choices are

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63 Id.
64 Id.
65 Specifically, the ASM guidelines recognize that there are valid concerns regarding the publication of information in scientific journals that could be out to inappropriate use. Accordingly, members of the ASM Publications Board are advised to evaluate any manuscript that might raise such issues during the review process. Research articles must contain sufficient detail to permit the work to be repeated by others. Editors of ASM journals should ask reviewers "if, in their opinion, the manuscript under review describes misuses of microbiology or of information derived from microbiology." In such a case, the manuscript should be examined by a broader group of editors who will "determine whether to resume the review process or to decline the manuscript and return it to the author." AM. SOC'Y FOR MICROBIOLOGY, POLICY GUIDELINES OF THE PUBLICATIONS BOARD OF THE ASM IN THE HANDLING OF MANUSCRIPTS DEALING WITH MICROBIOLOGICAL SENSITIVE ISSUES, at http://journals.asm.org/misc/Pathogens_and_toxins.shtml (last visited Nov. 3, 2002).
made about which research is and is not appropriate, and how information about relevant ongoing research is collected and shared. It will consider the biosafety practices that govern the conduct of research and the handling and transport of materials.

- Use the review to assess the adequacy of current US rules, regulations, and institutional arrangements and processes to prevent the destructive application of dangerous biological pathogens.

- Recommend changes in these practices that could improve US capacity to prevent the destructive application of dangerous biological pathogens while still enabling the conduct of legitimate research.

C. Recent Regulations Relating To International Exchanges of Scientific Information

The free-flow of scientific information on an international scale has been significantly affected by new government regulations. Prior to September 11, 2001, scientific research laboratories could run their labs with ease without "running afoul" of US export regulations. However, regulations currently under consideration could narrow exemptions which facilitate the international exchange of scientific information. According to Eugene Skolnikoff, professor of political science at the Massachusetts Institute of Technology, there is a level of overreaction that is very likely to damage the "very security we are trying to protect."

1. Department of Agriculture Regulations

On April 12th, the Department of Agriculture (USDA), citing national security concerns, decided to exclude foreign scientists from its laboratories. Furthermore, it will no longer sponsor any visas for foreign nationals. Non-citizens currently working in USDA laboratories must either obtain permanent resident status or seek an alternate visa sponsor when it comes time to renew. If circumstances preclude

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67 Id.

68 Id.

69 Id.
an individual from renewing their non-immigrant status, they must return to where they came from.

2. State Department Regulations

On March 29th, the State Department revised the International Traffic in Arms Regulations ("ITAR"), narrowing an exemption allowing for the free flow of information in the public domain. In particular, the new rules require that university researchers distinguish between students from NATO countries or other friendly nations and those who hail from unfriendly countries when discussing satellite-related sciences. These regulations apply to foreign nationals located both abroad and within the United States. In defense of the changes to the ITAR, Norman Neureiter, science and technology advisor to the Secretary of State stated that the ITAR is “munitions control”.

3. DOD Directives

A draft DOD directive would require that all US scientist work only with overseas colleagues whose staff are comprised only of people from NATO countries or other friendly nations, arousing fears that new regulations will criminalize discussions that are currently common place on research campuses. The DOD directives may have an impact on more than defense programs alone. It would essentially require that all DOD-sponsored articles and presentations be submitted to the military for review, effectively eliminating the research exemption and substantially narrowing freedom of research.

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70 See 22 C.F.R § 123.16(b)(10)(iii) (2002) (“If the article(s) is for permanent export, the platform or system in which the article(s) may be incorporated must be a satellite covered by § 125.4(d)(1)(iii) of this subchapter and be exclusively concerned with fundamental research and only be launched into space from countries and by nationals of countries identified in this section.”)

71 International Traffic in Arms Regulations; Exemptions for U.S. Institutions of Higher Learning, 67 Fed. Reg. 15099, 15100 (March 29, 2002), (to be codified at 22 C.F.R. § 123.16(b)(10)). These changes were never circulated outside of the government as proposals before being published in the Federal Register on March 29.

72 “You’re defining rules acceptable to the government relative to things that are classified as munitions, and the government needs to define those rules.” The changes were years in the making, and “there will be things in the changes that universities might not like, but this was an interagency consensus.” Brickley, supra note 66 at 52 (quoting Norman P. Neureiter), available at http://www.the-scientist.com/yr2002/jun/prof_020610.html.

73 Id.

74 According to Robert Killoren, assistant vice president for research at
4. Homeland Security Inquiry of OMB

The Office of Homeland Security has asked the Office of Management and Budget to develop new policy guidelines for so-called “sensitive but unclassified” (SBU) information. The purpose of this category is to preserve confidentiality without formal classification in such a way as to permit the sharing of such sensitive information with local law enforcement and emergency personnel who do not hold security clearances.  The scope of SBU information has not been described, nor has the meaning “sensitive” been defined, prompting concerns that it could function as a catch-all for whatever information the increasingly secretive executive branch does not want to release.

V. CONCLUSION

Rightly or not, policy makers have reached the conclusion that biology is too dangerous to be left exclusively to the biologists. Although the overwhelming majority of biological activities are wholly innocent, the magnitude of harm caused by even a single misuse argues for the introduction of some protective measures. That must, of course, be done in a rational and specifically tailored way, with substantial input from reputable scientists. Consideration must be given to some restrictions on access to biological research activities as well as some limitations on the distribution of information.

The initiatives discussed here are opening salvos in a controversy that is likely to go on for an extended period. That they are so measured, avoiding extremes and over-reaction, is a positive sign as to the ability of policy and scientific communities to work together to address difficult issues. Depending on one’s views on an array of strategic questions, one might favor more or less restriction, but no one could seriously argue that these issues are not getting a fair hearing nor that the proposed imposition of regulations is draconian.

There is one sense, however, in which this entire effort is decidedly lacking. Even where the choice to contain or restrict some scientific activity seems clear, it is crucial to recognize the limitations of doing so on a national basis. The United States can neither control the global spread of bio-technology nor the transfer of information – a truth that argues for an international approach. Much of the informa-

Pennsylvania State University, the directive would cover all DOD grants and contracts including those pertaining to life sciences. Id.

tion generated and many of the means of publication lie outside of the United States and, therefore, is outside of domestic control. Any procedure that does not enlist support from the major scientific groups outside the United States will be ineffective. The challenges raised here are for the global community to resolve, and it is time for that discussion to begin.