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Ensuring Biosecurity and Biosafety through Biopolicy Mechanisms: Addressing Threats of Bioterrorism and Biowarfare

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Abstract: Biosecurity has emerged as a critical measure that laboratories possessing dangerous pathogens must take to protect against terrorists from acquiring biothreat agents. Nations need to consider establishing biopolicy mechanisms for ensuring biosafety and biosecurity. Effective biosecurity and biosafety guidelines require international inputs and international harmonization to reduce the threat of bioterrorism. In the United States, several laws now restrict who is allowed to have access to select biological threat agents. Asian nations and all other countries, are being called upon to ensure the adequacy of biosafety policies to protect the public from the pathogens housed in laboratories and culture collections as well as to adopt new biosecurity policies that will help prevent terrorists from acquiring biothreat agents. All nations, scientists, practitioners, and scientific and medical institutions will need to adopt policies that will reduce the threat that the life sciences could become the death sciences.

Restricting Access to Biothreat Agents

Material control is a widely used measure for arms control. It prevents the proliferation of weapons of mass destruction by many nations; and also prevents terrorists from acquiring substances that could be used to do great harm. This is especially critical for preventing the proliferation of nuclear weapons which require plutonium or enriched uranium. Access to these critical elements for nuclear weapons is restricted through an international nuclear nonproliferation accord, export controls, and an internationally enforced system of inspections. Although there are important differences between nuclear and biological weapons, an effective biosecurity regime must include measures that

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limit access to dangerous pathogens that could be used as biological weapons. But, given the fact that pathogens that could be used as biological weapons are widely distributed in nature and that many laboratories around the world, including many Asian nations, possess potential biothreat agents, the challenge of preventing bioterrorism and biowarfare is considerably greater than preventing nuclear proliferation.

Even though it would not eliminate the threat that terrorists could acquire biothreat agents directly from nature, it is critical that laboratories and microbial culture collections (Biological Resource Centers— BRCs) institute appropriate security and safety procedures to prevent the accidental and/or intentional spread of infectious disease. This requires systems of national oversight and compliance within the scientific community to standards of practice necessary to ensure biosafety and biosecurity. The WHO (2004)) says: "National standards should be developed that recognize and address the ongoing responsibility of countries and institutions to protect specimens, pathogens and toxins from misuse."

Biosafety and Biosecurity

Before considering approaches for achieving the security of dangerous biothreat agents, there is a need to recognize that the term biosecurity has distinct meanings in different countries. It sometimes is applied in the area of plant protection and pest control; in this sense it can be synonymous with plant and animal quarantine. New Zealand, for example, published in August 2003 a biosecurity strategy aimed at economic, environmental, and health protection from pests and diseases.[1] In this case biosecurity means trying to prevent new pests and diseases arriving and eradicating or controlling those already present[2] which in the context of biosecurity is not as an arms control measure.

In the context of national security measures, biosecurity means protecting biological resources against acquisition by terrorists. The Biosafety in Microbiological and Biomedical Laboratories (BMBL) Manual[3] defines biosecurity as "the protection of high-consequence microbial agents and toxins, or critical relevant information, against theft or diversion by those who intend to pursue intentional misuse." The WHO (2004) employs a very similar meaning, defining laboratory biosecurity as "institutional and personal security measures designed

to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins."

There are various types of microbiology laboratories, ranging from university and school classrooms that house non-pathogenic microorganisms, to clinical laboratories that house pathogens isolated from infected individuals, to high containment BL3-BL4 laboratories that house especially infectious bacteria and viruses. Each of these laboratories requires different measures that safeguard the materials in the laboratory from potential theft and misuse. Accordingly, specific biosafety and biosecurity measures should be commensurate with the specific risks.

For the past several decades, the WHO has been encouraging countries to implement basic concepts in biological safety and to develop national codes of practice for the safe handling of pathogenic microorganisms in laboratories within their geographical borders. Now the WHO has expanded its guidance to include biological security issues facing the world in the current millennium.[4]

According to the WHO it has become necessary to expand the traditional approach to biosafety through the introduction of laboratory biosecurity measures: "Global events in the recent past have highlighted the need to protect laboratories and the materials they contain from being intentionally compromised in ways that may harm people, livestock, agriculture or the environment."

In general, biosecurity practices require that access to the laboratory should be controlled so that only authorized individuals can enter it. The degree of control, though, will vary but all laboratories should be locked when not in use and only authorized individuals should be able to gain entry. BRCs housing culture collections and diagnostic and other laboratories with plant, animal, and/or human pathogens, must commit to a high level of security. For research and clinical laboratories, the laboratory supervisor should be responsible for establishing a method for identifying authorized users of the laboratory and for establishing effective mechanisms for controlling access to the laboratory and for the detection of unauthorized individuals. The laboratory supervisor also must be responsible for ensuring the safe handling of biological agents.

Fortunately, the scientific and medical communities have become more cautious about who is provided with biological agents that could be used as biological weapons. This follows attempts by several groups

to acquire biological agents for nefarious purposes. In 1984, the Rajneesh cult in Dallas Oregon sickened more than 750 people by contaminating restaurant salad bars with *Salmonella* bacteria that were acquired from a clinical diagnostic laboratory. Iraq obtained cultures of the anthrax-causing bacterium *Bacillus anthracis* for its bioweapons program in the 1980s from the American Type Culture Collection. The Aum Shinrikyo, which carried out the Sarin attack in the Tokyo subway, obtained cultures of *Bacillus anthracis* from commercial sources for unsuccessful bioterrorist attacks in Japan. The Aum also attempted to acquire *B. anthracis* from soils in Australia and Ebola virus from Africa. In the early 1990s, members of the Aum released liquid sprays of anthrax bacteria from an office building and out the back of trucks upwind of the Imperial Palace.

The source of the Ames strain of *B. anthracis* used in the 2001 bioterrorist attacks in the United States in which anthrax sent through the mail was presumably from a U.S. laboratory. Hence, the clear need for biosecurity to limit who can obtain biothreat agents.

In contrast to biosecurity, which aims at the physical protection of disease-causing agents from theft and subversive uses, biosafety can be defined as the development and implementation of administrative policies, work practices, facility design, and safety equipment to prevent transmission of biologic agents to workers, other persons, and the environment; that is, biosafety aims at protecting people and the environment from exposure to disease-causing agents.[5] According to the WHO (2004) "laboratory biosafety is the term used to describe the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release."

But there can be conflicts between biosafety and biosecurity practices. For example, biosafety may require posting of signs that warn about the presence of dangerous pathogens, thereby allowing individuals to avoid those areas or to take necessary precautions to avoid inadvertent exposure. Biosecurity, however, may seek to hide the presence of agents that could be used to cause harm, and thus may seek to remove biosafety warnings. Indeed given their differing purposes biosafety and biosecurity can produce conflicts regarding laboratory and personnel practices that must be harmonized for the effective and safe conduct of critical biomedical research and clinical diagnostic laboratory activities.

Just as biosecurity is critical for limiting the potential for intentional spread of disease causing microorganisms, biosafety is critical for the prevention of accidental spread of infectious disease. Many biosafety procedures are aimed at protecting workers within laboratory settings. But some procedures and policies are aimed at preventing the escape of dangerous pathogens that could cause widespread disease, especially in densely populated areas, including many areas of Asia. The various laboratory containment levels are geared to the risks of specific pathogens, with BL-3 and BL-4 level facilities designed to house the most dangerous pathogens. But safety requires compliance with established procedures. The last case of smallpox in 1978 occurred as a result of a laboratory accident in Britain. When a filter was improperly changed at a bioweapons facility in Sverdlovsk in 1979, anthrax was released into the air, causing an epidemic that felled nearly 100. In 2004, a Russian scientist developed a fatal Ebola infection from a laboratory accident at a former weapons laboratory. Several laboratory accidental infections with SARS coronavirus in 2003 raised issues about the biosafety practices at Asian laboratories. When a senior scientist working at a BL-4 facility at the Institute of Preventive Medicine, National Defense University in Taipei failed to follow established biosafety procedures, he contracted SARS and risked spreading the disease to the public. Similarly, other accidental SARS infections in 2003 linked to a Singapore laboratory and to China's National Institute of Virology raised international concerns about biosafety at Asian laboratories housing the SARS coronavirus and other highly infectious pathogens. Clearly as new policies and procedures emerge for laboratory biosecurity a loss in focus on biosafety may result.

The WHO (2004) points out that "effective biosafety practices are the very foundation of laboratory biosecurity activities." According to the WHO (2004) each specific

> "laboratory biosecurity program must be prepared and implemented for each facility according to the requirements of the facility, the type of laboratory work conducted, and the local conditions. Laboratory biosecurity measures should be based on a comprehensive program of accountability for pathogens and toxins that includes an updated inventory with storage location, identification of personnel with access, description of use, documentation of internal and external transfers within and between facilities, and any inactivation

> and/or disposal of the materials. Likewise, an institutional laboratory biosecurity protocol should be established for identifying, reporting, investigating and remediating breaches in laboratory biosecurity, including discrepancies in inventory results. The involvement and roles and responsibilities of public health and security authorities in the event of a security infraction must be clearly defined. Laboratory biosecurity training, distinct from laboratory biosafety training, should be provided to all personnel. Such training should help personnel understand the need for protection of such materials and the rationale for the specific biosecurity measures, and should include a review of relevant national standards and institution specific procedures."

To summarize the WHO position,

> "security precautions should become a routine part of laboratory work, just as have aseptic techniques and other safe microbiological practices. Laboratory biosecurity measures should not hinder the efficient sharing of reference materials, clinical and epidemiological specimens and related information necessary for clinical or public health investigations. Competent security management should not unduly interfere with the day-to-day activities of scientific personnel or be an impediment to conducting research. Legitimate access to important research and clinical materials must be preserved. Assessment of the suitability of personnel, security-specific training and rigorous adherence to pathogen protection procedures are reasonable means of enhancing laboratory biosecurity. All such efforts must be established and maintained through regular risk and threat assessments, and regular review and updating of procedures. Checks for compliance with these procedures, with clear instructions on roles, responsibilities and remedial actions, should be integral to laboratory biosecurity programs and national standards for laboratory biosecurity."

National Biosecurity Policies: The U.S. as a Case Study

The development of legally mandated measures for controlling access to potential biothreat agents within the United States can serve as a

case study of how policies can be developed for biosecurity that involve the scientific, public health, and law enforcement communities. The rapid development of U.S. biosecurity policies reflects the seriousness with which the U.S. views the threat of bioterrorism to national security.

When Larry Wayne Harris in 1995 tried to obtain the plague-causing bacterium *Yersinia pestis* from the American Type Culture Collection (ATCC), there were no laws in the United States regarding possession or domestic acquisition of dangerous pathogens. Culture collections like the ATCC provided microorganisms to many individuals as a service to the scientific community. But, Larry Wayne Harris was a member of the radical group, the Aryan Nations, and the suspicion was that he was trying to obtain the plague bacteria for nefarious purposes. This case showed the potential vulnerability of microbial culture collections for "misuse" and that additional procedures and laws were needed to protect against the inappropriate acquisition of dangerous human pathogens from legitimate laboratories.

As a result of Harris' attempt to acquire a culture of *Y. pestis* from the ATCC, the Antiterrorism and Effective Death Penalty Act of (Public Law 104-132, 1996) was passed. That Act directed the U.S. Secretary of Health and Human Services to promulgate regulations identifying biological agents that pose a potential threat to public health and safety and governing their intentional or inadvertent transfer. The Centers for Disease Control and Prevention (CDC) were given responsibility for administration of the Laboratory Registration/ Select Agent Transfer Regulations which took effect in 1997 and which set regulations for shipping and handling of 36 pathogens and toxins.[6] The CDC also established regulatory requirements for laboratory facilities that transfer or receive select agents capable of causing substantial harm to human health. These regulations were designed to ensure that the agents posing the greatest risks for use by bioterrorists, designated 'select agents,' were not shipped to facilities that were not equipped to handle them safely or that lacked proper authorization for their requests.

The Select Agent Transfer Program also mandated adherence to the CDC Biosafety in Biomedical and Microbiological Laboratories Manual (BMBL). At the time of the implementation of the select agent shipping regulations the significance of the BMBL recommendations did not receive much attention within the research community. In reality, however, the BMBL Appendix establishes a series of critical measures aimed at ensuring biosecurity of the laboratory. The guidelines

go beyond biosafety and provide that each institution should: (1) recognize that laboratory security is related to, but different than, laboratory safety; (2) control access to areas where biologic agents or toxins are used and stored; (3) know who is in the laboratory area; (4) know what materials are being brought into the laboratory area; (5) know what materials are being removed from the laboratory area; (6) have an emergency plan; and (7) have a protocol for reporting incidents. In general, biosecurity practices require that access to the laboratory should be controlled so that only authorized individuals can enter the laboratory. The degree of control will vary, but all laboratories should be locked when not in use and only authorized individuals should be able to gain entry. Biological resources centers and laboratories housing many different types of microorganisms, including plant, animal, and/or human pathogens, must commit to a high level of security. For research and clinical laboratories the laboratory supervisor should be responsible for establishing a method for identifying authorized users of the laboratory and for establishing effective mechanisms for controlling access to the laboratory and detection of unauthorized individuals.

Public concern over possession of microorganisms and transfers from BRCs increased greatly as a result of the suspicion that the Ames strain of *Bacillus anthracis* used in the deadly bioterrorist attack in the fall of 2001 in Washington DC and the New York metropolitan regions came presumably from a domestic U.S. laboratory. The U.S. Congress held public hearings and openly considered draconian measures, including banning all foreigners from U.S. laboratories housing any microbial culture.

Acting against the atmosphere of fear that gripped the nation, the U.S. Congress passed the USA Patriot Act of 2001 which provided for significant, but limited, restrictions on the possession of select agents (Public Law 107-56, 2001). The USA Patriot Act bans aliens from countries designated as supporting terrorism from possessing select agents within the United States and also blocks individuals who are not permitted to purchase handguns from possessing select agents. Specifically, a restricted person who may not possess a select agent in the United States is defined as an individual who: is under indictment for a crime punishable by imprisonment for a term exceeding one year; has been convicted in any court of a crime punishable by imprisonment for a term exceeding one year; is a fugitive from justice; is an unlawful user of any controlled substance;

is an alien illegally or unlawfully in the U.S.; has been adjudicated as a mental defective or has been committed to any mental institution; is an alien who is a national of a country as to which the Secretary of State has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism; or has been discharged from the Armed Services of the United States under dishonorable conditions. There is no provision for exemptions under any circumstances.

The USA Patriot Act did not require registration for possession of select agents. It did make it an offense for a person to knowingly possess any biological agent, toxin or delivery system of a type or in a quantity that, under the circumstances, is not reasonably justified by prophylactic, protective, bona fide research or other peaceful purpose. Senator Patrick Leahy warned during passage of the USA Patriot Act that this provision could have unanticipated ramifications depending upon how one defined "bonafide" or "reasonably justified."

The provisions of the USA Patriot Act subsequently were incorporated into the Public Health Security and Bioterrorism Response Act, known as the Bioterrorism Act of 2002 (Public Law 107-188, 2002). The Public Health Security and Bioterrorism Act was signed into law on 12 June 2002, adding requirements for regulations governing possession of select agents. The Bioterrorism Act of 2002 required registration for possession of select agents; required the Departments of Health and Human Services (HHS) and Agriculture (USDA) to promulgate regulations controlling access to select agents; it required clearance by U.S. Department of Justice (DOJ) for individuals possessing select agents; required additional record keeping to track the acquisition, transfer and possession of certain biological agents and toxins; required safeguards and security regulations to be followed; required collection of information for law enforcement; and established a process for alerting authorities about unauthorized attempts to acquire select agents. The number of select agents was increased to about 100 with the addition of animal and plant pathogens.

Thus, in only five years, the regulatory regime for possession of certain microorganisms and toxins in the United States went from a permissive atmosphere, in which biosafety was the primary concern and the laboratory facility, not the individual scientist, the focus of regulation, to a situation in which biosecurity is of prime importance and individuals face criminal sanctions if they violate any of the restrictions outlined in the USA Patriot Act or the Bioterrorism Act of 2002.

Appendix F of the BMBL was revised to include consideration of the following biosecurity policies and procedures for select agents: risk and threat assessment; facility security plans; physical security; data and electronic technology systems; security policies for personnel; policies regarding accessing the laboratory and animal areas; specimen accountability; receipt of agents into the laboratory; transfer or shipping of select agents from the laboratory; emergency response plans; and reporting of incidents, unintentional injuries, and security breaches. The guidelines recommend institutions to: establish a facility security plan; establish security-related policies for all personnel, with screening procedures commensurate with the sensitivity of the data and work areas (e.g., federal security clearances for government employees and contractors); control access to areas where select agents are used or stored; establish a system of accountability for select agents; develop procedures for bringing select agent specimens into the laboratory; develop procedures for transferring or shipping select agents from the laboratory; implement an emergency response plan; and establish a protocol for reporting adverse incidents. As mentioned above, while the BMBL provides guidelines and makes recommendations, subsequent acts and regulations make compliance mandatory. Thus, culture collections supplying microorganisms within the United States face new scrutiny and regulatory requirements that limit their abilities to supply certain microorganisms to research, educational, and domestic laboratories.

In order to fulfill the Department of Justice responsibilities, the Federal Bureau of Investigation (FBI) was assigned responsibility for conducting security risk assessments, that is, law enforcement controls the clearances required for any individuals to enter a laboratory housing select agents. Within the laboratory, dangerous pathogens must be housed within secure incubators, refrigerators, or storage cabinets when not being used. When possible the incubators, refrigerators, or storage cabinets should be locked—however, this may not always be possible, e.g., in clinical laboratories where frequent movement of materials into incubators is necessary and where having to open a locked incubator would add risk and reduce biosafety. In such instances, special attention must be paid to ensure that only authorized individuals have access to the incubators or other locations where dangerous pathogens are housed.

Clinical laboratories are granted a special exemption in the Bioterrorism Act of 2002 to permit them to legally isolate and identify (and thereby possess) select agents from patients as part of the medical

diagnostic process, even if they are not registered to possess select agents. This was critical for medical diagnoses where there is no way to predict what disease a patient might have, thereby precluding the ability to register for specific select agents. The clinical laboratories, however, are mandated to destroy any select agents or transfer them to a registered laboratory that is permitted to possess that select agent within a few days, and they must also notify public health authorities.

U.S. government military laboratories are being required to implement especially stringent biosecurity measures termed biosurety. Carr et al. (2004) list four major elements of a biosurety program: security (limited access, internal and external monitoring, intrusion alert and monitoring, random search and inspection); safety (safety training and mentorship, risk management, environmental surveillance, occupational health screening); personnel reliability (background investigation, medical screening, mental health and behavior screening, urinalysis); and agent accountability (pinpoint location and agent registration, limited access, archive and working stock accountability, traceable to laboratory notebooks). The key to biosurety is increased scrutiny of those using select biological agents in registered research laboratories. Some personnel reliability programs will require mental and medical evaluations and random urinalyses to detect abuse of prohibited substances. All individuals in such programs would have to undergo personnel security investigation screening and personal interviews with a certifying official.

Clearly one of the impacts of the new U.S. regulatory regime for biosecurity is to make it more difficult to obtain cultures of certain pathogens. Clearances are needed and culture collections are reluctant to supply potential biothreat agents. This is a new challenge for researchers and the biotechnology industry within the United States and abroad, including in Asia where the development of vaccines and therapeutics to infectious diseases is vitally important to protect public health.

Extending Biosecurity to the International Arena

A variety of approaches have been proposed for extending the control of access to dangerous pathogens to the international front. Access available will still permit essential biomedical research, biotechnology development, and diagnostics for infectious diseases. These biopolicy mechanism options range from export controls—an approach promoted

by the 38 nations that comprise the Australia Group (US Department of State Bureau of Nonproliferation 2004)—to establishing a set of guidelines for biosecurity measures which would build on the existing consensus around biosafety practices—an approach favored by the WHO (2004)—to framing the issue as one of criminal behavior and moving enforcement to the domain of international police—an approach proposed by the Interpol.[7]

Some nations have already adopted measures similar to those of the United States, although the list of select agents is not uniform and the number of nations adopting such policies is still low. The United Kingdom has implemented restrictions on who may possess biothreat agents, giving their law enforcement agencies extended powers to control access to specified dangerous pathogens. In the United Kingdom, the Anti–terrorism, Crime and Security Act (ATCSA) of 2001 strengthened legislation controlling weapons of mass destruction, and tightened controls on access to pathogens and toxins used in research laboratories (Queen's Printer of Acts of Parliament 2001). Under this Act, premises such as universities and research establishments must notify the government if they hold certain dangerous substances and it also establishes a register of premises holding specified pathogens and toxins. The Act confers powers on the police to inspect such premises and give directions as to their security; requires managers of laboratories and other premises to furnish, on request, the police with details of people with access to any of the specified dangerous substances held there; gives the Home Secretary the power to direct that a named individual must not be allowed access to such disease strains or the premises in which they are held; and, provides for extension to animal or plant pathogens and toxins. Individuals who violate the provisions of the Act with regard to proper security of possession of certain pathogens and toxins are subject to fines and imprisonment for up to five years.

It is not realistic, however, to expect that all countries will take the rules set by the U.S. and U.K. as a pattern, if only because the cost of implementing select agent rules and background checks would overwhelm the bureaucratic resources and research budgets in many countries. Yet there must be international norms, which nations can rely upon in making international exchanges. This must be part of the international effort led by the World Health Organization aimed at enhancing the quality of laboratories engaged in research and diagnostics.

Confronting the Dual Use Dilemma

Beyond the issue of material control, i.e. how to prevent the acquisition by terrorists of dangerous pathogens, lies the more difficult issue of how to constrain information in the life sciences which is potentially dual use and could be misused to cause harm. The fear that information from the life science research may fall into the wrong hands is causing great anxiety within the scientific community and uncertainties among the public and policy makers as to how to balance national security with traditional openness of science. But how can we define what is dangerous and how can we design a system that contains that danger while allowing legitimate biomedical research to proceed in a manner acceptable to society? This is the critical question addressed by a committee of the National Academies of Science (NAS).[8] The following are representative of the questions with which the committee dealt. Should more research be declared classified? Should there be review boards to consider the national security implications of publications and presentations? Should we restrict access and dissemination of scientific information? Should scientists be constrained regarding which questions they can ask? Should journals reject papers containing potentially sensitive information?

The Fink Committee in its report, *Biotechnology Research in an Age of Terrorism: Confronting the Dual Use Dilemma* proposed a system that would establish a number of stages at which scientists would review experiments and their results to provide reassurance that advances in biotechnology with potential applications for bioterrorism or biological weapons development receive responsible oversight.[9] In essence, the committee proposed the development of an architectural structure to help protect the life sciences community against the potential misuse of biological materials and information; it was a bottoms up approach aimed at helping reduce the threat of misuse of the life sciences by mobilizing the scientific community to police itself. Like a previous 1982 NAS report known as the Corson report, which had dealt with the physical sciences, the report of the Fink committee sought to protect scientific enquiry from untoward government interference and to permit open communication to the maximum extent possible. The fundamental conclusion of the Fink Committee was that some information could be dangerous and that we should rely on self-governance by the scientific community to

reduce potential national security risks and the potential misuse of legitimate scientific enquiry and communication. The National Academies of Sciences (NAS)[10] in a separate report said that fundamental genomic sequence data should not be subject to restriction for security reasons since the benefits for biotechnology development would be greater than the risk of misuse.

The Fink Committee identified seven classes of "experiments of concern" that illustrate the types of endeavors or discoveries that might present special dangers and that therefore should undergo review and discussion by informed members of the scientific and medical community before they are undertaken or, if carried out, before they are published in full detail. The experiments of concern that would undergo special scrutiny are those that: (1) would demonstrate how to render a vaccine ineffective; (2) would confer resistance to therapeutically useful antibiotics or antiviral agents; (3) would enhance the virulence of a pathogen or render a nonpathogen virulent; (4) would increase transmissibility of a pathogen; (5) would alter the host range of a pathogen; (6) would enable the evasion of diagnostic/detection modalities; and (7) would enable the weaponization of a biological agent or toxin.

Within the United States, all of the experiments that fall within the seven areas of concern should currently require review by an Institutional Biosafety Committee (IBC), a review committee that already exists in most institutions to monitor experiments involving recombinant DNA. The Fink Committee recommended that IBCs be charged with specific oversight of experiments to judge not only biosafety and biosecurity of the materials involved, but also the safety of the information that would be generated and whether it needed to be classified or otherwise constrained. The Fink Committee further recommended that the U.S. government create a National Science Advisory Board for Biodefense (NSABB) to provide advice, guidance, and leadership for the system of review and oversight proposed in the report. At the most general (strategic) level, the NSABB would serve as a point of continuing dialogue between the scientific community and the national security community and as a forum for addressing issues of interest or concern. At the operational (tactical) level, the NSABB would provide case-specific advice on the oversight of research and the communication and dissemination of

life sciences research information that is relevant for national security and biodefense purposes.

The recommendation of the Fink Committee to rely upon self governance within the scientific community forms the basis for a new U.S. Government Biosecurity Initiative. The National Institutes of Health (NIH) have been charged with establishing the NSABB to advise and guide the government and research community. The NSABB is chartered to have up to 25 voting members with a broad range of expertise in molecular biology, microbiology, infectious diseases, biosafety, public health, veterinary medicine, plant health, national security, biodefense, law enforcement, scientific publishing, and related fields.

The NSABB is to provide advice and guidance regarding biological research that has the potential for misuse and could pose a biologic threat to public health or national security. The NSABB will advise the HHS Secretary, the NIH Director, and the heads of all Federal entities that conduct or support life sciences research. It will lead an effort to: (1) develop and promulgate national guidelines for local (e.g., IBCs) and federal oversight of dual use research; (2) develop a code of conduct for scientists and laboratory workers in life sciences research; (3) develop and implement programs for education and training in biosecurity issues for all scientists and laboratory workers at federal as well as federally-funded institutions; (4) develop and promulgate guidelines for the appropriate communication of dual use research methodology and research results; and (5) foster the extension of these biosecurity policies to the international arena.

Both the U.S. Government Biosecurity Initiative and the Fink Committee highlighted the importance of international dialogue for establishing safeguards within the life sciences community. The Fink Committee recommended an International Forum to address the following topics: education of the scientific community globally, including curricula, professional symposia, and training programs to raise awareness of potential threats and modalities for reducing risks, as well as to highlight ethical issues associated with the conduct of biological science; design of mechanisms for international jurisdiction that would foster cooperation in identifying and apprehending individuals who commit acts of bioterrorism; development of an internationally harmonized regime for control of pathogens within and between laboratories and facilities; development of systems of review to provide oversight of research, including defining an international

norm for identifying and managing "experiments of concern;" and, development of an international norm for the dissemination of "sensitive" information in the life sciences.

Clearly, any serious attempt to reduce the risks associated with biotechnology must ultimately be international in scope because the technologies that could be misused are available and being developed throughout the world. The dialogue within and between the life sciences and policymaking communities will need to include representatives from many Asian nations.

Concluding Remarks

The threat of bioterrorism has greatly altered the security requirements for work with dangerous pathogens. Both physical security and personnel security – that is determining who can safely possess dangerous pathogens and how they must be stored – have become mandatory requirements. It is important for members of the scientific community to help guide the institution of harmonized regulations that help protect against the potential misuse of microorganisms. It is also essential that scientists know and comply with national and international regulations governing the possession and uses of microorganisms. Many Asian nations will have key roles in helping ensure that the advancement of science occurs in a safe and secure manner. As responsible stewards of dangerous pathogens, laboratories will need to institute biosecurity measures that reduce the possibility of terrorists acquiring biological weapons. They will also need to be vigilant with regard to laboratory biosafety. As recognized by the World Health Organization, we live in a new era in which all of us must be willing to take prudent steps to enhance biosecurity and biosafety.

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