

Creating monsters for the greater good of humanity: Conflicting interests of science and homeland security

Patrick P. Rose, PhD
Clark J. Lee, JD
Sarah E. Sasor, MEng
Earl Stoddard III, PhD, MPH

ABSTRACT

Society's rising expectations for improved treatments and better health outcomes continuously push the boundaries of discovery in biomedical research. One focus of such research is to develop the newest drugs to address humanity's increasing exposure to emerging infectious diseases. This has led both privately and publicly funded researchers to take on the task of studying highly infectious diseases in laboratory settings. Illustrating this phenomenon is the recent work of two research laboratories at universities that have demonstrated how easily the avian flu virus (influenza A H5N1) could be manipulated into a highly infectious and deadly form for humans. These studies, which were funded by the United States Government through the National Institutes of Health of the US Department of Health and Human Services, have sparked a fierce debate as to their risks and benefits to humankind. Lacking in the current debate, however, is any significant attempt to describe in basic terms the risks and benefits of such research or the basic safeguards already built into the biomedical research enterprise that serves to protect the public's welfare.

In this article, the authors will attempt to frame the ongoing debate for those outside the scientific research community by discussing a number of competing public policy issues that the recent H5N1 controversy raises about research on dangerous pathogens or biological agents and the concerns that emergency planners and managers nation-wide face when such research is conducted in their communities.

Key words: H5N1, avian influenza, NSABB, dual-use research, biomedical research, preparedness, response, biosecurity

DEBATING DUAL-USE BIOMEDICAL RESEARCH

H5N1 is a highly virulent subtype of the influenza A virus that causes infectious illness in birds. Most avian viruses do not infect humans; however, some strains have the ability to cross the species barrier and cause serious disease in humans. Most cases have occurred in people who have had direct contact with infected poultry. There is no evidence that the disease is spread by consuming properly cooked food, and until recently, the disease was not found to be transmissible between humans.¹ The first confirmed case of human H5N1 infection occurred in 1997 in Hong Kong during a poultry outbreak.² After a widespread re-emergence in 2003-2004, the disease spread throughout Asia, Europe, and Africa. There have been 587 cases reported to the World Health Organization (WHO) since 2003 and 346 fatalities as of February 24, 2012.³

H5N1 infection in humans is poorly understood. Clinically, the disease is unusually aggressive, causing rapid deterioration and a high fatality rate. No effective treatment for H5N1 exists; however, Oseltamivir (Tamiflu) may shorten the course of disease if given within 48 hours after symptom onset. Its efficacy in preventing complications is uncertain.⁴ Despite the relatively low impact that the H5N1 virus has had on human populations over the past 15 years, public health experts worldwide are very concerned that

human to human transmission could develop over time as the virus evolves in the wild, resulting in an H5N1 outbreak and a major public health crisis with significant economic and social consequences worldwide.⁵

To improve general understanding of H5N1 infection in humans, scientific teams at the University of Wisconsin-Madison and Erasmus Medical Center in the Netherlands have been studying how this deadly virus may become transmissible from human to human, with the expectation that new information could improve disease surveillance and better inform the development of a vaccine. Both teams conducted research funded by the National Institutes of Health (NIH) in which the H5N1 virus was genetically engineered to make it readily transmissible among ferrets (the favored laboratory model for studying transmission potential in humans) and presumably among humans as well.^{6*}

When these researchers announced their findings several months ago, a fierce debate as to the usefulness and validity of such research ensued.⁷ As a result, scientific journals that were preparing to publish the results of this research sought guidance from the US Department of Health and Human Services (HHS, the parent agency of the NIH) through the National Science Advisory Board for Biosecurity (NSABB).⁸ The NSABB is a federal advisory panel tasked with providing advice, guidance, and leadership regarding dual-use research of concern in the life sciences. Research is considered dual-use when the legitimate biological information gained has the potential to be misused to threaten public health or national security. The NSABB makes recommendations on the conduct, communication, and publication of dual-use research of concern; provides strategies for effective oversight of federally supported biological research; and determines how to effectively address national security concerns while supporting the research community and promoting scientific progress.^{9,10}

*Yoshihiro Kawaoka and his Wisconsin team successfully modified the hemagglutinin protein on H5N1, easing the entry of the virus into human cells and allowing greater efficiency at causing disease. Ron Fouchier and his Netherlands team used a different approach, manipulating viral genes and repeatedly passing the virus among ferrets to facilitate adaptation to the new host.

In response to the request of the scientific journals for guidance regarding the H5N1 research, the NSABB advised the researchers to publish redacted versions of their research manuscripts that omitted details about their methodology and other information out of concerns that the H5N1 virus could be replicated and used as a bioweapon. The NSABB acknowledged that the research might lead to increased preparedness and disease control but had concerns that the risk of misuse would outweigh the benefits.^{9,11}

COMPETING INTERESTS

There are a number of voices in the recent debates concerning the controversial H5N1 research and the NSABB recommendations about publishing the research results. These voices represent a number of competing interests that key decision makers in government and society need to balance as a matter of public policy. Among the principal competing interests in this controversy are those of biomedical science, public health and medicine, and the public's general welfare.

The interests of biomedical science

Biomedical science is particularly concerned with the study of basic and complex concepts of biology that impact human health and physiology. Biomedical scientists face the greatest challenges when investigating the more complicated issues of human biology (eg, how people get cancer or how a virus causes disease), in part because researchers are not always equipped to conduct their work under conditions that best resemble or mimic conditions in nature. To address this challenge, researchers may attempt to engineer changes in biological systems to replicate some of the worst outcomes found in nature. These efforts may include the production of dangerous pathogens or biological agents, the study of which has the potential public benefit of enhancing general understanding of how emerging biological-based threats evolve and how they can be mitigated or prevented.

Researchers have taken such controversial steps before to advance the understanding of biology for the greater good of improving society's preparedness against public health threats. In 2005, scientists from the Centers for Disease Control and Prevention (a part

of HHS) recreated the virus responsible for the Spanish flu pandemic, which killed a conservatively estimated 60 million people worldwide at its peak in the early twentieth century.¹² Undertaken to improve general understanding of how such a virus could become so deadly and how governments and communities can prepare for future epidemics, this research has contributed to efforts to develop new and better medical countermeasures and treatments. These research efforts also have generated much debate and controversy.¹³

A significant portion of biomedical research has been supported through public sources of funding, such as those provided by the NIH. The stated mission of the NIH is to “[seek] fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.”¹⁴ The controversies over the Spanish flu research and the more recent H5N1 research publications, however, illustrate a serious contradiction embedded in this mission:

- On the one hand, the NIH promotes and directly funds research and discoveries leading toward novel pharmaceuticals and treatments to reduce morbidity and mortality from natural pathogens. This mission includes supporting scientists to develop applications to mitigate and prevent the next pandemic or bioterrorism attack.
- Conversely, the NIH must contend with the fact that threats identified as potential biosecurity risks, whether human-caused or natural, can easily be derived from NIH-sponsored research. Sophisticated laboratory settings, scientists proficiently trained in cutting-edge approaches of molecular biology, and readily available resources form the foundation not only for a good scientific working environment but also for creating the next biological weapon (whether unintentionally or intentionally).

Balancing these two contradictory components of its mission poses a significant challenge for the NIH. Adding

to this challenge are the difficulties inherent in trying to determine the ulterior motives of laboratories seeking NIH support, particularly those in the private sector.

The highly competitive and arduous process for obtaining NIH and other public sources of funding to support scientific research incentivizes researchers to use cutting-edge ideas to secure such funding. Unfortunately, being cutting-edge may draw laboratories dangerously close to the ethical limits of biomedical research. Although few people question the overwhelming contributions that basic science research has had in improving human health and well-being, NIH-sponsored research will continue to be a double-edged sword. The danger may be reduced, however, by enhancing accountability and oversight mechanisms in how NIH and other public research funds are spent.

The interests of public health and medicine

Public health is particularly concerned with preventing and managing disease in population. The field of medicine has similar goals but at the individual level. In both cases, achieving these goals effectively will require planners and decision makers in public health agencies, healthcare providers, and other components of the healthcare system to understand the following: 1) what are the potential threats to the public’s health; 2) which population are at risk from these threats; and 3) what is the magnitude of the risk that these threats pose to the population at risk (eg, accurate rates of morbidity and mortality)?

Knowledge of this information is also essential for planners and decision makers in government and the healthcare system to assess current needs and to develop emergency preparedness plans and activities (eg, enhancing surveillance capabilities) related to potential public health threats. This information often can be derived from the work of scientific researchers who have studied key elements of the public health threats that are of concern to planners and decision makers. In essence, public health and medicine are interested in obtaining information from biomedical research that is relevant to the prevention, management, and treatment of diseases without increasing the risk of exposure to these diseases.

Unfortunately, the US healthcare system has limited capacity to handle a catastrophic health emergency or a high-impact public health crisis. Many US hospitals presently operate at near 90 percent capacity, particularly in their emergency rooms and intensive care units. Although many hospitals have plans in place to manage emergencies, few (if any) are prepared to deal with a mass casualty or medical surge event. During an average influenza season, for example, hospitals often exceed their capacity with an influx of at-risk individuals who experience flu-associated complications (eg, newborns, adults more than 65 years old, and patients with chronic disorders such as asthma, diabetes, and cancer). Given these circumstances, it is easy to foresee that a catastrophic health emergency or other high-impact public health crisis (such as an avian influenza pandemic) would overwhelm the existing healthcare system in the United States.

Fortunately, the burden on the healthcare system could be alleviated in several ways by research findings on dangerous pathogens (such as the H5N1 virus) or biological agents that potentially could be at the center of a catastrophic health emergency or public health crisis. Increased understanding of these pathogens and agents will yield information that can be translated into clinical practice (eg, determination of risk factors, better characterization of symptoms leading to early diagnosis and treatment, and knowledge of potential complications) and epidemiological practice (eg, better monitoring of the spread of disease and improvements in predicting, observing, and minimizing harm caused by an outbreak). Continued research also will increase general understanding of the mechanisms that govern human infection, transmissibility, and virulence and aid in the development of countermeasures such as medications and vaccines. Finally, as mentioned previously, such research also facilitates public health emergency planning and preparedness efforts.

As research increases general understanding about infectious diseases and biological agents, as well as the factors that contribute to their transmission in human population, public health officials can better prepare to quickly and accurately disseminate information to healthcare providers and the public in

ways that (hopefully) can avert a pandemic or lessen the magnitude of its potentially catastrophic effects.

*The interests of the public's "general welfare":
public safety, security, and health*

The credibility and legitimacy of any government is undermined when it fails to protect the people over which it asserts authority.^{15(p2838)} This fundamental governmental responsibility is articulated clearly in the preamble to the foundational document of the United States Government:

We the People of the United States, in Order to form a more perfect Union, establish Justice, *insure domestic Tranquility, provide for the common defense, promote the general Welfare*, and secure the Blessings of Liberty to ourselves and our Posterity, do ordain and establish this Constitution for the United States of America.¹⁶

This responsibility is mentioned again later in the US Constitution in what is known as the "General Welfare Clause":

The [U.S.] Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and *provide for the common Defense and general Welfare of the United States*.[.]¹⁷

Domestic tranquility, the common defense, and general welfare all describe interests related to public safety, security, and health.[†] These constitutional texts thus provide the theoretical and legal authority for federally funded initiatives aimed at protecting and preserving the public's safety, security, and health throughout the United States. Furthermore, US states (and by extension, local political entities within states) exercise an inherent "police power" that allows them to "promote the public health, morals, or safety, and the general well-being of the community" and to "enact and enforce

[†]The ninth edition of *Black's Law Dictionary*¹⁸ defines the term "general welfare" to mean "[t]he public's health, peace, morals, and safety."

laws for the promotion of the general welfare[.]”^{19(p20)}‡ This inherent prerogative provides the theoretical and legal authority for state and local activities in the United States aimed at protecting and preserving the public’s safety, security, and health. Among the aforementioned public safety and security activities at the federal, state, and local levels of government are those related to emergency preparedness, emergency management, counterterrorism, and homeland security.[§]

Bioterrorism[¶] and other biosecurity threats to the public’s general welfare (ie, public safety, security, and health) have been a growing concern for national (federal), state, and local governments worldwide in recent years.^{19,21-23} These threats have also been brought to the attention of the public through events in the news (eg, the Fall 2001 anthrax mailings in the United States) and popular culture (eg, the 2011 Hollywood film *Contagion*). One reason for the growing concern about bioterrorism has been the quick pace of developments in general understanding of how biological agents can become highly transmissible and deadly in humans thanks to scientific advances and research such as the recent H5N1 studies. As one biosecurity scholar has commented, “It is undisputed that the fruits of scientific advancements may also be subject to harmful ‘dual use’ by enemy combatants, terrorists, and any number of other malefactors with the necessary skills and resources.”^{24(p492)} Another scholar has commented further that

‡The ninth edition of *Black’s Law Dictionary*¹⁸ defines the term “police power” to mean “[a U.S.] state’s Tenth Amendment right, subject to due process and other limitations, to establish and enforce laws protecting the public’s health, safety, and general welfare, or to delegate this right to local governments.” The Tenth Amendment to the US Constitution provides that “The powers not delegated to the United States [Government] by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.”

§In general, emergency preparedness and management are focused on mitigating (reducing) all hazards that potentially threaten a jurisdiction and on maximizing the jurisdiction’s response capabilities should the risks become realized. By contrast, counterterrorism and homeland security activities generally are more focused on preventing potential risks driven by human-caused sources from becoming realized in the first place.²⁰

¶Experts have defined the term “bioterrorism” in a number of ways: 1) The CDC equates “bioterrorism” with “bioterrorism attack,” which means “the deliberate release of viruses, bacteria, or other germs (agents) used to cause illness or death in people, animals, or plants.”²¹ 2) A team of public health law scholars has defined “bioterrorism” to mean “the intentional use of a pathogen or biological product to cause harm to a human, animal, plant, or other living organism to influence the conduct of government or to intimidate or coerce a civilian population.”^{23(p623)}

Unlike other weapons of mass destruction, biological weapons—whether developed by a state-sponsored program, terrorist organization, or lone actor—pose a very unique threat. The knowledge, tools, and techniques used to create biological weapons, as well as the biological agents themselves, are readily available in research laboratories throughout the world and in nature.^{25(p622)}

Governments have a legitimate interest in fulfilling their fundamental responsibility to protect their citizens that justifies taking reasonable actions to regulate activities that pose a significant threat to the general welfare of the public (and arguably have a compelling interest that justifies taking necessary actions to regulate such activities). In the United States, governments at the federal, state, and local levels have taken various steps to address bioterrorism and other biological-based threats to the public’s general welfare. These biosecurity actions include the following:

- initiatives to support research efforts aimed at developing medical countermeasures to dangerous pathogens and biological agents;
- efforts to develop various preparedness and response capabilities for bioterrorist incidences or natural events involving such pathogens or biological agents; and
- laws and regulations to restrict access to various aspects of such research and capability development efforts, including the select agents under study, the facilities where such work is done, and the key findings and products derived from such work.^{24(p492-515),25-28}

Despite the interest of the US Government, states, and local authorities to mitigate and prevent risks posed by biosecurity threats to the public’s general welfare, the actions governmental authorities may take to achieve these goals are subject to certain legal restrictions. More specifically, the powers of the US

Government authorized under the General Welfare Clause of the US Constitution and the police power of the states are limited by certain constitutional provisions, particularly those concerning individual rights to autonomy, liberty, property, and other legally protected interests.^{15(p2841),19(p20)} Furthermore, one pioneer scholar in the field of public health law has commented that “[a]chieving a just balance between the powers and duties of the state to defend and advance the public health and the constitutionally protected rights of individuals and businesses poses an enduring problem for public health law.”^{15(p2841)}

The recent NSABB recommendations regarding the controversial H5N1 studies prominently features a conflict between the government’s interest in promoting the public’s general welfare and the researchers’ rights under the First Amendment to the US Constitution** to publish and disseminate the findings from their NIH-funded research. Legal scholars have proposed and debated various theoretical solutions to this conflict.^{24,29} Another potential legal consideration that governmental biosecurity efforts need to take into account is the right of residents (under the First Amendment or as a matter of public policy) to be informed of the fact that dangerous biomedical research is taking place in their community. These examples illustrate the challenges governments face in achieving “a just balance” between promoting the public’s welfare and protecting individual rights when considering biosecurity measures as a matter of public policy.

In addition to legal obstacles, governmental biosecurity efforts may be undermined by the unintended consequences of these efforts. As discussed previously in this article, the findings of cutting-edge biomedical research have the potential both to threaten the public’s safety, security, and health and to benefit these aspects of the public’s general welfare by aiding in the development of countermeasures against these threats. As one expert has noted

**The First Amendment to the US Constitution provides that “Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.”

Nearly all biological research is done for peaceful and legitimate purposes, and all biological agents, with the exception of smallpox and the 1918 Influenza, are public health threats somewhere in the world. Therefore, it is vitally important to emphasize from the outset that biological research and the knowledge, tools, and techniques gleaned from this research are essential to improving the human condition, environment, and agriculture. Any attempt to prevent the development of biological weapons and access to dangerous biological agents must take into account the benefits of biological research and be implemented with the full aid and consent of the global biological sciences community. Only then will we be able to achieve the balance between promoting beneficial biological research while successfully preventing the development of and effectively responding to biological weapon attacks.^{25(p622)}

Even the NSABB acknowledged the legitimacy of this argument in its recent recommendations on the controversial H5N1 studies.⁹

IMPORTANCE TO THE EMERGENCY PREPAREDNESS AND MANAGEMENT COMMUNITIES

The recent controversy over H5N1 research and the competing interests surrounding this and similar types of biomedical research are important to the work of both the emergency preparedness and emergency management communities. At a theoretical level, such research advances the public health system and leads to best practices that enhance public response capabilities to catastrophic health emergencies and public health crises. Furthermore, free communication and dissemination of information about these research advances arguably facilitates strategic planning related to emergency preparedness and management. Emergency planners and managers therefore should be interested in dual-use research of concern, the NSABB’s recent H5N1-related recommendations, and the competing interests concerned. Moreover, the recent widespread

discourse about these issues in the academic and news media provides emergency planners and managers with an opportunity to engage their communities about emergency preparedness while they are already paying some attention to aspects of community preparedness.

The recent controversy over H5N1 also brings to light some practical issues at the planning and operational levels for emergency planners and managers to consider. Perhaps the most basic of these considerations is for emergency planners and managers to identify facilities located in their jurisdiction that may be conducting biomedical or other types of scientific research that pose a threat to the public's general welfare. Certain states require that laboratories (academic or private) using dangerous biological and chemical agents register their activities.^{30††} Local emergency managers would be well advised to 1) work with state partners to ensure up-to-date analyses of potential laboratory-driven hazards in their jurisdictions; 2) include entities that manage these laboratories and similar research facilities in the jurisdiction's emergency preparedness activities; and 3) integrate these entities into the jurisdiction's emergency response plans and emergency support functions. These principles reflect the core tenets of hazard identification and mitigation and are seminal components of emergency preparedness and management. Involving research facilities in a jurisdiction's interagency planning and preparedness efforts will 1) better prepare a community for emergencies resulting from incidents or events involving these facilities and 2) demonstrate to all governmental and community partners in a jurisdiction that they are critical partners in the community's emergency response operations during an actual incident or event.

These preparedness efforts should be communicated to residents of the neighborhoods surrounding the research facilities to inform and assure them that measures are being taken to protect their welfare. Such communications are intended 1) to facilitate and optimize the outcomes of emergency response operations to an actual incident or event involving the research facilities

and 2) to enable all interested stakeholders to work together before a disaster or catastrophic event occurs, thereby strengthening their respective and collective abilities to respond to, recover from, and mitigate the impacts of such a disaster or event.

CONCLUSIONS

As the NSABB acknowledged in its recent recommendations on the controversial H5N1 studies, the findings of cutting-edge biomedical research have the potential both to threaten and benefit the public's safety, security, and health.⁹ This article has highlighted several competing interests that are at stake when it comes to protecting the public from biological hazards. In balancing these interests, a key question needs to be addressed: Which combination of decisions and actions will maximize a jurisdiction's ability to safeguard its communities and residents from the hazards associated with natural and human-caused threats? One way to address this issue may be to have a jurisdiction's emergency planners and managers conduct hazards assessments from all perspectives for their community.

From a broader policy perspective, debate continues about the usefulness of biomedical research on dangerous pathogenic agents and disseminating the results of such research to the public. Some may raise "slippery slope" concerns about whether a decision to place narrow restrictions on the publication of publicly funded H5N1 research eventually will lead to acts of general censorship in the name of biosecurity. Furthermore, there is a public interest for the public health and healthcare systems to have at their disposal the best, most advanced technologies and treatments available to enhance and protect the quality of life of members of the public. Several scholars have commented on this tension between the interests of biomedical science and the public's general welfare.^{24-26,31-34} One such scholar has remarked:

The dilemma over open science arises from the incompatibility of restricting access to scientific findings in the interests of public welfare with a notion of public welfare that is itself reliant upon the open exchange of findings and scientific

††For example, the State of Maryland maintains a program to "register persons that possess, maintain, transfer, or receive biological agents in the State."³⁰

data. Therefore, great care is needed to avoid remedies that unnecessarily impede the exchange of information between researchers and deter important lines of inquiry. Thus, a carefully crafted remedy is needed to cease free-ride opportunities available to malefactors interested in mis-using scientific advancements without impeding much needed advancements in science.^{24(p492-493)}

Although experts often are tasked with providing recommendations on these matters,^{35,36} members of the general public need to understand this debate and what is at stake. A public discussion in plain language about this issue must include community representatives and private residents so that all potentially affected parties can take part in the debate and grasp the consequences of the decisions made as a result of this debate.^{‡‡} Such a public discourse among the various stakeholders will ensure that biosecurity-related decisions intended to “insure domestic Tranquility, provide for the common defense, [and] promote the general Welfare” are made while adhering to democratic processes and principles intended to “secure the Blessings of Liberty.”

ACKNOWLEDGMENTS

The authors thank the following individuals for their assistance and support in preparing this manuscript: Adrian Wilairat, JD and Trudy C. Henson, MA, JD, University of Maryland Center for Health and Homeland Security; and J. Corey Creek, University of Maryland School of Law.

Patrick P. Rose, PhD, Policy Analyst, Center for Health and Homeland Security, University of Maryland, Baltimore.

Clark J. Lee, JD, Sr. Law & Policy Analyst, Center for Health and Homeland Security, University of Maryland, Baltimore; Affiliate, University of Maryland School of Nursing.

Sarah E. Sasor, MEng, Doctor of Medicine (MD) Candidate, University of Maryland School of Medicine, University of Maryland, Baltimore.

Earl Stoddard III, PhD, MPH, Public Health Program Manager, Center for Health and Homeland Security, University of Maryland, Baltimore.

^{‡‡}The WHO has attempted to provide expert advice on the recent H5N1 controversy to inform such public debates and decision making.^{35,36}

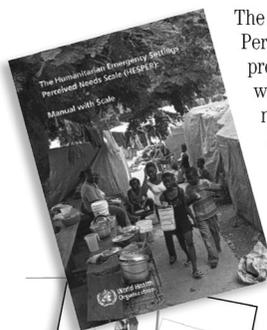
REFERENCES

1. Van Kerkhove MD, Mumford E, Mounst AW, et al.: Highly pathogenic avian influenza (H5N1): Pathways of exposure at the animal human interface, a systematic review. *PLoS ONE*. 2011; 6(1): e14582-e14590.
2. Claas EC, Osterhaus AD, van Beek R, et al.: Human influenza A H5N1 virus related to a highly pathogenic avian influenza virus. *Lancet*. 1998; 351(9101): 472-477.
3. World Health Organization: *Cumulative Number of Confirmed Human Cases of Avian Influenza A/(H5N1) Reported to WHO, 2003-2012*. Available at http://www.who.int/influenza/human_animal_interface/EN_GIP_20120224CumulativeNumberH5N1cases.pdf. Accessed February 26, 2012.
4. Saw JT, Hong LW: Oseltamivir in the treatment of avian flu (H5N1). *UCSI J Adv Sci Arts*. 2007; 2: 46-49. Available at <http://www.ucsi.edu.my/cervielijasa/volume2/pdf/08E.pdf>. Accessed March 5, 2012.
5. Marsh: *The Economic and Social Impact of Emerging Infectious Disease: Mitigation Through Detection, Research, and Response*. New York: Marsh Inc, 2008. Available at http://www.healthcare.philips.com/main/shared/assets/documents/bioshield/ecoandsocialimpactofemerginginfectiousdisease_111208.pdf. Accessed February 26, 2012.
6. Enserink M: Infectious diseases. Controversial studies give a deadly flu virus wings. *Science*. 2011; 334(6060): 1192-1193.
7. Butler D: Fears grow over lab-bred flu: Scientists call for stricter biosafety measures for dangerous avian-influenza variants. *Nature News*. December 20, 2011. Available at <http://www.nature.com/news/fears-grow-over-lab-bred-flu-1.9692>. Accessed February 26, 2012.
8. Ledford H: Call to censor flu studies draws fire: Critics say controversy over publication of mutant-H5N1 research highlights biosecurity weaknesses. *Nature News*. January 3, 2012. Available at <http://www.nature.com/news/call-to-censor-flu-studies-draws-fire-1.9729>. Accessed February 26, 2012.
9. Press Statement on the NSABB Review of H5N1 Research. National Institutes of Health Web site. December 20, 2011. Available at <http://www.nih.gov/news/health/dec2011/od-20.htm>. Accessed February 26, 2012.
10. Office of Biotechnology Activities, Office of Science Policy, National Institutes of Health: National Science Advisory Board on Biosecurity. Available at http://oba.od.nih.gov/biosecurity/about_nsabb.html. Accessed February 26, 2012.
11. Berns KI, Casadevall A, Cohen ML, et al.: Adaptations of avian flu virus are a cause for concern. *Science*. 2012; 335(6069): 660-661.
12. Kilbourne E: Influenza pandemics of the 20th century. *Emerg Infect Dis*. 2006; 12(1): 9-14.
13. Science: New insight on deadly Spanish flu may aid today's flu research. *AAAS News*. October 5, 2005. Available at <http://www.aaas.org/news/releases/2005/1005flu.shtml>. Accessed February 26, 2012.
14. US Department of Health and Human Services, National Institutes of Health [NIH]: *Mission—About NIH*. NIH Web site. Available at <http://www.nih.gov/about/mission.htm>. Accessed February 26, 2012.
15. Gostin LO: Public health law in a new century, Part I: Law as a tool to advance the community's health. *JAMA*. 2000; 283(21): 2837-2841.
16. US CONST. pmbl. (emphasis added).
17. US CONST. art. I, §8, cl. 1 (emphasis added).
18. Garner BA: *Black's Law Dictionary*. 9th ed. St. Paul, MN: West Group, 2009.

19. Galva JE, Atchison C, Levey S: Public Health Strategy and the Police Powers of the State. *Public Health Rep.* 2005; 120(Suppl 1): 20-27.
20. Lucus-McEwen V: *Is There Really a Difference Between 'Emergency Management' and 'Homeland Security'?* Emergency Management Blogs: Disaster Academia. 2010. Available at <http://www.emergencymgmt.com/emergency-blogs/campus/96033289.html>. Accessed March 6, 2012.
21. US Department of Health and Human Services, Centers for Disease Control and Prevention [CDC]: *Emergency Preparedness and Response—Bioterrorism Overview*. CDC Web site. Available at <http://www.bt.cdc.gov/bioterrorism/overview.asp#intro>. Accessed February 20, 2012.
22. Hylton WS: How ready are we for bioterrorism? *New York Times Magazine*. October 26, 2011. Available at <http://www.nytimes.com/2011/10/30/magazine/how-ready-are-we-for-bioterrorism.html>. Accessed February 17, 2012.
23. Gostin LO, Sapsin JW, Teret SP, et al.: The model state emergency powers act: Planning for and response to bioterrorism and naturally occurring infectious diseases. *JAMA*. 2002; 288(5): 622-628.
24. Gorman BJ: Balancing national security and open science: A proposal for due process vetting. *Yale J Law Technol.* 2005; 7: 491-533.
25. Berger KM: The role of science in preparedness and response. *Univ St Thomas Law J.* 2009; 6(3): 622-646.
26. Gorman BJ: Biosecurity and secrecy policy: Problems, theory, and a call for executive action. *IIS: J Law Policy Inform Soc.* 2006; 2(1): 53-102.
27. Greenberger M, Kovacs T, Mike M: Governance and biosecurity: Strengthening security and oversight of the nation's biological agent Laboratories. *DePaul J Health Care Law.* 2010; 13(1): 77-101.
28. Mabeus C: Fort Detrick: Watchdog group seeks state oversight of labs. *Frederick News Post*. February 15, 2012. Available at <http://www.fredericknewspost.com/sections/news/display.htm?StoryID=131875>. Accessed February 17, 2012.
29. Keane S: Note: The case against blanket first amendment protection of scientific research: Articulating a more limited scope of protection. *Stanford Law Rev.* 2006; 59(2): 505-550.
30. State of Maryland Department of Health and Mental Hygiene: Biological agents registry program, frequently asked questions.

- Available at http://dhmh.maryland.gov/laboratories/docs/BAR_FAQs.pdf. Accessed February 26, 2012.
31. Maurer SM: End of the beginning or beginning of the end? Synthetic biology's stalled security agenda and the prospects for restarting it. *Valparaiso Univ Law Rev.* 2011; 45(4): 1387-1446.
32. Gorman BJ: Patent office as biosecurity gatekeeper: Fostering responsible science and building public trust in DIY science. *J Marshall Rev Intell Property Law.* 2011; 10: 423-449.
33. Oriola TA: Against the plague: exemption of pharmaceutical patents rights as a biosecurity strategy. *Univ Illinois J Law, Technol Policy.* 2007; 2007(2): 287-343.
34. Rose P: *Creating Monsters for the Greater Good of Humanity* [Blog entry]. Baltimore, MD: University of Maryland Center for Health and Homeland Security, December 20, 2011. Available at <http://www.mdchhs.com/blog/creating-monsters-greater-good-humanity>. Accessed February 26, 2012.
35. Public health, influenza experts agree H5N1 research critical, but extend delay. World Health Organization Web site. February 17, 2012. Available at http://www.who.int/mediacentre/news/releases/2012/h5n1_research_20120217/en/index.html. Accessed February 26, 2012.
36. Technical consultation on H5N1 research issues—Consensus points. World Health Organization Web site. February 16-17, 2012. Available at http://www.who.int/influenza/human_animal_inter-face/consensus_points/en/index.html. Accessed February 26, 2012.

WHO Can Prepare You for an Emergency



The Humanitarian Emergency Settings Perceived Needs Scale (HESPER) provides a quick, scientifically robust way of assessing the perceived serious needs of people affected by large-scale humanitarian emergencies, such as war, conflict or major natural disaster.

The HESPER Guide

978 92 4 154823 6, \$30.00

You may also like...

The training package seeks to build the capacity of community health workers in supporting communities to respond more effectively during an influenza outbreak, thereby reducing mortality from influenza and to alleviate the pressure on health services during health emergencies.

Community Case Management During an Influenza Outbreak

978 92 4 150184 2, \$48.00



World Health Organization

For North America orders, visit:
www.whoopress.us

Use source code **JEM12** when purchasing online. Offer expires May 15, 2012.