Medical Countermeasures Dispensing

Emergency Use Authorization and the Postal Model

Workshop Summary

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Forum on Medical and Public Health Preparedness for Catastrophic Events

Board on Health Sciences Policy

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Willing is not enough; we must do."
—Goethe

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published summary as sound as possible and to ensure that the summary meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the process. We wish to thank the following individuals for their review of this summary:

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Although the reviewers listed above have provided many constructive comments and suggestions, they did not see the final draft of the summary before its release. The review of this summary was overseen by **Linda C. Degutis,** Yale Center for Public Health Preparedness, Yale University. Appointed by the Institute of Medicine, she was responsible for making certain that an independent examination of this summary was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this summary rests entirely with the authoring committee and the institution.

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INTRODUCTION[1]

The negative health impact of many large-scale public health emergencies, such as an intentional anthrax release, severe acute respiratory syndrome (SARS), or the recent 2009 H1N1 influenza pandemic, can be mitigated significantly by medical countermeasures such as antimicrobials, antivirals, and vaccines. To be effective, these countermeasures generally must be delivered in very large quantities in a short period of time. For example, in the event of an outdoor release of aerosolized anthrax over a wide geographic area, hundreds of thousands to millions of people would need prophylactic antibiotics within 48 hours of exposure to prevent deadly inhalational anthrax. In the event of an influenza pandemic, the timing is less urgent (although to be most effective antiviral medications should be taken by patients who have been symptomatic for no more than 2 days), but the entire population could be affected and extremely large quantities of antiviral medications would need to be dispensed.

Adding to these challenges, an extensive array of different medical countermeasures are needed to protect the public against the large number of known and unforeseen chemical, biological, radiological, and nuclear threats. Despite ongoing efforts to develop existing and new countermeasures from discovery through approval by the Food and Drug Administration (FDA), when a public health emergency occurs, the best

[1]The workshop series was organized by an independent planning committee whose role was limited to the identification of topics and speakers. This workshop summary was prepared by the rapporteurs as a factual summary of the presentations and discussions that took place at the workshops. Statements, recommendations, and opinions expressed are those of individual presenters and participants, and are not necessarily endorsed or verified by the Forum or The National Academies, and should not be construed as reflecting any group consensus.

countermeasure available to detect, prevent, or treat the disease or injury may be unapproved or approved for different indications. The restricted time frame of a response is unlikely to allow sufficient time to receive FDA approval.

Because of the scope of these programs and the tremendous challenges involved in implementing and executing them, the delivery of medical countermeasures during a public health emergency has been identified as one of the major challenges facing the medical and public health community.

In November 2009, the Institute of Medicine's (IOM's) Forum on Medical and Public Health Preparedness for Catastrophic Events convened a meeting to discuss recent progress made in the nation's ability to rapidly and effectively deploy medical countermeasures in response to public health threats, along with remaining challenges and vulnerabilities, and strategies to address these challenges in future work.

About the Preparedness Forum

The IOM's Forum on Medical and Public Health Preparedness for Catastrophic Events was established to foster dialogue among a broad range of stakeholders—practitioners, policy makers, community members, academics, and others—and provide ongoing opportunities to confront issues of mutual interest and concern. The Preparedness Forum provides a neutral venue for broad-ranging policy discussions that aid in the coordination and cooperation of public and private stakeholders in developing and enhancing the nation's medical and public health preparedness. Members include representatives and leaders from local, state, and federal governments; leaders of health professional and business associations; and other stakeholders and key decision makers.

The Preparedness Forum has a long-standing interest in medical countermeasures and has hosted several other workshops on this issue. The first workshop focused largely on opportunities to improve dispensing strategies, especially through public–private partnerships, and associated liability protections for corporations and nonprofit partners (IOM, 2008). A more recent workshop, held in February 2010, examined the Public Health Emergency Medical Countermeasures Enterprise and aimed to identify innovative strategies to enhance products from discovery through approval (IOM, 2010a). Finally, in the spring of 2010 the Forum hosted a series of three regional workshops to examine successes

and lessons learned from the 2009 H1N1 influenza vaccination campaign (IOM, 2010b).[2]

Workshop Objectives and Overview

The workshop described in this document was held in Washington, DC, on November 18, 2009. It aimed to provide an overview of the current threats, progress made, and remaining vulnerabilities in the public health system with regard to dispensing medical countermeasures. Workshop presentations and discussions focused in depth on two areas in which important advances have recently been made: Emergency Use Authorization (EUA) and the pilot of a U.S. Postal Service (USPS) medical countermeasures dispensing model in Minneapolis–St. Paul, Minnesota. These topics are introduced briefly here, and discussed in much greater detail in their respective sections (see Box 1 for a glossary of key terms). Workshop attendees included representatives from the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC) and others within the Department of Health and Human Services (HHS), as well as state and local health departments, the private sector, and others. The workshop agenda is in Appendix B and biographical sketches of planning committee members, speakers, and panelists are in Appendix C.

Due to the timing of the meeting, the response to the 2009 H1N1 influenza pandemic was at the forefront of participants' minds. The first section of this summary describes efforts—which, at the time of the workshop, were ongoing—to distribute and dispense medical countermeasures for 2009 H1N1, including antivirals, vaccine, and personal protective equipment, such as N95 respirators. This was a new kind of response; prior to 2009 H1N1, most mass dispensing planning efforts had been done through the Cities Readiness Initiative, discussed in more detail below, and focused primarily on rapidly dispensing antibiotics through points of dispensing (PODs). At the workshop, participants discussed lessons learned and opportunities for enhancing future medical countermeasures dispensing efforts based on their experiences during the response to 2009 H1N1. Nevertheless, they also noted that pandemic influenza is just one of the many threats facing public health, and empha-

[2]Summaries of these workshops and workshop audio files and slides are available for download via the Preparedness Forum's website, http://www.iom.edu/preparedness forum.

sized that many of the other potential threats would require an even more rapid response.

The *Project BioShield Act of 2004* (Public Law 108-276), among other measures, amended Section 564 of the *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 360bbb-3) to establish the EUA program. EUA permits the FDA Commissioner to authorize the use of an unapproved medical product, or an unapproved use of an approved medical product, during a declared emergency involving a heightened risk of attack on the public or U.S. military forces, or a significant potential to affect national security (FDA, 2007). The EUA program is designed to strengthen public health protections against biological, chemical, radiological, and nuclear agents by enabling access to the best available medical countermeasures when there are no adequate, approved, and available alternatives. Although the *Project BioShield Act* granted the authority for EUA in 2004, only two EUAs had been issued prior to 2009. In response to the 2009 H1N1 influenza pandemic, in 2009 and 2010 EUAs were issued for 22 products, covering pandemic vaccine, antivirals, N95 respirators, and diagnostic tests. Because of this, those involved in issuing, interpreting, and using EUAs gained much deeper experience during the year leading up to the workshop, and many new developments emerged. Workshop participants discussed policy implications of EUAs, strategies to limit potential logistical challenges that could delay the dispensing of medical countermeasures, and other challenges and outstanding issues.

The Postal Model for dispensing medical countermeasures uses postal carriers to rapidly deliver the countermeasures to residents for self-administration. A pilot of this model was undertaken recently in Minneapolis–St. Paul. Workshop participants from Minnesota, USPS, FDA, and the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) described the process of developing the pilot program. The process included developing a logistical plan, meeting USPS carrier union and management requirements, and obtaining an EUA for the placement of MedKits in the homes of the postal carriers who volunteer to participate in the program. Since the workshop, President Barack Obama has issued an Executive Order that, among other provisions, orders the federal government to pursue a national U.S. Postal Service medical countermeasures dispensing model to respond to a large-scale biological attack (The White House, 2009).

About This Summary

This document highlights and summarizes the workshop presentations and discussions, including recent developments, success stories, and lessons learned regarding distributing and dispensing medical countermeasures, EUA, and the pilot of the Postal Model. The summary also highlights opportunities and areas for future work, as identified by workshop participants. Whenever possible, unique ideas or concepts presented at the workshop are attributed to the individual who first advanced those concepts. In situations where many participants made similar points, the recurring themes are identified. Any opinions, conclusions, or recommendations discussed in this workshop summary are solely those of the individual participants and should not be construed as reflecting consensus or endorsement by the workshop, the Forum on Medical and Public Health Preparedness for Catastrophic Events, or The National Academies.

BOX 1
Glossary of Key Terms

Cities Readiness Initiative (CRI): The Centers for Disease Control and Prevention's Cities Readiness Initiative is a federally funded program designed to enhance preparedness in the nation's largest cities and metropolitan statistical areas, home to more than half of the U.S. population. Through CRI, state and large metropolitan public health departments develop plans to respond to a large-scale bioterrorist event by dispensing antibiotics to the entire population of an identified city or metropolitan statistical area with 48 hours (CDC, 2010a).

Dispensing[a]: Dispensing is the activity associated with providing prophylaxis and other related medical material to an affected population in response to a threat or incident. This activity, which is conducted at the local level, is the final interface between provider and public.

Distribution: Distribution is the activity associated with the delivery of federal Strategic National Stockpile assets from their original location to the state receiving, staging, and storing (RSS) warehouses as well as from the RSS warehouses to dispensing sites, alternate care facilities, and regional distribution sites/nodes.

Emergency Use Authorization (EUA): EUA is an authorization issued by the Food and Drug Administration (FDA) for the use of an unapproved medical product or an unapproved use of an approved medical product during a declared emergency involving a heightened risk of attack on the public or U.S. military forces, or a significant potential to affect national security (FDA, 2007).

Medical Countermeasure (MCM): MCM is a drug, biological product, or device that treats, identifies, or prevents harm from a biological, chemical, radiological, or nuclear agent that may cause a public health emergency.

Points of Dispensing (PODs): PODs are locations where medical countermeasures are dispensed to affected populations.

Pre-Emergency Use Authorization (pre-EUA): A pre-EUA is a submission sent to the FDA for review prior to the determination of an actual or potential emergency in order to reduce the time needed during an emergency to review the submission and consider authorization of the product (FDA, 2005).

***Project BioShield Act* (Public Law 108-276):** Passed in 2004, Project BioShield was designed to accelerate the research, development, purchase, and availability of effective medical countermeasures against biological, chemical, radiological, and nuclear agents. The legislation instituted a secure funding source for the purchase of critical medical countermeasures, took steps to facilitate research and development, and facilitated the use of medical countermeasures in an emergency by establishing the Emergency Use Authorization (HHS, 2010a).

***Public Readiness and Emergency Preparedness Act* (PREP Act) (Public Law 109-148):** Passed as part of the *Department of Defense Appropriations Act* in 2005, the PREP Act authorizes the Secretary of the Department of Health and Human Services ("Secretary") to issue a declaration ("PREP Act declaration") that provides immunity from tort liability (except for willful misconduct) for claims of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats, and conditions determined by the Secretary to constitute a present or credible risk of a future public health emergency to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures (HHS, 2010b).

Strategic National Stockpile (SNS): SNS is a national repository of antibiotics, chemical antidotes, antitoxins, life-support medications, IV administration and airway maintenance supplies, and medical/surgical items. The SNS is designed to supplement and resupply state and local public health agencies in the event of a national emergency anywhere and at anytime within the United States or its territories (CDC, 2010b).

[a]The above definition describes the use of the term *dispensing* in the field of preparedness and response. The profession of pharmacy defines *dispensing* as "the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient" (NABP, 2010, p. 7).

MEDICAL COUNTERMEASURES DISTRIBUTION AND DISPENSING IN RESPONSE TO THE 2009 H1N1 INFLUENZA PANDEMIC

Since the anthrax attack in 2001, many new programs, tools, and policies have been developed to enhance the nation's ability to use medical countermeasures to protect the public against acts of terrorism and other public health emergencies. These include the Cities Readiness Initiative (CRI), Project BioShield, the *Public Readiness and Emergency Preparedness Act* (PREP Act), and EUA. Despite these advances, the enormous scope and tremendous challenges involved in implementing and executing medical countermeasures programs leave much work to be

done. The threat may emerge anywhere or everywhere across the country, there are many different known and yet-unknown threats, and the time frame is always tight. The response to the 2009 H1N1 influenza pandemic, which was ongoing as of the date of the workshop, provided an important opportunity to assess the strengths and vulnerabilities of the medical countermeasures distribution and dispensing system, and, under the significant pressure associated with a real-world event, to develop new programs, tools, and policies that addressed needs as they arose.

At the workshop, representatives from several of the primary entities involved in the response—federal agencies, state and local public health departments, and the private sector—discussed their roles in distributing and dispensing countermeasures in response to the 2009 H1N1 influenza pandemic. While by no means a comprehensive review of medical countermeasures dispensing in the response to 2009 H1N1, workshop presentations and discussions did highlight some successes, pressing issues of concern, and areas for future work. This section begins by describing the activation and response of the CDC's Strategic National Stockpile (SNS), which supplied antiviral medications and other countermeasures to locations across the country. The section then briefly describes some of the challenges that state and local public health departments faced during the 2009 H1N1 response. Following that, it highlights two innovative public–private partnerships that were formed during the response: the *Commercial Supply Chain Dashboard* and the unprecedented level of involvement of pharmacies and pharmacists in countermeasures dispensing. Finally, the section mentions remaining issues to be addressed in order to enhance public–private partnerships, and outlines efforts recently made to provide liability protection for those involved in medical countermeasures dispensing. The use of EUAs during the 2009 H1N1 response was a central focus of the workshop and will be discussed in greater detail in the next main section.

Many of these issues were examined in more depth, and with the benefit of additional time for reflection, in a series of regional workshops hosted by the Preparedness Forum in April and May 2010. Participants examined the 2009 H1N1 vaccination campaign and identified strategies to improve future emergency vaccination programs and other medical countermeasures dispensing campaigns. A summary of these workshops is forthcoming (IOM, 2010b).

At the workshop described in this document, several participants noted that the 2009 H1N1 response provided an important opportunity to learn and enhance systems for medical countermeasures distribution and

dispensing. However, they also cautioned that lessons learned from the 2009 H1N1 response may not apply directly to responses to other threats because the specific nature of a threat imposes particular constraints on the response. For example, in the case of an anthrax release, the time for response is extremely short, but the affected geographic area may be more restricted than other threats. In response to these particular challenges, the CRI and the Postal Model, discussed in detail later in this summary, focus on dispensing antibiotics to the entire population of the nation's largest cities and metropolitan statistical areas within 48 hours, using mechanisms such as PODs and delivery by postal carriers.

By contrast, responding to an influenza pandemic involves different constraints, which will vary depending on the characteristics of the influenza strain. The pandemic may affect a very large geographic area, perhaps reaching most parts of the country, and different kinds of countermeasures may be required, including antivirals, vaccine, N95 respirators, and diagnostics. Unlike the anthrax scenario, the time for response will be longer than 48 hours, although time pressures exist in all situations in which medical countermeasures are needed. Because of differences in timing and in the kinds of countermeasures required, the mechanisms used to distribute and dispense countermeasures for an influenza pandemic are likely to be different than for an anthrax attack, and may focus more heavily on delivering the countermeasures to healthcare providers for administration to their patients.

Regardless of the scenario contemplated, workshop participants emphasized the importance of developing layered, multifaceted approaches to medical countermeasures distribution and dispensing. This could include "push mechanisms" that drive medical supplies directly out into the community immediately following an incident, forward prepositioning of materials so initial supplies are available locally, and MedKits prepositioned in individual residences, among other possible approaches. "No single strategy is going to work in being successful," said Matthew Minson, then-senior medical officer for strategic initiatives at HHS/ASPR. "It is going to have to be a combined effort."

Distribution from the Strategic National Stockpile (SNS)

Responding to an influenza pandemic is a major focus of medical countermeasures distribution and dispensing plans. Pandemics have occurred throughout history, and although a pandemic is declared based solely on the ease and speed of disease transmission (as opposed to the lethality of the disease), pandemic flu can have a high toll on health. Each year in the United States, between 5 and 20 percent of the population is infected with influenza A (the seasonal flu) and approximately 24,000 people die (range 3,300 to 48,600) (CDC, 2010c). In a pandemic, the infection rate can be much higher, and the death toll rises accordingly. The pandemic of 1918 killed an estimated 50 million people worldwide (about 3 percent of the global population), including approximately 675,000 people in the United States (CDC, 2010d). Pandemics also occurred in 1957 and 1968, but they were less severe.

With this as the backdrop, the first news of a new strain of Influenza A—2009 H1N1—in the United States and Mexico triggered surveillance for an emerging pandemic. It also triggered a nationwide plan for medical countermeasures distribution and dispensing.

At the federal level, a major component of the response plan was the release of stockpiled countermeasures (e.g., antivirals) from the SNS. The SNS response released the largest quantity of countermeasures yet, in a more accelerated time frame than ever, demonstrating the SNS capability to respond to influenza. Nevertheless, the situation also highlights the challenges of responding to a scenario such as the one involving anthrax; despite the speed of the 2009 H1N1 response relative to previous efforts, it would not be fast enough to protect the nation from an anthrax attack.

This subsection outlines the time line and logistical considerations of the SNS's response to 2009 H1N1, describes the development of a new public–private partnership designed to improve situational awareness of the commercial supply chain in order to enhance decision making and streamline information sharing, and highlights some areas that participants identified for additional work to enhance future responses.

Time Line and Logistics

In early spring, the CDC confirmed two cases of H1N1 in humans in California, the same virus determined to be circulating in Mexico (Box 2). Cases were also seen in Texas, Kansas, and New York. The flu was

BOX 2
Timeline of Division of SNS Activities in Response to the 2009 H1N1 Influenza Pandemic

Spring Timeline

- April 21, 2009: Centers for Disease control and Prevention (CDC) confirms five U.S. cases in California and Texas.
- April 23, 2009: Mexican officials announce the same virus is circulating in their country.
- April 25, 2009: CDC confirms more cases in Kansas and New York City.
- April 26, 2009: Department of Health and Human Services declares a public health emergency and HHS/CDC decide to push 25 percent of flu countermeasures contained in the Strategic National Stockpile. Trucks are on the road by 10 p.m. the same night.
- May 3, 2009: All but two target areas have influenza countermeasures.
- May 7, 2009: All product delivered to the 62 target areas.

Fall Timeline

- August 25, 2009: Commercial Supply Chain Dashboard initial meeting with commercial partners.
- October 1, 2009: Deployment of 300,000 Tamiflu oral suspension regimens.
- October 21, 2009: Deployment of 59.5 million N95 respirators.
- October 23, 2009: Commercial Supply Chain Dashboard launched.
- October 24, 2009: IV Peraminvir web portal launched; 1,200 5-day treatment courses available.
- November 2, 2009: Deployment of remaining 240,000 Tamiflu oral suspensions regimens.
- November 6, 2009: Receipt of additional 10,000 5-day courses of IV peramivir totaling 11,200 5-day courses.

occurring at an unusual time of year and was killing young, healthy patients, who are not usually at risk of death from influenza.

At the workshop, Greg Burel, director of the CDC's Division of Strategic National Stockpile (DSNS), described the time line of the DSNS response and the intense activity during the months following identification of the first cases. Within 5 days of the initial diagnosis, the CDC decided to release a quarter of the antiviral countermeasures from the SNS and push them out across the country to any states that chose to receive them. It was the first time that medical countermeasures had been released from the stockpile in such a massive effort to address an immediate threat.

To facilitate distribution of products, the United States and its protectorates are divided into 62 "project areas," or centers of population. Trucks began transporting materials out from the strategic stockpiles and toward project areas by 10 p.m. of the day the decision was made to begin releasing materials. Within 9 hours, the first trucks began to arrive in New York City. Within 7 days, all project areas except the two in the Pacific Island territories had received stockpiles of antiviral countermeasures. The last two project areas received countermeasures 4 days later.

To accomplish this task, two 12-hour shifts of 31 people loaded 363 trucks and 18 aircraft. A total of $265 million worth of product was moved at a rate of 60 pallets per hour.

In October and November, an additional 540,000 Tamiflu oral suspension regimens were deployed from the SNS as public health officials geared up for the reappearance of 2009 H1N1 during the traditional flu season. In addition, 59.5 million N95 respirators—personal protective equipment that protects against the transmission of virus—were distributed to state and local health departments.

While these preventive measures were happening, the SNS took on a second mission of a different character—the distribution of peramivir IV, an intravenous antiviral medication for hospitalized patients with complicated disease. The peramivir deployment brought two complicating factors to the process. First, peramivir IV had not yet been approved by the FDA for any use, and could only be deployed through an EUA. The EUA for peramivir will be discussed in additional detail in the next section. Second, its inventory was "vendor managed," meaning that the stockpiles did not physically reside in the SNS warehouses. Instead, physicians requested the treatment regimen through a web portal developed by the CDC. Once the order was received and approved, it was filled individually at the manufacturer, with shipments completed within 24 hours of order and delivered directly to the hospital where the patient and his/her physician were located.

Commercial Supply Chain Dashboard

During the crisis it became clear to federal and state health officials that there was limited visibility into the commercial supply chain for critical supplies such as antiviral drugs and N95 respirators. This made the task of responding to situations on the ground much more difficult. To address this issue, government and commercial partners came to-

gether to create the Commercial Supply Chain Dashboard. The objective was to help federal and state public health officials make more informed decisions about what to release and when by providing a snapshot of quantities on hand in the commercial supply chain as well as in federal and state stockpiles.

Driven by the urgent need for such a tool, the dashboard was developed very quickly. An initial planning meeting was held on August 25, 2009, and the dashboard was launched just 2 months later, on October 23, 2009, despite a steep learning curve. "In terms of trying to understand what is in the commercial supply chain, I never imagined how complicated this could be, and I thought I was relatively knowledgeable about how this industry works and what logistical challenges we may have to face," said the CDC's Burel.

Every week, commercial partners submitted data on quantities of materials on hand as well as an assessment of their ability to fill orders. The DSNS gathered its own data from its project-area stockpiles and inventories, aggregated data from commercial partners, and then generated reports for review. Data from the dashboard were only made available to certain individuals at the federal and state levels—local health departments did not have access. "We would love to make this information very widely available, but we are under constraints for data sharing with the partners who come to the table," Burel said. As a condition of sharing data about their supplies, which they had never shared to this extent before, the private-sector partners in the dashboard project wanted to limit the number of people who had access to the information.

Another challenge facing the project was the difficulty of maintaining current information. Commercial inventories move quickly, and participants often noted that by the time information was available in the dashboard, it was outdated.

Nevertheless, many viewed the dashboard as a success, especially given the short time frame in which it was developed. It involved an unprecedented level of data sharing from private partners, who previously had avoided this because of concerns stemming from competition as well as antitrust issues. The dashboard also represented an important step toward coordinated communications among stakeholders, and real-time situational awareness to help federal agencies and state public health departments make decisions. Several participants noted that bringing this kind of public–private partnership to other areas of public health preparedness and response could significantly enhance future efforts.

Gaps and Areas for Improvement

Because the 2009 H1N1 deployment was the most extensive SNS release yet, responders uncovered many gaps and areas for improvement that, if addressed, would significantly enhance future responses. These areas, discussed below, include situational awareness, the formulary of countermeasures in the SNS, triggers, and opportunities for research.

Situational Awareness The experience of the 2009 H1N1 response emphasized that the success of the SNS relies on situational awareness throughout the manufacturing and distribution chain. Workshop participants discussed difficulties with maintaining situational awareness that arose at various points along the chain, some of which are described below. Several participants noted that this is a particularly important area for future work because it impacts many stakeholders' ability to make effective decisions.

Strong relationships are critical with components of the private sector that provide supplies to the SNS, such as pharmaceutical and medical supply companies, as exemplified by their involvement in the dashboard project. The benefits of having stronger relationships with private-sector companies involved in monitoring and tracking shipments also became clear during the response to 2009 H1N1. Burel commented that this had been identified as an area for improvement, and noted that systems and partnerships are being established to address this issue.

Developing a better understanding of how the supply chain would work during a response that required a countermeasure that is not stockpiled within the SNS would be highly beneficial, Burel observed. "If we get better at understanding the supply chain, then we would be better able to help inform that supply chain where it needs to move to shore up those areas [for which we don't have countermeasures]," he said.

It is not only federal officials that benefit from situational awareness about the private-sector supply chain; this is also critical information for state and local public health authorities' planning and response efforts. As noted above, however, access to the supply chain information in the dashboard was limited to officials at the federal and state levels. Even at the state level, access was tightly restricted. Burel noted that access was offered to the state health official, some of whom substituted preparedness directors for themselves. In many states, however, the SNS coordinator was not given access to the dashboard, despite being the person responsible for SNS materials and facing frequent questions about the

supply chain. Local public health officials were also unable to use this information to improve their situational awareness and inform their countermeasures dispensing processes. Jack Herrmann, senior advisor for public health preparedness at the National Association of County and City Health Officials (NACCHO), noted that this is a shortcoming that "is on our list of things to improve."

Finally, some participants noted problems with communication from DSNS to state public health authorities about the timing and content of upcoming shipments. This caused problems with work flow and planning at the state level.

Countermeasures in the Stockpile Some areas for improvement deal directly with the countermeasures provided for the 2009 H1N1 situation. In particular, participants noted concerns about the strategy involved in providing N95 particulate-filtering face-piece respirators. Many models of N95 respirators from different manufacturers were released from the stockpile. This lack of standardization of materials caused problems among recipients of those materials. For example, in many cases recipients were provided with respirators that were different from the ones they normally used and for which their employees had received the fit testing required to ensure effectiveness. This issue, noted some participants, will need to be addressed as DSNS reconstitutes its personal protective equipment cache. In particular, it will be important to address challenges associated with federal procurement regulations, which currently complicate efforts to standardize the equipment held in the SNS.

Triggers Activation of the SNS can be driven by federal recognition of commercial marketplace shortages, epidemiological data, spot shortages, events, or provider requests. It can also be driven by states requesting materials due to local, on-the-ground conditions. While recognizing that this case-by-case determination of when to activate the SNS makes it highly flexible, participants also said that it would be beneficial to have further clarification of the triggers of various levels of response. They also noted that improvements could be made to the processes for communicating requests and for informing states that distributions are imminent.

Research Opportunities The 2009 H1N1 response provided a unique opportunity to do a rigorous after action analysis to see which parts of the system work well and which need improvement. With regard to the SNS response, James Blumenstock, chief program officer for public health practice at the Association of State and Territorial Health Officials, recommended the following question for further analysis: Did the information and data provided by the Commercial Supply Chain Dashboard really make a difference in regional, state, or local decisions? Given that the data are on a national level, he noted, the jury is still out on whether it affected regional, day-to-day decision making. "This is a significant issue from an after-action perspective—to see whether or not it can be pushed any further in its next generation, to provide more specific state or regional information," Blumenstock said.

Many other research needs and opportunities for future improvement were identified by participants in the subsequent IOM regional workshop series on the 2009 H1N1 vaccination campaign. They are detailed in the summary of those workshops (IOM, 2010b).

Challenges Facing Public Health Departments

State and local public health agencies are where medical countermeasures dispensing is implemented. Supplies come from the SNS to the states and territories, or directly from the commercial supply chain, and are managed at the state and local public health levels. States purchase their own assets, such as antivirals and N95 respirators, in addition to federal assets transferred to the states.

"When you look at the full formulary of what medical countermeasures are in play and what state health has a responsibility for, it is daunting," Blumenstock said when describing the public health department response to 2009 H1N1. "But it is also a success story because the infrastructure has been built to effectively manage and distribute those materials." During the recent 2009 H1N1 pandemic, he said, state public health systems were highly effective in "managing and coordinating a complex logistical operation of receiving, staging, storing, distributing, and dispensing medical countermeasures."

Although this section is not an exhaustive list, it outlines some of the challenges faced by state and local public health officials during the response to 2009 H1N1.

Situational Awareness

State public health departments face challenges in connecting with the commercial sector to maintain situational awareness. The availability (or lack of availability) of commercial-sector assets is a key trigger for the state to request materials from the SNS, and a critical piece of information for developing and implementing state countermeasures distribution and dispensing plans. However, public health departments do not have control or responsibility for commercial-sector assets, complicating efforts to gather information about supply chain availability. "State public health must have a very clear picture of what the commercial supply chain has and is able to bear," and that picture is not available yet, Blumenstock noted.

During the 2009 H1N1 response, state public health officials also faced challenges stemming from lack of knowledge about what is in the SNS and the timing and content of shipments to the states. As mentioned above, this made it more difficult for state public health officials to develop effective response plans.

Implementation Challenges in the 2009 H1N1 Vaccination Program

Although the CDC and other federal entities provided guidance during the response to 2009 H1N1, state and local public health departments were responsible for developing plans to administer the vaccine. This workshop was held at the height of the implementation of these plans. Based on their immediate experience, participants focused on the communications challenges associated with each state developing its own vaccine administration plan, and challenges that arose when initial vaccine supply was lower than anticipated.

Participants noted that flexibility to determine their own vaccine administration plans was appreciated by state and local jurisdictions because it allowed them to appropriately tailor plans to their own communities. Nevertheless, they also discussed how this can lead to confusion or the appearance of inequity, especially when different approaches are taken in neighboring jurisdictions. For example, some state and local public health departments planned many public or school vaccination clinics, while others relied more heavily on local physicians' practices to vaccinate the public. This difference in implementation put a communication burden on local health departments. NACCHO's

Herrmann noted, "It compels us then to be transparent and to articulate and communicate about why we are doing what we are doing, or else people look at the 36,000-foot view and say, 'There are inconsistencies in the way you are doing it.'"

Initially optimistic projections of vaccine supply focused much of the planning efforts on the logistics of mass distribution and administration rather than on planning for administration of a scarce public health resource. When the actual vaccine supply was smaller than anticipated, and not enough vaccine was available for all people for whom vaccination was recommended, state and local public health departments were forced to develop new plans to equitably and fairly distribute the vaccine available.[3] In many cases this caused logistical problems, such as forcing public health departments to cancel previously advertised plans for mass vaccinations because vaccine was unavailable.

These issues were discussed in much greater depth in the Preparedness Forum's regional workshop series examining the 2009 H1N1 vaccination campaign. On the basis of the presentations and the discussions at those workshops, a number of themes and opportunities for future efforts were identified in the following areas: (1) vaccine supply and demand; (2) state and local implementation of CDC's Advisory Committee on Immunization Practices recommendations, including prioritization for vaccination; (3) vaccine formulations and priority groups; (4) opportunities for developing and enhancing partnerships; (5) opportunities to increase seasonal vaccination rates among pregnant women and healthcare workers and to increase acceptance of live attenuated nasal spray vaccine; (6) standardization and improvement of immunization information management systems and state vaccine provider registries; (7) opportunities to simplify, systematize, and automate processes and practices; and (8) research needs and opportunities. For more details, see the forthcoming summary of these workshops (IOM, 2010b).

[3]The CDC's Advisory Committee on Immunization Practices (ACIP) recommended that vaccination efforts focus on five initial target groups: pregnant women, persons who live with or provide care for infants aged <6 months, healthcare and emergency medical services personnel, children and young adults aged 6 months–24 years, and persons aged 25–64 years who have medical conditions that put them at higher risk for influenza-related complications. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr58e0821a1.htm.

Funding

Several workshop participants warned that important partnerships that developed during the 2009 H1N1 response could be in danger because of the erosion of funding and the resulting layoffs and staff attrition that have hit public health departments in the wake of economic recession (NACCHO, 2010; Trust for America's Health, 2010). "In the first half of 2009, approximately 8,000 staff positions in local health departments were lost due to layoffs or attrition. An additional 12,000 local health department employees were subjected to reduced hours or mandatory furloughs," Herrmann reported. "A lot of the challenges we are experiencing today with H1N1 relate to funding challenges and the erosion of that funding that we have seen over the last few years," he said, and he warned that there are huge gaps in local health departments' abilities to respond to health issues and protect the nation's health.

Herrmann also noted that tracking and monitoring medical countermeasures is very challenging for some local health departments. "They don't have the resources at the local level to be able to tackle the huge logistical challenges that these responsibilities [entail], and they don't have the computer systems and technology in place to be able to achieve some of these responsibilities," Herrmann said.

Despite the challenges they faced, 2009 H1N1 gave local health departments the chance to test their emergency response plans. "They have an amazingly positive attitude and spin on this challenge," Herrmann said. "They see it as an opportunity to test their plans. They see it as an opportunity to challenge their systems and identify where those gaps are."

Public–Private Partnerships

Public–private partnerships are a critical component to successful medical countermeasures distribution and dispensing, according to many workshop participants. As Blumenstock said, "It is a requirement to really create a hybrid environment of both public and private assets, because certainly governmental entities can't do it alone, recognizing the amount of material, the time limits, and the challenges of distribution and administration."

The Commercial Supply Chain Dashboard, discussed earlier, is a good example of how public and private entities can work together to tackle critical issues in dispensing medical countermeasures, such as im-

proving situational awareness and supply chain visibility to enhance decision making for medical countermeasures dispensing. Another good example is the partnership that was developed between state and territorial public health departments and pharmacies to administer the 2009 H1N1 vaccine. Pharmacists in all 50 states and the District of Columbia are authorized to vaccinate to some extent, although the scope of practice varies by state. The framework developed for this partnership used national, regional, and independent pharmacies as sites for administration of the 2009 H1N1 vaccine (ASTHO, 2009). The process of developing this partnership provided a way for providers and public health systems to address various issues. Some of those issues are discussed in the following paragraphs. Although these issues arose in the context of the workshop discussion about the pharmacy program, participants noted that many similar issues also applied to other partners in the response, such as other healthcare providers, health systems, and large companies.

Payment

Who pays for medical countermeasures dispensing? The government provides the product, but providers, such as pharmacists, are responsible for compounding the medication. Healthcare providers spend staff time and resources administering vaccinations. Mitchel Rothholz, chief of staff of the American Pharmacists Association, said that tackling the issue of payment "and bringing those payers to the table is important to try to take down barriers that are occurring in the system."

Communication

Consistent messaging between partners is essential to keeping the public and providers informed. When conflicting information is generated, many problems can occur. Rothholz shared an example of one such misfire. "[The] Centers for Medicare & Medicaid Services did a great flyer to the elderly population that talked about getting vaccinated against H1N1," Rothholz explained. However, at that time no vaccine was available for that population, resulting in a confused and frustrated community. "I think we just need to look at timing of when messages come out and have a better coordination of that messaging," he said.

Documentation and Data Collection

What types of documentation need to be provided to the public health system? How should those data be collected? What is the minimum data standard that needs to be met? Are data being collected that will track how the products are being used, and can we learn anything from the data? Private providers asked all of these questions during the 2009 H1N1 response, and they also need to be addressed for future medical countermeasures responses.

Dealing with Multiple Jurisdictions

Some large, private-sector organizations, such as large chain pharmacies, have to work with multiple health department plans and even different state requirements because of the way the public health system is structured. Although guidelines are given from the national level, each state and local public health department may have the flexibility to decide the best way to serve its population. This means the private sector can be faced with a broad range of plans, which can be inconsistent and difficult to administer. Vaccination scopes of practice for pharmacists also vary state by state, providing an additional complicating factor for large chain pharmacies that participate in mass vaccination efforts. As Rothholz asked, "How do we simplify and standardize that as best we can, so that it becomes not a burden on the providers who are trying to serve multiple jurisdictions?"

Liability

Liability continues to be a concern, despite the provisions of the *Public Readiness and Emergency Preparedness Act*, which is discussed in more detail below. "The liability issue still seems to be an issue that continues with the private sector. It is either keeping private-sector participants out completely or it is keeping them in only a limited capacity to whatever level they feel somewhat comfortable until some of their issues are addressed," said Scott Mugno, managing director for FedEx Express Corporate Safety, Health, and Fire Prevention.

Mugno said that those private entities that are already in partnership with the government may be willing to become even more involved if

better protection is available, although others argued that the existing liability protections are sufficient and that instead the federal government should better clarify what specific protections exist for private sector actors involved in responses. "There is a lot of talk about logistics, and it is one of the issues that are on the table," Mugno said. "Certainly my company, my industry or sector of the industry certainly deals with that. We think we can help. We do on the national stockpile and our contract with the CDC to move [vaccine] and the push kits, but clearly we can do more."

Ultimately businesses benefit from being involved. "We too are the public. That is who our employees are," Mugno said. For example, in the Memphis area, FedEx is the second largest employer after the federal government, with 30,000 employees and their families. "If we can get to a good working relationship that covers doing the right thing right the first time, safely, and not being at risk in doing so, that is a huge hunk of the population we can take off your plate by also helping our own population and then also being part of the critical infrastructure," he added.

Liability Protection and the PREP Act

Various legal provisions have been implemented to provide protection from liability and to support healthcare providers, other workers, and private-sector entities' involvement in public health responses. Brooke Courtney from the Center for Biosecurity of UPMC noted: "It has been well established that during public health emergencies, the legal landscape can dramatically [change] to help facilitate responses, and to provide special liability protections for responders and, in particular, volunteers."

The primary source of liability protection is the *Public Readiness and Emergency Preparedness Act* (Public Law 109-148), which was passed as part of the *Department of Defense Appropriations Act* in 2005. The Act provides immunity from liability claims arising from the administration and use of covered countermeasures to manufacturers, distributors, program planners, and other qualified persons. The 2009 H1N1 response highlighted the need for additional education on the PREP Act before the event occurs. It also raised questions about the scope of the PREP Act that need further consideration. This section provides an outline of the provisions and implications of the PREP Act, then discusses areas for further work or consideration.

"The PREP Act provides limited immunity from tort liability, which means that no legal tort claim can be pursued in state or federal court," Courtney explained. Tort law is the area of law where someone who suffered an injury or other damages may be able to receive compensation from the person or entity legally responsible for causing the injuries or damages. However, the PREP Act is not unlimited; it does not provide protections for death or serious injury arising from willful misconduct. It also does not protect individuals who violate a patient's civil rights or who violate the Americans with Disabilities Act, to name a few exceptions. Furthermore, the PREP Act does not automatically protect everyone involved in any kind of medical response to an emergency. Liability protection under the PREP Act is limited to a specific emergency, and includes only the countermeasures and other conditions listed in the PREP Act declaration.

Even so, the PREP Act "has really broad liability protections," Courtney noted. Additionally, it includes a provision for an injury compensation fund for eligible individuals who suffer injuries from the administration or use of any of the covered countermeasures. At the time of the workshop, the fund had not yet been used. However, since then the PREP Act's Countermeasures Injury Compensation Program (CICP) has begun accepting *Letters of Intent to File a Request for Benefits* from those who seek CICP compensation (HRSA, 2010a, 2010b). The CICP has already received many such letters of intent for alleged injuries from the 2009 H1N1 vaccine, and one of these claims also alleges adverse events from the use of pandemic antivirals.

The following types of loss are covered by the PREP Act:

- Death;
- Physical, mental, or emotional injury, illness, disability, or condition;
- Fear of physical, mental, or emotional injury, illness, disability or condition (including any need for medical monitoring); and
- Loss of or damage to property (including business interruption loss).

Issuing a PREP Act Declaration

A PREP Act declaration is distinct from an HHS declaration of a public health emergency and requires no additional emergency declarations. The HHS Secretary can make a PREP Act declaration on the find-

ing that a disease or health threat constitutes a public health emergency, or that there is a credible risk it will constitute a future emergency. The PREP Act declaration must include the category of the disease, condition or health threat and covered countermeasures, population using the countermeasures, geographical area covered, and effective time period. The declaration can also include limitations on the means of distribution, if there are any, as well as who is qualified to prescribe, dispense, or administer the countermeasures.

Covered countermeasures include

- Qualified pandemic or epidemic products;
- Security countermeasures (defined in the *Public Health Service Act*); and
- Products authorized under an EUA.

Courtney noted that many questions have been asked about who is considered a qualified person. "[It is] intentionally open ended to give states flexibility in terms of whom they want to or they think should be involved in responding," she responded. Covered persons may include

- United States;
- Manufacturers and distributors of countermeasures;
- Program planners (e.g., those involved with planning and administering programs for countermeasures distribution);
- Qualified persons (e.g., licensed health professionals); and
- Officials, agents, and employees of above.

Some of the PREP Act declarations that have been made since passage of the Act in 2005 are shown in Table 1. For additional information about coverage under the PREP Act for 2009 H1N1 vaccination, see the CDC's website (CDC, 2010e).

TABLE 1 Examples of PREP Act Declarations

Category of Disease	Covered Countermeasure	Date of Declaration
Acute radiation syndrome	Vaccine, antimicrobial/antibiotic diagnostic, etc.	10/10/08
Anthrax	Vaccine, antimicrobial/antibiotic, diagnostic, etc.	10/01/08
Botulism	Vaccine, antimicrobial/antibiotic, diagnostic, etc.	10/10/08
Pandemic influenza	Diagnostics, personal respiratory protection devices, respiratory support devices	12/17/08
	Antivirals (Tamiflu® and Relenza®)	10/10/08; amended 6/11/09 (2009 H1N1)
	Vaccine	1/26/07 (H5N1); amended 11/21/07 (H7, H9), 10/10/08 (H2, H6), and 6/15/09 (2009 H1N1)
2009 H1N1 Influenza	Antiviral (peramivir)	9/25/09
Smallpox	Vaccine, antiviral, diagnostic, etc.	10/10/08

PREP Act Issues

Despite the progress made, many workshop participants noted the great need for education on the PREP Act before an event occurs. They suggested that some people may not understand the extent of the protections provided by the PREP Act, and therefore may be more hesitant to become involved in dispensing medical countermeasures.

Workshop participants also discussed a question that many said could benefit from further consideration and perhaps further action to address the situation: What is the legal situation for multiple pieces of the same equipment used in a single hospital during a disaster response, when some of those pieces of equipment came from the SNS and other pieces were already owned by the private hospital? Specifically, workshop participants discussed the hypothetical case of an emergency situation in which some of a hospital's ventilators were supplied by the SNS and others were owned by the hospital. Participants discussed which ventilators in this situation would be covered by the PREP Act. Susan

Sherman, senior attorney with the Office of the General Counsel of HHS, explained, "From a practical point of view, ventilator coverage is not probably as broad as you might wish." Declarations, and thus protections, are strictly limited to conditions specified by the HHS Secretary. In this hypothetical case, Sherman said, if the SNS released ventilators for use, they would be covered by the PREP Act. However, ventilators owned by private hospitals might not be covered under the PREP Act, unless the local public health authority states that everyone needs a ventilator. Workshop participants said this situation could cause a great deal of confusion and would require additional documentation and detailed tracking of equipment provenance, which would likely not be feasible in an emergency situation. They noted that additional consideration of this issue would be useful.

EMERGENCY USE AUTHORIZATION

Background

The EUA program was established in 2004, when the *Project BioShield Act*, among other measures, amended Section 564 of the *Federal Food, Drug, and Cosmetic Act* to include this provision (HHS, 2010a). EUA permits the FDA Commissioner to authorize the use of an unapproved medical product or an unapproved use of an approved medical product during a declared emergency involving a heightened risk of attack on the public or U.S. military forces, or a significant potential to affect national security (FDA, 2007).

EUA is an important tool for public health officials and physicians involved in an emergency response because it can enable them to use the best countermeasure available to detect, prevent, or treat a disease or injury in certain populations, even if that countermeasure is unapproved by the FDA or not approved for that particular use.

Prior to the response to H1N1 in 2009, only two EUAs had been issued—one for a medication for the prevention of inhalation anthrax (the authorization has since been terminated) and the second for antibiotic emergency kits for the postal model, which was issued in 2008 and is still in effect. The majority of EUAs issued have been in response to 2009 H1N1. At the time of the workshop, one EUA had been issued for N95 respirators, three for antiviral medications, and nine for in vitro diagnostics (FDA, 2010a, 2010b, 2010c, 2010d). Additional EUAs for nine

diagnostic tests were issued after the workshop. The declaration of a Public Health Emergency for 2009 H1N1 Influenza expired on June 23, 2010, and, therefore, the EUAs issued for the 2009 H1N1 response have been terminated (CDC, 2010f).

At the workshop, participants noted that EUA has a broader use beyond enabling the use of an unapproved product or extending the use of an approved product to populations for which it was not approved. In particular, it can also be used to address labeling requirements and other challenges that arise because of constraints inherent in a public health response. "From a legal perspective, there are a lot of situations where EUA helps get past all those requirements," said Sherman of HHS. "You can change the labeling. You can change the information. You can change the dosage. You can give it to populations for which wasn't approved." She continued, "In some sense we had to match up in practice a public health response where you might not have the precise labeling that your physician would prescribe to you. There are a lot of variables that are necessary for the public health responders that don't necessarily match what the approved drug would look like if you just went to your physician and got it because you had that illness."

This section will begin by outlining the role of EUA within the FDA's mission and the process by which an EUA may be issued. Following that, the section will consider the EUAs issued in response to 2009 H1N1, highlighting the successes and advances as well as the challenges and the areas identified by participants in which further work could enhance future emergency responses.

The Role of EUA Within the FDA's Mission

EUAs are issued by the FDA and, therefore, reflect the FDA's mission to protect the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation. The FDA is responsible for the following areas related to counterterrorism and emerging threats:

- Facilitating the development and availability of medical countermeasures;
- Protecting the safety and security of regulated medical products;
- Enhancing emergency preparedness and response capabilities;

- Implementing comprehensive food security strategy; and
- Ensuring safety and security of agency assets.

"The bottom line is that the FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of drugs, biologics, and devices," said Carmen Maher, policy analyst/senior nurse officer, Office of Counterterrorism and Emerging Threats, FDA. Included in that broad purview are ventilators and personal protective equipment.

As a general rule, health needs must be met with medical countermeasures that are supported by good science and that follow regulatory requirements. In non-emergency situations, explicit labeling laws and prescription and usage guidelines are required by FDA and state laws to protect the public. During an emergency, the FDA considers the potential benefit that an EUA would provide, while never abandoning its essential mission to ensure the safety, efficacy, and security of the medical countermeasures used. More information on FDA's policy regarding EUA can be found in the FDA guidance document on this topic (FDA, 2007).

The EUA Process

The process of issuing an EUA involves five steps:

1. Determination of an emergency;
2. Declaration of an emergency;
3. Review of the request for EUA by the FDA;
4. Issuance of the EUA or denial of the request; and
5. Termination of the EUA.

The determination of an emergency can be made by HHS, Department of Homeland Security, or Department of Defense. The emergency can be a military, domestic, or public health emergency that affects, or has a significant potential to affect, national security. Agents involved include chemical, biological, radiological, or nuclear agents. Both the determination and the declaration of the emergency must state the nature of the threat involved.

Once a determination of an emergency has been made and an emergency has been declared, the FDA reviews the EUA request and, if feasible and appropriate given the circumstances of the emergency, consults

with the National Institutes of Health and the CDC. If the request is found to meet statutory criteria, the FDA Commissioner issues an EUA. The termination of an EUA is linked to the declaration—once the declaration expires, so does the EUA. A single declaration can support multiple EUAs as necessary.

Pre-EUA

Although the law does not allow the FDA to preauthorize an EUA before the determination and declaration of an emergency, the process can begin before the actual emergency occurs. Specifically, a request can be submitted to the FDA regarding situations that may happen, such as potential anthrax attacks or smallpox outbreaks. This is called a pre-EUA. In these instances, informed speculations are made about what the emergency situation might be. Maher explained, "We are already looking at the data for the products that could be used in those situations, including what [are] the science and the data behind [those products] and how [they] would be used, as well as how the EUA would be crafted." A pre-EUA allows the FDA to begin work on fact sheets and other documentation. "What we have done with the pre-EUA situation is get the fact sheets as close as we can to what we think the final fact sheets would be and allow the state to go and reproduce that," Maher said. If an emergency is declared and the EUA is formally requested, final review could be done, and if any substantive changes were needed, the FDA would work with the state to make sure those changes were incorporated.

What Can an EUA Cover?

The development pathway for medical countermeasures (and other drugs) has three phases—pre-IND (investigational new drug), IND, and NDA (new drug application). The NDA is how drug sponsors formally propose that the FDA approve new pharmaceuticals for sale and marketing. It is not a requirement that products be in a specific point of the development pathway to be considered for EUA, but it is implied that the product is currently undergoing development or has been developed and therefore has gone partially down the pathway. It is important to recognize that an EUA is not part of the development pathway; it is an entirely separate entity that is used only during emergency situations and is not part of the drug approval process.

An EUA must meet the following four statutory criteria to be considered. The goal of these criteria is to ensure that even in an emergency, the public is receiving the best, safest, most appropriate care possible.

1. There must be a serious or life-threatening illness caused by a specified chemical, biological, radiological, or nuclear agent.
2. It must be reasonable to believe that the product covered by the EUA is going to be effective for the intended use—diagnosing, treating, or preventing either an illness or condition caused by a specific agent, or an illness or condition caused by an approved or authorized medical countermeasure deployed against the agent.
3. The known and potential benefits need to outweigh the known and potential risks.
4. There must be no adequate approved, alternative medical countermeasures available for the situation.

EUAs may waive a number of regulatory requirements to allow unapproved products or approved products to be used in unapproved situations as emergency medical countermeasures. Typically, for instance, when an unapproved product is used in a clinical setting, it requires either informed consent or review and approval by an institutional review board. EUAs can waive that requirement for the duration of the emergency. For example, one EUA issued for the 2009 H1N1 pandemic allowed the use of the (as-yet-unapproved) peramivir IV in clinical settings to combat severe influenza, without either informed consent or board review. In this case, no other intravenous antivirals were effective against these severe infections, and the FDA determined that there were sufficient data and need to allow administration of peramivir IV under an EUA.

"In the specific situation of EUA or emergency use of any product, we are looking at the emergency, the circumstances of the emergency, the product's regulatory status, proposed indication, safety and efficacy data, adverse events described in the product labeling or in the investigators' brochure if it was there," Maher said.

The FDA also looks at various operational issues and partners with the CDC to consider issues such as:

- When will it be dispensed: before or after the event?
- How will it be dispensed and by whom? In a hospital setting or not, by licensed or non-licensed providers?
- What is the time frame—is there a therapeutic window that needs to be met?
- What are the operational limitations on the ground and how will they be handled?
- Is the product available in sufficient quantities to meet the need or will it be made available? Can it be manufactured in time to meet the need at hand?

"We have to strike that balance to ensure the safe and efficacious use of the product, but [also] to ensure that the right product is getting to the right person at the right time," Maher said.

Conditions of Authorization

The letter of authorization issued by the Commissioner of the FDA includes the conditions of authorization, which address all the elements that are part of the EUA. This is where roles are clarified, and specific conditions are laid out for different parties, such as public health authorities, manufacturers, healthcare facilities and providers, and others who dispense or distribute the products. Examples of what can be addressed within the conditions of authorization include the following:

- Specific information for healthcare practitioners and authorized dispensers;
- Specific information for recipients;
- Adverse event reporting and monitoring;
- Recordkeeping/access;
- Restrictions on distributing and administration;
- Restrictions on advertising;
- Data collection and analysis; and
- Compliance with good manufacturing practice.

Intersection of EUA and the PREP Act

Healthcare providers, manufacturers, and healthcare organizations are often concerned about liability protection during medical countermeasures dispensing campaigns. This is especially true when the use of medical countermeasures is authorized under an EUA. Workshop participants noted that they often receive questions about the relationship between the issuance of an EUA and a PREP Act declaration, which provides immunity from liability claims arising from administration and use of covered countermeasures to manufacturers, distributors, program planners, and other qualified persons.

An EUA is issued separately from a PREP Act declaration. "It's not automatic that an EUA will have a PREP Act declaration," Courtney said. It is also not a requirement that a PREP Act declaration be made for an EUA to be issued.

Courtney continued, "In addition, according to the FDA, if a PREP Act declaration does exist for a product that has an EUA, but the terms of the EUA are violated, then the PREP Act protections might not apply."

The PREP Act itself has sometimes been an additional motivating factor for requesting an EUA. The statute states that coverage is only available for medical countermeasures that are approved and licensed by the FDA under an IND, investigational device exemption (IDE), or EUA. "We have made commitments by issuing these PREP Act declarations to various folks, the manufacturers, the distributors, and everyone in the chain, that they will have this liability protection," said Sherman of HHS. "If we can't be sure that the product is covered by one of those FDA mechanisms, we can't necessarily guarantee that the PREP Act for liability coverage would remain in place."

Successes in the Response to 2009 H1N1

The response to H1N1 was made possible largely because of the use of multiple EUAs, which allowed use of a yet-unapproved antiviral medication, deemed to be critical in caring for severely ill patients, and extended the use of other antiviral medications and countermeasures to larger populations than would otherwise be allowed. EUAs also assisted public health authorities with addressing challenges such as labeling restrictions and changes in the information provided to recipients of the countermeasures. Although the *Project BioShield Act* granted the author-

ity for EUA in 2004, only 2 EUAs had been issued prior to 2009. In 2009 and 2010, EUAs were issued for 22 products in response to 2009 H1N1. Three were issued for antiviral medications and one for personal respiratory protection devices (Table 2) (FDA, 2010a, 2010b, 2010c). In addition, EUAs were issued for 18 diagnostic tests; some of these were issued after the workshop took place (FDA, 2010d). Because of this, those involved in issuing, interpreting, and using EUAs gained much deeper experience during the year leading up to the workshop, and many new developments emerged.

TABLE 2 2009 H1N1 Influenza Emergency Use Authorizations for Antivirals and Personal Respiratory Protection Devices

Product	Purpose[a]	Date of Original Issue
	Antivirals	
Tamiflu® (oseltamivir)	• Extends use for treatment and prevention to children <1 year; authorizes alternative dosing for children >1 year • Permits distribution or dispensing without complying with certain prescription label requirements • Allows for use in patients who are symptomatic for >2 days or sick enough to be hospitalized • Authorizes distribution of SNS SLEP Tamiflu • Notes that persons may distribute to recipients in accordance with applicable state and local law and/or in accordance with the public health and medical emergency response of the authority having jurisdiction	August 27, 2009 (amended April 27, 2009; July 14, 2009)
Relenza® (zanamivir)	• Permits distribution or dispensing without complying with certain prescription label requirements • Allows for use in patients who are symptomatic for >2 days and in patients sick enough to be hospitalized • Notes that persons may distribute to recipients in accordance with	April 27, 2009 (amended April 27, 2009)

	applicable state and local law and/or in accordance with the public health and medical emergency response of the authority having jurisdiction	
Peramivir IV	• Allows for use in hospitalized adult and pediatric patients for whom therapy with an IV agent is clinically appropriate because (i) the patient is not responding to either oral or inhaled antiviral therapy, or (ii) because drug delivery by a route other than IV is not expected to be dependable or is not feasible, or (iii) (for adult patients only) the clinician judges IV therapy is appropriate due to other circumstances.	October 23, 2009 (amended November 19, 2009)
Personal Respiratory Protection Devices		
Disposable N95 Respirators	• Allows for use of 15 types of N95 respirators from the SNS by the general public	April 27, 2009 (amended May 1, 2009)

[a]Each of these was subject to conditions specified in the respective EUAs.
SOURCE: Adapted from Sherman et al. (2009). Reprinted with permission from Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science, published by Mary Ann Liebert, Inc., New Rochelle, NY.

The first part of this document described several aspects of medical countermeasures dispensing in response to the 2009 H1N1 pandemic, including distribution from the SNS, challenges faced by public health departments, public–private partnerships, and liability protection. This second look at the response to the 2009 H1N1 influenza pandemic focuses on the use of EUA during the response, improvements to the EUA process based on this experience, and areas that should be addressed when moving forward.

EUAs issued during the 2009 H1N1 response included both unapproved uses of approved drugs as well as the use of an unapproved drug. "We sought to address what we perceived as a drug shortage issue," said Brad Leissa, deputy director in the Office of Counter-Terrorism and Emergency Coordination at the FDA's Center for Drug Evaluation and Research. For example, some areas of the country experienced acute shortages of Tamiflu oral suspension that were addressed by making

available expired lots of medication that had been tested through the FDA's Shelf-Life Extension Program (SLEP). These "expired" lots would usually require relabeling before use. The lots would have needed to be sent to a relabeler, then back to the SNS for redistribution to the states. "If the public health authority wanted to [relabel], they have the authority under the EUA to do that. If they chose not to, they did not have to," Leissa explained.

The prescribing guidelines for Tamiflu were expanded to include children under a year old and patients who had been symptomatic for more than 2 days or who were sick enough to be hospitalized (FDA, 2010a). These uses were beyond the usual guidelines, but were determined to be necessary for the most people to receive the best care possible. The guidelines for the use of Relenza were also expanded to include patients who were symptomatic for more than 2 days or who were hospitalized, and certain "expired" lots were tested and authorized for use (FDA, 2010a).

The response to 2009 H1N1 also marked the first time that an EUA has covered an unapproved product—peramivir (FDA, 2010b). Peramivir IV is not approved by the FDA for any indication. "Here we had an unmet medical need," Leissa recalled. There was no approved IV antiviral product that was effective against this virus. In generating the EUA, the FDA put together a 40-page fact sheet that attempted to include the best information available for practitioners, covering what was known of the risks and benefits of the investigational product as well as what was unknown.

The FDA and the CDC put the approved EUAs on their websites for public view, making them easily accessible and completely transparent.[4] Susan Gorman, associate director for science at the SNS, noted it was the first time "we have had such a multifaceted, extensive communication campaign."

Gorman also noted that the EUA system was flexible enough to enable various amendments to existing EUAs that were needed during the 2009 H1N1 response to allow the use of expired assets that had been tested through SLEP.

[4]Since the termination of the EUAs issued for H1N1, the CDC has removed them from its website. Likewise, the FDA has also updated its website to reflect the termination.

Challenges and Areas for Further Work

The 2009 H1N1 response also made clear a number of challenges, gaps, and barriers associated with EUAs, participants noted during the workshop. Over the course of the workshop, participants highlighted some of these challenges and discussed directions for further work. While by no means a comprehensive review, some of the more pressing concerns and needs are described below.

Communication About EUAs

Workshop participants noted that despite efforts by the FDA and the CDC to post EUAs and associated information on their websites, many providers, public health officials, their legal counsels, and members of the public continued to have questions about EUAs in general, and about the specific EUAs issued in response to 2009 H1N1.

The FDA attempted to clarify what the EUAs covered and what they did not by revisiting the questions and answers it published. In an effort to make the process as transparent as possible, Sherman said, the emergency declarations behind the EUAs, which are handled by her office, should be posted in a more timely manner. "Lawyers are a lot happier if they can see every step in the process," she noted.

Some providers and members of the public were also confused about why an EUA was needed in certain cases and what impact, if any, the EUA had on other regulations, standards, and usual procedures. For example, the release of an EUA for N95 respirators caused some confusion. "As people in occupations were having their respirators fit-tested, and they were using them on a regular basis, they did not understand why now an EUA would be needed for those things," Gorman explained. Some personnel thought the EUA meant that the respirator-protection standard no longer applied, and the work that employees were doing was no longer protected by Occupational Safety and Health Administration (OSHA) standards. The question became, Did the EUA supersede OSHA's fit-testing requirements for occupations that required these respirators? To clarify matters, the EUA was quickly amended to include the following text: "For the purposes of this letter of authorization, the term 'general public' is broad and includes people performing work-related duties. This authorization affects only requirements applicable under the *Federal Food, Drug and Cosmetic Act*. If respirators are used

for people performing work-related duties, employers must comply with the OSHA Respiratory Protection Standard, 29 CFR 1920.134, found at www.osha.gov." That such clarification was needed illustrates the importance of communicating with a wide range of stakeholders during the EUA process.

Providers also need to be better educated about what each new EUA means because it may affect their liability. Gloria Addo-Ayensu, health director of the Fairfax County Health Department in Virginia, suggested that information given to providers be put into simple bullet points, so that when patients ask about the risk associated with the medication that is being prescribed, the physician has a quick and easy reference. She noted, "Patients often ask their providers what the risk of using the drugs are and so on, and many practitioners don't have any idea, which in itself is a liability issue."

Fact Sheets and Documentation

The need to create millions of fact sheets that explain to patients what medication they are taking, how to take it, and what side effects may occur, along with documentation tracking medical countermeasures dispensing, is a major challenge for emergency planners and responders. This problem is exacerbated for countermeasures that are used under an EUA because, as discussed earlier, the EUA cannot be issued prior to the declaration of the emergency. Because of this, the conditions of authorization for that EUA are not known in advance, and these conditions specify the information that must be provided to healthcare practitioners, authorized dispensers, and recipients, as well as requirements for recordkeeping and data collection. Therefore, it is impossible to fully produce fact sheets and recordkeeping documentation before the emergency and issuance of the EUA.

Kevin Sell, pharmacist consultant to the Minnesota Department of Health's Office of Emergency Preparedness, illustrated that point using the example of the state of Minnesota. "We are only 1.7 percent of the population in the United States, yet we still potentially have to generate up to 5 million forms in dozens of languages. At a minimum, in our metro area alone, we would have to generate [forms in] at least five different languages beyond English." He went on to say, "Patient information, drug information: We can't wait until game day. We need to have

that stuff up front. We simply can't plan in a vacuum. I can't magically generate 5 million forms for a small state."

Many states have already spent significant time, money, and staff resources working on documentation such as screening forms for their emergency preparedness and response plans. But those forms may not be exactly what are required under an EUA. As Sell explained, "We spent years; resources; talent; toil; emotion; bickering; painful, painful, painful hours . . . tens of thousands of hours nationwide developing screening forms at an individual, state level, and now we are being told 'not so fast.' You are going to have to wait. You are going to have to wait for those to become available."

At the workshop, participants discussed potential ways to address this challenge. In some cases, creating templates might make sense, such as in the case of treatment for anthrax. "If the plan is to do a 10-day regimen of meds and then go back and get a 60-day regimen of meds," said Gretchen Michael, communications director for ASPR/HHS, "why can't the basic fact sheets be created as a template? Don't print it anywhere. Just keep it in the computer. Start translating. There is certain information about taking a pill or doing it whether in a language or in pictures that is going to be factually correct no matter what the situation is." The pre-EUA process available through the FDA could be helpful here, because the FDA could use this process to begin to consider possible scenarios, what medical countermeasures could be needed, and what accompanying fact sheets they are likely to require if an EUA were to be issued. But even if fact sheets could be prepared and translated in advance, if printing had to wait until the EUA was issued in order to confirm the contents, it would still be very difficult to produce the documentation without using up a significant portion of the 48-hour timeframe for anthrax prophylaxis.

Late in 2008, in an effort to standardize and streamline fact sheet production, the SNS committed to leading a project to create fact sheets to replace the ones the states had done, including handling the expense of translating them into multiple languages. The fact sheets would be made available in an electronic form, so that states could print what was needed in a timely manner. Burel said, "We have had this discussion with [the] FDA. [The] FDA understands the need and they are supportive of doing that." Unfortunately, due to the 2009 H1N1 pandemic, those meetings were suspended, but Burel stated, "We do know we owe that to the states and we will get that out to the states as soon as possible."

Shelf-Life Extension Program

SLEP allows the FDA, after extensive safety and potency testing, to extend the shelf life of expired drugs, allowing them to be used instead of discarded. During the response to 2009 H1N1, many lots of drugs such as Tamiflu went through SLEP and became available for distribution. But a number of questions arose about drugs that have gone through SLEP.

Some clinicians and members of the public have reservations about products that have expired dates on them. "Even though you can point back to the website that shows what lots have been tested," Gorman said, "The fact that you are getting a bottle with a date that looks like it is expired is still a problem for some people." Questions are being directed at the FDA about what kinds of testing are being done to ensure the quality of these drugs. Leissa explained, "We need to provide more information up at our website to assure people what kind of testing and what rigor of data we have about the quality of products. That is something that we are working to address."

Labeling

According to Gorman, current legal interpretation of the PREP Act coverage requires EUAs for reasons that have nothing to do with whether a drug is FDA approved for the emergency at hand, but often for simple labeling issues. For example, many medications stored in the SNS have "for SNS use only" on the label. This "SNS use only" notation was not part of the NDA, so it is a labeling deviation. This also applies to items that have gone through SLEP and are extended with a new expiration date, but not relabeled. Additionally, Gorman noted, "Things that have been in storage conditions that may have exceeded label temperature ranges are not part of the approved new drug application. For all these reasons, which would technically apply to every asset in the SNS that has undergone shelf-life extension [or] has 'SNS use only' on the label, we would require an EUA for everything." She went on to note, "That is going to hinder [our ability] to deploy [materials] in a timely manner. . . . We need a better mechanism to be able to use these products that are going to have labeling changes."

EUAs and State Dispensing Laws

Complicating the EUA process, each state may have its own unique requirements for dispensing medications—especially concerning what information must be included on the label. Because of these requirements, many questions have been raised about whether the EUA would supersede the state dispensing law or if state law trumps the EUA. Gorman reported that this issue is being addressed, and no clear guidelines have been provided yet.

Data Collection and Research

The use of unapproved medications and devices under an EUA presents a potential opportunity to collect data on their use and results in clinical settings. However, participants noted that collecting and analyzing data under these circumstances is likely to be very challenging. For example, with peramivir, which was being dispensed under an EUA at the time of the workshop, the letter of authorization included a mechanism to try to obtain the best safety information possible. However, this is not a simple issue: As Leissa said, "These are very sick populations. Many of the patients that are receiving the drug are getting it when they are already near death . . . so being able to learn anything from that is difficult." Additionally, Leissa noted that administering these drugs in an emergency situation is nothing like the randomized, controlled clinical trials that are necessary to evaluate safety and efficacy, making data analysis difficult.

Participants also noted that there is a great need for policy research on the use of EUAs themselves. Leissa asked, "Are we doing *good* things with Emergency Use Authorization?"

Streamlining and Standardizing the EUA Process

Workshop participants acknowledged that, as people have gained more experience with EUAs, the process has become smoother. It is known now what information needs to be provided to the FDA, and the lines of communication are more open. Furthermore, others beyond the provider community are gaining experience with EUAs. "The FDA's experience with EUAs is also something that has risen dramatically with

the H1N1 situation," noted Aubrey Miller of the FDA's Office of Counterterrorism and Emerging Threats. "Obviously we have been on a learning curve along with everyone else, and one of our main objectives as this begins to slow down is to actually look at the EUA guidance and reevaluate how to make it a better process and [have] more uniformity with respect to it."

Beyond EUAs

Several workshop participants emphasized that although EUAs facilitate getting appropriate materials where they are needed in a timely fashion, they are not the ideal end solution. As Minson said, "The idea here is not to have an interminable number of EUAs that are being kicked out, but ultimately to say at some point that this is a 'patch.' This gets us to where we might want to be on a permanent footing."

Many workshop participants questioned whether EUAs are currently required for too wide a range of medical countermeasures dispensing situations. Because many of the current EUAs were written to address labeling changes or storage conditions of assets in the SNS, some participants wondered if there was another way to provide PREP Act coverage rather than generating EUAs for everything in the stockpile. Gorman wondered, "Do we need a reinterpretation or an amendment of the PREP Act to include coverage of all those things so they don't need to be a separate EUA for every countermeasure in the SNS?"

Gerald Parker of HHS also raised the question, "Should we engage in a policy discussion about a new legal definition of an approved product that is somewhere between what we consider an EUA today and an approved product today, somewhere in the middle?" This would be a product approved only for an emergency low probability, but extremely high consequence, event. Workshop participants also discussed the potential for an FDA-approved product list for high-risk threats, such as anthrax.

"As much as we are trying to move toward better processes, better situations, working with our state partners to identify what the limitations are and effect changes to those limitations where we can, you are very limited with an EUA," Maher noted. "The ideal situation is having a marketed product for that emergency use. EUA is not the answer."

Summary

Many workshop participants agreed that EUAs are an important tool in helping to protect public health. "It is clearly better than not having the drugs available and certainly better than investigation of a new drug requirement," Blumenstock said. "The key here is how to take all these new requirements and new challenges, getting a better comfort level—a better understanding—so that we can be more effective and efficient in its administration."

Frustration has grown as people realize that EUAs are needed more often than anticipated, and they are concerned about what would happen if an event occurs before pre-EUA discussions have begun. The need to quickly become knowledgeable in the science, public health needs, and logistics during an unforeseen event will have a steep learning curve, and many fear the compromises that may occur.

Although getting approved medical countermeasures for emergency use will not erase the need for the EUA tool, it would minimize that need and allow countermeasures to be dispensed more quickly to where they are needed. "That is what everybody's goal should be: to get these products in their emergency settings to be approved," Leissa said.

THE POSTAL MODEL

The Cities Readiness Initiative (CRI) is a federally funded effort to help major U.S. cities and metropolitan areas respond effectively to large-scale bioterrorist events such as an anthrax attack (CDC, 2010a). Through the CRI program, state and large metropolitan public health departments develop plans to dispense antibiotics to the entire population of the metropolitan area within 48 hours. This is generally assumed to be the time window following an attack during which people must receive prophylactic antibiotics in order to prevent deadly inhalational anthrax. The CRI project began in 2004, and 72 cities and metropolitan areas are currently funded under the program, with at least one in each state.

The U.S. Postal Service (USPS) is working with select CRI cities to develop dispensing plans in which postal carriers who volunteer to participate in the program will deliver antibiotics to residences in certain zip codes. This model builds on the existing capability of the USPS to service every residential address in the country. The postal model is intended to increase the speed of medical countermeasures dispensing, and to supplement local capacity and as well as reduce the population surge

at points of dispensing (PODs) while they are being set up. The current intent of the model is not to replace the need for PODs. Ten million dollars were appropriated to HHS in the 2010 fiscal year to support the delivery of medical countermeasures; of this, up to 8 million dollars could be transferred to USPS. The funding was to remain available over a two-year period.

In 2006 and 2007, operational drills were conducted in Seattle, Philadelphia, and Boston. Results from these drills led to the development of a comprehensive pilot of this model in Minneapolis–St. Paul. Through extensive analysis, the Minnesota Department of Health discovered that they could not meet the 48-hour requirement by relying on more traditional mechanisms of medical countermeasures dispensing such as PODs that require the public to attend the POD to receive the countermeasure. Instead, their analysis showed that a push mechanism was required, that is, a process of actively pushing medication out to the population.

The development of the pilot program in Minneapolis–St. Paul involved collaboration among many stakeholders, including the state department of health, local public health, local and state law enforcement in Minnesota, the National Guard, HHS, the CDC, USPS, and the FDA. This section describes some of the challenges faced in developing the pilot, lessons learned, and solutions developed to address these challenges. It also highlights several areas for future work. First, however, the section briefly highlights recent developments related to the postal model.

Recent Developments

On December 30, 2009, President Obama signed an Executive Order concerning medical countermeasures following a biological attack (The White House, 2009). The order outlines what needs to be done to establish the federal government's ability to provide medical countermeasures, in a timely fashion, after a biological attack such as anthrax. To do this, it mandates the establishment of a national USPS medical countermeasures dispensing model within 180 days of the date of the Executive Order. Also included are the directives to establish what needs to be done for a federal rapid response and a corresponding concept of operations, with the development of an accompanying plan to supplement, as neces-

sary, local law enforcement personnel serving as security escorts with local federal law enforcement.

The expansion of the Postal Model for dispensing medical countermeasures has also been included in legislative proposals. In September 2009, Senator Joseph Lieberman introduced Senate bill 1649, the *WMD Prevention and Preparedness Act of 2009,* "a bill to prevent the proliferation of weapons of mass destruction, to prepare for attacks using weapons of mass destruction, and for other purposes." If passed, it would direct the HHS Secretary to expand the Postal Model pilot program. This language also appeared in a House bill, H.R. 5057, *The WMD Prevention and Preparedness Act of 2010*. However, as of the writing of this report, neither of these legislative proposals had been taken up by the Senate or House, respectively, as a whole.

These efforts to expand the postal pilot to a national scale make the logistical plans, lessons learned, and areas for future work identified by workshop participants even more important and relevant to national medical countermeasures dispensing efforts.

Logistics

In the Minneapolis–St. Paul area, there are 205,000 residences with an estimated 2.8 persons per home. That equals 575,000 persons who need to be covered within 20 zip codes. Within those zip codes, there are nine consolidated delivery units (also known as post offices or carrier annexes). The Minneapolis Postal Service determined that, by having each postal carrier who volunteers cover two normal postal routes, 179 volunteers can deliver medication to the entire 575,000 people within 8 to 9 hours. For security, one security officer would be assigned to each carrier, plus additional security for the consolidated delivery units that have been activated.

"The postal plan is not mandated for our employees; it is a volunteer program response to a wide-scale anthrax attack. From the start—from the very origin of this plan—it was recognized these had to be volunteers," said Jude Plessas, manager of the CRI Postal Plan Program. The project currently has 385 qualified volunteers in Minneapolis–St. Paul—311 carriers and 74 from management. This is 80 percent more than what is needed in terms of carriers to cover the project area.

MedKits

To successfully complete a mission of this magnitude, volunteers themselves need to have rapid access to antimicrobials and personal protective equipment so they are protected as they deliver medication to the community. Families of the volunteers should have access to antimicrobials as well so that the volunteers would know that their families were protected. "They would not have to worry about seeing those family members into a POD or clinic and then get in to effect the mission," Plessas said. In fact, the union leadership of the postal carriers and management at the USPS required, as a condition of participation in the program, that their members be provided with antibiotics in advance of an incident. "They felt they wouldn't be able to respond minuteman-like if they didn't have that stuff already in hand. The challenge then fell to the federal government to try and help in making that happen," said Minson of HHS.

In response to this concern, postal carriers who volunteer have received MedKits to keep in their homes. MedKits are medical kits containing supplies of needed prescription pharmaceuticals for use by members of the household only as directed during a declared public health emergency. In this case, the kits contain doxycycline hyclate tablets. The kits are also known as Household Antibiotic Kits (HAKs). Qualified healthcare providers, under the auspices of the public health authorities, screened and cleared the postal carriers to receive the MedKits. Postal carriers who had a contraindication for doxycycline were not permitted to volunteer to participate in the postal program.

The use of MedKits has been controversial because of concerns regarding the ability of households to properly store and maintain the kits and to reserve them for emergency use, as well as safety concerns about the self-administration of prescription medications without medical supervision. A pilot study was conducted in St. Louis to evaluate the use of MedKits in households (CDC, 2007). They were provided to approximately 4,000 households. The study looked at the ability of households to maintain MedKits in the home as directed and reserve them for emergency use, and attitudes and perceptions regarding the MedKits. Participants included corporation employees, first responders, and clients and staff of a community health clinic. At the workshop, Laura Eiklenborg, formerly deputy director of emergency preparedness for the City of Minneapolis and now director of public-sector solutions at OptumHealth, pointed to this study as an example of what has worked in the pre-event

placement of post-exposure prophylaxis. At the end of the study, 97 percent of participants were able to return their MedKits intact.

However, despite the promising results of the pilot study, others have noted that additional studies should be conducted to ensure safety and prevent misuse before the MedKit program is implemented on a wide scale (IOM, 2008). In particular, the pilot study was not able to test whether participants were able to accurately and safely prepare and use the medication by following the enclosed instructions during an actual emergency. Nor did the study test the effects of the conditions under which the MedKits were stored in participants' households. At the workshop, Erin Mullen of PhRMA's Rx Response noted that the bathroom medicine cabinet is one of the worst places to keep medications because it tends to be warm and humid.

Before MedKits could be provided to the postal carriers, however, the planners had to overcome a legal restriction. Specifically, given the materials and instructions in the volunteer kits, the FDA deemed the MedKit to constitute an off-label use, thus requiring an EUA. Following standard emergency protocol, the individual MedKits contain a 10-day regimen of doxycycline instead of the usual 60-day treatment regimen for anthrax exposure. The household kits included doxycycline and instructions for use to cover anyone in that household for 10 days—adults and children of all ages, including people with medical conditions, pregnant women; they even have preparation instructions for dysphagic adults. Because of both the 10-day regimen and the written information that would accompany the medication, the kits were identified as involving the unapproved use of an approved product, thus requiring an EUA.

Postal Model EUA

As noted above, a key feature of the postal model is that the postal carriers who volunteer are provided with MedKits to keep in their homes before an emergency occurs. This complicated the effort to obtain an EUA to cover the MedKits because an EUA can only be issued following the determination of a threat and declaration of an emergency, as discussed earlier. For all other EUAs that have been issued, the threat determination and declaration of an emergency were made after the emergency had been detected. In the case of the MedKits for the postal model, however, the Secretary of the Department of Homeland Security made the threat determination in advance of an actual event. He stated

that there is a significant potential for a domestic emergency involving a heightened risk of attack with *Bacillus anthracis* (DHS, 2008). On the basis of this threat determination, the Secretary of HHS declared an emergency justifying an EUA for the MedKit. Based on the threat determination and the emergency declaration, the FDA was able to review the request and issue the EUA. Additional details, including the conditions of authorization, can be found in the letter of authorization (FDA, 2008).

Because the EUA is dependent on the emergency declaration, the EUA is valid until the emergency is declared over. The emergency declaration justifying the EUA was renewed in 2009, and continued to be effective as of the date of the workshop.

With the EUA in place, home MedKits were packaged and provisioned to the volunteers. Supplies for the delivery units were prepositioned and fit tests for N95 masks have been completed. In addition to the 10-day MedKits for placement in their households, Plessas said that individual-dose MedKits will be provided to the volunteers so they can be activated on the day of the emergency. These have also been called individual Household Antibiotic Kits (iHAKs). "Literally, if [the postal carriers] are there in the morning, or if they are coming off the street, we can send them back out," Plessas said.

This EUA is the only EUA to have been issued before an actual event, and it was only the second EUA of any kind issued by the FDA. Therefore, those involved gained much experience and insight into the process. The lessons learned, as reported by the workshop participants, are detailed below.

Lessons Learned During the EUA Process

Negotiations and discussions about the EUA request were drawn out because, as Plessas explained, "The urgency of [an] attack already suffered didn't exist." Throughout the process, several issues came to light:

1. End-user needs: Targeted end-users should brief the FDA directly on issues such as operational response requirements, Plessas said. In the case of the postal model, many operational considerations needed to be addressed because volunteers were going to act as medical countermeasures responders. For example, the plan needed to address what happens if someone has the day off. Everything needs to be properly understood for the EUA

to effectively and efficiently support the end-users in their mission. Plessas noted that direct dialog with the FDA might have helped smooth things along during the process.

2. Forms: There was a huge disconnect between state and federal authorities about what basic forms, such as anthrax screening forms and patient information sheets, needed to look like. "Keep in mind that by this time in history, the states had spent at least 6 years developing their own screening form for things like anthrax; we already had those tools in place," said Sell of the Minnesota Department of Health. "And then I was given a federal form that didn't jibe with, for instance, our state epidemiologist, who has to sign off on these kinds of things." Negotiating these types of differences was time consuming and difficult, especially because there was little clarity on what could be changed and what could not. The people who needed to be at the table discussing these issues weren't present at the beginning, meaning that these issues had to be worked out late in the process.
3. Roles and responsibilities: Roles and responsibilities need to be explicitly articulated in the EUA request, or amendments may be necessary after the EUA is released, Plessas said. This occurred with the postal EUA. After the EUA was released in October 2008, amendments were made that went into effect in February 2009. Two additional minor changes were being pursued as of the date of the workshop.
4. Communication: Specific to the postal EUA, an HHS press release went out to the general public about the program before the volunteers had received the final word from postal management. This resulted in some internal consternation. The take-home lesson is that internal partners and stakeholders should be kept up to date before anything is released to the public.
5. Medication expiration dates and annual renewal requirements: As currently stated in the EUA, MedKits have an annual expiration date, with an annual renewal process in place. Eiklenborg noted that it requires significant effort from both USPS and public health authorities to manage the logistics related to the expiration of drugs, redispensing medications, and rescreening volunteers.

Security and Workforce Protection

The Postal Model relies heavily on law enforcement to protect the USPS workers and the stockpile. The postal carriers who volunteer need to feel safe to complete their mission, and the delivery units (post offices and delivery annexes) need to be secure areas for the medications to be processed for delivery.

In developing the pilot, the Minneapolis Department of Health determined what was needed to complete the plan, and then presented the findings and the mission to the local and state law enforcement agencies in the area to seek their collaboration. They began by determining what the law enforcement requirements would be for the postal model, compared with what would be needed to provide security for a plan that was based solely on PODs. It became clear quickly that, while the demand on local law enforcement in the first 12–24 hours of the postal model is slightly higher, demand remained much more intensive with the PODs, requiring multiple shifts over multiple days. "It became readily apparent to the law enforcement partners that the postal model actually provides the best opportunity for the optimization of law enforcement use in getting meds into people's mouths," Plessas said. Nevertheless, the law enforcement requirement—one law enforcement officer to accompany each postal carrier—continues to be considered one of the more challenging aspects of the postal model.

Despite these concerns, by taking advantage of existing memorandums of understanding among the Minneapolis Police Department, the St. Paul Police Department, and the Minnesota State Patrol, there are now commitments well in excess of what is actually needed to execute the postal model as it currently stands.

It is important to note that the postal EUA is specific to postal employees, so it does not cover the law enforcement partners. Therefore, these partners are not able to have MedKits pre-positioned in their homes. Instead, Plessas explained, "They have a cache program for prophylaxis whereby there is a cache dedicated for emergency responders within the Twin City areas." Programs to supply emergency responders with protective equipment such as N95 respirators are also in place within the different departments.

Although much of the workshop discussion focused on the security requirements of the postal model, FedEx's Mugno also emphasized that security is a concern throughout the countermeasures dispensing system. He mentioned an example of a hospital emergency department being

overrun in Memphis when 2009 H1N1 vaccine was first available. "Security is definitely still an issue and [it] needs to be resolved and talked about a lot more," he said.

Areas for Future Work

Workshop participants discussed areas for future work arising from the issues seen in the Minneapolis–St. Paul pilot of the Postal Model for dispensing medical countermeasures. The key areas were an EUA to cover first responders, as well as issues surrounding expiration dates and which medications are included in the model.

EUA for First Responders

Workshop participants discussed the idea of creating an EUA for first responders that would be similar to the one for the USPS postal carriers who volunteered to participate in the countermeasures delivery plan. This would enable the law enforcement officers who accompany the postal carriers on their routes to also have MedKits in their homes. Several workshop participants noted that these law enforcement officers would have the same safety concerns for themselves and their families as the postal carriers who have been provided with MedKits. Providing MedKits only to the postal carrier could raise questions of equity. Furthermore, because the model calls for each postal carrier to be accompanied by a law enforcement officer, these first responders must be available to begin the dispensing route as quickly as possible. However, there are a number of challenges associated with developing such as EUA, including lack of familiarity with EUAs and the complexity of the first-responder community.

Tim Conley, director of preparedness and planning for the Village of Western Springs Department of Fire/EMS Services and Emergency Management in Illinois noted that most first responders have never heard of EUAs. "In general there is a huge lack of understanding and training in the first responder community when it comes to public health. They do not know what they are facing," he said. "We would run into a fire, point, go. They will go. They will chase the bad guys down the street, getting shot at. They will run at them, they will go. [But] they do not understand a biological event."

The second, more difficult challenge is that the first responder community has a very complex structure that varies across jurisdictions. Even within one metropolitan area, there are multiple law enforcement agencies operating. By contrast, the USPS is one federal entity—a postal carrier in one city has the same paycheck, reporting structure, mandate, job responsibilities, and even uniform as a postal carrier in another city. In fact, the postal model and its associated EUA are not specific to Minneapolis–St. Paul, but can be applied to any CRI location where the participating public health authority is willing to take on the roles and responsibilities spelled out in the postal model and the EUA. In order to have an EUA for first responders, there would need to be some type of umbrella structure that can create the ability for the fragmented community of first responders to act together.

As Minson explained, "EUA requires [that] you have some element of medical direction, an accountable measure, a reporting structure and ultimately the ability to recoup the kits if the EUA comes to determine this. When you start to talk about the very complex interplay with emergency service districts and EMS and fire departments and shared personnel . . . it begins to look like you really want to get . . . not so much an EUA, but an approved kit if that is where you are going to go."

Although EUAs are extremely helpful, Plessas said, "EUA is not the desired end-state. It exists to bridge to some kind of FDA-endorsed MedKit. At some point we need them move out what's an emergency use—recognize that this threat continues to exist and move toward being able to have a MedKit available." He suggested that a future MedKit could go beyond just treating for anthrax, perhaps expanding to include materials that could be deployed for multiple threats.

Mullen of PhRMA and Rothholz of the American Pharmacists Association also noted that restricting MedKits to first responders (as well as postal carriers) may raise issues of equity. They noted that many other people may be considered "essential personnel" and provide critical services during an emergency. Rothholz noted that if pharmacists are not available to handle their regular patient needs, then the healthcare system may become overloaded. Mullen said many companies had told her that all of their personnel are essential to their operations, and they were not willing to categorize their employees in this way. When asked whether she advocated that everyone receive a MedKit, Mullen replied that it should at least be considered.

Expiration and Annual Renewal Process

Workshop participants discussed various issues surrounding drug expiration and the annual renewal process, in order to avoid having to collect MedKits annually from each household and reissue new ones. Suggestions ranged from stocking medications with longer expiration dates to including more shelf-life potency testing and data collection in the drug development process. In fact, Gorman stated that stability and potency testing for a 10-year period has already been added to some of the new contracts for products that are not yet FDA approved, in order to avoid going through the Shelf-Life Extension Program. Mullen reminded participants that regardless of the conditions of the EUA, many state dispensing laws are stricter than federal laws, and most limit prescriptions to one year, thus necessitating annual renewal.

Choice of Medication

Workshop participants brought up the fact that the Postal EUA only covers the placement of doxycycline, while Ciprofloxacin is also indicated in the clinical guidelines for the prophylaxis and treatment of inhalational anthrax. The SNS and local caches include both drugs. Eiklenborg noted, "First responders and mission-critical personnel outside of the postal workers will actually have access to either indicated antibiotic, Cipro or doxy." She noted that while 98 percent of the population is indicated for doxycycline, "The discrepancy between the available types of antibiotics for postal really is inconsistent and it is confusing."

Workshop participants noted that, during the anthrax attacks in 2001, people in certain areas were given doxycycline, and people in other areas were given Ciprofloxacin. Even though both are indicated for the treatment of anthrax, Ciprofloxacin costs more than doxycycline, and was therefore perceived as better. Regarding the postal model, there has been no pushback on the use of the cheaper doxycycline because the postal workers are volunteers who were told at the onset that doxycycline would be used, and to qualify for the program, they could not be contraindicated for doxycycline.

CONCLUSION

Since the anthrax attack in 2001, many new plans, programs, and tools have been developed to enable rapid and effective medical countermeasures dispensing, including EUA, the PREP Act, Project BioShield, the Cities Readiness Initiative, and a pilot of the Postal Model. These activities have been directed toward countermeasures distribution and dispensing for public health emergencies such as a rapidly emerging anthrax attack or widespread influenza pandemic.

The response to 2009 H1N1 provided many workshop participants and their respective organizations with extensive practical experience; insight into how tools, legislation, and plans function during an actual response; and the opportunity to refine procedures and develop stronger partnerships among stakeholders. In particular, participants described two public–private partnerships that significantly enhanced the effectiveness and efficiency of the countermeasures dispensing system: one project improved situational awareness of the supply chain and the other enabled pharmacies and pharmacists to administer 2009 H1N1 vaccine. At the same time, participants noted several areas where additional discussions and work could further enhance these partnerships, including issues related to payment, communication, documentation and data collection, working with multiple jurisdictions, and liability.

Among the developments that occurred during the 2009 H1N1 response was the issuance of an unprecedented number of EUAs that allowed the use of approved countermeasures for unapproved uses, and in one case, the use of a medication that has not yet been approved by the FDA for any use. Workshop participants discussed how this provided stakeholders with much greater experience and understanding of the process involved in issuing EUAs, and also resulted in improvements to these processes. Nevertheless, participants identified a number of areas in which further work would be beneficial, including education and communication about EUAs, fact sheets and documentation, SLEP, labeling, EUAs and state dispensing laws, data collection, and streamlining and standardizing the EUA process. Several participants emphasized that although EUA is an important tool for disaster response, it is not always the ideal end solution, particularly for high-risk scenarios in which countermeasures already exist and the response needs can be anticipated. They said that the end goal for these kinds of countermeasures should be an approved product. Over the course of the workshop, participants also

discussed other potential solutions that could help move beyond reliance on large numbers of EUAs during disaster responses.

Despite the progress made during the 2009 H1N1 response, many workshop participants noted that the next public health threat may be even more challenging. The next threat could be more lethal and fast moving; there may not be any approved medications to treat or contain the problem; legal concerns could prevent healthcare provider and private-sector organizations from fully supporting response efforts; and communication gaps could lead to public confusion and suppress acceptance of the medical countermeasure.

The Cities Readiness Initiative, including the recent pilot of the Postal Model, is designed to specifically address a fast-moving threat that requires countermeasures dispensing within a short period of time. Workshop participants involved in the pilot in Minneapolis–St. Paul described the features of this program, outlined the challenges they had faced in developing and implementing it, and shared the solutions they had found to address these challenges. These insights should be particularly useful as the pilot is extended into a national model, as required by President Obama's Executive Order. Participants also mentioned several areas for future work, including an EUA to allow first responders to have MedKits in their homes and issues about expiration and the annual renewal process.

Overall, a recurring theme of the workshop was that much progress has been made in the area of medical countermeasures dispensing, but much work remains to protect the health of the public in the face of biological, chemical, radiological, and nuclear threats.

A

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B

Workshop Agenda

November 18, 2009
The Keck Center of The National Academies
500 Fifth Street, NW
Washington, DC 20001

Workshop Objectives:
Building on the recent progress in countermeasure delivery and dispensing strategies, the objectives of this workshop are to:

- Provide an overview of the current threats, progress made, and remaining vulnerabilities in the public health system as it pertains to the dispensing of medical countermeasures;
- Discuss policy implications of emergency use authorization (EUA) and strategies to limit potential logistical challenges that could delay the delivery and dispensing of medical counter-measures; and
- Discuss outstanding issues related to EUAs and how these issues are impacting the nation's preparedness and response capabilities.

Welcome and Introductions

LEWIS GOLDFRANK, *Forum Chair*
Professor and Chair
Department of Emergency Medicine
New York University School of Medicine

Charge to Workshop Speakers and Participants

GREGORY BUREL, *Workshop Co-Chair*
Director
Strategic National Stockpile
Coordinating Office for Terrorism Preparedness and Emergency Response
Centers for Disease Control and Prevention

SCOTT MUGNO, *Workshop Co-Chair*
Managing Director
Corporate Safety, Health, and Fire Protection
FedEx Express

SESSION I: OVERVIEW AND NEW POLICIES TO IMPROVE MEDICAL COUNTERMEASURE DISPENSING

Session Objective: Provide an overview of the current threats, progress made, and remaining vulnerabilities in the public health system as it pertains to the dispensing of medical countermeasures, including both antibiotics and antivirals.

GREGORY BUREL, *Session Chair and Workshop Co-Chair*
Director
Strategic National Stockpile
Coordinating Office for Terrorism Preparedness and Emergency Response
Centers for Disease Control and Prevention

Federal Policy Developments Related to Countermeasure Dispensing

MATTHEW MINSON
Senior Medical Officer for Strategic Initiatives
Office of the Assistant Secretary for Preparedness and Response
Department of Health and Human Services

State and Local Opportunities and Challenges

JAMES BLUMENSTOCK
Chief Program Officer for Public Health Practice
Association of State and Territorial Health Officials

JACK HERRMANN
Senior Advisor
Public Health Preparedness
National Association of County and City Health Officials

Dispensing Antibiotic Countermeasures: Progress, Opportunities, and Challenges: Moving Forward from the PREP Act

BROOKE COURTNEY
Associate
Center for Biosecurity of UPMC

Dispensing Antiviral Countermeasures: Progress, Opportunities, and Challenges from the Local Response to H1N1

GREGORY BUREL
Director
Strategic National Stockpile
Coordinating Office for Terrorism Preparedness and Emergency Response
Centers for Disease Control and Prevention

A Systems View of POD Operations: Integrating All the Elements

EVA LEE
Director, Center for Operations Research in Medicine and HealthCare
Associate Professor, School of Industrial and Systems Engineering
Georgia Institute of Technology

Discussion with Panelists and Attendees

- How have previous policy decisions prepared the nation for the H1N1 response?
- What are the lessons learned from the H1N1 response to date?
- Do any specific areas require additional attention as we move forward in responding to the next influenza wave or preparing for other biological threats?
    - What were some of the differences between state and local MCM allocation plans, and how did these impact the overall effectiveness of their plans?
- What are some key differences between antibiotic and antiviral dispensing plans, and how should these impact future policy discussions?

SESSION II: EMERGENCY USE AUTHORIZATION: STRATEGIES TO LIMIT POTENTIAL LOGISTICAL CHALLENGES

Session Objective: Explore the impact of EUA and strategies to limit potential logistical challenges that could delay the delivery and dispensing of medical countermeasures.

Understanding the EUA Process: Authorization for Medical Products for a Catastrophic Health Event

CDR CARMEN MAHER
Policy Analyst
Office of Counterterrorism and Emerging Threats
Food and Drug Administration

Panel Discussion: Lessons Learned from Recent EUA Signings: H1N1 and the Minneapolis Postal Plan

SUSAN GORMAN, *Panel Chair*
Associate Director for Science
Division of Strategic National Stockpile
Coordinating Office for Terrorism Preparedness and Emergency Response
Centers for Disease Control and Prevention

SUSAN SHERMAN
Senior Attorney
Office of the General Counsel
Department of Health and Human Services

KEVIN SELL
Pharmacist Consultant
Office of Emergency Preparedness
Minnesota Department of Health and
Minnesota Poison Control System

JUDE PLESSAS
Operations Specialist
United States Postal Service

BRAD LEISSA
Deputy Director
Office of Counter-Terrorism and Emergency Coordination
Center for Drug Evaluation and Research
Food and Drug Administration

Discussion with Panelists and Attendees

- What is the "update from the field?"
  - Have any previously identified impediments been successfully addressed during the recent activity related to H1N1?
  - Have any glaring new problems emerged?
- What remaining impediments related to EUA continue to delay the dispensing of medical countermeasures?
- What strategies or mechanisms can be used to address these impediments, and how can they be implemented?
- What potential solutions should be highlighted?

Panel Discussion: Pre-EUA Issues Related to Communication Strategies

AGGIE LEITHEISER, *Panel Chair*
Director of Emergency Preparedness
Minnesota Department of Health

GRETCHEN MICHAEL
Communications Director
Office of the Assistant Secretary for Preparedness and Response
Department of Health and Human Services

LAURA ROSS
Health Communication Specialist
Division of Strategic National Stockpile
Centers for Disease Control and Prevention

PAMELA BLACKWELL
Director
Center for Emergency Preparedness & Response
Cobb & Douglas Public Health

Discussion with Panelists and Attendees

- What can be done during the pre-EUA process to account for the logistical challenges associated with printing information and disseminating it to the public in a timely manner?
- How can EUAs be modified during an event to facilitate timely communication?
- How can Web 2.0 technologies be leveraged to alleviate challenges related to disseminating information to the public in a timely manner?
- How do we prepare for issues such as producing materials in multiple languages or for people with low literacy?
- How do we deal with guidance that may change every day, as was the case with H1N1?

Panel Discussion: Workforce Protection

KATHRYN BRINSFIELD, *Panel Chair*
Associate Chief Medical Officer
Office of Component Services
Office of Health Affairs
Department of Homeland Security

TIM STEPHENS
Public Health Advisor
National Sheriffs' Association

LAURA EIKLENBORG
Director
Solutions Development
OptumHealth Public Sector

TIMOTHY CONLEY
Director
Preparedness and Planning
Department of Fire/EMS Services and Emergency Management
Village of Western Springs, IL

Discussion with Panelists and Attendees

- How should priorities be set and what are the best mechanisms to ensure that workers get the protection they need?
- How can we effectively communicate with workers prior to an emergency?
- What operational issues need to be considered to ensure that the workforce is protected?
- What are the respective responsibilities of public and private stakeholders, and how should they function together?

SESSION III: GENERAL DISCUSSION WITH WORKSHOP PARTICIPANTS AND ATTENDEES

Session Objective: Discuss opportunities and constraints identified during the workshop. What new ideas have surfaced in this meeting today that should be explored further? What issues remain related to EUAs and their impact on the nation's preparedness and response, and how should these issues be addressed?

Panel Discussion: Remaining Areas That Require Attention (e.g., workforce, liability, security, logistics, communications)

SCOTT MUGNO, *Session Chair and Workshop Co-Chair*
Managing Director
Corporate Safety, Health, and Fire Protection
FedEx Express

GLORIA ADDO-AYENSU
Health Director
Fairfax County Health Department, Virginia

ATKINSON (JACK) LONGMIRE
Medical Officer
Office of Occupational Medicine
Occupational Safety and Health Administration

MITCHEL ROTHHOLZ
Chief of Staff
American Pharmacists Association

DARRELL KLEIN
Assistant Agency Counsel
Nebraska Department of Health and Human Services

Discussion with Panelists and Attendees

- What other issues related to EUA have not yet been discussed during the workshop, for example, issues regarding liability, security, and logistics?
- What strategies, mechanisms, or solutions can be used to address these issues, and how can they be implemented?

Closing Remarks

GREGORY BUREL, *Workshop Co-Chair*
Director
Strategic National Stockpile
Coordinating Office for Terrorism Preparedness and Emergency Response
Centers for Disease Control and Prevention

SCOTT MUGNO, *Workshop Co-Chair*
Managing Director
Corporate Safety, Health, and Fire Protection
FedEx Express

C

Biographical Sketches of Invited Speakers and Panelists and Workshop Planning Committee Members

INVITED SPEAKERS AND PANELISTS

Greg Burel (*Workshop Co-Chair*), is director of the Division of Strategic National Stockpile (DSNS) at the Centers for Disease Control and Prevention (CDC). Prior to joining CDC, Mr. Burel spent 6 years at Federal Emergency Management Agency (FEMA) Region IV, where he served as director of the Administration and Resource Planning Division. He oversaw the activities of two branches responsible for all administrative, personnel, financial, acquisition, communications, information technology, facilities, and disaster logistics operations. He worked in numerous declared disasters and emergencies as logistics chief and Regional Operations Center director. He was responsible for all disaster logistics responses and plans in the Southeastern United States. He evaluated disaster operations and was a member of the FEMA Logistics Advisory Group. Since joining CDC in 2005, Mr. Burel has been responsible for a number of critical, agency-wide efforts, including coordinating the Public Health Integrated Business Services High Performing Organization, chairing the Epidemiology and Laboratory Branch-sponsored Hiring Workgroup, and chairing the Management Council Contracting Strategy Committee. Mr. Burel holds a B.B.A. from Georgia State University. He is a graduate of the Federal Executive Institute's Leadership for a Democratic Society and has completed numerous courses in process improvement, contracting, finance, and incident command.

Scott A. Mugno, J.D. (*Workshop Co-Chair*), is the managing director for FedEx Express Corporate Safety, Health, and Fire Protection. Mr.

Mugno and his department of more than 100 employees develop, promote, and facilitate the safety and health program and culture for all non-flight FedEx Express domestic operations. His department also provides technical support to the FedEx Express international operations and other FedEx operating companies. Mr. Mugno has been in the environmental, health, safety, or transportation arenas for 20 years. He joined FedEx Express as a senior attorney in the Legal and Regulatory Affairs Department before accepting his current position. Prior to FedEx, Mr. Mugno was division counsel at Westinghouse Electric Corporation's Waste Isolation Division and deputy staff judge advocate for the Eastern Region U.S. Army Military Traffic Management command. He has held other legal positions in the Army JAG Corps and in private-practice law firms. Mr. Mugno regularly represents FedEx at various trade and safety association and committee meetings and is a frequent speaker before those and other groups.

Gloria Addo-Ayensu, M.D., M.P.H., is director of health for Fairfax County Health Department, VA. She provides overall direction for public health programs in the county, including emergency preparedness. She has led Fairfax County's comprehensive pandemic influenza preparedness efforts and engaged a wide range of community stakeholders in the process. As past chair of the Metropolitan Washington Council of Governments Health Officials Committee, she facilitated initial coordination of the National Capital Region's pandemic planning in 2006. Dr. Addo-Ayensu is interested in international health and has served as a consultant to research and public health programs in Ghana. Dr. Addo-Ayensu received her medical degree from Tulane University School of Medicine. Following her residency training in preventive medicine from the Loma Linda University Medical Center, she spent two years with the Loma Linda University Preventive Medicine Faculty Group before joining the Fairfax County Health Department in 1999.

Pamela Blackwell, R.N., is the director of the Center for Emergency Preparedness & Response for Cobb & Douglas Public Health in Georgia. Ms. Blackwell has 35 years of experience in emergency medicine and trauma care and served as the state trauma director for Georgia's Office of Emergency Medical Services. The Center for Emergency Preparedness & Response supports the "all-hazards" approach to planning and response and recognizes the current emphasis on threats from biological, chemical, nuclear, radiological, and pandemic influenza incidents.

James Blumenstock, M.A., is chief program officer for public health practice for the Association of State and Territorial Health Officials (ASTHO). His portfolio includes the state public health practice program areas of infectious and emerging diseases, immunization, environmental health, and public health preparedness and security, including pandemic influenza preparedness. Mr. Blumenstock also serves as a member of the ASTHO's Executive Management Team responsible for enterprise-wide strategic planning, administrative services, member support, and public health advocacy. Before joining ASTHO in 2005, Mr. Blumenstock was the deputy commissioner of health for the New Jersey Department of Health and Senior Services, where he retired after nearly 32 years of career public health service. In this capacity, he had executive oversight responsibilities for a department branch of more than 650 staff and an operating budget of approximately $125 million. He oversaw the Division of Public Health and Environmental Laboratories; Division of Epidemiology, Occupational and Environmental Health; Division of Local Health Practice and Regional Systems Development; Division of Health Emergency Preparedness and Response; and Office of Animal Welfare. During his tenure, Mr. Blumenstock also represented the department on a number of boards, councils, and commissions, including the New Jersey Domestic Security Preparedness Task Force. Mr. Blumenstock is the recipient of the ASTHO 2004 Noble J. Swearingen Award for excellence in public health administration and the Dennis J. Sullivan Award, the highest honor bestowed by the New Jersey Public Health Association for dedicated and outstanding service and contribution to the cause of public health. He is also a Year 14 Scholar of the Public Health Leadership Institute and held an elected office in his community for 12 years. He received his B.S. in Environmental Science from Rutgers University and his M.A. in Health Sciences Administration from Jersey City State College.

Kathryn Brinsfield, **M.D., M.P.H., FACEP,** is the associate chief medical officer for Component Services in the U.S. Department of Homeland Security Office of Health Affairs (DHS/OHA). She joined DHS/OHA in 2008 to serve as operational and medical support medical director. Dr. Brinsfield was an associate professor of Boston University's Schools of Medicine and Public Health, with 13 years of experience as an attending physician at Boston City Hospital/Boston Medical Center. She has held medical director/associate medical director positions in various organizations, including Boston Emergency Services, Boston

Homeland Security, and Boston Public Health Preparedness. She chaired the American College of Emergency Physicians' Disaster Committee; cochaired the Massachusetts State Surge Committee; helped to create the Massachusetts Alternate Standards of Care Committee; and was commander of the Massachusetts-1 Disaster Medical Assistance Team. In addition, she was a supervisory medical officer for the International Medical and Surgical Response Team, which responded to the September 11, 2001, attacks. Dr. Brinsfield graduated with honors from Brown University, and received her M.D. from Tufts School of Medicine and her M.P.H. from Boston University. She completed her residency in Emergency Medicine at Cook County Hospital in Chicago, and her emergency medical services (EMS) fellowship at Boston EMS.

Timothy Conley, EMT-P, is the director of preparedness and planning for the Village of Western Springs Department of Fire/EMS Services and Emergency Management in Illinois. Mr. Conley's current duties also include H1N1 planning for the village and for the Illinois Fire Service Mutual Aid Box Alarm System Division 10, which has 18 fire departments. He is also a planning section chief for the Missouri State Disaster Medical Team. His other experience includes serving as the team commander and management support team coordinator of the Illinois Medical Emergency Response Team, and as a member of the Illinois Terrorism Task Force Bioterrorism and Pandemic Flu committees.

Brooke Courtney, J.D., M.P.H., is an associate at the Center for Biosecurity of UPMC. Ms. Courtney's research focuses on public health and hospital preparedness, legal preparedness, and mass dispensing of medical countermeasures. She is an associate editor of the peer-reviewed journal, *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, and editor of the journal's Legal Perspectives column. Prior to joining the Center, Ms. Courtney served as director of the Office of Public Health Preparedness and Response for the Baltimore City Health Department, where she provided oversight of the city's responses to public health emergencies. Earlier, she worked on surge capacity and pandemic influenza planning with the University of Maryland Center for Health and Homeland Security. She has also worked as a Law Fellow for the U.S. Senate Committee on Health, Education, Labor, and Pensions and for the Public Health Division of the U.S. Department of Health and Human Services' Office of the General Counsel, as well as a Law Clerk in the Health Fraud Division of the U.S. Attorney's Office for the Dis-

trict of Maryland. In addition, Ms. Courtney has worked on international relations and disaster response at the American Red Cross national headquarters; on outcomes research at Pfizer Inc.; on issues related to healthcare coverage at the Maryland Health Care Commission; and on tobacco control, obesity, and health disparities issues. She received her M.P.H. from Yale University, and is a Phi Beta Kappa graduate of the University of Colorado–Boulder. Ms. Courtney received her J.D. and certificate in health law from the University of Maryland School of Law and is admitted to practice in Maryland.

Laura Eiklenborg, M.P.H., is the director of solutions development at OptumHealth Public Sector. Ms. Eiklenborg's work focuses on the development and enhancement of health and wellness initiatives for Medicaid and Medicare beneficiaries. Prior to joining OptumHealth in 2009, she was deputy director of emergency preparedness for the City of Minneapolis, where she led the development and implementation of the postal plan for dispensing countermeasures. She also held the positions of Minnesota metro regional preparedness coordinator and public health emergency preparedness coordinator with Anoka County Community Health and Environmental Services, MN. Ms. Eiklenborg holds an M.P.H. from the University of Minnesota.

Susan E. Gorman, Pharm.D., M.S., DABAT, is the associate director for science at the Division of Strategic National Stockpile, Coordinating Office for Terrorism Preparedness and Emergency Response, CDC. Her primary roles include oversight of the SNS formulary and provision of technical and scientific advice on all SNS pharmacological and toxicological issues. In her SNS position, she responded to events such as the September 11, 2001, and anthrax attacks; natural disasters such as hurricanes; and, most recently, the H1N1 outbreak. She participates in numerous intergovernmental working groups on counterterrorism involving radiological, chemical, and biological agents, and is a nationally and internationally recognized speaker on stockpiling for terrorist events and other large-scale public health emergencies. Before joining the CDC 10 years ago, Dr. Gorman was the assistant director of the Georgia Poison Center, and continues to serve as a toxicologist. She is actively involved in the American Board of Applied Toxicology, and has held a seat on the Board of Directors for 6 years. Dr. Gorman received her B.S. in Pharmacy from Duquesne University and her Pharm.D. from the University of Maryland. She completed a postdoctoral residency in Emergency

Medicine and Toxicology at the University of Illinois–Chicago. She became a Diplomate of the American Board of Applied Toxicology in 1994. She also earned an M.S. in BioSecurity and Disaster Preparedness from the St. Louis University School of Public Health.

Jack Herrmann, M.S.Ed., NCC, LMHC, is the senior advisor for public health preparedness at the National Association of County and City Health Officials (NACCHO), an association that represents the approximately 3,000 local public health departments across the country. In this role, he oversees the organization's preparedness portfolio of five federally funded programs aimed at enhancing and strengthening the preparedness and response capacity of local health departments. He establishes the priorities for public health preparedness within the organization and serves as the organization's liaison to local, state, and federal partner agencies. Previously, Mr. Herrmann was assistant professor of psychiatry and director of the Program in Disaster Mental Health at the University of Rochester Medical Center, Department of Psychiatry. As the former founder and director of Strong EAP, he specialized in developing critical response teams for local police, fire, and healthcare organizations. Mr. Herrmann is also a long-time volunteer with the American Red Cross. Since 1993, he has responded to numerous disasters, including the September 11, 2001, attacks in New York City; Hurricanes Katrina and Rita; the Northridge, California, earthquake; the explosion of TWA Flight 800; and the crash of Comair Flight 5191 in Lexington, Kentucky. He was also the American Red Cross disaster mental health consultant for the northeastern region of the United States (including Puerto Rico and the Virgin Islands) and a member of the Red Cross National Critical Response Team. He coauthored the Foundations of Disaster Mental Health and Psychological First Aid training curriculums, which are nationally recognized and required training for all Red Cross disaster mental health volunteers. In 2006, he adapted the *Psychological First Aid: A Field Guide,* developed by the National Center for Posttraumatic Stress Disorder and National Child Traumatic Stress Network for the National Medical Reserve Corps. Mr. Herrmann earned an M.S.Ed. from the University of Rochester, is certified by the National Board of Certified Counselors, and is a licensed mental health counselor in the state of New York.

Darrell Klein, J.D., is assistant agency counsel for the Nebraska Department of Health & Human Services. Mr. Klein's practice focuses on public health emergency preparedness, including bioterrorism response

and pandemic influenza preparedness, coordination with Nebraska's local public health departments, and ongoing development and implementation of public health responsibilities with emergency management for all-hazards response. Mr. Klein developed Directed Health Measure (Quarantine and Isolation) regulations for Nebraska's Department of Health & Human Services and a template for the state's local public health departments. He is the Nebraska legal representative to the regional Mid-America Alliance. Since 2005, Mr. Klein has been a speaker at a variety of national, regional, and intrastate presentations on public health preparedness sponsored by the CDC Public Health Law Program, NACCHO, ASTHO, and others. He supports healthcare professional boards, advises on public policy and legislative issues, and was previously a prosecutor for environmental health and healthcare facilities, professions, occupations, and services programs at the administrative level and in court upon appointment. He is a member of the Nebraska State Bar Association and has been admitted to practice before the Nebraska state and federal courts since 1982. He has a B.A. in History and Political Science from Doane College and a J.D. from Creighton University Law School.

Eva Lee, Ph.D., is an associate professor in the H. Milton Stewart School of Industrial and Systems Engineering at Georgia Institute of Technology, and director of the Center for Operations Research in Medicine and Health Care. She is also a senior research professor at the Atlanta Veterans Affairs Medical Center. Dr. Lee was awarded a National Science Foundation (NSF)/North Atlantic Treaty Organization (NATO) postdoctoral fellowship on Scientific Computing, and a postdoctoral fellowship from Konrad-Zuse-Zentrum Informationstechnik Berlin for Parallel Computation. In 1996, she received the NSF Presidential Young Investigator Award for research on integer programming and parallel algorithms and their applications to medical diagnosis and cancer treatment. She was the first operations research/industrial engineering recipient for the prestigious Whitaker Foundation Biomedical Grant for Young Investigators, awarded for her work in combining biological imaging and optimal treatment design for prostate cancer. In 2004, she was selected as an Extraordinary Women Engineer. In 2005, she received the Institute for Operations Research and the Management Sciences (INFORMS) Pierskalla Award for research excellence in healthcare and management science for her work on emergency response and planning, large-scale prophylaxis dispensing, and resource allocation for bioterrorism and in-

fectious disease outbreaks. Together, Dr. Lee and a Memorial Sloan-Kettering Cancer Center physician were named winners of the 2007 Franz Edelman Award for their work on using operations research to advance cancer therapeutics. Dr. Lee is currently the secretary and treasurer for the INFORMS Optimization Society, and a Subdivision Council member of the INFORMS Health Applications Section. She is coeditor for the *Annals of Operations Research* subseries, *Operations Research in Medicine—Computing and Optimization in Medicine and Life Sciences.* She is also issue editor for *Asia Pacific Journal of Operations Research on Medical and Biological Applications.* She also serves on the Editorial Board for *Cancer Informatics*. Dr. Lee has received seven patents for innovative medical systems and devices. She received her undergraduate degree in Mathematics from Hong Kong Baptist University, where she graduated with Highest Distinction, earned a Ph.D. at Rice University in the Department of Computational and Applied Mathematics.

Brad Leissa, M.D., holds the position of deputy director in the Office of Counter-Terrorism and Emergency Coordination, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA). He began his career at the FDA's CDER as a medical officer with a focus on anti-infective drug development. During the October 2001 anthrax attacks, Dr. Leissa was temporarily assigned to the Secretary's Bioterrorism Command Center at the Department of Health and Human Services. Since then he has continued to work on medical countermeasure development at the FDA. Dr. Leissa received his M.D. from The Ohio State University. He received postgraduate training in Internal Medicine and Pediatrics at The Ohio State University Hospitals. He went on to receive subspecialty training in Pediatric Infectious Diseases from George Washington University and the Children's National Medical Center in Washington, DC.

Aggie Leitheiser, R.N., M.P.H., is the director of emergency preparedness for the Minnesota Department of Health. She is responsible for ensuring the Minnesota Department of Health is ready to respond to emergencies that affect the public's health and that the department's programs and activities are coordinated with local public health agencies, hospitals, and other government and emergency responders. Ms. Leitheiser has held several other positions in the Department, including assistant commissioner of the Health Protection Bureau and director of the Disease Prevention and Control Division. Prior to state service,

Ms. Leitheiser was the supervisor of public health for the Wright County Human Services Agency in Minnesota. Ms. Leitheiser also serves as the director of the Public Health Certificate in Preparedness, Response, and Recovery and is an instructor in the Public Health Practice Program at the University of Minnesota School of Public Health. Ms. Leitheiser earned a B.S.N. at South Dakota State University and an M.P.H. in Public Health Administration at the University of Minnesota–Minneapolis.

Atkinson (Jack) Longmire, M.D., has been employed for 9 years as an occupational physician in the Office of Occupational Medicine in the Directorate of Technical Support and Emergency Management at the National Office of the Occupational Safety and Health Administration. Dr. Longmire holds an M.D. and has completed postdoctorate medical training at Walter Reed Medical Center and Vanderbilt University Medical Center. He has received medical board certification and has practiced emergency medicine, clinical pharmacology, and occupational medicine.

Carmen T. Maher (Commander, U.S. Public Health Service), M.A., R.N., RAC, is a senior nurse officer in the U.S. Public Health Service (PHS) Commissioned Corps and currently serves as a regulatory policy analyst in the FDA's Office of Counterterrorism and Emerging Threats in the Office of the Commissioner. Commander Maher collaborates with senior agency staff in developing and updating agency and interagency counterterrorism and chemical, biological, radiological, and nuclear consequence management and mitigation policies and plans. Prior to joining the FDA, Commander Maher was assigned to the National Institute of Allergy and Infectious Diseases, Division of Microbiology and Infectious Diseases, as a lead regulatory officer for preclinical and early clinical development of vaccines and therapeutics to prevent or treat illnesses caused by smallpox, anthrax, and influenza disease agents. As a federal first responder, Commander Maher has assisted state and local response efforts and was an active member of the PHS-1 Disaster Medical Assistance Team, serving on its leadership cadre for 2 years. Commander Maher earned her B.S.N. and her associate degree in life sciences from the University of Puerto Rico. She earned her M.A. in national security and strategic studies with highest distinction from the U.S. Naval War College, Rhode Island. She holds a Regulatory Affairs Certification in U.S. healthcare products regulations.

Gretchen Michael, J.D., is the communications director for the Office of the Assistant Secretary for Preparedness and Response (ASPR) for the Department of Health and Human Services (HHS). Her responsibilities include overall strategic communications for ASPR, including media relations, web communications, and emergency risk communications. She was the communications lead for the H1N1 Task Force, the agency's coordinating body for the 2009 H1N1 pandemic as formalized in the *National Framework for 2009-H1N1 Influenza Preparedness and Response*. Prior to joining ASPR, Ms. Michael was an associate with Booz Allen Hamilton, where she supported a project for the Veterans Health Administration for Afghanistan and Iraq war veterans. She also developed and conducted media trainings for the Department of Homeland Security's Office of Science and Technology. For 3 years, Ms. Michael served as communications director for the New Jersey Department of Health and Senior Services (NJDHSS), where she directed all communications, media relations, marketing, and public awareness activities for the state health department. While with NJDHSS, she led the public health communications activities for the TOPOFF3 bioterrorism exercise. Ms. Michael earned her B.S. from American University and her J.D. from University of Denver.

Matthew Minson, M.D., is the medical director for the Emergency Response and Rescue Division at Texas A&M University. Before that, he was the senior medical officer for strategic initiatives at HHS/ASPR. He also serves on the Chancellor's Council for the University of Texas and is a principal member of the National Fire Protection Association's Technical Committee, 471, 472, and 473. Prior to joining HHS/ASPR, Dr. Minson was the director of the Maryland Department of Health and Mental Hygiene, Office of Preparedness and Response. He previously worked as the medical program coordinator for the National Emergency Response and Rescue Training Center located at Texas A&M University, and served on the Oil and Gas Industry's Corporate Emergency Response Team. He also held the position of director of emergency management and medical review for Harris County, TX. He was an FDA sponsor-investigator during his appointment at the MD Anderson Cancer Center. He has been a Counter Narcotics and Terrorism Operational Medical Support physician in support of the Federal Bureau of Investigation; the Bureau of Alcohol, Tobacco, Firearms and Explosives; and the Texas Department of Public Safety. Dr. Minson is an expert on mass casualty medical management. He has responded to a number of disas-

ters, including the World Trade Center attacks, the Columbia Shuttle recovery, and several hurricanes, including Katrina and Rita. Dr. Minson received his M.D. from the University of Texas Medical Branch and completed his residency in Anesthesiology at the University of Texas Medical School–Houston.

Jude M. Plessas is an operations specialist with the U.S. Postal Service (USPS) and manager of the Cities Readiness Initiative (CRI) Postal Plan Program. He was hired as a USPS contractor and later became an employee. In project management and technical writing support roles, he has helped establish USPS emergency management and continuity-related policy, guidance, and standardized procedure. Since late 2004, Mr. Plessas has managed the CRI Postal Plan Program, including outreach and engagement efforts, strategic planning with a subset of CRI cities, planning and execution of three proof-of-concept drills, and oversight of a comprehensive pilot in Minneapolis–St. Paul that will serve as a national, replicable model. Mr. Plessas represents the USPS on the National Security Staff's Biodefense Sub-Interagency Policy Committee and its working groups.

Laura Ross, M.P.H., is a health communication specialist in CDC's Division of Strategic National Stockpile. She provides training and technical assistance to state and local public information personnel and other planners preparing for an incident that requires the deployment of SNS assets. Earlier, Ms. Ross served as the campaign manager for the CDC Campaign to Prevent Antimicrobial Resistance in Healthcare Settings. She also worked for a global public health consulting company and on health communication projects in Thailand, Peru, Russia, Honduras, and Costa Rica.

Mitchel C. Rothholz, R.Ph., M.B.A., is chief of staff of the American Pharmacists Association (APhA). Mr. Rothholz is responsible for implementation of key strategic initiatives within the association's Strategic Plan as well as management of APhA alliance participation and other external activities. He is a graduate of the University of Florida College of Pharmacy and has worked as an association executive for more than 24 years. Before taking a position with APhA, Mr. Rothholz served as executive director of the Alabama Pharmacy Association, and was the first pharmacist executive for that organization. Prior to his tenure in Alabama, he served on the staff of the Florida Pharmacy Association. He

has practiced in chain and independent community pharmacies as well as nursing home, hospital, and managed-care practice settings. His professional experience includes developing continuing education programs, editing professional publications, overseeing legislative and regulatory activities, and developing pharmaceutical care programs such as the implementation of pharmacy-based immunization services. Mr. Rothholz is a member of several immunization coalitions and serves on the Executive Committee of the American Medical Association/CDC National Influenza Vaccine Summit and Advisory Board of the Immunization Action Coalition. He has worked on projects involving collaborations among pharmacists, physicians, and other healthcare professionals leading to improved patient care outcomes. He earned an M.B.A. with an emphasis in healthcare management from Regis University.

Kevin Sell, R.Ph., CSPI, serves as pharmacist consultant to the Minnesota Department of Health (MDH) Office of Emergency Preparedness. He provides subject-matter expertise, including logistical, legal, and clinical guidance for the CHEMPACK, Push Pack/Managed Inventory, Pandemic Influenza, mass dispensing, and Regional Pharmaceutical Cache programs of MDH. Mr. Sell has been with the Minnesota Poison Control System since 1996 as a nationally certified specialist in poison information. He is the pharmacy lead for the Minnesota-1 Disaster Medical Assistance Team, the pharmacy chair for Minneapolis–St. Paul Metropolitan Medical Response System, a clinical instructor for the University of Minnesota College of Pharmacy, and a certified instructor for the Advanced Hazardous Materials Life Support course.

Susan E. Sherman, J.D., is a senior attorney with the HHS Office of the General Counsel, where she has worked for 20 years. She leads the team that provides legal advice to HHS/ASPR, and advises on a wide variety of legal issues related to emergency preparedness and response, including authorities available during a declared public health emergency, liability protections for medical countermeasure development and distribution, and authorities to deploy healthcare personnel and assets. Earlier in her HHS career, she advised the National Institutes of Health on legal issues related to biomedical research, including grants administration, human subjects protection, animal welfare, stem cell research, and scientific misconduct. Prior to attending law school, she worked at the National Academy of Sciences' Institute of Medicine on The Future of Public Health and Quality of Care in Nursing Homes, and for the

Maryland State Health Department. She holds a bachelor's degree from Vassar College, a master's degree in Health Science from the Johns Hopkins Bloomberg School of Public Health, and a J.D. from the George Washington University National Law Center.

Tim Stephens is the principal associate at Rescobie Associates, Inc., and the public health advisor to the National Sheriffs' Association. He has more than 10 years of experience in advanced public health communications. In the 1990s he led the leading online learning program at the University of North Carolina School of Public Health. From 2000 to 2001, he was a consultant in a global online education marketing and technology support initiative based in Hong Kong. From 2002 to 2005, he directed the state public health directors' preparedness policy initiatives through their association, ASTHO. In 2005, he led the development of the first meeting of all state directors of public health preparedness. Mr. Stephens has developed programs on bioterrorism planning, identity theft, SNS, interruptions to the food supply, gaps in the workforce, the National Electronic Disease Surveillance System (NEDSS), and public health infrastructure. He is also deeply engaged in his Washington, DC, community and serves as the elected Advisory Neighborhood Commissioner. He is an advocate for public transit, transit-oriented development, and neighborhood retail opportunities.

WORKSHOP PLANNING COMMITTEE

Greg Burel (*Workshop Co-Chair*), *see speakers/panelists biographical sketch.*

Scott A. Mugno, J.D. (*Workshop Co-Chair*), *see speakers/panelists biographical sketch.*

Pamela Blackwell, R.N., *see speakers/panelists biographical sketch.*

Brooke Courtney, **J.D., M.P.H.,** *see speakers/panelists biographical sketch.*

Lynne Kidder, M.A., is a senior advisor at the Center for Excellence in Disaster Management and Humanitarian Assistance. Before that, she was senior vice president of Business Executives for National Security

(BENS). She oversees all operations of the BENS Business Force, providing management support to BENS' six regional public–private partnerships (New Jersey, Georgia, Kansas City, Iowa, the San Francisco Bay Area, and Los Angeles/Orange County in Southern California), and facilitating the development of new homeland security partnerships at the request of key stakeholders. Prior to joining BENS, Ms. Kidder served as the executive director of a non-profit business leadership organization in Northern California. Her experience also includes executive-level management in state government, 8 years as a professional staff member in the U.S. Senate, and corporate government affairs for Bechtel Corporation. She holds a B.A. from Indiana University and a master's degree from the University of Texas–Austin. She did additional postgraduate study in Public Administration at George Mason University.

Eva Lee, Ph.D., *see speakers/panelists biographical sketch.*

Jayne Lux, M.S., is the director of the Global Health Benefits Institute of the National Business Group on Health. Previously, she was the director of board operations at the American Psychological Association (APA), where she oversaw the activities of the Board of Professional Affairs. She also served as the liaison to the World Health Organization (WHO) for a collaborative project between the two organizations. Prior to joining the APA, Ms. Lux served as a WHO senior technical officer in Geneva, Switzerland, where she coordinated field trials in 18 countries for the development of the International Classification of Functioning, Disability and Health, a system used worldwide to describe human functioning in the context of health conditions. Additionally, she oversaw field activities in 19 countries for the development of a cross-culturally applicable measure of disability. Ms. Lux's earlier experience included 4 years at Washington University School of Medicine, where she directed the Professional Development Office in the Program in Occupational Therapy. For the first 10 years of her career, Ms. Lux was on the staff at the National Rehabilitation Hospital in Washington, DC, where she practiced as a supervisory speech-language pathologist in the Brain and Spinal Cord Injury Programs. She is a member of the Global Health Council and the American Speech-Language-Hearing Association. She earned her B.S. and M.S. in Communication Disorders from the Pennsylvania State University.

Matthew Minson, M.D., *see speakers/panelists biographical sketch.*

Erin Mullen, R.Ph., Ph.D., is the assistant vice president, Rx Response, for the Pharmaceutical Researchers and Manufacturers of America (PhRMA). She oversees and manages the Rx Response program, which is an information-sharing forum composed of pharmaceutical manufacturers, distributors, pharmacies, hospitals, disaster relief agencies, and state/federal government agencies designed to help support the continuing provision of medicines to patients whose health is threatened by a severe public health emergency. Rx Response engages during a severe natural disaster, a large-scale terrorist attack, or a pandemic that disrupts the normal supply of medicines. Prior to leading Rx Response, Ms. Mullen practiced pharmacy in a variety of settings: as a community pharmacist, as a clinical adjunct faculty member with the Colleges of Pharmacy at the University of Florida and Florida A&M University, and as a disaster responder. Ms. Mullen graduated from the Massachusetts College of Pharmacy with a B.S. in Pharmacy. She earned her Ph.D. in Microbiology and Immunology from the University of Miami.