

A CLOSER LOOK

MAXIMIZING STATE AND LOCAL MEDICAL COUNTERMEASURE STOCKPILE INVESTMENTS THROUGH THE SHELF-LIFE EXTENSION PROGRAM

Brooke Courtney, Joshua Easton, Thomas V. Inglesby, and Christine SooHoo

THE U.S. DEPARTMENT OF DEFENSE (DoD) and other federal agencies, including the U.S. Department of Health and Human Services (HHS) through its Strategic National Stockpile (SNS), maintain significant amounts of pre-positioned medicines and vaccines—also known as medical countermeasures—to prepare for public health and medical emergencies. To have rapid access to critical medicines to protect their first responders, healthcare workers, and other critical infrastructure (as well as the general public, under certain circumstances) before the SNS or other federal assets arrive in response to a public health emergency, many states and local jurisdictions have also purchased and locally pre-positioned their own supplies of antivirals (eg, Tamiflu® for an influenza pandemic) and antibiotics (eg, ciprofloxacin and doxycycline for an anthrax attack).

While all medicines have an expiration date set by the manufacturer, the actual shelf life of certain products, if stored properly, can be much longer.^{1,2} In the mid-1980s, the military faced challenges with expiring stockpiles of critical medicines, which led to the development of the Shelf-Life Extension Program (SLEP). This federal initiative is designed to defer and reduce the replacement costs of federal stockpiles of critical medicine by extending the drugs' useful shelf life through periodic Food and Drug Ad-

ministration (FDA) stability testing and strict environmental controls.^{3,4}

Currently, only select federal stockpiles are eligible for SLEP; state and local medical countermeasure stockpiles are not permitted to participate, and no similar program exists for these caches.⁵ Therefore, the antivirals and antibiotics being stockpiled at the state and local levels must be discarded when their expiration date is reached, even though federal agencies participating in SLEP are receiving shelf-life extensions for the same medicines and federal funds or federal subsidies have often been used to purchase the stockpiles. Because of a lack of practical alternatives, including product rotation, state and local jurisdictions that stockpile countermeasures will have caches of medicine with expired dates of use. The impact of this is significant, as it will lead to an additional and unnecessary taxpayer burden to regularly replace expired stockpiles every few years. It also has the potential to put critical health and infrastructure employees at risk during actual emergencies if jurisdictions facing budget constraints determine that they are unable to afford to replace their expired caches.

This article provides an overview of SLEP and its shelf-life and cost benefits, state and local antiviral and antibiotic stockpiling efforts, and recommendations for maximizing the shelf life of critical medicines being stockpiled at the

Brooke Courtney, JD, MPH, is an Associate; Thomas V. Inglesby, MD, is Chief Operating Officer and Deputy Director; and Christine SooHoo, MS, is an Analyst, all at the Center for Biosecurity of the University of Pittsburgh Medical Center, Baltimore, Maryland. Joshua Easton, JD, MA, is a Law and Policy Analyst at the Center for Health and Homeland Security at the University of Maryland School of Law, where he is the Program Coordinator for the Baltimore Urban Area Security Initiative.

state and local levels throughout the U.S. It is our position that state and local antiviral and antibiotic stockpiles should become eligible to participate in SLEP or a similar program.

SHELF-LIFE EXTENSION PROGRAM

Overview

Federal law requires manufacturers to assign an expiration date to their drug products and to print this date on the label; the shelf life printed on a product's label is based on stability testing and current FDA good manufacturing practices.^{1,6} Prescription drug products usually have expiration dates of 12 to 60 months from the time of original manufacture,² but state pharmacy dispensing laws typically shorten that timeframe to 6 to 12 months from the date of dispensing for individual patient prescriptions.^{7,8}

In an effort to conserve costs, the Air Force approached the FDA in the mid-1980s about the possibility of safely extending the expiration dates of some of the drugs that it had stockpiled.^{4,9} The inquiry led to SLEP, which was formally established through an interagency agreement in 1986 to extend the useful shelf life of "military significant" medicines that have limited commercial use (eg, chemical agent antidotes) or which the government holds in such large quantities that vendors will not accept them for credit when they expire.^{3,4} The program is jointly administered by the FDA and DoD, with the Defense Medical Standardization Board (DMSB) serving as a liaison between SLEP participants and the FDA. It is "a key component of the Medical Readiness Strategic Plan as developed by the DoD Health Affairs and the Military Medical Departments."^{1(p1550),3} SLEP participants include DoD, the Strategic National Stockpile, the Defense Supply Center-Philadelphia (DSCP), the U.S. Postal Service (USPS), and the U.S. Department of Veterans Affairs (VA).⁴

How SLEP Extends Shelf Life

To determine whether the expiration dates of SLEP participants' products can be extended, the FDA requests samples of stockpiled medicines from various storage locations by lots, which are stored under specified environmental conditions in closely monitored, controlled-temperature warehouses.⁴ The agency then comprehensively tests and evaluates each lot to assure "the stability and quality of extended drug products."^{1(p1560),2} Stability testing consists of real-time and accelerated (or stress) tests for drug products based on the procedures outlined in the New Drug Applications (NDAs).² The FDA is cautious in its testing. "Date extensions are conservative estimates of useful life of the product as substantiated by stress testing," and a minimum

of 95% of the product must be chemically available.⁴ If a lot is approved for extension, then the extended product is relabeled with the lot number, new expiration date, and FDA project number, and it will be retested biannually or annually until it fails testing or stocks of the product become depleted.^{3,4} SLEP participants fund the program and manage their respective stockpiles.³

According to DoD, SLEP does not test biological products (eg, vaccines), less than \$10,000 of a lot, products with previous instability reported in the manufacturer's data or that are not stored under the manufacturer's recommended temperature, or products without an FDA test protocol (USP or manufacturer's) for the item or a cost benefit associated with testing.^{4,10} Individual patient prescriptions are excluded from SLEP consideration.³ The program also focuses on testing products that are known to have a high probability of being extended.³

Shelf-Life Benefits

SLEP has resulted in significant shelf-life extensions for many of the drugs tested in the program.¹ In 1985, 56 items were sent to the FDA for testing; the agency extended 80% of the items and 84% of the tested lots by as much as 3 years.⁴ A comprehensive 2006 SLEP study, which summarized extended stability profiles for 122 different drug products (3,005 different lots) generated by SLEP since 1986, found that "[b]ased on testing and stability assessment, 88% of the lots were extended at least 1 year beyond their original date for an average extension of 66 months."^{1(p1549)} While the study also found that the additional stability period was highly variable, the authors concluded that their results support "the assertion that many drug products, if properly stored, can be extended past the expiration date."^{1(p1549)}

Ciprofloxacin, which is a commonly stockpiled antibiotic for responding to an anthrax attack and has a manufacturer-assigned shelf life of 3 years, provides a strong example of the significant benefits of this program. The military stockpiles such large quantities of the drug that the manufacturer will not permit the expired drugs to be returned for credit.⁹ Through SLEP, DoD has reported that the program can potentially add an average of 10 years to the shelf life of ciprofloxacin, for a total shelf life of 13 years.³ Another report showed that the shelf life of ciprofloxacin with an original expiration date of 1993 was extended to 2001, and it was believed that further testing could potentially extend it further.⁹ For another lot that had an expiration date of March 1989, FDA found that the samples of the drug remained stable more than 9.5 years later and then extended a portion of the lot for 18 to 24 additional months.⁷ The average cost for testing a lot of ciprofloxacin through SLEP has been reported to be approximately \$1,800.⁴

Financial Benefits

Estimates of the cost savings associated with SLEP vary but have been significant. In 2005, DoD reported that the cost of testing SLEP items was about \$350,000 per year and that the value of materiel tested annually by the program was over \$33 million in recent years.³ This means that for every dollar that was spent on SLEP testing, approximately \$94 in expenditures for new, replacement materiel was avoided.³ In FY1998, DoD spent \$260,000 on testing but saved \$40 million.⁹ In FY1997, DoD spent \$172,000 on SLEP testing but avoided spending \$23 million to replace stockpiled drugs; this translates to \$135 saved for every dollar spent.⁹

Cost savings through SLEP also have been realized for the SNS. In 2002, the Centers for Disease Control and Prevention (CDC) entered into a memorandum of agreement for SLEP to reduce the cost of replacing SNS inventory.¹¹ A 2005 analysis of the SNS reported that for every \$1 spent on SLEP costs (ie, testing, shipping, relabeling, etc), the Division of Strategic National Stockpile (DSNS) avoided \$22 in replacement costs (based on the total estimated replacement costs divided by the total estimated SLEP costs for 10 FDA SLEP projects submitted in 2004 by DSNS).¹¹ The report also noted that SNS assets included large amounts of antibiotics that could not be rotated into the market, and it projected that cost savings for 2008, 2009, and 2010 would increase to \$28 for every \$1 spent on SLEP.¹¹ Other CDC data showed that the SNS saved \$13 for every dollar spent on SLEP.¹²

STATE AND LOCAL EFFORTS TO STOCKPILE CRITICAL MEDICAL COUNTERMEASURES

Many state and local jurisdictions have purchased and are locally storing antivirals for an influenza pandemic and antibiotics for bioterror events to be better prepared to respond to such emergencies. These stockpiles are typically created to ensure early access to medicines to protect the general public, under certain circumstances, and first responders, critical infrastructure personnel, and their family members so that these essential employees can quickly respond to the emergency. Following is a brief overview of these types of stockpiling efforts.

Antiviral Stockpiling

The use of the antivirals oseltamivir (Tamiflu[®]) and zanamivir (Relenza[®]) is one of several measures that could contribute to mitigating a pandemic, and it is believed that their use “could provide an additional layer of protection during a pandemic.”¹³ As part of a goal of the 2005 HHS *Pandemic Influenza Plan* to ensure that antiviral drug treatment courses are available for 25% of the U.S. population,

the federal government has recommended that states and certain employers stockpile these antivirals to prepare for an influenza pandemic^{13,14} and has provided a 25% subsidy for states that elected to purchase the medicines.¹⁵ To date, state governments have purchased 23 million of 31 million available treatment courses of antivirals for their pandemic stockpiles, and 22 million of those courses have been delivered to the states.^{15,16} States have spent approximately \$300 million on these antivirals, as well as at least an estimated \$6.1 million in cumulative costs for storage and management.¹⁷ Through recent guidance, HHS is also encouraging certain employers to stockpile antivirals.^{18,19}

The current FDA-approved expiration date for Tamiflu[®] and Relenza[®] is 5 years from the date of manufacture. However, in December 2007, Roche, the manufacturer of Tamiflu[®], received FDA approval to extend the shelf life of its antivirals purchased for federal and state stockpiles to 7 years.²⁰ In addition, employers have an option to participate in purchasing and storage programs directly through the manufacturers. Business purchasers of Tamiflu[®], for example, can pay a fee to have Roche, through the company’s Antiviral Protection Program, store and rotate a specific quantity of antivirals so that they never expire, and then have the option to purchase the medicines when needed (eg, at the onset of a pandemic).²¹ GlaxoSmithKline, the manufacturer of Relenza[®], has also established an employer purchasing program, the Pandemic Readiness for Employers Program (PREP).²²

However, although purchased with the federal subsidy and critical for maintaining the HHS antiviral goals, the state stockpiles are not eligible to participate in SLEP.²³ States also are not permitted to rotate stocks of antivirals under the terms and conditions of the federal contracts with antiviral stocks routinely purchased and used for annual influenza response.²⁴ In addition, the extended 7-year dating for Tamiflu[®] only applies to government-purchased Tamiflu[®] in bottles, not those caches purchased and stockpiled by businesses or other entities at their individual locations.²⁰ The September 2007 Antiviral Survey conducted by the Association of State and Territorial Health Officials (ASTHO) found that, at the time, challenges reported by states in “acquiring their desired stockpile amounts” included “reluctance to invest in antivirals without a shelf-life extension program for sustaining state stockpiles” and “additional funding obligations to store and maintain existing caches.”^{17(p1),25}

Antibiotic Stockpiling

State and local jurisdictions have also purchased large quantities of doxycycline and ciprofloxacin, which have shelf lives of 2 years and 3 years, respectively,³ to stockpile and pre-position in preparation for an anthrax attack. For example, in response to an informal email survey sent to the

largest metropolitan areas receiving Department of Homeland Security (DHS) Urban Area Security Initiative (UASI) grant funds, we found that 16 of the respondents reported maintaining a local mass prophylaxis cache.²⁶ Jurisdictions have faced difficulties in seeking contracts with pharmaceutical distributors for storage and rotation to extend the shelf life and with rotating these antibiotics into the local market because the quantities are too large for local demand.²⁷ As mentioned, DoD has reported that SLEP could potentially add an average of 10 years to the shelf life of ciprofloxacin (for a total potential shelf life of 13 years) and 5 years to the shelf life of doxycycline (for a total potential shelf life of 7 years).³ However, nonfederal antibiotic caches are not eligible for SLEP, and local jurisdictions lack other practical options for extending the shelf life of these critical medicines.

As an example, the Baltimore (Maryland) UASI, which consists of Baltimore City and multiple surrounding counties, purchased a stockpile of ciprofloxacin and doxycycline in early 2008 for the region's 106,000 first responders, healthcare workers, and their family members. The Baltimore UASI has taken steps to maximize available shelf life by requiring that vendors deliver drugs with a minimum labeled shelf life of 2 years for doxycycline and 3 years for ciprofloxacin.²⁸ Baltimore also ensures that the security and storage of the stockpile complies with the humidity and temperature requirements of the manufacturer and the available FDA guidelines for SLEP participation. Without a shelf-life extension option, however, the Baltimore UASI will have to dispose of 6 million pills every 2 to 3 years at a recurring total cost of approximately \$500,000.

FEDERAL AND NATIONAL CONSIDERATION OF EXTENDING SLEP

The issue of allowing state and local antiviral stockpiles to become eligible for SLEP has been raised in several federal documents, but no significant movement appears to have occurred:

- The 2006 *National Strategy for Pandemic Influenza Implementation Plan* directed "HHS, DOD, VA and the States . . . [to] explore the possibility of broadening SLEP to include equivalently maintained State stockpiles, within 6 months. Measure of performance: . . . decision made on broadening SLEP to State stockpiles."²⁹(pp119-120)
- However, the *National Strategy for Pandemic Influenza Implementation Plan: Summary of Progress*, which was issued later the same year, stated that "after careful consideration of this matter, HHS, DOD and VA have determined that the inclusion of State stockpiles in the SLEP program is not feasible at this time," but without providing additional information about the rationale for the decision.³⁰

- The 2008 *National Strategy for Pandemic Influenza Implementation Plan: Two Year Summary* simply noted that the "[d]evelopment of a shelf life extension program for State stockpiles of antiviral drugs is currently under consideration by HHS."³¹
- Also in 2008, an Institute of Medicine committee recommended that SLEP should "be expanded to include other public and private sector entities that are stockpiling antivirals for use in an influenza pandemic," and that HHS should "develop a process to use the knowledge acquired by FDA in the operation of the [SLEP] to facilitate the use of properly stored, recently expired medications that exist in supplies outside the [SLEP] in the event these medications are needed because of a shortage."²⁰(pp26-27) The committee concluded that "[t]he shelf-life of antivirals . . . is an important factor and an economic barrier because a short shelf-life would require discarding previously purchased drugs and buying new ones. . . . Beyond that, the exclusion of state and private sector stockpiles from the federal Shelf-Life Extension Program presents a considerable barrier to further stockpiling."²⁰(p26).³²

National public health organizations also have commented on shelf-life extension for antivirals. For example:

- In 2006, ASTHO issued a position statement that the SNS "should be available as an option to store and manage all state allocations of antivirals. . . . Antivirals stored outside of the SNS, including those maintained in the states, should be eligible for the . . . (FDA) Shelf-Life Extension Program. . . . Every effort must be made to extend the safe and efficacious use of the antivirals."²⁴(p2)
- In its recent Health Policy Priorities document for the Obama Administration transition, ASTHO stated that "[w]hile we have been successful in having the label life of Tamiflu recently be extended from five to seven years, the formal creation of an enduring state shelf-life extension program is necessary to cover certain state assets. Efforts on this issue have been stalled."³³(p4)
- Trust for America's Health (TFAH) recommended in its 2008 *Ready or Not?* report that "Congress should extend the Shelf Life Extension Program (or establish a new, parallel, SLEP-like program within FDA) to include state and local antiviral and antibiotic stockpiles,"²³(p93) and noted that "[g]iven the projected budget shortfalls, many states are reluctant to spend resources on purchasing and stockpiling antivirals that have a limited shelf-life. Though this shelf-life recently expanded from five years to seven years, it is still too short for many state health officials."²³(p24)
- The Agenda for Modernizing Public Health section of TFAH's 2008 report, *Blueprint for a Healthier America: Modernizing the Federal Public Health System to Focus on Prevention and Preparedness*, noted that for pandemic in-

influenza preparedness “[c]onsideration should also be given to making shelf-life extensions available for certain pharmaceuticals owned and managed by states as part of their emergency stockpiles to reduce potential waste and increase availability of critical materials.”^{34(p107)}

CONCLUSIONS AND RECOMMENDATIONS

The efficient management of state and local medical countermeasure stockpiles through SLEP—or a similarly managed program—is essential to reducing waste associated with frequently replacing stockpiles, enabling the maximum benefit to be derived from the countermeasures,²⁴ and ensuring that critical antivirals and antibiotics remain readily available and in sufficient quantities during emergencies for responders, healthcare workers, and the general public. More broadly, this is an issue of national significance as state and local governments face the imminent expiration dates of their stockpiles and confront significant budget challenges that render them unable to replace expiring medicines to protect their critical infrastructure and residents. Therefore, we propose that:

- State and local stockpiles of antivirals and antibiotics should become eligible to participate in the current SLEP program.
- Alternatively, a new program based on the federal SLEP could be developed solely within the FDA for state and local medical countermeasure stockpile shelf-life extension.

With either approach, sufficient funding must be provided to the FDA to expand shelf-life testing and administration without negatively affecting the current SLEP or other critical FDA initiatives. Requirements for state and local participation, including specific types and minimum quantities of medicines, as well as stringent storage and security guidelines, would also need to be established. In the interim, one possible strategy to mitigate the shelf-life issue for antivirals includes providing states with the ability to rotate stocks of antivirals purchased through the federal contracts with stocks used for annual influenza response.²⁴

It should be noted that it is difficult to fully assess the feasibility and practicality of extending SLEP eligibility to state and local stockpiles, because very limited publicly available information about the program exists.^{35,36} Also, potential drawbacks of extending the shelf life of drugs in state and local stockpiles do exist and must be addressed—for example, negative public perception or pushback about using what might be perceived as “old” medicines; misunderstanding among members of the public, who might erroneously think that they could similarly use medicines they have at home beyond their expiration dates; and out-

dated package inserts. However, the public health and national security benefits of having these medicines available during emergencies greatly outweigh the risks.

ACKNOWLEDGMENTS

The authors would especially like to thank James S. Blumenstock, Chief Program Officer, and Anna DeBlois Buchanan, Senior Director, Immunization and Infectious Disease Policy, for their thorough and insightful review of and recommendations for this article; both are at the Association of State and Territorial Health Officials (ASTHO). We would also like to thank the dedicated emergency planners in the Baltimore UASI region and the staff of the Anne Arundel County, Maryland, Department of Health and Office of Emergency Management.

REFERENCES

1. Lyon RC, Taylor JS, Porter DA, et al. Stability profiles of drug products extended beyond labeled expiration dates. *J Pharm Sci* 2006;95(7):1549-1560.
2. American Medical Association. Report 1 of the Council on Scientific Affairs (A-01). Pharmaceutical expiration dates. 2001. http://www.ama-assn.org/ama/no-index/about-ama/13652_print.html. Accessed March 23, 2009.
3. Extending the shelf life of critical “war reserves” medical materiel using the FDA/DoD Shelf Life Extension Program. March 31, 2005. <http://www.usamma.army.mil/documents/SLEPInfoPaper-Mar2005.pdf>. Accessed February 26, 2009.
4. Kavanagh E. Defense Medical Standardization Board. DoD FDA Shelf Life Extension Program (presentation). www.dla.mil/J-4/Training_expo/minutes/shelflife/day2/DoD_fda_extension_program.ppt. Accessed February 26, 2009.
5. The FDA has released guidance for state and local governments on shelf-life extension for potassium iodide (KI) stockpiles that would be used in response to a radiological incident. This guidance, however, is limited to KI and merely summarizes the FDA recommendations on the subject; it does not create a sanctioned SLEP for state and local stockpiles. See U.S. Food and Drug Administration. *Guidance for Federal Agencies and State and Local Governments: Potassium Iodide Tablets Shelf Life Extension*. March 2004. <http://www.fda.gov/Cder/guidance/5666fml.pdf>. Accessed January 26, 2009.
6. 21 C.F.R. Parts 201, 211.137, 211.166 (2008).
7. Cohen LP. Many medicines are potent years past expiration dates. *Wall Street Journal* March 28, 2000.
8. U.S. Department of Health and Human Services. *Proposed Considerations for Antiviral Drug Stockpiling by Employers in Preparation for an Influenza Pandemic*. Washington, DC: HHS; 2008. <http://aspe.hhs.gov/panflu/stockpiling.html>. Accessed February 26, 2009.
9. Garamone J. Program extends drug shelf-life. *American Forces Press Service* March 29, 2000. <http://www.defenselink.mil/news/newarticle.aspx?id=44979>. Accessed February 26, 2009.

10. U.S. Army Medical Materiel Agency. Food and Drug Administration (FDA) Shelf-Life Extension Program. http://www.usamma.army.mil/DoD_slep.cfm. Accessed November 13, 2008.
11. U.S. Office of Management and Budget. ExpectMore.gov. Detailed information on the Strategic National Stockpile assessment. 2005. <http://www.whitehouse.gov/omb/expectmore/detail/10003512.2005.html>. Accessed January 16, 2009.
12. Trust for America's Health. *Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism*. December 2008. <http://healthyamericans.org/assets/files/bioterror-report-2008.pdf> [accessed February 26, 2009], citing U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. *FY 2009 Justification of Estimates for Appropriation Committees*. Washington, DC: U.S. Department of Health and Human Services; 2008.
13. U.S. Department of Health and Human Services. HHS releases guidance for the use and stockpiling of antiviral drugs for pandemic influenza [news release]. December 15, 2008. <http://www.globalhealth.gov/news/news/121508.html>. Accessed on January 16, 2009.
14. "Stockpiling these antiviral drugs and planning for their use is the responsibility of employers in these sectors [healthcare and emergency services; particularly those employees who are at very high risk of exposure to the virus] as part of comprehensive pandemic preparedness. The new antiviral drug guidance, by placing responsibility on employers, highlights the importance of preparedness within both the public and private sectors."¹³
15. U.S. Department of Health and Human Services. *Pandemic Planning Update VI: A Report from Secretary Michael O. Leavitt*. January 8, 2009. <http://www.pandemicflu.gov/plan/pdf/panfureport6.pdf>. Accessed February 26, 2009.
16. Specific state antiviral allocations can be viewed at <http://www.pandemicflu.gov/plan/states/antivirals.html>. Accessed February 26, 2009.
17. Association of State and Territorial Health Officials. *ASTHO Antiviral Survey Summary*. December 2007. <http://www.astho.org/pubs/ASTHOAntiviralSurvey-SummaryFactSheet011008.pdf>. Accessed January 30, 2009.
18. U.S. Department of Health and Human Services. *Considerations for Antiviral Drug Stockpiling by Employers in Preparation for an Influenza Pandemic*. December 2008. http://www.pandemicflu.gov/vaccine/antiviral_employers.pdf. Accessed February 26, 2009.
19. For additional information on employer antiviral stockpiling issues, see, eg, Comments from the Center for Biosecurity of UPMC on draft guidances for pandemic influenza planning. *Biosecur Bioterror* 2008;6(3):279-284, and Trust for America's Health, ref. 12.
20. Committee on Implementation of Antiviral Medication Strategies for an Influenza Pandemic, Institute of Medicine. *Antivirals for Pandemic Influenza: Guidance on Developing a Distribution and Dispensing Program*. Washington, DC: National Academies Press; 2008. http://www.nap.edu/catalog.php?record_id=12170. Accessed February 26, 2009.
21. Hoffmann-La Roche, Inc. Antiviral stockpiling solution: the Roche Antiviral Protection Program. <http://www.pandemic toolkit.com/tamiflu-supplyordering/stockpiling-dilemma.aspx>. Accessed on January 21, 2009. Through the program, medication is secured for a nominal annual fee with an option to purchase at the wholesale acquisition cost at any time; corporations have the ability to reassess the investment annually and adjust plans and decisions accordingly. Storage is handled by Roche, the stock of antivirals is rotated by the company so that it never expires, and the product can be delivered within 48 hours under most circumstances.
22. GlaxoSmithKline. Pandemic planning. Introducing P.R.E.P., 2 options to help you build an antiviral stockpile. <http://www.pandemicplan.gsk.com/>. Accessed February 26, 2009.
23. Trust for America's Health. *Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism*. December 2008. <http://healthyamericans.org/assets/files/bioterror-report-2008.pdf>. Accessed February 26, 2009.
24. Association of State and Territorial Health Officials. Position Statement: Pandemic Influenza Antiviral Stockpiling, 2006. <http://www.astho.org/pubs/AntiviralStockpiling2008.pdf>. Accessed January 29, 2009.
25. The ASTHO Antiviral Survey Summary (December 2007) also found that "[m]ost states (37 jurisdictions) monitor and record storage conditions, and other jurisdictions (11) reported that arrangements with local health departments or partnering entities ensure that stockpiles are in environmentally controlled and secured facilities."^{17(p2)}
26. Survey results on file with authors. January 2009. The email was sent to the 60 largest metropolitan areas receiving UASI funding. Because the results reflect only the 16 jurisdictions that responded, the number of jurisdictions that also stockpile antibiotics is likely higher. To more accurately assess the full extent of local mass prophylaxis stockpiling and the potential cost savings under a shelf-life extension program, a comprehensive survey should be conducted.
27. For example, the Invitation for Bid for the Baltimore UASI mass prophylaxis cache specifically invited vendors to offer and include rotation as a cost in submitted proposals, but none of the responding vendors would provide this service.
28. Anne Arundel County, Maryland. Invitation for Bid, Medication Cache. 2007. (on file with authors)
29. Homeland Security Council. *National Strategy for Pandemic Influenza Implementation Plan*. May 2006. <http://www.lib.umich.edu/govdocs/pdf/fluplan.pdf>. Accessed March 23, 2009.
30. *National Strategy for Pandemic Influenza Implementation Plan: Summary of Progress*. December 2006. <http://www.pandemicflu.gov/plan/federal/strategyimplementationplan.html>. Accessed February 26, 2009.
31. *National Strategy for Pandemic Influenza Implementation Plan: Two Year Summary*. 2008. <http://www.pandemicflu.gov/plan/federal/summaryprogress2008.html>. Accessed February 26, 2009.
32. The IOM Committee on Implementation of Antiviral Medication Strategies for an Influenza Pandemic (2008) also noted that "[t]hirty-one million of the 81 million course goal for the [SNS] would be held in state stockpiles. This raises the possibility that in the absence of a pandemic, large amounts of the drugs will expire and need to be discarded, an outcome that could be avoided or delayed if this considerable proportion of the nation's government stockpile were included in SLEP."^{20(p25)}
33. Association of State and Territorial Health Officials. ASTHO Health Policy Priorities. <http://www.astho.org/pubs/ASTHOHealthPolicyPriorities.pdf>. Accessed January 29, 2009.

34. Trust for America's Health. *Blueprint for a Healthier America: Modernizing the Federal Public Health System to Focus on Prevention and Preparedness* (Appendix 3). October 2008. <http://healthyamericans.org/assets/files/Blueprint.pdf>. Accessed January 29, 2009.
35. See, eg, Institute of Medicine Committee on Implementation of Antiviral Medication Strategies for an Influenza Pandemic (2008), commenting that they "found a modest amount of information about SLEP and nothing about the feasibility, cost, and other barriers of extending the program to properly maintained non-Federal stockpiles, including state and perhaps even some private sector stockpiles."^{20(p25)}
36. For example, the U.S. Army Medical Materiel Agency website states that "all testing and extension data provided to the Shelf Life Extension Program (SLEP) by the Food and Drug Administration is considered For Official Use Only and cannot be shared with anyone outside the user's organization. SLEP Administrators have fielded several calls recently from individuals

wanting to share this information with local, civilian counterparts. That is not permissible, as it is not only a violation of the terms agreed to by the FDA but also a violation of the Memorandum of Agreement each participant organization signs prior to entering the SLEP program. SLEP website accounts of violators will immediately be terminated and inventories may be eliminated from the program. . . . Additionally, non-SLEP organizations that use SLEP information are in violation of Federal law that governs misbranded pharmaceuticals."¹⁰

Address correspondence to:
Brooke Courtney, JD, MPH
Center for Biosecurity of UPMC
The Pier IV Building
621 E. Pratt Street, Suite 210
Baltimore, MD 21202

E-mail: bcourtney@upmc-biosecurity.org