

HEALTH CARE POLICY / BRIEFING PAPER



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The Strategic National Stockpile: Vital to Maintain, Critical to Improve

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Introduction

Since 2000, the United States has been faced with an unprecedented series of natural and man-made disasters and threats that have generated concerns about the government's ability to respond to future emergencies. As Nate Silver, one of America's most prominent prognosticators, observed in his book *The Signal and the Noise*, "the first twelve years of the new millennium have been rough, with one unpredicted disaster after another."¹ As bad as the first decade of the twenty-first century was, with the terror attacks of 9/11, the anthrax scare, and deadly hurricanes, there are troubling indications that things are on track to be even worse in the 2010s. *Wall Street Journal* "Numbers Guy" Carl Bialik recently wrote, referring to events such as Hurricane Sandy and the 2012 *derecho*, among others, that "the current decade is on pace to outrank the prior three in cost from inflation-adjusted climate catastrophes costing at least \$1 billion in 2013 dollars."² And emergencies related to severe weather events are just one of the many types of crisis we could face. To deal with the potential problems of the future, including bioterror attacks as well as natural disasters, the U.S. government needs to maintain a robust toolkit.

One of these crucial tools for dealing with the medical consequences of natural and man-caused disasters is the Strategic National Stockpile (SNS). The SNS provides the United States with an extensive supply of countermeasures—antibiotics, vaccines, and a variety of other life-supporting drugs and devices—that can be distributed by government officials in the event of national emergencies. The SNS is one of the best ways that the United States can prepare for a range of emergencies and disasters, especially in the realm of biological threats. But the SNS, like all government programs, is not perfect, and only through continual reassessment, analysis, and reform can we ensure that it is as effective as it needs to be when a crisis emerges.

¹ Nate Silver, "Conclusion," in *The Signal and the Noise: Why So Many Predictions Fail—But Some Don't* (New York: Penguin Press, 2012), 454.

² Carl Bialik, "Statshot: Carl Bialik, 'The Numbers Guy,'" *The Wall Street Journal*, June 28, 2013, <http://online.wsj.com/article/SB10001424127887323419604578571951493356518.html> (accessed July 15, 2013).

SNS: A Public Good with a Declining Budget

Established in 1999, the SNS evolved from the National Pharmaceutical Stockpile (NPS), headed by the Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS). Its purpose, as directed by Congress, was to “provide a re-supply of large quantities of essential medical materiel to states and communities during an emergency within twelve hours of the federal decision to deploy.”³ After the 9/11 terror attacks, which dislodged Americans from a state of complacency about disasters, policymakers took a more careful look at the NPS and discovered a number of flaws. These shortcomings included a slow response time, inadequate supplies on hand, and responders who were often unqualified to handle specific emergencies.⁴ To address these shortcomings, the Homeland Security Act of 2002 transferred responsibility of the NPS to the Department of Homeland Security, under whose authority the NPS officially became the Strategic National Stockpile in March 2003.⁵

In 2004, the enactment of Project Bioshield further increased preparedness efforts by appropriately restoring jurisdiction of the SNS to the CDC—which is part of HHS, not the Department of Homeland Security—as well as calling for the strengthening of the SNS’ capacity to store and distribute countermeasures such as vaccines and drugs in the event of a bioterror attack. The Bioshield Special Reserve Fund encouraged private business involvement in building up the SNS by offering a guaranteed federal market for medical supplies.⁶ Establishing such a market was, and is, essential to stockpiling efforts,

³ “CDC – PPHR – Strategic National Stockpile,” Centers for Disease Control and Prevention, <http://www.cdc.gov/phpr/stockpile/stockpile.htm> (accessed July 15, 2013).

⁴ Ali S. Khan, “Public health preparedness and response in the USA since 9/11: a national health security imperative,” Centers for Disease Control and Prevention, www.cdc.gov/phpr/documents/Lancet_Article_Sept2011.pdf (accessed July 15, 2013).

⁵ U.S. Department of Health and Human Services, Chemical Hazards Emergency Medical Management, “Strategic National Stockpile – SNS,” <http://chemm.nlm.nih.gov/sns.htm> (accessed July 15, 2013).

⁶ Congressional Research Service, “Medical Countermeasures to Chemical, Biological, Radiological, and Nuclear Terrorism,” Issues in Homeland Security Policy for the 113th Congress, fpc.state.gov/documents/organization/206134.pdf (accessed July 15, 2013).

as individuals are unlikely to purchase many of the key countermeasures needed in case of a biological, radiological, or chemical incident. Since developing these countermeasures is both costly and time intensive, manufacturers are similarly unlikely to develop them unless they know that they have a reliable customer in the form of the U.S. government. This concept was critical to the thinking behind Project Bioshield, which remains a pillar of the United States' preparation efforts for potential bioterrorist attacks.

Of course, developing a stockpile is costly, which is a challenge in these days of high budget deficits and even higher government debt. Project Bioshield was originally established with funding of \$5.6 billion for a 10-year plan from FY 2004 to FY 2013, of which \$2.078 billion went to other related programs. Only \$2.625 billion in Bioshield funds (46.8 percent of the original budget) has been used to purchase countermeasures for the SNS.⁷ The monetary transfers have mostly benefited BARDA, which, since 2011, has received \$415 million every year from the Bioshield funds.⁸ Recent appropriations for the SNS have been in a steady decline, from \$591 million in 2011, to \$534 million in 2012, to \$486 million this past year, a \$105 million decrease over that period (see Figure 1).⁹ In March 2013, the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) renewed funding for Project Bioshield, appropriating \$2.8 billion for FY 2014–FY 2018, in addition to reauthorizing the SNS.¹⁰

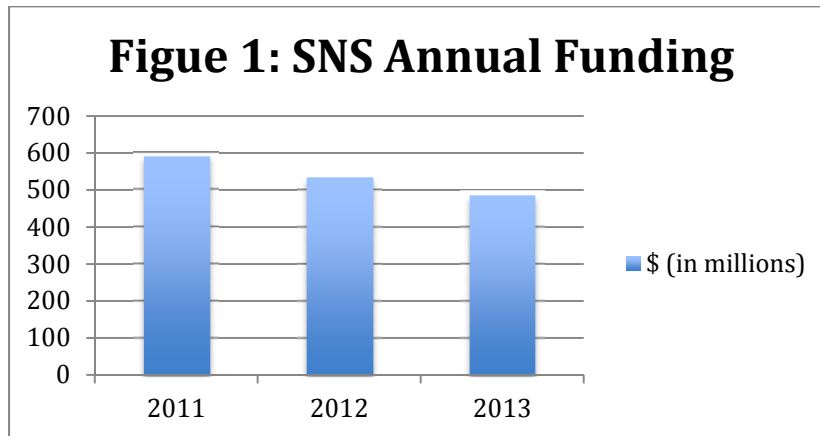
⁷ Congressional Research Service, “Medical Countermeasures to Chemical, Biological, Radiological, and Nuclear Terrorism.”

⁸ U.S. Department of Health and Human Services, “Overview of Budget Request,” Fiscal Year 2014 Public Health and Social Services Emergency Fund, www.hhs.gov/budget/fy2014/fy2014-phssef.pdf (accessed July 15, 2013).

⁹ U.S. Department of Health and Human Services, “Strengthening Health and Opportunity for All Americans,” Fiscal Year 2013 Budget in Brief, www.hhs.gov/budget/budget-brief-fy2013.pdf (accessed July 15, 2013).

¹⁰ H.R. 307 Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, Congressional Budget Office Cost Estimate, www.cbo.gov/sites/default/files/cbofiles/attachments/hr307.pdf (accessed July 18, 2013).

Figure 1:



These numbers may sound huge, and they are. But the SNS is a classic example of a public good, something that the nation requires, but that individuals are unlikely to procure for themselves. Historically, the paradigmatic example of a public good has been a lighthouse, especially in days when cross-oceanic transport took place exclusively by ship. These days, lighthouses are relatively rare, but the need for public goods continues. According to a recent analysis by Kevin Williamson, author of *The End Is Near and It's Going to Be Awesome*, only about one-third of federal spending today is on public goods.¹¹ Our problem today is perhaps not a lack of resources as much as a need to re-examine our priorities. The SNS is a strategic necessity for the United States government. Given that there are many forms of government spending that are not strategic priorities, the United States needs to find ways to trim non-priority spending before reducing its commitment to the SNS. Decreasing funds for the SNS inhibits its ability to provide adequately for the ever-increasing population of the United States, forcing it to do more with fewer resources.

If funds continue to dwindle, the SNS will need to allocate its limited dollars more strategically by evaluating different platform technologies that could promote more efficient innovation in the future. Also, the “one bug, one drug” method that is currently employed should be re-evaluated and redirected to a “many bugs, one drug” approach.

¹¹ Kevin D. Williamson, *The End Is Near and It's Going to Be Awesome: How Going Broke Will Leave America Richer, Happier, and More Secure* (New York: Broadside Books, 2013).

Establishing the right platform technologies could put us on the path for more innovations in the future. Another budgetary challenge has always been the need to replace products rather frequently as they reach their expiration dates. Fortunately, PAHPRA has extended the shelf life of expired SNS products that the FDA has deemed are still effective and usable, which will help further stretch limited SNS spending.¹²

The Promise of the SNS

The SNS' arsenal of drugs and vaccines has been deployed only a few times since its creation. SNS was deployed as a response to the attacks on September 11, 2001, the anthrax threat in October 2001, and Hurricanes Katrina and Rita in August–September 2005.¹³ Even when unused, however, the SNS serves a valuable purpose. Its very existence enables government officials to focus on other priorities, knowing that there is a stockpile of key countermeasures available in case of a crisis. Similarly, it grants individuals peace of mind, the knowledge that they do not have to purchase every conceivable countermeasure for every possible contingency. While home medkits make sense, and will be discussed later, it is an unrealistic expectation that every American citizen could or would purchase all of the potential countermeasures necessary in case of an emergency. Furthermore, the SNS creates a marketplace for many relatively rare or expensive medical products that would not be manufactured otherwise. The SNS marketplace also enables manufacturers to innovate, creating life-saving, life-extending, and life-improving products that could be useful even in the absence of a crisis.

When a crisis does strike, however, the SNS is even more valuable, allowing government officials to send needed countermeasures anywhere in the United States on very short notice, thereby reducing the danger of a bio-event's spiraling out of control. One of the

¹² “About the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA),” U.S. Food and Drug Administration, <http://www.fda.gov/emergencypreparedness/medicalcountermeasures/ucm346195.htm> (accessed September 13, 2013).

¹³ Stacy A. Robarge-Silkiner, “Introduction to the Strategic National Stockpile,” KDHE Center for Public Health Preparedness, http://www.kdheks.gov/cphp/download/Intro_SNS.pdf (accessed September 13, 2013).

best examples of the SNS' potential benefit is in the area of anthrax, which came to the public's attention during the attacks via the U.S. Postal Service in the autumn of 2001. Anthrax, an infectious disease that affects the skin, gastrointestinal tract, and/or lungs, can be spread rapidly, over great distances, in relatively minute amounts by persons wishing to do us harm. In 2009, the National Security Council reported that a biological attack with an agent such as anthrax could cause casualties in the "hundreds of thousands of people and [could] cost more than \$1 trillion."¹⁴ Yet anthrax, while indeed a deadly disease, is relatively treatable with Ciprofloxacin in the first 48 hours after exposure to the bacteria. After the first 48 hours, however, inhalational anthrax (the type that would likely be used in a biological attack) develops a 95 percent mortality rate.¹⁵ Should there be an anthrax outbreak, having Ciprofloxacin already stockpiled and ready to deploy could help ensure that a deadly attack does not become a mass-casualty disaster.

Suggested Improvements in the SNS

The SNS is not a first response mechanism, but rather an option to be utilized in the last resort, when commercial supplies are depleted or unable to provide for the public during an emergency. As such, the SNS faces certain challenges that are potential areas for reform and improvement, including better tracking of supplies dispensed and a more efficient distribution system.

There does not need to be a declaration of state or federal emergency to deploy the SNS. Once the Secretary of Homeland Security or the Secretary of HHS recognizes the emergency, the appropriate medical supplies can be dispensed by the SNS and delivered to citizens within a prompt time frame. Unlabeled, secret SNS warehouses are strategically placed at 12 locations throughout the country to ensure the efficient delivery

¹⁴ Wil S. Hylton, "How Ready Are We for Bioterrorism?" *The New York Times*, October 26, 2011, http://www.nytimes.com/2011/10/30/magazine/how-ready-are-we-for-bioterrorism.html?pagewanted=all&_r=0 (accessed July 17, 2013).

¹⁵ Col. Jim A. Davis and Dr. Anna Johnson-Winegar, "The Anthrax Terror: DOD's Number-One Biological Threat," *Air and Space Power Journal* (Winter 2000), 15–29, <http://www.au.af.mil/au/awc/awcgate/cpc-pubs/biostorm/winegar.pdf> (accessed July 17, 2013).

of the supplies, with a goal of being able to get a crucial countermeasure to any location in the country within 24 hours. The first provisions to be deployed are 12-hour “Push Packages” that provide an extensive array of drugs and rations within the early hours of an immediate threat. In the event of a bioterror attack, antibiotics hypothetically would be distributed to a designated metropolitan area within 48 hours of the deployment.¹⁶

Tracking distribution of products

It is at this point that we encounter one of the first challenges of the SNS, the limitation on its ability to determine the disposition of products. Since distribution, not analysis, is the SNS’ primary concern, this may not be surprising. In the case of a national emergency, we want federal officials to focus their efforts on getting the countermeasures to where they need to go, and not necessarily on filling out paperwork regarding where they sent them. Still, it remains somewhat disturbing that we did not until recently know what happened to a large percentage of the Tamiflu that was sent out to states during the 2009 H1N1 (swine flu) outbreak. At the start of the outbreak, 11 million courses, amounting to 25 percent of the entire supply in the SNS, were sent out to the states, and it took four years to learn the ultimate disposition of those courses.¹⁷ Of course, stockpiling antivirals such as Tamiflu helped deal with the crisis at that time. On the other hand, knowing quickly exactly what happened to the distributed courses would help us plan better for future events and might incidentally help the SNS better defend its budget in the face of legislators who demand accountability.

¹⁶ “Strategic National Stockpile Fact Sheet,” Association of State and Territorial Health Officials, <http://www.astho.org/Programs/Preparedness/Public-Health-Emergency-Law/Emergency-Use-Authorization-Toolkit/Strategic-National-Stockpile-Fact-Sheet/> (accessed July 17, 2013).

¹⁷ U.S. Department of Health and Human Services, 2009 H1N1 Influenza Improvement Plan, www.phe.gov/Preparedness/mcm/h1n1-retrospective/Documents/2009-h1n1-improvementplan.pdf (accessed July 17, 2013).

Distribution methods

Beyond the big-picture goal of the distribution of large quantities of product to a general area, there is the question of how best to distribute product to the specific people in need. Currently, the primary method for dispensing SNS supplies is by the “Points of Dispensing” (POD) system. The drugs are delivered to a central location (schools, public spaces, etc.), and people are given the responsibility of accessing them on their own. While this method on the surface seems fair and low-maintenance, it raises some significant concerns. First, such a method discriminates against people who lack the means to drive or transport themselves to acquire the drugs.¹⁸ Furthermore, rural Americans are at a disadvantage, as they are located the furthest from cities, where medical provisions are primarily centralized. After the H1N1 outbreak of 2009, Representative Frank Pallone of New Jersey complained about vaccine distribution, saying, “I am concerned that the distribution of the vaccine is resulting in favored treatment for the privileged.”¹⁹ One of the major stories in 2009 was the accusation that well-connected Wall Street banks and corporate officials received disproportionate shares of the scarce flu vaccine. These Wall Street banks obtained these vaccines after doctors and health centers, but before other actors. Although these well-connected individuals did not get their vaccines via the SNS distribution or a POD, Pallone’s statement is indicative of the kind of complaints that a POD distribution could potentially generate in the future.

The POD method is also a “blind” distribution. In aiming for fairness, it does not necessarily target those who require the countermeasures the most. If there were a particularly high-risk population, the POD method might not reach that particular population. The government does in fact draw up lists of priority recipients of crucial countermeasures, including first responders, vulnerable populations, the military, and a select few key government officials. POD-based distribution, however, does not coordinate with that kind of prioritization.

¹⁸ Lawrence M. Wein, “Neither Snow, Nor Rain, Nor Anthrax...,” *The New York Times*, October 13, 2008, http://www.nytimes.com/2008/10/13/opinion/13wein.html?pagewanted=print&_r=0 (accessed July 17, 2013).

¹⁹ Shirley S. Wang, “South Korean FDA Probes Roche for Aiding Tamiflu Stockpiling,” *The Wall Street Journal*, Nov. 6, 2009, <http://blogs.wsj.com/health/2009/11/06/south-korean-fda-probes-roche-for-aiding-tamiflu-stockpiling/> (accessed July 17, 2013).

Overall coordination

Another challenge, as the case of the missing Tamiflu suggests, is the apparent lack of an overarching central authority to coordinate all aspects of public health. Under Section 2811 of the PHSA, the authority for coordination of this sort falls squarely under the Secretary of Health and Human Service, specifically in the office of the Assistant Secretary for Preparedness and Response. National Response Framework Emergency Support Function (ESF) #8 is quite explicit on this front: “The Secretary of HHS leads the ESF #8 response. ESF #8, when activated, is coordinated by the Assistant Secretary for Preparedness and Response (ASPR).”²⁰

And yet, as with many government responsibilities and activities, public health data and information remains scattered among various HHS agencies and other public health offices like the National Institute of Health Services, Centers for Medicare and Medicaid Services, and other parts of CDC. Recognizing this challenge, in 2013 the National Biodefense Science Board (NBSB) recommended to Assistant HHS Secretary Dr. Nicole Lurie the gathering of public health information under a centralized agency to allow for a comprehensive national “situational awareness” that would improve the effectiveness of the SNS.²¹ Collaboration among these agencies is imperative to attain maximum efficiency for SNS activities. Implementing the NBSB’s suggestion of a collaborative situational awareness authority would unite the public health forces and their distinct data and analysis resources. The authority would be responsible for the sharing and consultation of public health information among both public and private entities, as well as the intelligence community. It would also oversee the accumulation of information

²⁰ U.S. Department of Homeland Security, “Overview: ESF and Support Annexes Coordinating Federal Assistance in Support of the National Response Framework,” January, 2008, 27, <http://www.fema.gov/pdf/emergency/nrf/nrf-overview.pdf> (accessed August 29, 2013).

²¹ Lisa Schnirring, “NBSB unveils situational awareness, SNS recommendations,” Center for Infectious Disease Research and Policy, April 23, 2013, <http://www.cidrap.umn.edu/news-perspective/2013/04/nbsb-unveils-situational-awareness-sns-recommendations> (accessed July 18, 2013).

from agricultural, zoonotic (animal-to-human disease transmission), and other kinds of public health crises to contribute to a comprehensive situational awareness.²²

Other recommendations by the NBSB report included that HHS articulate an SNS vision for 2020 and that the SNS further define its surge capacity, enhance critical review processes, and use cost-benefit analysis more heavily. Developing a vision for 2020 would allow the SNS to plan proactively for the expiration of its current in 2018. Such advance planning could forestall the significant turmoil in the SNS' operations that would ensue were the funding to expire without being renewed. The recommendation to establish realistic goals, always a wise approach, would also prompt the implementation of improvements within a realistic timetable. And increasing the use of recent science and technological advances could potentially curb the costs of some medical supplies and vaccines.²³

Since the report is so recent, it remains to be seen if HHS will act on the recommendations, but it is clearly a good thing that the report gives HHS the opportunity to consider these serious issues.

Budgetary hurdles

Of course, all of these recommendations take place in the context of a challenging budget environment. The FY 2013 Health and Human Services budget allotted \$1.3 billion for biodefense and emergency response spending, a \$54 million decrease from the FY 2012 budget. The SNS budget was reduced to \$486 million, down \$47 million from 2012, and \$105 million from 2011.²⁴

²² Final Report from the NBSB Situational Awareness Strategy and Implementation Plan Working Group, Department of Health and Human Services, April 2, 2013, www.phe.gov/Preparedness/legal/boards/nbsb/Documents/sa-evaluation.pdf (accessed July 18, 2013).

²³ Lisa Schnirring, "NBSB unveils situational awareness, SNS recommendations."

²⁴ U.S. Department of Health and Human Services. "Strengthening Health and Opportunity for All Americans," Fiscal Year 2013 Budget in Brief, www.hhs.gov/budget/budget-brief-fy2013.pdf (accessed July 15, 2013).

Offsetting the cuts in SNS funding is a difficult task, especially considering the \$16.7 trillion national debt and the concerns about budget sequestration. Some options include transferring funds from other public health agencies including the Indian Health Services (IHS), Agency for Healthcare Research and Quality (AHRQ), and Centers for Medicare and Medicaid Services (CMS), to name a few. These agencies' combined budgets were increased \$296 million with the 2013 FY budget. Perhaps with the establishment of the situational awareness authority uniting the public health agencies, appropriate budget transfers could be made among the agencies, although the bureaucratic tendency to defend one's turf makes this somewhat unlikely. The second option involves deriving funds from the Prevention and Public Health Fund of \$903 million. This too seems unlikely, given that Congress has already cut this fund for 2013 by \$250 million, and that the fund has certain powerful advocates in Congress.²⁵ Of course, there is always the option to accept the cuts, and simply reduce spending within the SNS. For example, the SNS is already preparing to save money by choosing to replace only high-priority expiring supplies, and cutting low priority items.²⁶ Careful consideration must be applied to decisions about which provisions are absolutely necessary, versus those that can be done away with.²⁷

The difficult budget environment clearly means that SNS, as with nearly all government programs, will experience cuts. The outstanding question is whether the SNS budget cuts will threaten the efficiency of the program. As Ali Khan, director of CDC's Office of Public Health Preparedness and Response, has said, "The [stockpile] will be buying less. There's no doubt about it."²⁸ Whether the smaller stockpile will be able to maintain the right level of preparedness depends on the strategic decisions HHS officials make in the months ahead.

²⁵ Meredith Wadman, "US disease agency in fiscal peril," *Nature*, February 28, 2012, <http://www.nature.com/news/us-disease-agency-in-fiscal-peril-1.10109#core> (accessed July 18, 2013).

²⁶ Budget Highlights, Centers for Disease Control and Prevention, www.cdc.gov/fmo/topic/budget%20information/factsheets/PHPR_Factsheet.pdf (accessed July 18, 2013).

²⁷ Erika Check Hayden, "Budget forces tough look at biodefense," *Nature*, April 10, 2013, <http://www.nature.com/news/budget-forces-tough-look-at-biodefence-1.12766#/stockpile> (accessed July 18, 2013).

²⁸ Erika Check Hayden, "Budget forces tough look at biodefense."

Improving distribution methods

The area perhaps most in need of improvement within the SNS is the distribution of supplies in a national emergency or disaster. While SNS is good at getting materials to a general area within a short time frame, the deliveries to specific individuals within that area is left largely up to local officials. Proposed solutions come in two main categories: improved versions of the POD method, and completely changing the current approach.

1. **U.S. Postal Service:** One of the most talked-about methods of distribution involves the U.S. Postal Service and its fleet of approximately 300,000 mail carriers nationwide. Utilizing the Postal Service to dispense medical supplies makes a certain amount of logistical sense: it is perhaps the only service that literally goes door-to-door and reaches each household within entire communities. This process also covers those who lack the means to drive to pick up supplies, especially high-risk elderly people. This method of distribution would allow the government to efficiently target affected areas of the nation.

In theory, this approach makes reasonable sense. It is not perfect, though. The American Postal Workers Union has expressed understandable concern over the safety of their employees when handling highly sought-after supplies during periods of tension and high risk. To ensure the safety of the workers, the union has demanded that a public safety officer accompany each worker. This would create an unrealistically high demand for police officers at a time when they are most needed elsewhere. Furthermore, there remains the very real possibility that a portion of public safety workers could potentially be unavailable in the event of a national emergency. During the Hurricane Katrina disaster, for example, an estimated one-third of the members of the New Orleans Police Department, approximately 500 officers, abandoned their posts.²⁹ It is unclear if the desertion rate would be this high during a national emergency, but public safety officials do have to account for at least some drop-off in their modeling.

²⁹ Kevin Johnson, "Katrina made police choose between duty and loved ones," *USA Today*, February 20, 2006, http://usatoday30.usatoday.com/news/nation/2006-02-20-neworleanspolice_x.htm?csp=34 (accessed July 18, 2013).

2. **Community Polling Sites used as “PODs”:** Using polling or other community sites as PODs is another possible approach for the POD method. Polling sites in particular are typically more numerous within communities than the standard public PODs (high schools, pharmacies, etc.). Their locations are specifically designed to efficiently handle large crowds of people during a short, discrete time period (i.e., Election Day) and to provide service to a significant, but unknown, number of citizens in a timely manner. Typically, the locations are convenient and familiar to people, and furthermore they are designed to prevent congestion and limit long lines. Election personnel, moreover, are experienced in handling crowds and equipment at sites, and would presumably work well in conjunction with public health officials. They are also predisposed to volunteer and are engaged in their communities. Overall, employing workers or volunteers already used to staffing community centers for civic purposes could address the potential shortage of public health workers who could quickly and efficiently distribute drugs in case of emergency.

While the polling place POD method has many advantages, it presents some challenges as well. Increasing the number of locations may reduce congestion, but it also requires more complex logistics for organizers.³⁰ In addition, the heavy reliance on volunteer, civically-minded, non-health experts might cause some consternation with the recipient population since the volunteers would be inexperienced in the administration of the materials.³¹ It probably would not require too much time and effort to train them, but any additional tension during an already nerve-wracking situation requires careful consideration.

Transporting the provisions to the polling sites is another issue, especially if there is a crisis and the provisions are highly sought after. Ideally, the local police force

³⁰ National Association of County and City Health Officials, “Alternative Methods of Dispensing: Model Highlights,” www.naccho.org/topics/emergency/SNS/upload/POD-Article-4_polling-places.pdf (accessed July 18, 2013).

³¹ Tevi Troy, “Preparing for Bioterrorism,” *The Weekly Standard*, February 23, 2010, <http://www.weeklystandard.com/blogs/preparing-bioterrorism?page=1> (accessed July 18, 2013).

would be tasked with picking up the supplies at the pre-determined general location to which the SNS sent the materials, and would then distribute those materials among the voting sites.

- 3. Employing Private Sector Commercial Infrastructure:** Another promising distributional approach would be to employ the private sector through retail stores and drug manufacturers. Most retail pharmacies have experience with administering flu vaccines, so they already possess basic experience with medical supplies and civilians. Furthermore, they are ideal for handling large crowds looking to procure specific items—that is what they do. Their resources for doing so include large parking lots, storage units to receive large shipments, extensive indoor space laid out for the purpose of dealing with customers, and an available and expandable supply of staff. Perhaps most importantly, retailers also have experience dealing with sales crunches, which a countermeasure supply effort would resemble. On the other side of the equation, retail stores are also familiar and convenient for people. If there is one thing the American people like to do, it is shop. Consequently, there is a retail store within five miles of 95 percent of U.S. residences.

This idea, while promising, has challenges as well. Primary among these issues is the question of liability. If someone were to be injured during the distribution process, or even by the administration of the countermeasure, who would be held liable? As non-governmental employees, the private sector retail workers would face significant liability exposure. Furthermore, the retail stores themselves, as well as their parent companies, could also have some exposure, which would likely make them extremely wary of participating. In fact, it is likely that the only way that the retail store option could be utilized would be if Congress were to provide blanket and explicit liability protection for the workers, the individual locations, and their parent companies.³²

³² Onora Lien, Crystal Franco, Gigi Kwik Gronvall, and Beth Maldin, “Getting Medicine to Millions: New Strategies for Mass Distribution,” UPMC Center for Health Security, *Biosecurity and Bioterrorism* 4, no. 2 (2006), <http://www.upmchealthsecurity.org/website/resources/publications/2006/2006-06-15-medicinetomillions.html> (accessed July 18, 2013).

Fortunately, Congress has already passed similar legislation that exempts volunteers from liability in the event of a national crisis. In 1997, Congress passed the Federal Volunteer Protection Act (FVPA), granting immunity to public health volunteers from non-profits. The FVPA is limited though, for it fails to include punitive or non-economic damages.³³ The Federal Tort Claims Act (FTCA) was extended in 2002 to protect health care professionals that are, or are considered, federal workers. It expanded the definition of federal employees to include workers under federal initiatives, such as the National Disaster Medical System or the Emergency Management Assistance Compact. Protection under FTCA, however, can only be applied in a “federally declared emergency” and fails to completely immunize providers from liability charges. Instead, it shifts the costs of liability to the federal government, but fails to guarantee entire immunity for volunteers or organizations.³⁴ While legislation has been passed with the intention of providing volunteer health workers with protection, more comprehensive liability protection will be required to entice the corporate entities to lend a hand.

4. **Manufacturer Distribution:** Another, somewhat similar private sector option is to utilize drug manufacturers’ pre-existing commercial routes to distribute drugs to recipients. This approach is particularly attractive because it employs routine, pre-established methods of distribution: the manufacturers’ commercial channels have already been put to use multiple times. This option also allows for a single, central dispensing method to avoid the confusion and complexity of various, separate allocation modes.

The way this option could work is as follows: a manufacturer of a particular countermeasure gets a contract with BARDA to provide a specific product to the SNS. Depending on the arrangement, the manufacturer might not even have to

³³ Volunteer Protection Act of 1997, U.S. Government Printing Office, www.gpo.gov/fdsys/pkg/PLAW-105publ19/pdf/PLAW-105publ19.pdf (accessed July 18, 2013).

³⁴ Sara Rosenbaum, Ross Margulies, Orriel L. Richardson, and Jennifer Lee, “Liability Protections for Emergency Volunteer Health Practitioners and Entities,” George Washington University Department of Public Policy, sphhs.gwu.edu/departments/healthpolicy/dhp_publications/pub_uploads/dhpPublication_C05D8938-5056-9D20-3DD91D653A4F563A.pdf (accessed July 18, 2013).

provide the physical product itself to the 12 SNS locations but would instead sell the government a guarantee that they would provide the product to the requested location in case of emergency. In doing so, the manufacturer could use its existing logistics, storage, and security operations to hold on to the product until needed, at which point it could serve as the single distributing force when directed by the SNS, or even after a signal from the marketplace that commercial supplies had been depleted to a pre-arranged degree. The necessary supplies would be dispersed to communities via manufacturer's existing commercial modes of transportation.

In 2008, Roche undertook a similar arrangement with private-sector companies, offering—for a fee—to store guaranteed supplies of Tamiflu for interested corporations that Roche would then supply and distribute within 24 hours in case of a pandemic. Roche's initiative, which is no longer active, was effectively a lease program. It enabled corporations to stake a claim to Tamiflu in the event of a pandemic by ordering a minimum stockpile of 2,500 courses of Tamiflu, amounting to a \$15,000 annual purchase. Each Tamiflu course (10 capsules, the prescribed dosage for an adult) was priced at \$6, which was less than 10 percent of the final market price of Tamiflu. If they did need the product, the companies would then pay the difference between the amount they had already paid and the negotiated corporate price. If the stockpile was not utilized throughout the year, the company had the option to purchase the stockpile at the current market price.³⁵ The company also had the choice to either renew or discontinue the service each year. This kind of arrangement could potentially spare the government significant outlays, as well as logistical hassles, by taking advantage of manufacturers' existing storage facilities, security operations, and supply networks.

5. **Home Medkits:** Home medkits have received a fair amount of attention as an alternative method of supply distribution. These kits would be stored at home,

³⁵ Mary Brophy Marcus, "U.S. firms can stockpile Tamiflu," *USA Today*, June 27, 2008 (updated), http://usatoday30.usatoday.com/money/industries/health/drugs/2008-06-26-Tamiflu_N.htm (accessed July 18, 2013).

making them convenient and available for the entire population. Furthermore, the kits could be purchased by large companies and universities and distributed to large groups of employees and students. The option of home medkits appears attractive since it addresses the issues of panic and the need for rapid deployment after a crisis has already commenced. Citizens are more likely to remain calm during a pandemic knowing they have immediate access to health provisions within the safety and convenience of their own homes.

As with all potential solutions, home medkits have a few drawbacks. Most vaccines have specific requirements, such as administration by a health professional or storage in temperature-sensitive environments. Neither of these restrictions can be accommodated through the use of home medkits. Vaccines would therefore not be included in the kits. In 2008, Secretary of Health and Human Services Mike Leavitt met almost unanimous opposition regarding home medkits from skeptical public health authorities, who distrust citizens' ability to handle the medkits properly. However, a 2006 study performed in St. Louis by the CDC revealed that when given the home medkits, 97 percent of citizens followed the directions of health officials.³⁶ These findings suggest that home medkits can be useful sources of basic provisions, although they obviously cannot cover the entire scope of emergency products.

³⁶ "CDC's Division of Strategic National Stockpile Emergency MedKit Evaluation Study Summary: Background, Key Results, and Next Steps," Centers for Disease Control and Prevention, www.bt.cdc.gov/agent/anthrax/prep/pdf/medkit-evaluation-summary-2007.pdf (accessed July 18, 2013).

Conclusion: Should we have an SNS?

Of course, this discussion about improving the SNS presupposes that we should continue to keep such a stockpile. While most analysts on both sides of the political aisle agree on the value of the SNS, it is not a unanimous view. FDA economist Marta Wosinska, for instance, has argued that the government can't accurately predict which countermeasures will be needed in a crisis, and that stockpiling only serves to drive up prices for the selected countermeasures the SNS does select. This argument may make some sense at a theoretical level, but fails to take into account the state of the American mindset after the most recent, disturbing decade. Furthermore, she argues, stockpiling cannot realistically cover the entire population of the United States, resulting in prioritizing populations that will receive SNS supplies versus those who receive nothing.³⁷ Of course if we were to improve the SNS' documentation procedures and improve the distribution process along the lines argued for in this paper, that would help address Wosinska's concern.

Nate Silver's depiction of an America buffeted by "one unpredicted disaster after another" reminds us that the American people are nervous about what unforeseen catastrophe might lurk around the corner. The SNS, while not perfect, goes a long way toward alleviating that concern by ensuring that the federal government won't be helpless in the case of a crisis. The existence of the SNS itself even arguably deters terrorist bio-threats, since the impact of an attack will be mitigated by the medical countermeasures. Theorists can debate whether there should be a stockpile, or whether government should provide public goods at all, but the most responsible way to arm ourselves against unknown future threats is to make sure that we have the best, most robust, and most efficient SNS possible.

³⁷ Marta Wosinska, "Drug Shortages: Why a Government Stockpile Falls Short as a Solution – Health Affairs Blog," *Health Affairs*, May 2, 2012, <http://healthaffairs.org/blog/2012/05/02/drug-shortages-why-a-government-stockpile-falls-short-as-a-solution/> (accessed July 18, 2013).

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In 2007, he was unanimously confirmed by the U.S. Senate as the Deputy Secretary of the U.S. Department of Health and Human Services. As Deputy Secretary, Troy was the chief operating officer of the largest civilian department in the federal government, with a budget of \$716 billion and over 67,000 employees. In that position, he oversaw all operations, including Medicare, Medicaid, public health, medical research, food and drug safety, welfare, child and family services, disease prevention, and mental health services. He served as the regulatory Policy Officer for HHS, overseeing the development and approval of all HHS regulations and significant guidance. In addition, he led a number of initiatives at HHS, including implementing the President's Management Agenda, combating bio-terrorism, and public health emergency preparedness. He also sponsored a series of key conferences on improving HHS' role with respect to innovation in the pharmaceutical, biomedical, and medical device industries. Troy has led U.S. government delegations to Asia, the Middle East, Europe, North America, and Africa.

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