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A Practical Examination of the Strategic National Stockpile in Response to Public Health Crises

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EXECUTIVE SUMMARY¹

The question of an American public health crisis is not "if," but "when." Accordingly, federal, state, and local governments have worked diligently to institute preparedness mechanisms to address a pandemic. This report seeks to present an evaluation of the Department of Health and Human Services and Centers for Disease Control and Prevention's Strategic National Stockpile as well as other relevant mechanisms to accurately examine whether America is truly ready to respond to a public health emergency.

Included in "Are We Ready?" is a full-scale scenario portraying how the many levels of preparedness mechanisms interact, both positively and negatively. By presenting the research through both a policy-based and applied stance, this report presents the many policy facets involved in public health readiness while detailing their courses of action and working relationships in a larger incident.

As this report proves, the current preparedness mechanisms address many of the emerging public health threats. Advanced planning through national strategies combined with federal, state and local level coordination of many capable systems has strengthened the ability of the government to withstand many health-related incidents. Yet an examination of these mechanisms in practical terms exposes overlaps in management jurisdictions, confusion in decision making situations, and lack of full capacity in supply distribution and infrastructures, and illuminates many of the shortcomings in our full preparedness capability. At the center of such practical shortcomings are the current planning redundancies present, which compound on the decision making confusion and seem to exist completely independent of each other, lacking coordination or information-sharing mechanisms. Our research also showed that while such an abundance of strategies with overlapping jurisdictions and tasks exist, there is a lack of focus on how information travels through the government to the highest levels of the administration, including to the President himself. Furthermore, such an examination as the one found in this report can only begin to fully grasp the larger working inadequacies that will play out in each unique crisis situation.

It is important to note at the outset that as with many preparedness examinations, the levels of unpredictable variables such as levels of panic leading to absenteeism of crucial infrastructure personnel, only further exacerbate an incident; yet do so at an undeterminable level. Again, as the aforementioned states, the analysis of a panic-based situation through practical scenario portrayed here cannot fully predict how such variables will fully be impacted in individual crises.

The recommendations of this report address three main categories of public health preparedness: federal decision making and distribution mechanisms, state and local decision making and distribution mechanisms, and vaccines. Many of these recommendations address specific shortcomings in current policies and warrant further action to rectify the noted limitations.

¹ This report was prepared as part of the MPA Workshop, a required capstone course in the Master of Public Administration program at The Maxwell School of Citizenship and Public Affairs. William C. Banks, Professor of Law and Public Administration and Director of the Institute for National Security and Counterterrorism at Syracuse University provided direction and supervision.

RECOMMENDATIONS

Federal Decision Making and Distribution of SNS Assets

The federal decision making process and distribution systems are a key element to effectively and rapidly responding to a crisis and deploying SNS resources. However, both components of federal responsibility have their shortcomings. The lack of clarity in public health response structures may lead to competition between the Department of Homeland Security (DHS) and the Department of Health and Human Services (HHS) to direct the federal response. This competition for lead agency designation could undermine the federal government's leadership during a public health crisis and with the distribution of Strategic National Stockpile (SNS) assets. The various regimes for requesting federal help and the difficulty of cabinet agencies to lead the response may cause confusion on how to obtain and distribute the SNS supplies. Importantly, the respective agencies, including the Centers for Disease Control and Prevention (CDC), and HHS have faced only regional health crises of limited duration such as the response to Hurricane Katrina. They lack the experience on leading and collaborating with other federal agencies to counter a national health crisis of significant duration.

As the federal government prepares for a public health crisis, it must delineate the authorities of federal agencies leading the response and ensure that the decision making process does not impair the ability to distribute medical assets. Furthermore, in the event of a nation wide emergency, two central problems with the federal distribution systems emerge: an unstandardized tracking system and disrupted multi-point delivery inconsistent from the federal to local level. The first six recommendations specifically address these shortcomings of federal responsibility for decision making and distribution.

Our first recommendation is to ensure a clear and comprehensive process for governors to request assets from the Strategic National Stockpile. The number of plans and overlapping legislative jurisdictions may lead to confusion for governors when requesting assistance. At the same time, governors may also be requesting non-HHS federal support. The plans should be clear and consistent on where to obtain HHS assets.

Our second recommendation is to maintain clear lines of authority over who can plan for and deploy assets during an emergency. The numerous plans may lead to competition between HHS and DHS over the public health response to a nationwide crisis. DHS and its subordinate agencies should maintain unambiguous authority to plan for the purchase, logistics and deployment of SNS assets which is consistent with epidemiological intelligence.

Our third recommendation is to conduct a confidential review of HHS, CDC, and SNS ability to prioritize assets around the country. While responsive to localized incidents, such as September 11 and Hurricane Katrina, the SNS program has never faced a crisis of large proportion and duration which will require strategic planning to mitigate the spread of a pandemic. The review should investigate whether the SNS has the capacity to handle a crisis that large, the ability to prioritize response and the capability to advise the Secretary of HHS and the President in response to the crisis.

Our fourth recommendation is to use RFID to track delivery and distribution of SNS and VMI materials. RFID (radio frequency identification devices) uses paper-like tags to electronically store and receive product data. They "can be attached to or incorporated into a product such as a carton of pharmaceuticals." RFID will allow for real-time electronic tracking of the Push Packages, VMI materials, and CHEMPACKS. Indeed, "moving forward supplies received under emergency conditions must not be hindered by inventory control paperwork" or rely heavily on individual labor. Local authorities should begin incorporating RFID into their RSS operations as soon as possible. Also, "the DHS should provide a prototype software module to utilize RFID" at the state and local levels – expediting the national progress to automation.

Our fifth recommendation is to conduct a multi-point SNS delivery exercise. CDC has conducted single point exercise in the past, which simulated the delivery of one Push Package to a single location. As a result, there is no available information on the federal capability to simultaneously deliver multiple SNS Push Packages and VMI assets to the same region. A multi-point delivery exercise would provide a capability assessment for a multi-point event.

Our sixth recommendation is to increase funding for state and local preparedness training to manage SNS assets. Efforts such as the Cities Readiness Initiative (CRI) help raise local awareness of federal emergency management programs. The more state and local agencies practice working with these programs, the more routine they become and the more prepared they will be when they need to request SNS materiel. States and local governments need more federal funding to carry out local preparedness training and expand the programs under the CRI.

State and Local Decision Making and Distribution of SNS Assets

Ultimately, the effectiveness of a federal response to a medical emergency depends upon the preparedness at the community level. The local capability to handle incoming federal assets, operate effectively with neighboring communities, and fully utilize an unspecified business and citizen volunteer base is key to an effective local response plan. Many state and local governments have worked extensively to improve their emergency preparedness following the devastation of Hurricane Katrina. Through programs like the Cities Readiness Initiative (CRI), the CDC is being proactive by educating state and local officials about assets available for their local communities through the SNS programs. SNS Program Coordinators are heavily involved in providing SNS training exercises, coordinating with pandemic flu state summits, and other emergency preparedness activities. Moreover, some states established initiatives to garner a volunteer base with the hope of producing a skilled response force prior to the actual crisis. However, more needs to be done.

² Belson, David. "Storage, Distribution and Dispensing of Medical Supplies." Online Posting. 12 April 2003. Center for Risk and Economic Analysis of Terrorism Events, University of Southern California.

http://www.usc.edu/dept/create/reports/Med_Supplies_Report_v5.pdf>.

³ *Id*.

⁴ Belson, David. "Storage, Distribution and Dispensing of Medical Supplies." Online Posting. 12 April 2003. Center for Risk and Economic Analysis of Terrorism Events, University of Southern California. http://www.usc.edu/dept/create/reports/Med Supplies Report v5.pdf>.

Despite these tremendous efforts, state and local preparedness varies across the nation and many smaller or rural communities lack any preparedness planning at all. A recent report from the Department of Homeland Security, *Nation-wide Plan Review: Phase Two Report*, acknowledges the variance and numerous shortcomings that must to be addressed. While they found more planning initiatives and general movement in the right direction, there was significant concern over the current status of most community plans. The following five recommendations prescribe possible methods to enhance the planning process, and consequently state and local emergency response.

Our seventh recommendation is to clarify ownership and liability concerns for sharing SNS assets among states and across communities. Both the U.S. government and individual states must be proactive in addressing legal issues before a crisis hits. The CDC should spell out exactly who is legally liable for SNS assets if they are transferred between states. At the state level, the Emergency Management Assistance Compact (EMAC) provides states with sample legislation and other resources for streamlining mutual aid. All states should ensure that they have such legislation in place and that it is incorporated into their emergency response plans.

Our eighth recommendation is to streamline and clarify procedures for sharing SNS assets among states. The most recent draft of the CDC's Preparedness Guide does not give clear guidance for dealing with questions related to multi-state coordination. In a nationwide emergency it will be imperative that states are able to distribute SNS assets quickly to other states to meet rapidly changing priorities.

Our ninth recommendation is to encourage every community to have and practice an emergency preparedness plan. Communities and states that lack a comprehensive emergency preparedness plan should immediately form a Task Force dedicated to the creation and practice of such a plan. Following an intense simulated response (preferably including all local, state, federal components) states should complete a 360-degree review of the implementation to determine where their plan is inadequate.

Our tenth recommendation is to arrange formal agreements with private business to assist with the distribution of SNS assets. Each community possesses most of the necessary infrastructure, both private and public sectors, to distribute the SNS assets. However, local officials must first recognize and then formalize this partnership with the private business sector. Using the guidelines and templates provided by the federal government, local officials can easily arrange formal agreements with these private businesses to include them in the local emergency preparedness plan.

Our eleventh recommendation is for state and local governments to take more of an initiative in recruiting volunteers before a public health emergency and/or terrorist incident occurs. Due to the fact that the distribution of SNS assets on the state and local level relies heavily on volunteers, state and local communities should solicit, train and assign to specific roles in preparation for a response to public health crises. The state government and

⁵ United States Department of Homeland Security in cooperation with the United States Department of Transportation. <u>Nationwide Plan Review: Phase 2 Report.</u> 16 June 2006.

http://www.dhs.gov/interweb/assetlibrary/Prep NationwidePlanReview.pdf>.

local communities cannot make the assumption that volunteers will be easily recruited and organized during a national health emergency. As soon as possible, states need to institute necessary measures following the guidelines provided by the Centers for Disease Control and Prevention. These include implementing "a state volunteer coordinator and staff; a recruitment program that draws from appropriate community resources and maintains accurate records on potential volunteers; an effective training program for all volunteers; a mechanism to regularly exercise volunteers to maintain interest and skill levels; and an evaluation mechanism to assess volunteer performance and program effectiveness post event or post exercise."

Vaccines

Addressing the policy issues involved with the decision making and distribution structures of the Strategic National Stockpile (SNS) can only strengthen national preparedness to a certain extent. The United States must also take the initiative in ensuring the adequacy of medical countermeasures. It is clear that the preeminent defense against a pandemic involving a biological agent is intense doses of antibiotics, anti-virals, or vaccination. However, it is also the most complicated defense to attain. "A fully effective vaccine cannot be developed until the virus strain it must protect against has evolved and been identified. And once developed, there must be the production capacity to manufacture enough vaccine to protect the population."⁷ The United States must work diligently to bolster the vaccine industry because its failure to do so has become the main reason the nation is highly vulnerable to a public health crisis. There are a limited number of vaccine plants currently located in the United States and their production capacity is severely limited. The right steps are being taken in that "the U.S. has recently announced a plan to provide incentives to industry to switch to modern vaccine production methods."8 However, more needs to be done. For instance, increasing vaccine production capability is especially significant in the case of pandemic influenza. The United States is inadequately prepared to produce enough doses of a vaccine, once the influenza virus strain is identified, for all Americans in a reasonable period time.. The following recommendations help to address this issue as well as concerns regarding liability, regulatory flexibility, and transparency.

Our twelfth recommendation is for the United States government to continue to reduce liability for vaccine manufacturers and increase regulatory flexibility. The Department of Health and Human Services (HHS) in coordination with the Department of Justice (DOJ) recently aided Congress in proposing legislation to address the problem of liability for vaccine manufacturers. The PREP Act provides the vaccine industry with limited liability when supplying vaccines during a declared public health emergency. Additionally, "if a pandemic occurs prior to licensure of a vaccine, the Food and Drug Administration (FDA) can use its

⁶ Centers for Disease Control and Prevention Strategic National Stockpile Program. <u>Volunteers:</u>

<u>Where to find them; how to train them; and how to keep them.</u> https://www.orau.gov/snsnet/Volunteerism_2003-07.htm#volunteerism>.

⁷ United States Department of Health and Human Services. <u>Pandemic Planning Update: A Report from Secretary Michael O. Leavitt</u>. 13 March 2006. < http://www.pandemicflu.gov/plan/pdf/panflu20060313.pdf>.

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⁹ Russert, Tim. Interview with Dr. Julie Gerberding, Director of the Centers for Disease Control and Prevention. 20 November 2005. Meet the Press Transcript. http://www.msnbc.msn.com/id/10042399/>.

¹⁰ United States Department of Health and Human Services. <u>Pandemic Planning Update: A Report from Secretary Michael O. Leavitt</u>. 13 March 2006. < http://www.pandemicflu.gov/plan/pdf/panflu20060313.pdf>.

Emergency Use Authorization authority to permit the use of unapproved products if there is a reasonable belief the products may be effective and if the benefits would outweigh the risks." However, despite these recent developments the threat of liability still remains a "major obstacle to developing a strong domestic vaccine industry."

Our thirteenth recommendation is for the United States government to ensure that there is a market for the vaccines that are being developed. The BioShield Act designated funds to stockpile vaccines for the purpose of responding to a biological and chemical incident or other public health emergency. These funds must continue to be dedicated to securing vaccines for the entire U.S. population in case of a pandemic influenza or other biological incident. These efforts should be similar to what has already been accomplished in preparation for a response to a smallpox outbreak. Most recently, HHS secured Congressional funding for, "the development of a cell-based influenza vaccine, and expects to award additional contracts for developing cell-based vaccines this Spring." Nevertheless, more efforts need to be made in this area in order for the United States to be sufficiently equipped to respond to a pandemic.

Our fourteenth recommendation is for the United States to strengthen international cooperation and global disease surveillance systems in an effort to increase transparency. The first line of defense against a pandemic is early detection of the virus. "Early detection will give the United States the opportunity to respond, to attempt containment and to quickly gain the virus samples necessary for the development of a true pandemic vaccine." A network of federal, state and local agencies should be in place to be able to diagnose the disease when symptoms appear in patients submitted to hospitals and public health care facilities. State and local capabilities need to be strengthened to ensure that measures can then be implemented to help contain "the virus and reduce the spread to vulnerable people in the population." 15

Our fifteenth and final recommendation is to obligate state and local authorities to create a supply chain management plan suited to their community. Disaster response plans are purposefully initiated, implemented and resourced by state and local communities because they are better suited than the federal government to directly address and respond to the needs of their constituents. Consequently, state and local officials must be required to effectively plan the complex transportation systems that will be needed to distribute vaccines and anti-virals that may be required in an emergency situation. Contact should be initiated with private distribution and logistics firms as either advisors or distribution partners to assist with planning and implementation.

¹¹ United States Department of Health and Human Services. <u>Pandemic Planning Update: A Report from Secretary Michael O. Leavitt.</u> 13 March 2006. < http://www.pandemicflu.gov/plan/pdf/panflu20060313.pdf>.

 $[\]overline{^{12}} Id.$

¹³ *Id*.

¹⁴ *Id*.

¹⁵ Russert, Tim. Interview with Dr. Julie Gerberding, Director of the Centers for Disease Control and Prevention. 20 November 2005. Meet the Press Transcript. http://www.msnbc.msn.com/id/10042399/.

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LIST OF ABBREVIATIONS

APSPHEP Assistant Secretary for Public Health and Emergency Preparedness

ASD/HA Assistant Secretary of Defense for Health Affairs

BOL Bureau of Laboratories

CBIRF Chemical and Biological Incident Response Force

CBNRE Chemical, Biological, Radiological, Nuclear, or High Yield

Explosive

CDC Centers for Disease Control and Prevention

CRI Cities Readiness Initiative

CS Civil Support

DEA Drug Enforcement Administration

DEOC CDC Director's Emergency Operations Center

DHS Department of Homeland Security

DLA Defense Logistics Agency

DNSC Defense National Stockpile Center

DOD Department of Defense

DSCP Defense Supply Center Philadelphia
DSNS Division of Strategic National Stockpile
EMAC Emergency Management Assistance Compact

EMS Emergency Medical Service EOC Emergency Operations Center

ESF #8 Emergency Support Function #8: Public Health and Medical

Services Annex

FEMA Federal Emergency Management Agency

HAN Health Alert Network

HDMA The Healthcare Distribution Management Association

HHS, DHHS Department of Health and Human Services
HSPD-5 Homeland Security Presidential Directive – 5

ICS Incident Command System

IDE Infectious Disease Epidemiology

JFO Joint Field Office

JIC Joint Information Center JOC Joint Operations Center LFA Lead Federal Agency

MACA Military Assistance to Civil Authorities

MSA Metropolitan Statistical Area

NG National Guard

NIMS National Incident Management System NPS National Pharmaceutical Stockpile

NRP National Response Plan

NSPI: IP The National Strategy for Pandemic Influenza: Implementation

Plan

NYSDOH New York State Department of Health

OTC Over The Counter

PADOH Pennsylvania Department of Health

PDPH Philadelphia Department of Public Health

PHIN Public Health Information Network

PMC Presbyterian Medical Center

POD Point of Distribution

RFID Radio Frequency Identification Devices

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RSS Receipt, Store, Stage SecDef Secretary of Defense SKU Stock Keeping Units

SLEP Shelf-Life Extension Program
SNS Strategic National Stockpile
TARU Technical Advisory Response Unit
TFAH The Trust for America's Health
TRANSCOM Transportation Command

UC Unified Command

UDR Universal Data Repository
USPS United States Postal Service

USTRANSCOM United States Transportation Command

VA Department of Veterans Affairs VMI Vendor Managed Inventory

THE STRATEGIC NATIONAL STOCKPILE

The Centers for Disease Control and Prevention's (CDC) Strategic National Stockpile (SNS) contains massive quantities of medicine and medical supplies to protect the American public in the event of a public health emergency severe enough to eradicate local supplies. The stockpile "ensures the availability and rapid deployment of medical assets and countermeasures to the site of a terrorist attack or other national public health emergency." It includes items such as antibiotics, chemical antidotes, antitoxins, life-support medications, IV administration, and ventilators. ¹⁸

The SNS is not a first response tool, but rather assets that supplement state and local resources in a public health crisis. "Once federal and local authorities agree that the SNS is needed, medical supplies will be delivered to any state in the United States within twelve hours. Each state has plans to receive and distribute SNS assets to local communities as quickly as possible." ¹⁹

The main purpose of the SNS is to "address the ongoing problem of threats from the intentional release of smallpox, anthrax or plague, radiological/nuclear attacks, chemical attacks and other threats such as an influenza pandemic." The United States is equally vulnerable to all of these threats. Therefore, the government must refine the decision making and distribution processes for SNS assets and to ensure that they are adequate to respond to both small-scale and large-scale incidents.

History and Jurisdiction of the Strategic National Stockpile

In 1999, the U.S. Congress tasked the Department of Health and Human Services (HHS) and Centers for Disease Control and Prevention (CDC) with establishing the National Pharmaceutical Stockpile (NPS) that could "re-supply large quantities of essential medical materiel to states and communities during an emergency within twelve hours of a federal decision to deploy." The responsibility of the NPS has rotated among several government agencies leading to possible confusion over its control. Under the Homeland Security Act of 2002, Congress created the Department of Homeland Security (DHS), and charged them with the responsibility for "defining the goals and performance requirements of the program, as well as managing the actual deployment of assets" for the SNS program. Leadership shifted once again in March 2003 when the National Pharmaceutical Stockpile program became the Strategic National Stockpile program, under shared management of the departments of Homeland Security

¹⁶ <u>Strategic National Stockpile Site.</u> 14 April 2005. Centers for Disease Control and Prevention and Department of Health and Human Services. http://www.bt.cdc.gov/stockpile/>.

¹⁷ Strategic National Stockpile Program Site. Program Assessment 2005. U.S. Office of Management and Budget. .

¹⁸ Strategic National Stockpile Site. 14 April 2005. Centers for Disease Control and Prevention and Department of Health and Human Services. http://www.bt.cdc.gov/stockpile/.

²⁰ <u>Strategic National Stockpile Program Site</u>. Program Assessment 2005. U.S. Office of Management and Budget. www.ExpectMore.gov>.

²¹ Prior, Stephen. Report Commissioned by the National Defense University Center for Technology and National Security Policy. Who You Gonna Call?: Responding to a Medical Emergency with the Strategic National Stockpile. June 2004.

and Health and Human Services. Finally, the SNS was placed in its current jurisdiction under the Department of Health and Human Services.²² We will discuss the decision making process of how the SNS is deployed and details on how the jurisdictional agencies exercise their control in emergency situations in greater detail later in this report.

How will the United States Respond?

"We are not as prepared as we need to be. We're better prepared today than we were yesterday. We'll be better prepared tomorrow. It's a continuum of preparedness."²³

Any future federal government response to a public health emergency must utilize the lessons learned from Hurricane Katrina. The Select Bipartisan Committee to Investigate the Preparation for the Response to Hurricane Katrina highlights the importance of preventing competing federal command-and-control systems from undermining a response by requiring a lead agency to take command of operations.²⁴ The sustained difficulty of prioritizing assets and the multiplicity of plans will hinder the federal response.

Currently, the federal government has several federal response structures involving public health crises:

- Homeland Security Presidential Directive 5
 - o National Incident Management System
- The National Response Plan
 - o Emergency Support Function #8: Public Health and Medical Services Annex
 - Biological Incident Annex
- National Strategy for Pandemic Influenza: Implementation Plan
 - o Health and Human Services Strategy on Pandemic Influenza

Homeland Security Presidential Directive - 5

Under Homeland Security Presidential Directive – 5 (HSPD-5), the Secretary of the Department of Homeland Security is the domestic incident manager. "As the domestic incident manager, the Secretary of DHS will coordinate the overall federal response to an incident in order to ensure the continuity of our government, maintain civil order, preserve the functioning of society and mitigate the consequences of an outbreak. The Secretary of DHS serves as the principal federal official for overall domestic incident management." ²⁵

²² Strategic National Stockpile Site. 14 April 2005. Centers for Disease Control and Prevention and Department of Health and Human Services. http://www.bt.cdc.gov/stockpile/>.

²³ Russert, Tim. Interview with Secretary of the Department of Health and Human Services Michael Leavitt. 20 November 2005. Meet the Press Transcript. http://www.msnbc.msn.com/id/10042399/.

²⁴ Select Bipartisan Committee to Investigation the Preparation for and Response to Hurricane Katrina. <u>A Failure of Initiative</u>. 15 February 2006. http://katrina.house.gov/full_katrina_report.htm.

W. Runge, M.D., Acting Undersecretary for Science and Technology and Chief Medical Officer, U.S Department of Homeland Security. 11 May 2006. http://www.dhs.gov/dhspublic/display?theme=45&content=5615.

When issuing Homeland Security Presidential Directive – 5, the President also directed the Secretary of Homeland Security to create the National Incident Management System (NIMS). Consistent with the purpose behind the creation of the Department of Homeland Security as a whole, NIMS is a coordination mechanism meant to streamline many similar processes as well as a method of distributing best practices and lessons learned for planning purposes. NIMS was created to provide, "a consistent national template to enable federal, state, local, and tribal governments and private-sector and nongovernmental organizations to work together effectively and efficiently to prepare for, respond to, prevent, and recover from domestic incidents, regardless of cause, size, or complexity, including acts of catastrophic terrorism." The original directive also called for the adoption of NIMS-based management and cooperation of federal agencies at the outset with the added cooperation of other agencies including state and local governments and nonprofit institutions to comply with the system starting with their FY2005 assistance. ²⁶

At the heart of the NIMS structure are six basic components: command and management, preparedness, resource management, communications and information management, supporting technologies, and ongoing management and maintenance. Most important to the overall operation is the Incident Command System (ICS), which works as a conduit for command authority and information, ensuring consistency across all levels of an operation. Furthermore, the ICS integrates the planning and management of, "facilities, equipment, personnel, procedures, and communications," to more aptly and efficiently address both large and small-scale incidents stemming from natural and manmade disasters, in this case, including public health crises.²⁷

The National Response Plan

A public health emergency will require activation of the *National Response Plan* (NRP), "especially if the first appearance of a disease or virus in the U.S. occurs in one or a few isolated communities and an intense multi-party containment effort led by the federal government seems feasible." There are two regimes under the NRP that would be used in a nationwide health emergency. The federal government may choose to activate the Emergency Support Function #8: Public Health and Medical Services Annex (ESF #8) of the NRP. In doing so, HHS would become the primary agency that "coordinates the provision of federal health and medical assistance to fulfill the requirements" identified by state and local authorities. A for the assets contained in the Strategic National Stockpile, the NRP declares HHS as the agency that "evaluates state requests for deployment or pre-deployment of the SNS based upon relevant threat information." In addition, "HHS may request that DHS, DOD, or VA (Department of Veteran's Affairs) provide medical equipment and supplies, including medical, diagnostic, and

²⁶ United States Department of Homeland Security. <u>National Incident Management System: NIMS Document.</u> 1 March 2004. http://www.fema.gov/pdf/emergency/nims/nims_doc_full.pdf. ²⁷ *Id.*

²⁸ Our analysis found no changes in the Notice of Change to the National Response Plan in regards to the public health response.

United States Department of Homeland Security. <u>National Response Plan: Biological Incident Annex</u>. December 2004. http://www.dhs.gov/dhspublic/interapp/editorial/editorial_0566.xml. ²⁹ *Id*

³⁰ *Id*.

radiation-emitting devices, pharmaceuticals, and biological products in support of immediate medical response operations and for restocking health care facilities in an area affected by a major disaster or emergency."³¹

On the other hand, the *National Response Plan* could also be activated under the Biological Incident Annex. HHS will again take sole responsibility for coordinating "the public health and medical preparation for and response to a biological terrorism attack or naturally occurring outbreak that results from either a known or novel pathogen, including an emerging infectious disease." However, state and local governments are "primarily responsible for detecting and responding to disease outbreaks and implementing measures to minimize the health, social and economic consequences of an outbreak." The state and local public health system is required to initiate appropriate measures to protect and respond to the infected population with immediate emphasis on first responders and health care workers. These procedures may include mass vaccination or prophylaxis. "An overarching goal is to develop, as early as possible in the management of a biological incident, a dynamic, prioritized list of treatment recommendations based on epidemiologic risk assessment and the biology of the disease/microorganism in question, linked to the deployment of the SNS and communicated to the general public." "

National Strategy for Pandemic Influenza

The Homeland Security Council issued *The National Strategy for Pandemic Influenza: Implementation Plan* (NSPI: IP) in November 2005. The NSPI: IP details the President's Homeland Security Advisor's strategy. It reaffirms the *National Response Plan* and the role of DHS in the overall coordination of the federal response. DHS will support HHS in the response to the public health emergency and HHS is charged with the responsibility of, "maintenance, prioritization, and distribution of countermeasures in the Strategic National Stockpile." ³⁵

The NSPI: IP is meant to "guide the preparedness and response to an influenza pandemic, with the intent of (1) stopping, slowing or otherwise limiting the spread of a pandemic to the United States; (2) limiting the domestic spread of a pandemic, and mitigating disease, suffering and death; and (3) sustaining infrastructure and mitigating impact to the economy and the functioning of society." The strategy was constructed to be consistent with the *National Security Strategy* and the *National Strategy for Homeland Security* and is framed around three pillars: preparedness and communication, surveillance and detection, and response and containment.

In regards to preparedness and communication, the strategy calls for developing federal implementation plans, collaborating with other nations through multilateral health organizations, continuing work with state and local governments, encouraging states to develop production capacity and stockpiles and subsidizing the development of state-based antiviral stockpiles. The

³¹ United States Department of Homeland Security. <u>National Response Plan: Biological Incident Annex</u>. December 2004. http://www.dhs.gov/dhspublic/interapp/editorial/editorial_0566.xml.

 $^{^{32}}$ Id.

 $^{^{33}}$ Id.

³⁴ *Id*.

³⁵ The Homeland Security Council. <u>The National Strategy for Pandemic Influenza: Implementation Plan.</u> 1 November 2005: 29. http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html. ³⁶ *Id.*

U.S. needs to "ensure that our national stockpile and stockpiles based in states and communities are properly configured to respond to the diversity of medical requirements presented by a pandemic, including personal protective equipment, antibiotics and general supplies." The plan also calls for distribution plans to be established for vaccines and anti-virals and for federal agencies to prioritize countermeasures allocation.

To strengthen surveillance and detection, the U.S. government needs to ensure the rapid reporting of outbreaks and increase surveillance to limit their spread. As for response and containment, the federal government should work to "develop a coalition of strong partners to coordinate actions to limit the spread of a virus; leverage national medical and public health surge capacity; sustain infrastructure, essential services and the economy; and work to ensure clear, effective and coordinated risk communication."

Within the NSPI: IP, the *Health and Human Services Strategy on Pandemic Influenza* discusses the roles of HHS agencies during pandemic flu. The Secretary of HHS "directs all HHS pandemic response activities" and the CDC would "coordinate antiviral and other drug delivery from the Strategic National Stockpile."

The Joint Information Center

The distribution of information to the public during a health or medical emergency is a critical element to both the federal and state response. To address this issue, the primary Joint Information Center was established in support of the *National Response Plan* and the *National Incident Management System* and is coordinated by DHS. The Joint Information Center (JIC) is a "central point for coordination of incident information, public affairs activities, and media access to information regarding the latest developments." In the event of a disaster, the JIC coordinates communications among the federal, state, local, and private sector to deliver a consistent message to the public. However, it is only "authorized to release general medical and public health response information to the public after consultation with HHS."

There are two types of Joint Information Centers, a national JIC and a specific incident JIC. The National JIC is initially a virtual forum established to coordinate information among affected states, federal departments, and agencies.⁴² When an incident is expected to be of long duration (i.e. weeks or months) or affects a large area(s) of the country, a physical National JIC is established.⁴³

³⁷ The Homeland Security Council. The National Strategy for Pandemic Influenza: Implementation Plan. 1 November 2005. http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.htm.

 $^{^{38}}$ Id.

³⁹ United States Department of Health and Human Services. <u>HHS Pandemic Influenza Plan</u>. November 2005: 28. http://www.hhs.gov/pandemicflu/plan/pdf/HHSPandemicInfluenzaPlan.pdf.

⁴⁰ United States Department of Homeland Security. National Response Plan. December 2004.

http://www.dhs.gov/interweb/assetlibrary/NRP FullText.pdf>.

⁴¹ United States Department of Homeland Security. <u>National Response Plan: Biological Incident Annex</u>. December 2004. http://www.dhs.gov/dhspublic/interapp/editorial/editorial/o566.xml.

⁴² United States Department of Homeland Security. <u>National Response Plan</u>. December 2004.

http://www.dhs.gov/interweb/assetlibrary/NRP FullText.pdf>.

⁴³ *Id*.

"The Incident JIC is the physical location from which public affairs professionals from organizations involved in the response work together to provide critical emergency information, media response, and public affairs functions. It serves as a focal point for the coordination and dissemination of information to the public and media concerning incident prevention, preparedness, response, recovery, and mitigation. The Incident JIC may be established at an on-scene location in coordination with state, local, and tribal agencies depending on the requirements of the incident. In most cases, the JIC is established at or is virtually connected to the Joint Field Office (JFO), under the coordination of DHS Public Affairs."

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Each Joint Information Center is staffed with a number of personnel including DHS and Federal Emergency Management Agency (FEMA) public information officers and staff, the FBI public information officer and staff (when activated in support of a terrorist incident), other federal agency public information officers, as required; along with state, local, tribal, and non-governmental organizations public information officers.⁴⁵

"In conjunction with strategic communications guidance from DHS, [federal agencies and departments] assume certain primary agency responsibilities for incident communications with the public when assigned or consistent with specific departmental and agency authorities." For example, "the Department of State assumes primary responsibility for public affairs issues during incidents requiring federal coordination, which involves another nation, aliens, foreignowned transportation modes, or international policy issues."

Potential Conflicts with a National Response

The multiple response regimes at the federal level may lead to confusion on the role of cabinet agencies during a national crisis. The existing response plans do not clearly distinguish the roles of DHS and HHS in responding to a public health emergency. For instance, DHS and HHS each have a lead role under the Biological Incident Annex and Emergency Support Function #8. Unfortunately, during a national public health crisis, the scope of the crisis will strain existing response plans; the secretaries will struggle to coordinate the federal response. The lack clarity in the roles of DHS and HHS may undermine the deployment of medical countermeasures from the SNS. The activation of agency authorities under the Public Health Services Act, Stafford Act, and National Emergencies Act will also increase coordination problems, as some agencies may believe they have greater authority to lead. Although these existing response plans seem comprehensive, they lack guidance on the interaction between DHS and HHS or attention to the importance of deploying the nation's medical countermeasures within the SNS.

⁴⁴ United States Department of Homeland Security. National Response Plan. December 2004.

http://www.dhs.gov/interweb/assetlibrary/NRP FullText.pdf>.

⁴⁵ Id.

⁴⁶ Id.

⁴⁷ United States Department of Homeland Security. Notice of Change to the <u>National Response Plan</u>. 25 May 2006. http://www.dhs.gov/interweb/assetlibrary/NRP Notice of Change 5-22-06.pdf>.

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The following shaded areas illustrate a hypothetical scenario portraying the positive and negative interactions of the various preparedness mechanisms. By presenting the research through both a policy-based and applied stance, this report presents the many policy facets involved in public health readiness while detailing their courses of action and working relationships in a larger incident.

SCENARIO: Flight 815 Arrives in the United States

As flight 815 boards for Los Angeles, the passengers traveling back from their Christmas vacation in South East Asia do not pay much attention to the coughing gate attendant. Eighteen hours later, Flight 815 lands in Los Angeles and its compliment of mostly American passengers run to catch their connecting flights home. Over the next 48 hours, the passengers of Flight 815 begin exhibiting symptoms of the flu. Most think nothing of their illness and believe the symptoms are side-effects of travel and jet-lag.

At 7 pm on a cold January night, a young man from Flight 815 rushes to Presbyterian Medical Center (PMC) Emergency room in Philadelphia, Pennsylvania. He is sweating profusely as the attending nurse quickly checks him over. The nurse notes the high fever and takes his vitals. The doctor, who later receives the report of the nurse, orders a blod sample and sends the blood to an onsite labratory. At 9 pm, the attending doctor receives a report that the patient is suffering from an unknown virus that is highly contagious. The doctor orders the patient moved to a separate room. In a matter of minutes the administrator makes a call to the Philadelphia Department of Public Health (PDPH) and arranges for the specimen to be tested by the Bureau of Laboratories (BOL), simultaneously activating an initial epidemiology to determine the extent and methods of transmission. Under advice from the PDPH, the doctor quarantines the patient.

Several other passengers in multiple cities around the United States visit their physicians. Some physicians, believing the illness to be nothing more than the common flu (winter is flu season in the U.S.), give them an anti-viral and send them home with orders to rest. Yet other physicians, out of concern, send those who visited to hospitals. Unknown to the passengers of Flight 815 and their physicians, they are carriers of an unknown virus – contracted from the gate attendant days earlier.

In Philadelphia, confirmation of a novel virus from the BOL is quickly passed to PDPH, Division of Infectious Disease Epidemiology (IDE), Bureau of Community Health Systems, and the Secretary of the Penusylvania Department of Health. Within hours, the collaborative research team discovers that the

⁴⁸ City of Philadelphia Department of Health. <u>Pandemic Influenza Preparedness Plan</u>. 12 May 2006. Philadelphia, PA represents a busy hub for business, travel, and education; the fifth largest city in the United States and possesses an implemental pandemic influenza draft. Likewise, Pennsylvania represented a standard state plan: cohesive, with implemental structure and defined roles, but lacking in some areas, with notable gaps for implementation. Based on a report by the Trust for America's Health, Pennsylvania's health preparedness ranked 5 on a scale from zero to ten. According to Philadelphia's Emergency Preparedness Plan, when assuming the most severe scenario, the city of Philadelphia could expect approximately 8,000 hospital admissions and approximately 1,750 deaths related to pandemic influenza...and 32,000 additional patient days in the hospital if the average influenza patient had a four-day admission" (CDC FluSurge program for pandemic impact: Severe assumptions equates a 35percent attack rate and 12 week duration).

⁴⁹ City of Philadelphia Department of Health. Pandemic Influenza Preparedness Plan. 12 May 2006.

⁵⁰ Bureau of Laboratories Site. State of Pennsylvania Department of Health.

. The Department of Health through the Bureau of Laboratories operates the State Health Laboratory that maintains a state of readiness to support the investigation of disease outbreaks or threats to the public health.

young man has recently returned from vacationing in a region in Southeast Asia suspected to harbor the virus. After flying from LAX to JFK International Airport, he took Amtrak from NYC to Philadelphia. The Philadelphia Department of Health immediately contacts the Pennsylvania Department of Health, New York State Department of Health (NYSDOH), the California State Department of Health, and the CDC to notify them of the potential for contact transmission. Pennsylvania, New York, and California immediately set up an Emergency Operations Center (EOC) to coordinate the forthcoming efforts between the federal, state, and local agencies. The Health Alert Network (HAN), a part of the Public Health Information Network (PHIN)⁵³, notifies the nation of the confirmed cases in three major cities.

As the virus spreads, the public becomes extremely concerned. Many, fearing they have the virus, head to hospitals only to find overworked staff and limited supplies. Fear of the virus triggers a rush of orders to medical suppliers. As a result, medical supplies begin to dwindle in the region. Indeed, as resources become scarce even individual hospitals, local governments, and states become unwilling to share resources with other facilities.⁵⁴

Fearing an imminent exacerbation of local medical supplies and hospital capacity, the Governor of Pennsylvania – already in constant communication with the departments of Homeland Security (DHS), Health and Human Services (HHS), and the Centers for Disease Control and Prevention (CDC) – declares a State of Emergency for Pennsylvania. Standing alone, Philadelphia is a city of about 1.5 million people⁵⁵. However, it has a large labor population that commutes from other areas of Pennsylvania, Delaware, and New Jersey – facilitating a quick spread of the virus to suburbia and beyond.

Over the next week, thousands of cases are reported in over 20 major U.S. cities (including Philadelphia, New York, Washington DC, Los Angeles, Chicago, Memphis, Houston, Denver, Seattle, Boston, Miami, and Atlanta). As states deplete their internal medical and emergency management assets, they turn to the federal government for SNS assistance.

⁵¹ New York State's Response to Terrorism Site. New York State Office of Homeland Security.

http://www.security.state.ny.us/response.html. The Northeast Regional Homeland Security Agreement Initiative links New York with Delaware, Pennsylvania, New Jersey, Connecticut, Rhode Island, Massachusetts, Vermont, New Hampshire and Maine on critical counter-terrorism issues (mutual assistance, best homeland security practices and information-sharing). In essence, this permits information to be transferred without alerting the public and causing a pre-mature alarm.

⁵² Health Network Site. United States Department of Health and Human Services Centers for Disease Control and Prevention. http://www.phppo.cdc.gov/han/. From the site: HAN provides vital health information and the infrastructure to support the dissemination of that information at the State and Local levels, and beyond. A vast majority of the State-based HAN programs have over 90percent of their population covered under the umbrella of HAN. The HAN Messaging System currently directly and indirectly transmits Health Alerts, Advisories, and Updates to over one million recipients. The current system is being phased into the overall PHIN messaging component.

⁵³ <u>Public Health Information Network Site</u>. United States Department of Health and Human Services Centers for Disease Control and Prevention. http://www.cdc.gov/phin/. From the site: The Public Health Information Network (PHIN) is CDC's vision for advancing fully capable and interoperable information systems in the many organizations that participate in public health. PHIN is a national initiative to implement a multi-organizational business and technical architecture for public health information systems.

⁵⁴ United States Homeland Security Council. <u>National Planning Scenarios: Created for Use in National, Federal, State and Local Homeland Security Preparedness Activities</u>. April 2005. http://media.washingtonpost.com/wp-srv/nation/nationalsecurity/earlywarning/NationalPlanningScenariosApril2005.pdf.

^{55 &}lt;u>United States Census Bureau 2004 Estimate Site</u>. United States Census Bureau. http://quickfacts.census.gov/qfd/states/42/42101.html.

STATE AND LOCAL COMMAND AND CONTROL

Individual states' emergency communication plans will play a central role in any use of SNS supplies. While these plans vary depending on the local context, the CDC identifies several key roles that should be included in all state SNS plans. The governor's office, in conjunction with the head of the state health department makes the decision to request SNS assets. The federal government expects states to designate an SNS Operations Management Team which will operate out of the state's Emergency Operations Center (EOC). The Operations Management Team will oversee communications, security, Receipt, Store and Stage (RSS)⁵⁷ site operations, distribution, and repackaging. The Operations Management Team plays a central coordinating role, and thus should be involved in pre-event training, exercises, and evaluation. As the key decision making body at the state level, the Operations Management Team should coordinate with designated local-level incident commanders. A state agency, such as law enforcement or a state emergency management agency, should be in charge of coordinating communications for the SNS Operations Management Team. ⁵⁸

At the ground level, each individual Point of Delivery (POD)⁵⁹ should have its own management team making decisions at the local level and serving as a point of contact for higher level decision makers. While smaller in scale, these teams should serve the same functions as the Operations Management Team, but at the local level.

Depending on the scale of the emergency, several states or counties in a large state may have to organize their efforts. For a large scale event, a Unified Command (UC) will coordinate activities across a wider region. Interstate planning and coordination presents a variety of challenges, as discussed below.

PLANNING, REQUESTING AND DEPLOYING OF SNS ASSETS: THE ROLE OF THE FEDERAL GOVERNMENT AND THE STATES

The U.S. government can deploy the Strategic National Stockpile in two ways: following a request from a state governor or by determination of the Secretary of HHS.

The State Process

Each state possesses an SNS plan addressing specific procedures for requesting support from the Strategic National Stockpile. Generally, hospitals will monitor the situation, and when it appears that they may need additional supplies, they coordinate with county-level officials to obtain local stockpiles. When it appears that local supplies will not be sufficient, they then notify state health

⁶⁰ Id.

⁵⁶ United States Homeland Security Council. <u>National Planning Scenarios: Created for Use in National, Federal, State and Local Homeland Security Preparedness Activities</u>. April 2005. http://media.washingtonpost.com/wp-srv/nation/nationalsecurity/earlywarning/NationalPlanningScenariosApril2005.pdf.

⁵⁷ For further information on Receipt Store and Stage site operations, refer to pages 16 and 23.

⁵⁸ Centers for Disease Control and Prevention Division of the Strategic National Stockpile. <u>Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness.</u> Version 10.01 – Draft, Chapter 4. May 2006.

⁵⁹ For more information on Points of Distribution (PODs), refer to page 24.

officials or the governor's office that they expect that SNS assets will be needed. The governor or a designated official calls the CDC Director's Emergency Operations Center (DEOC) to formally request SNS materiel.⁶¹

A governor need not meet any *statutory* criteria to request these resources. A CDC report other possible reasons to distribute SNS assets:

- The occurrence of a chemical, biological, nuclear or radiological event
- · Natural disaster emergency
- Claim by intelligence or law enforcement on release
- Clinical, laboratory or epidemiological indications
- Number of casualties and capacity of state and local authorities⁶²

"The process of requesting and allocating the SNS is straightforward: the state requests the SNS, the CDC provides it after consultation with other federal partners." 63

The SNS Program Consultant

SNS Program Consultants are liaisons for SNS programs and are assigned to a region that includes from two to five states. They provide information to state health and homeland security officials about the SNS and assist in state planning. States submit their state SNS plans to the Program Consultant. The Program Consultants work closely with state officials in providing training for local officials about SNS programs, such as CHEMPACK, Push Packages, VMI, and the Cities Readiness Initiative. They also work with states in conducting SNS drills and exercises. In short, the SNS Program Consultants are at the center of all activities between states and the SNS.

The Federal Process

The federal government may order a deployment of SNS assets without declaration by the President under the Stafford Act or the Secretary of HHS under the Public Health Service Act. 67

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⁶³ Association of State and Territorial Health Officials. <u>Interstate Planning for the Strategic National Stockpile:</u>
Supplement on Legal Issues. 2005. < http://www.astho.org/pubs/SNS_supplement.pdf>.

⁶¹ Centers for Disease Control and Prevention Division of the Strategic National Stockpile. <u>Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness.</u> Version 10.01 – Draft, Chapter 4. May 2006.

⁶² *Id*.

⁶⁴ Centers for Disease Control and Prevention Division of the Strategic National Stockpile. <u>Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness.</u> Version 10.01 – Draft. May 2006.

⁶⁶ Quinn, Tim. Letter to State SNS Coordinators. 9 August 2004. Centers for Disease Control and Prevention Strategic National Stockpile Program, Program Preparedness Branch.

⁶⁷ Rossmann, Nicholas. Interview with Official at HHS Office of Terrorism Preparedness. 23 May 2006. and Centers for Disease Control and Prevention Division of the Strategic National Stockpile. Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness. Version 10.01 – Draft, Chapter 4. May 2006. The Stafford Act: "The Stafford Act authorizes the President to issue major disaster declarations, whereupon federal agencies are authorized to provide assistance to states overwhelmed by disasters." Lister, Sarah. "Hurricane Katrina: The Public Health and Medical Response." CRS Report for Congress. 21 September 2005. http://fpc.state.gov/documents/organization/54255.pdf. The Public Health Service Act: "Section 319 of the

For instance, the United States has pre-positioned SNS assets to major events and to prepare for crises, such as Hurricane Katrina. ⁶⁸

Once the CDC Emergency Operation Center receives a request, they conference with HHS, DHS and state officials.⁶⁹ States can make their request by phone or they can submit an "Action Request Form." The CDC assists the state in determining what specific SNS assets are needed. While determinations on the SNS remain under HHS, it is a "collaborative" effort with DHS.⁷¹

Collaboration with DHS is important because of its leadership role in the National Response Plan. Within DHS, the DHS Chief Medical Officer acts as "the primary point of interface with HHS." In regards to the SNS, HHS does not need the concurrence of DHS to deploy the stockpile. Likewise, DHS does *not* retain the statutory authority to order CDC to deploy the SNS. 73

The CDC responds to the state's request after consulting with other federal partners and the requesting state. If the event occurs in multiple states, the CDC allows the states to share SNS materiel.⁷⁴ Unfortunately, the CDC "has not provided specific guidance for an event in which multiple states request SNS Push Packages, but it is clear that resources would be limited in such an instance."⁷⁵

The Office of the Secretary of HHS makes the decision on deployment of the SNS.⁷⁶ To meet the needs of a state, the Division of the SNS can then deploy (the following items discussed in Description and Distribution of SNS Assets on page 14):

- Items from the Vendor Managed Inventory
- A 12-hour Push Package and a TARU team
- Materials not in the VMI and purchased by Department of Veterans Affairs, the SNS's acquisition partner, but required for a response⁷⁷

Public Health Service Act provides broad authority for the Secretary of HHS to declare a public health emergency at the federal level." Lister, Sarah. "Hurricane Katrina: The Public Health and Medical Response." <u>CRS Report for Congress</u>. 21 September 2005. http://fpc.state.gov/documents/organization/54255.pdf.

42 USCS § 247d-6b, Section a, 2, (G) states that the Secretary of HHS may: "deploy the stockpile at the discretion of the Secretary to respond to an actual or potential public health emergency or other situation in which deployment is necessary to protect the public health or safety."

⁶⁸ Select Bipartisan Committee to Investigate the Preparation for and Response to Hurricane Katrina. <u>A Failure of Initiative</u>. 15 February 2006. http://katrina.house.gov/>.

⁶⁹ Prior, Stephen. Report Commissioned by the National Defense University Center for Technology and National Security Policy. Who You Gonna Call?: Responding to a Medical Emergency with the Strategic National Stockpile. June 2004.

⁷⁰ Rossmann, Nicholas. Interview with Official at HHS Office of Terrorism Preparedness. 23 May 2006.

⁷¹ Id.

⁷² United States House of Representatives Committee on Government Reform. <u>Statement by the Honorable Jeffrey W. Runge, M.D., Acting Undersecretary for Science and Technology and Chief Medical Officer, U.S. Department of Homeland Security.</u> 11 May 2006. http://www.dhs.gov/dhspublic/display?theme=45&content=5615.

⁷³ MPA Workshop Group. Interview with Dr. William Raub, Science Advisor to the Secretary of the Department of Health and Human Services. 6 June 2006.

⁷⁴ Id.

⁷⁵ Id.

⁷⁶ Rossmann, Nicholas. Interview with Official at HHS Office of Terrorism Preparedness. 23 May 2006.

The decision to deploy is filtered down from the Office of the Secretary to the CDC and then to SNS. 78 Once tasked, SNS plans logistics and purchasing for the requested assets. For instance, the SNS determines the schedule and method of delivery. 79

After SNS assets are requested and approved by the federal government, SNS calls the state emergency operations center (EOC) and/or state SNS Coordinator and warehouse manager to make the actual arrangements for delivery of SNS assets. Together, they decide upon the Receipt, Store and Stage (RSS) site (where materiel and Technical Advisory Response Unit (TARU) teams will be sent), the method of delivery, and the level of security for the site. In addition, they determine the number of PODs that will receive SNS materiel, and they discuss the state's transportation plans to the PODs. They also determine the treatment regimen and the population that will receive prophylaxis. If appropriate, the state provides information about its policies and decisions regarding the use of investigational new drugs. Finally, they decide whether or not to make media announcements or health alerts. (Figure 1: Requesting SNS Assets on page 38 illustrates the contact process described above.)

Advising the President

During a public health crisis, HHS advises the President on the epidemiological response. Normally the National Security Council and Homeland Security Council would be the lead advisors, however, they may lack the epidemiological expertise to guide planning on deployment of assets to contain an outbreak. Moreover, the Homeland Security Council remains untested at handling an enduring homeland crisis and the general homeland security interagency process has suffered numerous breakdowns with incidents of a limited scope, such as the response to Hurricane Katrina.

In addition to HHS other federal agencies may give their own advice. For instance, the Intelligence Community generally monitors public health for biological, chemical, radiological incidents. DHS possesses its own medical expertise, the DHS Chief Medical Officer. "The DHS Chief Medical Officer is the primary point of interface with HHS and is responsible for advising the Secretary of DHS on all medical issues."

⁷⁷ For instance in reaction to Katrina, to prevent waste SNS allowed states to request specific items from an SNS, rather than an entire Push Package. Select Bipartisan Committee to Investigate the Preparation for and Response to Hurricane Katrina. A Failure of Initiative. 15 February 2006: 275. < http://katrina.house.gov/>. Deploying only specific assets, and not a push package which may not be valuable to a flu pandemic, may prevent wasted resources and the need for states to collaborate on the dispersal of un-needed goods.

Rossmann, Nicholas. Interview with Official at HHS Office of Terrorism Preparedness. 23 May 2006.
 Id

⁸⁰ Centers for Disease Control and Prevention Division of the Strategic National Stockpile. <u>Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness.</u> Version 10.01 – Draft, Chapter 4. May 2006.

⁸¹ Principals of the Homeland Security Council: Treasury, Defense, AG, HHS, Transport, OMB, HAS, DHS, DCI, FBI, Director of FEMA, Chief of Staff to President and VP and Interagency Policy Coordination Committees (HSC/PCC)

⁸² United States House of Representatives Committee on Government Reform. <u>Statement by the Honorable Jeffrey W. Runge, M.D., Acting Undersecretary for Science and Technology and Chief Medical Officer, U.S. Department of Homeland Security.</u> 11 May 2006. http://www.dhs.gov/dhspublic/display?theme=45&content=5615.

The President must know who is in charge of deploying assets during a national biological emergency. As the crisis worsens, decision making will most likely move from the Secretary of HHS to the President. In distributing SNS assets, the Secretary of HHS and the President will likely need to:

- Consider competing advice from departments or agencies that may undermine the effort to distribute medicines
- Lead other federal agencies, state and local authorities burdened by their own tasks
- Coordinate messages amongst branches and levels of government on the status of supplies and vaccines
- Organize and mediate disputes between states (SNS assets are sent directly to a state and it is a state's decision to share materials)

The Importance of the Federal Decision Making Process

To contend with threats of various scopes and durations, the federal government's decision making process must be robust. HHS states, "The disease may appear in many different parts of the nation almost simultaneously, or disease may occur in only one or a few communities, and if not contained there, proceed to affect other communities." If the size of a health crisis is large enough, federal decision makers will have to prioritize where to send supplies, essentially determining the survival rates of communities around the United States.

DESCRIPTION AND DISTRIBUTION OF SNS ASSETS

The Vendor Managed Inventory

The Vendor Managed Inventory (VMI) is a stockpile of pharmaceuticals and health-related supplies owned by the federal government's Strategic National Stockpile Program. It can be used to supplement Push Packages with additional materials or to supply medical products tailored to local needs. Moreover, if the agent is identified, "the VMI [can] act as the first option for immediate response from the SNS Program."

The VMI accomplishes vaccine cold chain management by utilizing equipment that regulates and records temperature during storage and distribution.⁸⁵ The VMI distribution from the warehouse to the state RSS sites is conducted via commercial carriers – UPS and FedEx.⁸⁶ Security for VMI distribution is provided by U.S. Marshals.⁸⁷

While the VMI is owned by the government, it is managed by pharmaceutical vendors under contract with the SNS program. Accounting for 90 to 95 percent of the total SNS inventory, the

⁸³ United States Department of Health and Human Services. <u>HHS Pandemic Flu Influenza Plan</u>. November 2005: 51. http://www.hhs.gov/pandemicflu/plan/pdf/HHSPandemicInfluenzaPlan.pdf.

⁸⁴ <u>Strategic National Stockpile Site</u>. 14 April 2005. Department of Health and Human Services Centers for Disease Control and Prevention. http://www.bt.cdc.gov/stockpile/.

⁸⁵ MPA Workshop Group. Interview with Dr. William Raub, Science Advisor to the Secretary of the Department of Health and Human Services. 6 June 2006.
⁸⁶ Id.

⁸⁷ *Id.*

VMI is capable of arriving within 24 to 36 hours after being requested. Unlike the Push Packages (below), VMI shipments may go either to the RSS sites or directly to the distribution sites depending on the situation.⁸⁸ Furthermore, private vendors maintain and rotate the stock within their own pipelines to keep the VMI current and reduce on wasted products.⁸⁹

By the end of 2006, the VMI will have 26 million treatment courses of flu anti-virals. 20 million have been earmarked among the states by population. The federal government's goal is to ultimately have 60 million antiviral treatment courses. Additionally, the VMI currently has enough small pox vaccine to treat every person in the country. Finally, the VMI currently has 30 million sixty-day treatment courses of antibiotics - enough to respond to simultaneous outbreaks of Anthrax, Plague, or Tularemia in several major U.S. cities. 91

The 12-Hour Push Package

As mentioned above, in an emergency requiring SNS assistance, the federal government can deploy three critical assets to the states; a 12-hour Push Package, medicines delivered from the Vendor Managed Inventory (VMI), and a CHEMPACK. They are specifically designed to "provide rapid delivery of a broad spectrum of assets for an ill-defined threat in the early hours of an event."⁹² The SNS Push Package is usually delivered to states in response to a localized natural disaster or a mass casualty terrorist attack.⁹³ A 12-hour Push Package is "pre-identified," pre-packaged inventory that can be 'pushed out' to the state requesting medical assets...within twelve hours of a request."94

Currently, there are 12 Push Packages in the SNS. The Push Packages are "caches of pharmaceuticals, antidotes, and medical supplies designed to provide rapid delivery of a broad spectrum of assets for an ill defined threat in the early hours of an event," as well as antibiotics, antitoxins, life-support medications, IV administration, and ventilators. 95 The SNS also

⁸⁸ Belson, David. "Storage, Distribution and Dispensing of Medical Supplies." Online Posting. 12 April 2003. Center for Risk and Economic Analysis of Terrorism Events, University of Southern California.

http://www.usc.edu/dept/create/reports/Med Supplies Report v5.pdf>.

⁸⁹ Owens, David H. "The Strategic National Stockpile in Washington State." Online Posting. State of Washington Department of Health.

http://courses.son.washington.edu/win05/uconi445/The%20Strategic%20National%20Stockpile%20UW%20class %20v2005%20Owens.ppt>.

⁹⁰ MPA Workshop Group. Interview with Dr. William Raub, Science Advisor to the Secretary of the Department of Health and Human Services. 6 June 2006.

⁹² Strategic National Stockpile Site. 14 April 2005. Department of Health and Human Services Centers for Disease Control and Prevention. http://www.bt.cdc.gov/stockpile/>.

⁹³ Rossman, Nicholas. Correspondence with Anand Parekh, Department of Health and Human Services Employee at the Office of Public Health and Emergency Preparedness. 7 June 2006. "I think it's fair to say that a push package may be deployed in the event of a public health emergency where the contents of the push package might serve to reduce morbidity or mortality from the event. Not all natural disasters or terrorist attacks will necessitate push packages to be deployed. Note, there are very specific medicines and medical materiel in the push packages." ⁴ Strategic National Stockpile Frequently Asked Questions Site. State of Massachusetts Department of Public

Health. Center for Emergency Preparedness.

http://www.mass.gov/dph/bioterrorism/advisorygrps/pdfs/sns fags.pdf>.

⁹⁵ Strategic National Stockpile Site. 14 April 2005. Department of Health and Human Services Centers for Disease Control and Prevention. http://www.bt.cdc.gov/stockpile/>.

possesses 5.5 million treatments of antiviral drugs in case of pandemic influenza.⁹⁶ These Push Packages are strategically positioned in secure warehouses throughout the United States.⁹⁷ However, the Push Packages are not intended to provide surge capacity for hospitals.⁹⁸

The Push Packages have been configured to be ready to load on commercial carriers to distribute to states using either 2 wide-body aircraft or 7 fifty-three foot trucks per Push Package.⁹⁹ The federal government hopes that the existing contracts create enough redundancy to ensure timely delivery of SNS assets in an emergency.¹⁰⁰ However, should these companies fail to honor the terms of their contracts, the federal government can enlist/commandeer necessary private assets to assist in a national emergency.

Each Push Package weighs 94,424 pounds of materiel in 130 specialized containers that are color-coded for easy identification. A 13,000 square foot facility is needed to receive, store and stage Push Package materiel. Volunteers are also needed to repackage bulk antibiotics. Once at the RSS site, the Push Packages are signed over to state officials. If any Schedule I or II Narcotics come with the Push Package, a Drug Enforcement Administration (DEA) official must sign over the materials to the state officials. The U.S. Marshals, under the authority of the Department of Justice, protect the SNS while it is in transit from the SNS storage site to the RSS site.

To assist in the action plans of the Strategic National Stockpile, and specifically in the deployment of the 12-hour Push Packages, the Centers for Disease Control and Prevention established Technical Advisory Response Unit (TARU) teams. TARU teams were created to streamline the process in breaking down the Push Package and to deploy along with the 12-hour

⁹⁷ <u>Strategic National Stockpile Site</u>. 14 April 2005. Department of Health and Human Services Centers for Disease Control and Prevention. http://www.bt.cdc.gov/stockpile/>.

⁹⁹ American Public Health Association. <u>Chapter 3: Structure and Organization of Health Management in Disaster Response</u>. 4 February 2005: 63. www.apha.org/preparedness/Chapter_03.qxd.pdf. www.apha.org/preparedness/chap

MPA Workshop Group. Interview with Dr. William Raub, Science Advisor to the Secretary of the Department of Health and Human Services. 6 June 2006.

101 Strategic National Stockpile Site. 14 April 2005. Department of Health and Human Services Centers for Disease Control and Prevention. http://www.bt.cdc.gov/stockpile/.

102 Owens, David H. "The Strategic National Stockpile in Washington State." Online Posting. State of Washington Department of Health.

http://courses.son.washington.edu/win05/uconj445/The%20Strategic%20National%20Stockpile%20UW%20class%20v2005%20Owens.ppt.

Centers for Disease Control and Prevention Division of the Strategic National Stockpile. <u>Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness.</u> Version 10.01 – Draft, Chapter 3. May 2006.

104 Centers for Disease Control and Prevention Division of the Strategic National Stockpile. <u>Receiving Distributing and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness.</u> Version 10.01 – Draft, Appendix J: DEA Form-222 for Transferring Controlled Substance. May 2006.

¹⁰⁶ MPA Workshop Group. Interview with Dr. William Raub, Science Advisor to the Secretary of the Department of Health and Human Services. 6 June 2006.

⁹⁶ United States Department of Health and Human Services. "HHS Buys Additional Antiviral Medication As Preparations for Potential Influenza Pandemic Continue." Department of Health and Human Services. <u>Press Release</u>. 1 March 1, 2006. <, http://www.hhs.gov/news/press/2006pres/20060301.html>.

⁹⁸ MPA Workshop Group. Interview with Dr. William Raub, Science Advisor to the Secretary of the Department of Health and Human Services. 6 June 2006.

Push Package. Their goal is to arrive at the RSS site before the Push Package. ¹⁰⁶/¹⁰⁷ Once they arrive on site, they provide local officials with face-to-face guidance, advisory support, and information about SNS assets. The TARU team can also to assist the state in requesting additional supplies. As the CDC describes them, TARU teams are part of the response team to, "Coordinate with state and local officials so that the SNS assets can be efficiently received and distributed upon arrival at the site." ¹⁰⁸

As of 2005 there were five TARU teams, with plans to increase to six teams in 2006 and nine by 2008. Given that there are 12 Push Packages and currently only six TARU teams, in a nationwide emergency the TARU teams may be required to assist multiple states simultaneously. In this case, they would redeploy to a second site after the initial SNS material have been received. 110

TARU Teams are on call 24 hours a day to deploy within 90 minutes via chartered aircraft.¹¹¹ The TARU team receives a copy of the individual state's SNS plan before they are deployed and brings their own communications equipment, including radio systems, cellular phones and a series of satellite phones.¹¹³ Recently restructured, TARU Teams are comprised of five to seven members:

- A *lead officer* supervises team activities and is responsible for management of the TARU Team and coordination of all activities
- Two liaison officers represent duties of the SNS program as a whole, and serve as a
 conduit for any information dispersed to localities. These two liaison officers work
 apart from the rest of the TARU Team, and are positioned to serve as spokesmen for
 the SNS as well. They are also responsible for obtaining locations and directions of
 state operations and for keeping the TARU lead officer informed of the actions by the
 state
- Two *team logisticians* are responsible for all logistical operations of the Push Package, including the management of "Receipt, Store, Stage" (RSS) activities, the Vendor Managed Inventory (VMI), and coordination of off-loading logistical support
- The *TARU operations officer* acts as the coordination officer, coordinating TARU activities and operations with all team members, and works as a researcher and distributor of relevant emergency information to team members

¹⁰⁷ <u>Strategic National Stockpile Site</u>. 14 April 2005. Department of Health and Human Services Centers for Disease Control and Prevention. http://www.bt.edc.gov/stockpile/>.

¹⁰⁸ Strategic National Stockpile Site. 14 April 2005. Department of Health and Human Services Centers for Disease Control and Prevention. http://www.bt.cdc.gov/stockpile/>.

¹⁰⁹ United States Office of Management and Budget. <u>Program Assessment: Strategic National Stockpile</u>. 2005. http://www.whitehouse.gov/omb/expectmore/detail.10003512.2005.html.

¹¹⁰ Staley, Mike. "The Strategic National Stockpile Program Tutorial." Online posting. University of North Carolina Preparedness Center Training Site.

http://www.sph.unc.edu/nccphp/training/login/index.cfm?endup=strat nat stockp>.

Strategic National Stockpile Site. 14 April 2005. Department of Health and Human Services Centers for Disease Control and Prevention. http://www.bt.cdc.gov/stockpile/>..

Centers for Disease Control and Prevention Division of the Strategic National Stockpile. Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness. Version 10.01 – Draft. May 2006,
 Strategic National Stockpile Site. 14 April 2005. Department of Health and Human Services Centers for Disease Control and Prevention. http://www.bt.cdc.gov/stockpile/>.

- The communications/IT team member is responsible for all communication operations, including establishment and maintenance of a communications and IT system, and assisting in running the TARU Operations Center (TOC)
- *United States Marshals* provide security for the TARU teams, protecting team members and the stockpile materials they are accompanying 114

CHEMPACK

Similar to 12-hour Push Packages, a CHEMPACK is a deployed container of resources for use in a nerve or chemical agent attack. Push Packages are useless in a nerve agent attack because immediate treatment is required. Forward placement of CHEMPACKS allows for an immediate reaction to chemical threats unlike the 12 hours needed to receive Push Packages. The original CHEMPACK program was designed to initiate forward placement of nerve antidotes and provide states with a sustainable resource; and improve their capability to respond quickly to a chemical agent attack. ¹¹⁵

Like the VMI packages, the CHEMPACKS are not generic deployments, but rather are designed to handle specific chemical or nerve agent threats. The standards the SNS program has developed for CHEMPACKS includes treatments relevant to exposure rates, broken down into 30 percent mild, 40 percent moderate, and 30 percent severe exposure rates. Each CHEMPACK is capable of treating approximately 1,000 symptomatic victims. CHEMPACKS are sealed by the Drug Enforcement Agency at the outset, and must have a seal completely broken for usage, preventing partial depletion of goods over time. SNS owns the CHEMPACKS, but states and cities manage them.

Communities around the country already store CHEMPACKS containers.¹¹⁹ As of February 2005, the SNS had purchased 1,274 emergency medical service (EMS) containers and 850 hospital containers for distribution throughout the states and territories.¹²⁰ Participation by public health agencies in the local storage of CHEMPACKS is voluntary, although it is far

¹¹⁴ State of Missouri Department of Health. Missouri's Plan for Receiving, Distributing, and Dispensing the Strategic National Stockpile: A Guide for State and Local Planning. Annex K 1.7. Emergency Response and Terrorism Plan. October 2003.

¹¹⁵ United States Department of Homeland Security and Centers for Disease Control and Prevention. <u>CHEMPACK Project: Current Status and National Deployment Concept</u>. The National Strategic Stockpile Program. 13 October 2003.

¹¹⁶ United States Department of Health and Human Services Centers for Disease Control and Prevention.

<u>Continuation Guidance – Budget Year Five: Attachment J – CHEMPACK.</u> Public Health Preparedness and Response for Bioterrorism. 14 June 2004. < http://www.bt.cdc.gov/planning/continuationguidance/docs/chempack-attachj.doc>.

¹¹⁷ State of Montana Department of Public Health and Human Services. "Fact Sheet: CHEMPACK: What You Need To Know." Online posting. June 2005. http://www.dphhs.mt.gov/PHSD/risk-communication/pdf/Chempack.doc>.

¹¹⁸ United States Department of Health and Human Services Centers for Disease Control and Prevention.

Continuation Guidance — Budget Year Five: Attachment J — CHEMPACK. Public Health Preparedness and Response for Bioterrorism. 14 June 2004. < http://www.bt.cdc.gov/planning/continuationguidance/docs/chempack-attachj.doc>.

119 Id

¹²⁰ SEMP Biot #171: What is the Strategic National Stockpile Site. Suburban Emergency Management Project Site. 5 February 2005. http://www.semp.us/biots/biot-171.htm.

cheaper when local agencies participate. The cost to the SNS is significantly lower because their supplies are purchased in bulk. For example, the cost of one hospital container to a state would be \$260,509.08 if the supplies were purchased locally. The cost to SNS is \$38,230.52, a savings of \$222,278.56. Based on a pilot study conducted in New York City, South Dakota, and Washington State, the average cost for CHEMPACK container storage is approximately \$2,000 to \$2,500. 122

Asset Acquisition

A critical node of the SNS and VMI distribution system are the private companies that are contracted to produce vaccines and to deliver the Push Packages and VMI inventory. While there are numerous vendors contributing to the overall supplies of the Strategic National Stockpile, an examination of the most recent contracts for pharmaceutical treatments provides information on the larger corporations charged with supplying the SNS.

The Department of Health and Human Services awarded GlaxoSmithKline, a pharmaceutical company based in the United Kingdom with operations in the United States, a contract for 1.75 million treatments of their Relenza drug to help prepare for pandemic flu. Furthermore, the company was awarded a \$2.8 million contract in September 2005 for 84,300 treatments of the same drug. Relenza, an anti-viral drug, is an inhaled powder cleared for treatment of uncomplicated flu illnesses, specifically type A and B influenza. Relenza however, is not a flu vaccine. Roche, a Switzerland-based pharmaceutical company was also awarded a contract on March 1, 2006 for 12.4 million treatments of their Tamiflu to add to the SNS for the same reason. Roche's Tamiflu is similar to Relenza in that it is an anti-viral created as a treatment for influenza. The main difference between these two drugs is that Tamiflu can be used on anyone over age one, whereas Relenza cannot be used on children under the age of seven. Both drugs may help reduce flu outbreaks and reduce chances of getting the flu. 127

In recognition of the lack of a working vaccine to combat diseases such as the avian flu, Secretary of Health and Human Services Michael Leavitt stated in an October 2005 press release

Response for Bioterrorism. 14 June 2004. < http://www.bt.cdc.gov/planning/continuationguidance/docs/chempack-attachj.doc>.

¹²¹ State of Virginia Department of Health. The CHEMPACK Project: A Strategic National Stockpile Initiative. 16 May 2004. http://www.vdh.virginia.gov/epr/pdf/MaySeminar/The_CHEMPACK_Project.pdf#search='chempack. 122 United States Department of Health and Human Services Centers for Disease Control and Prevention. Continuation Guidance — Budget Year Five: Attachment J—CHEMPACK. Public Health Preparedness and

¹²³ United States Department of Health and Human Services. "HHS Buys Additional Antiviral Medication As Preparations for Potential Influenza Pandemic Continue." <u>Press Release</u>. 1 March 2006.
http://www.hhs.gov/news/press/2006pres/20060301.html>.

¹²⁴ United States Department of Health and Human Services. "HHS Buys Vaccine and Antivirals in Preparation for a Potential Influenza Pandemic." <u>Press Release</u>. 5 September 2005.

http://www.hhs.gov/news/press/2005pres/20050915.html.

¹²⁵ United States Food and Drug Administration Center for Drug Evaluation and Research. "Relenza (zanamivir)." 14 April 2006. http://www.fda.gov/cder/news/relenza/default.htm.

¹²⁶ United States Department of Health and Human Services. "HHS Buys Additional Antiviral Medication As Preparations for Potential Influenza Pandemic Continue." <u>Press Release</u>. 1 March 2006. http://www.hhs.gov/news/press/2006pres/20060301.html>.

¹²⁷ United States Food and Drug Administration Center for Drug Evaluation and Research. "Tamiflu." http://www.fda.gov/cder/consumerinfo/druginfo/tamiflu.htm>.

that, "An influenza vaccine effective against the H5N1 virus is our best hope of protecting the American people from a virus for which they have no immunity." The same press release announced the awarding of a \$62.5 million contract to Chiron, a subsidiary of the European pharmaceutical giant Novartis for the development of such a vaccine. At the same time, HHS announced that it had given a \$100 million contract for the development of a similar drug to Sanofi Pasteur, the third largest pharmaceutical company in the world and Europe's largest. 128

The government has procurement and acquisition programs in place in the event of a public health emergency. Through the Department of Veterans Affairs (VA) (the SNS Program's acquisitions partner), the SNS is able to negotiate immediate purchases of medical and health-related materials at lower prices than the normal federal supply schedule. Furthermore, this program benefits from the VA's efficiency in procurement of health products for its normal business. For the procurement process, the VA analyzes the current market and pre-selects certain materials to be held in inventory in large quantities to accommodate any surge problems. Through the use of programs such as the Universal Data Repository (UDR), the SNS takes a "snap-shot" of the current capabilities of health-related stocks, and then decides accordingly which areas to work with the VA for to develop stronger supplies. 129

Routine Private Sector Distribution

Under normal business conditions, pharmaceutical companies do not handle the distribution of drugs to retail stores. Most manufacturers avoid the responsibilities of the physical logistics and customer service involved with pharmaceutical distribution. Specific pharmaceutical distributors "manage the movement of supplies from the manufacturers to the retailers." The top three distributing companies by revenue are: McKesson (\$78 billion annually), Cardinal Health (\$70 billion annually), and AmerisourceBergen (\$53 billion annually). These distributors store newly manufactured pharmaceuticals at their warehouses. The Healthcare Distribution Management Association (HDMA) "reports that healthcare distributors warehouse more than 20,000 SKUs (stock keeping units), including pharmaceutical products, sundry/general merchandise, health and personal care items, durable medical equipment, home health supplies, and OTC (over the counter) drugs." Retailers negotiate prices with the manufacturer but purchase through their distributors. The distributor may track inventory levels and rapidly refill shelves – allowing "the retailer to maintain low inventory levels and thereby reduce its

Analysis of Terrorism Events, University of Southern California. 21 April 2005: 23.

¹²⁸ United States Department of Health and Human Services. "HHS Buys Additional Vaccine As Preparations For Potential Influenza Pandemic Continue." <u>Press Release</u>. 27 October 2005.

http://www.hhs.gov/news/press/2005pres/20051027.html.

¹²⁹ State of Montana Department of Public Health and Human Services. "A Five-Tiered Emergency Response Approach." September 2003. http://www.dphhs.mt.gov/PHSD/SNS/pdf/5-tierResponseApproach.pdf. ladd Belson, David. "Storage, Distribution and Dispensing of Medical Supplies." Center for Risk and Economic

http://www.usc.edu/dept/create/reports/Med_Supplies_Report_v5.pdf>.

¹³¹ *Id.*

¹³² *Id*.

¹³³ *Id*.

inventory holding costs." Finally, these distributors often package and repackage the pharmaceuticals.

SCENARIO: More States Request SNS Assistance

Overall, 14 states request SNS assistance. Federal authorities begin deliberating on how best to deploy the SNS assets. With 14 states requesting assistance and only limited assets in the SNS arsenal the federal government faces a horrible decision: which requests do they fulfill and which do they deny? Additionally, if no vaccine exists for the virus, how long will it take to produce one?

Timeline of Decision Making

The stockpile planners think of an 'incident' in one place at one time. Pandemic Influenza is not an 'incident' – it's everywhere. The Federal Government can't deal with 5.000 Katrina's. 135

If an incident "were to occur in the next several years the U.S. response may be affected by the limited availability of a vaccine [depending on the disease], as well as the limited availability of certain drugs used to treat severe infections, and by the general lack of surge capacity within our healthcare system." According to the *National Response Plan*, if a number of states request assets from the SNS simultaneously, and "critical resources for protecting human life are insufficient to meet all domestic needs, [then] the Secretary of HHS makes recommendations to the Secretary of DHS regarding the allocation of scarce federal public health and medical resources." ¹³⁷

The timeline for deploying federal medical assets will depend on the situation. The government must first recognize that a health crisis (such as a pandemic) is occurring, either within the United States or around the world and then determine the strain of the disease or virus. If a vaccine is not available or is in limited supply, then manufacturers must begin producing the vaccine—a process that could take several months. Additionally, the government will have to determine the cause of the incident and respond to the epidemiological concerns of an emerging disease.

If a public health emergency occurred today, manufacturers would not be able to rapidly produce the required number of vaccines for the entire U.S. population. For example, in regards to pandemic influenza, the United States does not currently have the vaccine production capacity to make enough vaccine for the people who will need it. The U.S. is insufficiently prepared for mass prophylaxis, and at current vaccine development capacity it would take approximately six

http://www.usc.edu/dept/create/reports/Med_Supplies_Report_v5.pdf>.

¹³⁴ Belson, David. "Storage, Distribution and Dispensing of Medical Supplies." Center for Risk and Economic Analysis of Terrorism Events, University of Southern California. 21 April 2005: 23.

¹³⁵ MPA Workshop Group. Interview with Dr. William Raub, Science Advisor to the Secretary of the Department of Health and Human Services. 6 June 2006.

¹³⁶ Lister, Sarah. "Pandemic Influenza: Domestic Preparedness Efforts." <u>CRS Report for Congress</u>. 10 November 2005. http://www.fas.org/sgp/crs/homesec/RL33145.pdf>.

¹³⁷ United States Department of Homeland Security. National Response Plan: Biological Incident Annex. December 2004. http://www.dhs.gov/dhspublic/interapp/editorial/editorial 0566.xml>.

to eight months to develop a vaccine once the flu strain has been identified. "The U.S. will not have the capacity to produce 300 million doses of a vaccine for three to five years." ¹³⁸

Thus, during the six months to a year of a pandemic influenza outbreak, the U.S. will have to rely solely on anti-virals such as Tamiflu. However, depending on the virus strain, Tamiflu and other anti-virals may be ineffective. There are currently 4.3 million doses of Tamiflu in the SNS and the federal government has announced plans to purchase 20 million courses of anti-virals by the end of 2006. The country may have enough for 25 percent of the population by the middle of 2007. Nevertheless, "it is doubtful those stocks will be adequate in a pandemic for a nation of nearly 300 million people, and it may be a long time before enough is available." ¹⁴⁰

SCENARIO: Delivery of VMI Assets to Pennsylvania

The CDC approves Pennsylvania's request for SNS assistance. Upon approval, the government contacts a private company previously contracted for SNS distribution and notifies them that they need to deliver materials from the Vendor Managed Inventory to Pennsylvania's RSS site within the next 36 hours. This company sends either a contingent of trucks or aircraft to pick-up and load the materials. The shipment arrives within the allotted 36 hours and its contents are signed over to Pennsylvania state officials who begin breaking it down for delivery to the distribution sites.

DISTRIBUTION OF SNS ASSETS AT THE STATE AND LOCAL LEVEL

State and local distribution of SNS assets requires infrastructure capacity and supply distribution management for the SNS during a pandemic emergency. The federal government has provided communities with preparedness templates and general requirements for the receipt of SNS assets. This section will touch upon the varying capabilities of state and local plans. It will not conduct a comprehensive review of national preparedness capabilities. Rather, we provide clarification about the requirements for state and local capacity and distribution, followed by the potential options to meet this need.

Infrastructure Capacity

At three possible nodes of activity the SNS assets become the possession of the state officials: the RSS facilities, intermediate storage sites, and the Points of Distribution (PODs). The state and local communities must be capable of meeting a minimum infrastructure capacity at each of these points. The SNS provides minimum criteria and functional templates for state and local plans. ¹⁴¹ Instructions accompany the inventory in most cases. ¹⁴² Most communities do not have implemental plans that meet these requirements.

¹³⁸ Russert, Tim. Interview with Secretary of the Department of Health and Human Services Michael Leavitt. 20 November 2005. Meet the Press Transcript. http://www.msnbc.msn.com/id/10042399/>.

Russert, Tim. Interview with Dr. Julie Gerberding, Director of the Centers for Disease Control and Prevention. 20 November 2005. Meet the Press Transcript. http://www.msnbc.msn.com/id/10042399/.

Fauber, John and Rust, Susanne. "Race for vaccine, anti-virals is lagging." Milwaukee Journal Sentinel. 12 November 2005.

¹⁴¹ Division of the Strategic National Stockpile. "Receiving Staging, and Storing Assets". <u>Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness.</u> Version 10.0 – Draft, Chapter 8. May 2006. https://www.orau.gov/snsnet/resources/PlanVersion10/08%20Receiving%20storing%20staging.pdf

Receipt, Store, Stage (RSS) Facilities

- Capacity Requirements: Each state should plan for at least one RSS facility within their state borders, so that a drop-off the SNS assets can be easily accommodated. The general requirements for the RSS site are 13,000 square feet of open space, a staging area for incoming and outgoing assets, close proximity to a major transportation hub, easily secured, and having technological capabilities. Additionally, any preplanning must consider that the RSS facilities not only receive and store the SNS assets, but also act as a dispensing site within the community in which they are located.
- Potential Options: The large space requirements for a RSS site limit the utilization of government facilities or public buildings, forcing communities to consider private partnerships to accommodate these needs. One option in most communities is a national retail or grocery chain. They possess distribution warehouses located strategically across the nation to support local branches and are typically located near transportation hubs, in larger metropolitan areas. Furthermore, these national chains constantly endeavor to create a sense of community to their local branches by focusing on community needs and attempting to engage in their communities.

Private business have been an essential component of past emergency response efforts. When Hurricane Katrina devastated Louisiana and Mississippi, private firms responded immediately to the needs of these states' residents, ¹⁴⁴ often reaching devastated victims before government agencies. Most importantly, large retail stores already possess the required space to accommodate SNS assets. Larger national retail chains boast of distribution centers of over one million square feet and with more than two hundred and fifty dock doors. ¹⁴⁵ Warehouses of this size could accommodate the RSS facility and continue nearly normal operations. National grocery chains also provide unique benefits. There are over 34,000 grocery stores in the United States. The median store size is about 50,000 square feet ¹⁴⁶ and typically possesses accessible loading dock(s) for their own retail operations. Furthermore, an increasing number of these grocery chains provide their customers with the convenience of an internal pharmacy. These pharmacies would be beneficial for on-site consultations (a federally-suggested component of the RSS facility implementation team).

¹⁴² Centers for Disease Control and Prevention Division of the Strategic National Stockpile. <u>Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness.</u> Version 10.01 – Draft, Chapter 8. May 2006.

¹⁴³ Centers for Disease Control and Prevention Division of the Strategic National Stockpile. <u>Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness.</u> Version 10.01 – Draft, Sites for the RSS Function. https://www.orau.gov/snsnet/RSS_Site_Selection_2003-09.htm. This barely touches upon the detail provided to state and local officials on the necessary requirements for these areas.

¹⁴⁴ WalMart. "WalMart and SAM'S CLUB's Response to Hurricane Disaster Continues." <u>WalMart Facts</u>.
http://www.walmartfacts.com/community/article.aspx?id=1331. WalMart specifically raised more than 2.5 million for local organizations and opened a temporary 16,000 tent store to accommodate the needs of Louisiana's residents.

¹⁴⁵ Walmart Distribution Centers Site. Walmart Facts. http://www.walmart.com/wal-mart-distribution-centers.aspx.

¹⁴⁶ Supermarket Facts Industry Overview 2005 Site. Food Marking Institute. May 2005.
http://www.fmi.org/facts-figs/superfact.htm>.

Intermediate Transfer Points

- Capacity Requirements: The intermediate storage sites are smaller than the RSS facility and merely act in a holding capacity until assets can be delivered to PODs.
- Potential options: Regions with large populations utilize intermediate sites to repackage SNS assets for delivery to metropolitan or congested areas. Similar to the RSS sites, these intermediate sites would require the same type of infrastructure (loading docks, access to transportation, etc.), but on a smaller scale. While in some cases states require an intermediate site, more transfer points create a greater logistical headache for the tracking of the SNS assets and would require more infrastructure and security resources.

Community Contact

- Capacity Requirements: Getting SNS assets into the community is accomplished with a "pull in" or "push out" method. 147 "Pull in" refers to the effort of local officials to set up PODs in the community to pull the local population in to receive supplies, treatment, or antibiotics. "Push out" refers to the utilization of government transportation assets partnered with private companies to deliver SNS assets directly to individual households, businesses, health care facilities, etc. While the "pull in" methods require less government coordination and logistical planning, the "push out" methods allow for greater population control.
 - o *Pull In*: The SNS Stakeholders Conference suggests two methods for "pulling in:" drive-thru and walk-thru PODs. The walk-thru POD is a series of stations using a pre-determined and streamlined system (a local preparedness initiative), to "walk" people through the process of medical attention, and dispense SNS assets. The drive-thru would consist of maneuvering a flow of traffic to pass through a designated area to receive pre-determined packages of assets for those people in the vehicle. Local officials determine the specific operation of the facilities depending on the nature of the emergency. ¹⁴⁸
 - O Push Out: The "push out" method equates to effective supply chain management, which requires the local government to either provide the transportation infrastructure and logistics or partner with the military or private companies capable of these essential operations. The "push out" method requires the SNS assets to be delivered to households, businesses, special needs communities (elder home facilities, mental health institutions, etc.). The mode of transport could be via air, rail, or highway, and would require qualified emergency personnel, constant communication, an inventory tracking system, accompanying security, primary and alternate routing, and practiced emergency plans.
- Potential Options:

¹⁴⁷ Thornburg, Ruth. "PODs, PODs, PODs: Is it the Only Way?" Online Posting. SNS Stakeholders Conference. https://www.orau.gov/snsnet/resources/SNSSummit2006/Wednesday%20pm/Thornburg%20-%20Dispensing.ppt. The presentation defines "pull in" and "push out" methods.

¹⁴⁸ Id. Successful simulated "pull in" dispensing has occurred in Miami, Florida and Springfield, Illinois.

- o Pull In: A large warehouse would work most effectively to handle the dispensing of these SNS assets. Unfortunately, most local communities do not possess this available space. Similar to the dilemma faced with the RSS facilities, the local community would benefit from private partnerships with the local grocery/retail chains. However, another option for local dispensing could be through local pharmacy chains. Similar to retail and grocery chains, pharmacies are located in nearly every community.
- Push Out: (See the section Options for Transport from the POD to the Individual on page 26.)

Transport Logistics

Once the state receives the SNS assets, state and local communities must jointly disseminate the materials.¹⁴⁹ Federal assets (VMI and Push Packages) could hit as many as three transfer points: from the RSS site (arrival point for the Push Package) to a possible intermediate (holding) site to the POD or individual recipients. As mentioned previously, transporting the 12-hour Push Package requires several tractor trailers. Therefore, the state and local officials must be capable of a transport infrastructure and logistical support to handle the arrival of over 94,000 pounds of federal emergency assets into their communities.

Options for Transport from the RSS facility to Intermediate Sites or PODS

State jurisdiction over the Push Package (or VMI) assets begins when a designated state official signs for them at the RSS facility. From this point, state and local authorities must cooperate to secure and distribute these medical assets. Many local officials may not have the resources or the logistics capabilities to distribute the assets themselves. Private partnerships would therefore At the RSS site, the state emergency officials divide the Push Package for be needed. dissemination to prioritized PODs within the state. Since statewide distribution can be rather extensive, especially in a state with a dispersed population, state and local officials could benefit significantly from well-established private distribution networks within their own states.

Distribution and logistics companies already respond to the massive distribution needs of their customers. During an emergency, the government could leverage their distribution capabilities. Using their extensive supply networks, proven systems, and experienced personnel, they could effectively fulfill the transport requirements of the federal assets. The private sector is host to numerous retail and distribution partnerships. For instance, FedEx has an enduring partnership with Amazon due to their effective and efficient distribution, allowing textbooks purchased on Amazon to be on the customer's doorstep within forty-eight hours. FedEx's distribution success is due to their ability to streamline the key components of distribution, i.e. effective

¹⁴⁹ Centers for Disease Control and Prevention Division of the Strategic National Stockpile. Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness. Version 10.01 - Draft, Chapter 8. May 2006. https://www.orau.gov/snsnet/resources/PlanVersion10/08%20Receiving%20storing%20staging.pdf. 150 LT Staff. "10 Best Supply Chains of 2004." <u>Logistics Today</u>. December 2004. LT Staff. "10 Best Supply Chains of 2004." <u>Logistics Today</u>. December 2004. LT Staff. "10 Best Supply Chains of 2004." <u>Logistics Today</u>. December 2004.

supply chain management: the surge capacity to respond quickly to increased demand, strong information systems¹⁵¹ and likewise a strong management culture.¹⁵²

As mentioned above, there are two challenges to using intermediate sites: the tracking of inventory and the greater number of facilities and security required for the extra sites. However, the "break-bulk" role¹⁵³ of supply chain management has one advantage in certain situations. This extra "holding" site could reduce the transportation costs for high cost shipments (refrigeration, precise tracking), if the smaller shipments (from RSS to POD) could be transported over a shorter distance. Transportation costs will fall by reducing the distance traveled by high cost, small shipment quantities. ¹⁵⁴

Options for Transport from the POD to the Individual

If the "pull in" method for dispensing medical supplies is used in the local community, local officials will need to plan for the flow of traffic into and out of the dispensing site, but the transportation will be minimal (special needs individuals: elderly, health facilities, retirement homes, mental health facilities, etc.). The "push out" method for dispensing of vaccines or otherwise would require the most logistical consideration and transport infrastructure, and for many densely populated areas across the nation is the only option.

The federal government is currently working on plans to partner local officials with the United States Postal Service (USPS) to operate in this "push out" capacity. Key reasons for the partnership are: USPS maintains assets, (such as vehicles, warehouses, leadership and personnel) in a local community, possess the transportation infrastructure necessary for delivery, employ postal workers familiar with the local addresses to which they deliver on a regular basis and most importantly, capable of delivering medical countermeasures quickly. However, the partnership is occurring at the preliminary strategies through the federal Cities Readiness Initiative implemented in 36 cities across the nation. The plan describes the health threat in zip codes the concentrated. Unfortunately at this point, there has been no simulation to test the implementation of this USPS partnership. Plans for this partnership are based on individual city

¹⁵¹ Weir, Kerri. Interview with Dr. Scott Webster, Professor of Supply Chain Management at the Whitman School of Business, Syracuse University. 29 May 2006. Tracking systems utilize by these supply chains include GPS boxes (attached to rail cars, containers, and trucks), RFID, an emerging technology that tracks materials as it passes through certain points, and bar coding with scanners.

¹⁵² Weir, Kerri. Interview with Dr. Scott Webster, Professor of Supply Chain Management at the Whitman School of Business, Syracuse University. 29 May 2006. Recommended reading from Dr. Webster for supply chain management is Sheffi, Yossi. <u>Resilient Supply Chains</u>.

¹⁵³ Break-bulk describes the point in which larger packages are broken down into smaller components for further distribution.

¹⁵⁴ Weir, Kerri. Interview with Dr. Scott Webster, Professor of Supply Chain Management at the Whitman School of Business, Syracuse University. 29 May 2006.

¹⁵⁵ Memorandum of Agreement Between the Departments of Health and Human Services and Homeland Security and the United States Postal Service for the Delivery of Antibiotics During a Catastrophic Event. 18 Feb 2004. https://www.orau.gov/snsnet/resources/CRI2005/MOA_021804_Signed.pdf. The current MOAs with the USPA specifically addresses the delivery to the households in densely populated areas to reduce the confusion and congestion of massive crowds coming into one area to receive the medical supplies/vaccines AND to the special needs populations. Thus, this plan is to merely augment the dispensing efforts.

¹⁵⁶ MPA Workshop Group. Interview with the United States Postal Service. 6 June 2006.

initiative, and consist of an agreement between the participating federal agencies, American Postal Worker's Union, and USPS. The postal workers' involvement is completely voluntary, with security measures met by local law enforcement.¹⁵⁷

Volunteerism: An Essential Component to State and Local Efforts

The Federal government repeatedly acknowledges that preparedness starts with the local community. Unfortunately, no local emergency infrastructure is robust enough to handle a health crisis and the federal government's assets are limited. Due to this evident lack of internal assets during a health crisis, the local officials must rely upon a communal willingness through volunteerism to supplement the state and local emergency forces.

Although during an emergency the public will hopefully volunteer, agencies have difficulty predicting the levels of volunteerism. No one can ever expect one hundred percent. Indeed, the lack of specific figures for a volunteer force makes planning for an emergency extremely difficult, and unfortunately for any health crisis, planning is a necessary component to city readiness. The volunteer force comprises of two components: resident volunteers at the facilities (RSS sites and PODs) and private business volunteerism for distribution of the medical supplies. Local communities and cities have already started posting forms on their city websites to seek out willing volunteers for the deployment of SNS assets into their local communities (refer to Figure 2 on page 39). Agreements between the postal service and the local community encourage the American Postal Worker's Union to foster the volunteerism among postal employees to support local distribution of the SNS assets in the event of a health crisis. While volunteerism is never definite, the local communities (and the federal government) hope that they can rely on a "community mentality" to produce enough manpower to support incoming SNS assets during a public health incident.

Distribution Security

During a health crisis the potential for panic and tremendous chaos exists; people will resort to whatever measures are necessary for survival. Therefore, while precautions have been made to classify the specifics of vaccine and medical supply distribution, people will likely discover the methods and carriers for these federal assets. For precautionary reasons, the federal government has proposed that all emergency planners, especially state and local, assure the necessary security for facilities and transport during this time. This means that state and local communities must provide security for SNS assets once the federal governments signs the assets over to the state. Most state and local law enforcement are not sufficient for this additional need during a national emergency. In order to solve this dilemma, state and local authorities must preempt the emergency situation with a practiced plan for state and local coordination of law enforcement, supplemented with the National Guard. The federal government requires the states to secure

¹⁵⁷ MPA Workshop Group. Interview with the United States Postal Service. 6 June 2006.

¹⁵⁸ It may also be risky for the states to rely on the National Guard to assist greatly during a public health crisis or terrorism incident of significant scale. Within the states, National Guard forces may be hampered by: overseeing border support deployments; providing additional support to strained law enforcement; providing security to hospitals burdened by individuals seeking treatment; and sickness or absences of their own personnel. As multiple agencies expect the National Guard to support their mission during an emergency, it will be unrealistic to task them with protecting medical assets.

these important federal assets from contact points and in-between. (Please see Figure 3 on page 38 for an example of state distribution model).

SCENARIO: The Virus Spreads throughout the United States

Two months have passed since the initial distribution of the VMI. The virus is now widespread throughout the country and states continue to request SNS assets. The federal government struggles to fill new requests as the essential VMI elements are nearly depleted. The CDC and the VA work together to acquire VMI replacement supplies. The federal government faces several critical decisions and challenges. First, how best can they deploy their remaining SNS assets? Second, how can they best acquire and deliver short-term public health assets? Third, how does the federal government resolve the competition between DHS and HHS for leadership and response to a public health crisis?

Competing Purchasing

During a public health crisis of a national scale, basic medical supplies such as IV drips, syringes, needles, sodium chloride, may not be readily available because of the lack of supply and lack of strategic management. Typically, hospitals do not maintain a large surplus of supplies, because under routine operation, they can resupply their inventory. Usually, only large urban hospitals maintain a warehouse, while local hospitals do not. Each relies on just-in-time delivery from suppliers, both national and regional, for medical supplies. But during a national public health crisis, such as the later stages pandemic influenza which impairs communities across the country, a hospital's medical supplies may reach their limits. At the onset of a public health crisis, when a virus does not affect the entire country, hospitals may turn to their regular suppliers for basic medical supplies to backfill or prepare for an increase in patients. Many of the vendors and distributors will be able to deliver, because the pathogen may not affect their national or regional workforce.

But as a crisis grows to national levels, the public may expect a coordinated approach, with supplies going to communities and hospitals hardest hit by a pathogen. Instead, the vendors may direct supplies to communities and hospitals which can pay for them, but do not require the supplies to deal directly with a crisis. Unfortunately, HHS only plans to manage backfilling supplies until HHS depletes the Vendor Managed Inventory. HHS will continue purchasing supplies as manufactures can make them. But, comments by HHS seem to leave communities and states on their own in backfilling their supply. Instead of a national, strategic effort to manage a public health problem, such as a national pandemic influenza crisis, thousands communities would compete for scarce medical resources.

Politicization of Deployment of the SNS

The decisions on where to send supplies and vaccines may quickly become political, rather than epidemiological in a widespread crisis. The fact that the CDC does not possess public, statutory rules may undermine public confidence in the CDC's ability to properly distribute assets.

Moreover, the President may become more involved in the decision making and leading the federal response as public health crisis grows nationally. The President may have to arbitrate between HHS and DHS as they compete to lead the response during a public health crisis. Unfortunately, as the President becomes more involved, he becomes further removed from the expertise at the CDC and SNS on guiding the epidemiological response. It is unclear if the

President would be advised by the DHS Chief Medical Officer, the intelligence community (which monitors the U.S. public for incidents of biological, nuclear, chemical and radiological disasters), or the CDC. Instead of developing and implementing a comprehensive strategy to counter an infection, the President and federal authorities may focus on mitigating the discord between competing federal agencies.

Requesting Additional SNS Assets under Multiple Federal Emergency Regimes

Federal response structures permit states to request assets from different federal sources. For example, states approach HHS to obtain public health assets. In a national calamity, other centers such as DHS may become a source for federal assistance. The CDC states:

"If you require additional assets for an appropriate response, you can request further assistance from DSNS. The level of federal response will help determine the avenues you will use to request additional assets. For example, if there is a declared national emergency, the National Response Plan may be executed. DHS would establish a Joint Operations Center (JOC) with an Emergency Support Function #8 (ESF #8) section responsible for public health and medical services. Most likely, a state representative would request assistance through ESF #8 at the JOC. The JOC would task HHS to provide the additional support to DSNS. In contrast, under a public health emergency enacted by the HHS Secretary, a state representative may request additional support directly from the HHS's Secretary's Operation Center (SOC) or from a deployed HHS response team." ¹⁵⁹

However, multiple regimes for requesting assets may undermine the response further, compounded by confusion between DHS and HHS on who leads the response to the public health crisis.

DECISION MAKING ON THE STATE AND LOCAL LEVEL

The Challenges

There are two broad problems at the state level with the potential to cause delays in the deployment of SNS assets: confusion about the differences between the various SNS-related programs, and the lack of interstate planning.

One of the biggest challenges faced by state, and especially local, officials is that they may not understand the differences between the various SNS programs. The 12-hour Push Packages, Vendor Managed Inventory, the CHEMPACK program, the Cities Readiness Initiative, and the smallpox vaccine stockpile each have different procedures for disseminating SNS assets. The Push Packages are sent to a single site for redistribution to the local level. Vendor Managed Inventory can be sent directly to PODs, for example, in October 2001 antibiotics for anthrax

¹⁵⁹ Centers for Disease Control and Prevention Division of the Strategic National Stockpile. <u>Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness.</u> Version 10.01 – Draft. May 2006.

were delivered directly to treatment centers in Florida. 160 However, in the case of a nationwide emergency they may be sent only to the RSS site. 161 The Cities Readiness Initiative has plans that would allow local governments to make arrangements to use the Postal Service to deliver prophylaxis directly to homes, with the goal of providing 100 percent prophylaxis within 48 hours. 162 However, this system would not allow for delivery to Post Office boxes, or businesses (such as retirement communities or prisons), meaning that alternate arrangements will have to be made for these communities. With all these different arrangements, state and local officials may not understand which system is being used in a given case, especially if more than one program is activated simultaneously, as may be expected in the case of a national health crisis. The variety of SNS programs means that the roles of the SNS Program Coordinator and the TARU teams as liaisons and sources of information are key in successfully deploying SNS assets. States will require their advice, especially in the case of interstate management of a crisis.

SCENARIO: Interstate Management

Individuals living in Ohio and West Virginia near the Pennsylvania state border begin seeking treatment in Pennsylvania, in some cases overwhelming hospitals' ability to treat people. In other areas, PODs (points of distribution) in Pennsylvania have received more SNS assets than they need. Many small towns in Ohio and West Virginia border regions ask nearby hospitals in Pennsylvania to send them some of their excess SNS supplies. While the overall situation in Pennsylvania appears to be under control at the moment, Pennsylvania health officials are hesitant to give away supplies they may need if the situation worsens.

Also a number of challenges hinder the distribution of SNS assets when multiple jurisdictions are involved. If SNS assets are deployed to one state, and then a neighboring state requests SNS assets as well, there does not appear to be a mechanism for sharing or transferring assets between states. Given that there are only 12 Push Packages, states may have an incentive to request assets before they truly need them if they believe that there will not be anything left once other states request them. In such a situation, the use of VMI, which constitutes the majority of SNS assets, would play a central role. It is not clear how HHS would prioritize which states would receive Push Packages in such a situation.

Once SNS assets are handed over to the states, the federal government largely surrenders control of the assets. The state receiving the assets signs an indemnification of agreement before the first shipment. This agreement gives the state legal responsibility for managing and using the assets. As a result, the federal government cannot redirect assets to another state. Moreover, the memorandum indicates the states must return certain assets, including computer equipment, ventilators, repackaging equipment, refrigeration systems, as well as unused medications that remained at the RSS facility. ¹⁶⁴ As a result, a state cannot simply transfer SNS assets to another

¹⁶⁰ Staley, Mike. "The Strategic National Stockpile Program Tutorial." Online posting. University of North Carolina Preparedness Center Training Site.

http://www.sph.unc.edu/nccphp/training/login/index.cfm?endup=strat_nat_stockp>.

Centers for Disease Control and Prevention. <u>Cities Readiness Initiative Pilot Cities Year 1 Progress Report.</u> 9 August 2005: 5. https://www.orau.gov/snsnet/resources.htm.

¹⁶⁴ Centers for Disease Control and Prevention Division of the Strategic National Stockpile. <u>Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness.</u> Version 10.01 – Draft. May 2006.

state as they must first be returned to the SNS. In an emergency, this can result in considerable delays when time is of the essence.

The state SNS plans focus primarily on problems within their own borders. However, many metropolitan areas span multiple jurisdictions. For individuals living near state borders it may make more sense to go to a city or a POD in a neighboring state than the nearest city or POD within their state. These considerations should be included in the states' SNS plans. However, states lack the time, staff and money. Some states have made informal agreements for sharing resources or distributing SNS assets across state borders. In addition, the Cities Readiness Initiative appears to be helping state and local officials plan for these challenges. This program initially provided \$27 million in funding to 21 cities for six months. An additional \$3 million is being provided to expand the CRI to include 15 more cities, but future funding is not assured. Some have even conducted joint exercises. However, this remains the exception rather than the rule, and more attention needs to be paid to interstate coordination.

SCENARIO: The Situation in Ohio and West Virginia Deteriorates

The problem in Ohio and West Virginia continues to deteriorate, and their governors begin making more strident public calls for Pennsylvania's SNS assets. The conflict between these states receives wide coverage in the media, further exacerbating tensions. Pennsylvania recognizes the Emergency Management Assistance Compact (EMAC) and has passed laws allowing for the sharing of resources with other states, as well as good Samaritan laws limiting the liability of out-of-state volunteers. However, there is still confusion over who will be legally responsible for SNS equipment after it is transferred to another state. Pennsylvania is worried that the indemnification agreement it signed with the CDC upon receiving the Push Package will hold Pennsylvania liable for any SNS assets it transfers to Ohio and West Virginia. As a result, Pennsylvania is refusing to transfer its SNS assets without clarification over who will be legally responsible for SNS equipment and supplies.

Interstate Legal Concerns

There are also several legal issues that need to be addressed in a multi-state incident including the federal decision making process for SNS allocation, the interstate sharing of personnel, and the liability for the asset transfer across borders. ¹⁷⁰

Allocation among States

The federal decision making process for allocating SNS assets is not clear. No stated mechanism exists for determining which states receive SNS assets, if there are competing requests. Instead,

Association of State and Territorial Health Officials. <u>Interstate Planning for the Strategic National Stockpile: Experiences in Five Regions</u>. 2005. http://www.astho.org/pubs/SNSfinalreport.pdf.

¹⁶⁷ Centers for Disease Control and Prevention. <u>Cities Readiness Initiative Pilot Cities Year 1 Progress Report.</u> 9 August 2005: 5. https://www.orau.gov/snsnet/resources.htm.

Association of State and Territorial Health Officials. <u>Interstate Planning for the Strategic National Stockpile:</u> <u>Experiences in Five Regions.</u> 2005. http://www.astho.org/pubs/SNSfinalreport.pdf.

Experiences in Five Regions. 2005. http://www.astho.org/pubs/SNSfinalreport.pdf. State of Pennsylvania Department of Health. Pandemic Response Plan: Attachment B – Statutory Authority. http://www.dsf.health.state.pa.us/health/flu/PandemicFluInfo2005.pdf.

Authority. Authority. <a hr

states may find themselves competing for supplies. 171 Such a situation would likely hinder interstate coordination and assistance. Any conflicts would likely be highlighted in the media and could undermine the faith in the country's emergency management efforts. 172

Personnel

Sharing personnel across state borders creates three sets of challenges. First, professional licenses may not be recognized in other states. Second, if a volunteer is injured, compensation laws may be different between the two states. Third, volunteer medical workers may be subject to medical malpractice lawsuits outside of their home state.¹⁷³ The Emergency Management Assistance Compacts (see below) generally address these issues, but states must be proactive in ensuring that their legislation addresses these concerns.

Asset Transfers

Finally, transferring SNS assets across state borders creates a variety of challenges. When a state receives SNS assets the indemnification agreement it signs with the CDC, holding the state liable for any claims related to the assets. Both states may be held liable if the materiel were to be transferred to another state, meaning that the original state could face lawsuits for actions that occur when the materiel is no longer under its control.¹⁷⁴ In addition, the agreement requires that states return equipment and unused supplies. If assets were to be transferred to another state, the first state may still have responsibility for ensuring that these assets are returned to the SNS. 175

States can take steps to mitigate these interstate challenges. The Emergency Management Assistance Compact (EMAC) is one resource for improving cooperative efforts. The EMAC is an organization that was set up by Congress in 1996 to provide form and structure to interstate aid. The EMAC can help states adopt standardized laws and procedures for mutual aid, making it easier to share resources quickly in an emergency. However, it remains up to individual states to take the initiative to join the EMAC and adopt mutual aid legislation. ¹⁷⁶

SCENARIO: Distribution to the States Grows Difficult

As the disease continues to claim victims, private sector drivers, logisticians, and packagers increasingly fall ill. The distribution of SNS assets at both the federal and state levels decreases severely because private contractors are too sick or too afraid to continue delivery. Citizen frustration and panic begins to reach critical mass as the scarcity of medical materials mounts. Government officials realize that civilian response systems are failing, leaving only one option - the military. Governors order their National Guard units (already activated to provide security for internal state distribution) to augment and assist civilian response. These units immediately take over the distribution and delivery of SNS and VMI materials from the overwhelmed commercial carriers. Some states even use their National Guard units to

¹⁷¹ Association of State and Territorial Health Officials. <u>Interstate Planning for the Strategic National Stockpile:</u> Supplement on Legal Issues. 2005. < http://www.astho.org/pubs/SNS_supplement.pdf>.

¹⁷³ *Id*.

¹⁷⁴ *Id*.

¹⁷⁶ Emergency Management Assistance Compact (EMAC) Site. National Emergency Management Association (NEMA). 2005. http://www.emacweb.org.

conduct primary law enforcement, as civilian law enforcement capacity is degraded due to illness and resource scarcity.

Officials from HHS and DHS request federal military assistance. These federal requests are sent to the Secretary of Defense for rapid review and approval. Once authorized, domestically based active military units begin deploying around the nation to assist state and local governments in emergency response. Active duty units take over the distribution of the remaining SNS and VMI assets to state RSS sites. When needed, both the National Guard and the active duty forces requisition materials and transportation assets (i.e. trucks and aircraft) from private sector companies. Finally, military medical personnel either deploy to civilian hospitals or set up their own clinics to provide medical care to the general population.

DEPARTMENT OF DEFENSE RESPONSE PLANS

The Department of Defense possesses plans to treat military personnel during a public health crisis. To accommodate military treatments, DOD utilizes the Defense Supply Center Philadelphia (DSCP). A subsidiary of the Defense Logistics Agency (DLA) and thus the Department of Defense, the DSCP is charged with stockpiling medical equipment and medicines, in addition to the food, clothing, and other general supplies already stockpiled for American military and civilian customers. As one of the largest activities of the DLA, the DSCP "supplies and manages over \$12.7 billion" in supplies each year. A readiness tool, the DSCP's mission is to stockpile and hold inventories of relevant materials, including vaccines, to insure continuity of the military in the event of an emergency or supply shortage.¹⁷⁸

The Center's Directorate of Medical Material, the subset that directly handles the vaccines sector, is responsible to federal agencies and other local organizations receiving federal funds for vaccine supplies, and includes programs in readiness enacted to handle worldwide surge capacities. In response to the recent surge of stories regarding pandemic flu, the DSCP boasted its readiness in ensuring continuity in the military through vaccines in an article entitled, *Medical Supply Chain Ahead of Possible Avian Flu Pandemic*. In the article, various members of the medical supply chain team detail how they have worked closely with the Office of the Assistant Secretary of Defense for Health Affairs to coordinate the stockpiling of Tamiflu and other treatments to "insure that troops have the necessary supplies available to minimize the effect of the potential pandemic in a timely manner so that their missions are not compromised," as Commander Kim Lefebvre, Chief of the Depot/DVD Pharmaceuticals Branch cited. Thus, DOD is fully prepared to manage and respond to the needs of its own personnel.

DOD Civil Support During National Emergencies

In addition to its own internal responsibilities, DOD will assist in emergency response at all levels of government. When a federal agency such as DHS or HHS requests aid from DOD, the Secretary of Defense (SecDef) can authorize assistance via Military Assistance to Civil

¹⁷⁷ Requisition powers are granted under the Stafford Act.

About Defense Supply Center Philadelphia Site. Department of Defense: Defense Logistics Agency. http://www.dscp.dla.mil/aboutdscp/.

¹⁷⁹ Defense Supply Center Philadelphia Site. Directorate of Medical Material. https://dmmonline.dscp.dla.mil/.
180 "Medical Supply Chain Ahead of Possible Avian Flu Pandemic." Provider. A news publication about the Defense Supply Center Philadelphia." Spring 2006. http://www.dscp.dla.mil/corpcomm/current/story16.htm.

Authorities (MACA) or Civil Support (CS) missions. ¹⁸¹ "Except in cases of immediate response, DOD cannot provide MACA [or CS] without an official request from another federal agency or direction from the President." During these missions, DOD may help restore essential government services, protect public health and safety, and provide emergency relief to those in need. ¹⁸³ Regardless of the emergency, DOD is a vital component of emergency response due to the amount of personnel, transportation, logistics, and materials it can provide.

State and local governments can also request DOD assistance directly. "DOD resources are provided only when response or recovery requirements are beyond the capabilities of local, state, and federal civil authorities, and when they are requested by an LFA (Lead Federal Agency) and approved by [the Secretary of Defense]." For most states and localities, the National Guard (NG) will constitute DOD support. Generally, governors employ their National Gaurd units under state active duty or Title 32 status. State active duty and Title 32 utilization is advantageous because they do not produce any Posse Comitatus constraints and units remain under state control – allowing for states to tailor DOD asset response and utilization.

Active duty (i.e. Title 10)¹⁸⁷ forces and DOD civilian personnel may also be used in domestic emergency situations. For example, when requested, DOD can employ the Chemical and Biological Incident Response Force (CBIRF). The CBIRF mission is to "forward-deploy and /or respond to a credible threat of a Chemical, Biological, Radiological, Nuclear, or High Yield explosive (CBRNE) incident in order to assist local, state, or federal agencies and Unified Combat Commanders in the conduct of consequence management operations." CBIRF can significantly assist in the following: "agent detection and identification; casualty search, rescue, and personnel decontamination; and emergency medical care and stabilization of contaminated personnel." Finally, under the Immediate Response Authority domestic federal commanders, such as a local base commander, can respond (with domestically based active duty forces and assets) without the authorization of the Secretary of Defense in order to "save lives, prevent human suffering, or mitigate great property damage." Commanders acting under the

 ^{181 &}quot;Medical Supply Chain Ahead of Possible Avian Flu Pandemic." Provider. A news publication about the Defense Supply Center Philadelphia." Spring 2006. http://www.dscp.dla.mil/corpcomm/current/story16.htm.
 182 "Medical Supply Chain Ahead of Possible Avian Flu Pandemic." Provider. A news publication about the Defense Supply Center Philadelphia." Spring 2006. http://www.dscp.dla.mil/corpcomm/current/story16.htm.
 183 Walker, David M. "Enclosure I: Statement by Comptroller General David M. Walker on GAO's Preliminary Observations Regarding Preparedness and Response to Hurricanes Katrina and Rita." 1 February 2006.

Observations Regarding Preparedness and Response to Hurricanes Katrina and Rita." 1 February 2006. http://www.gao.gov/new.items/d06365r.pdf. The agencies involved are the Department of Defense, Department of Energy, Department of Health and Human Services, Environmental Protection Agency, Federal Emergency Management Agency, Federal Bureau of Investigation, and the Department of Justice.

¹⁸⁴ United States Department of Defense, Joint Chiefs of Staff. <u>Joint Publication 6-23: Homeland Security</u>. 2 August 2005: IV-12. http://www.dtic.mil/doctrine/jel/new pubs/jp3 26.pdf>.

¹⁸⁵ Id. During state active duty missions, National Guard units receive their orders and funding from their state. During Title 32 missions, National Guard units receive their orders from their state and their funding from the federal government.

Id. Posse Comitatus Act prevents federal military forces from assisting or conducting civilian law enforcement.
 Id. During Title 10 missions, National Guard units receive their orders and funding from the federal government.
 Chemical Biological Incident Response Force: Mission Site. United States Marine Corps. 22 May 2006.
 http://www.cbirf.usmc.mil/mission.htm>.

United States Department of Defense, Joint Chiefs of Staff. <u>Joint Publication 6-23: Homeland Security</u>. 2 August 2005: IV-12. http://www.dtic.mil/doctrine/jel/new_pubs/jp3_26.pdf.

Immediate Response Authority are required to notify the Secretary of Defense as soon as possible of their actions and to return emergency response over to civilian authority and assets as soon as practicable. ¹⁹¹

¹⁹¹ United States Department of Defense. <u>Military Support to Civil Authorities (MSCA)</u>. 15 January 1993: 8. http://www.dtic.mil/whs/directives/corres/pdf/d30251_011593/d30251p.pdf.

LESSONS LEARNED?

The federal government intends to use the SNS to supplement the state and local response when they have exhausted their supplies. While the federal government has deployed the SNS in three different emergencies, the SNS process was only publicly reviewed in one case, the response to Hurricane Katrina. The House Committee on Homeland Security report, A Failure of Initiative, brought to light gaps in the deployment and breakdowns in the SNS process. 192 Moreover, this report exposed the inability of state and local governments to manage these essential federal assets during an emergency.

The first deployment of the SNS arose after the terrorist attacks on September 11, 2001. The CDC dispatched a Push Package to New York City, "which arrived within seven hours of the HHS Secretary's order to deploy." The second deployment occurred on October 8, 2001 in response to the anthrax attacks in the State of Florida. The CDC utilized the VMI to send 100 cases of anti-infectives by plane to Florida's Palm Beach County Health Department. 194

The third deployment of SNS assets transpired prior to Hurricane Katrina making landfall. The CDC, under the authorization of HHS Secretary Michael Leavitt, shipped twenty-seven pallets of requested medical supplies to Louisiana along with an SNS Technical Advisory Response Unit (TARU) Team. "The pallets included basic first aid material, blankets and patient clothing, suture kits, sterile gloves, stethoscopes, blood pressure measuring kits, and portable oxygen tanks."197 The pallets and TARU Teams were in place prior to the landfall of Katrina. However, Mississippi's requested Push Package arrived four days after Katrina hit the region. 198

Unfortunately, the Push Packages were originally designed to respond to a bioterrorist attack rather than a general health emergency. Thus, some of the Push Package materials sent to Mississippi were not useful—a fact eventually recognized by officials at all levels of government. In response, the CDC informed state and local officials they could request specific supplies without requesting an entire Push Package.

A Failure of Initiative also concluded that there was a lapse in management in HHS, with the result that some SNS assets were never received. 199 Moreover, the report highlighted the fact

197 United States Department of Health and Human Services. "HHS Supports Medical Response to Hurricane Katrina." News Release. 29 August 2005. http://www.hhs.gov/news/press/2005pres/20050829a.html.

¹⁹² Select Bipartisan Committee to Investigation the Preparation for and Response to Hurricane Katrina. A Failure

of Initiative. 15 February 2006. http://katrina.house.gov/full_katrina_report.htm.

193 Prior, Stephen. Report Commissioned by the National Defense University Center for Technology and National Security Policy. Who You Gonna Call?: Responding to a Medical Emergency with the Strategic National Stockpile. June 2004.

¹⁹⁸ Select Bipartisan Committee to Investigation the Preparation for and Response to Hurricane Katrina. A Failure of Initiative. 15 February 2006. http://katrina.house.gov/full_katrina_report.htm.

15 February 2006. http://katrina.house.gov/full_katrina_report.htm.

26 Failure

of Initiative. 15 February 2006. http://katrina.house.gov/full-katrina-report.htm.

that some of the assets received by the states were useless. Indeed, Hurricane Katrina showed that state and local level officials were insufficiently informed about SNS programs and the federal government was ill-prepared to manage the crisis.

State and local communities are slowly launching their own emergency preparedness plans to respond to large-scale public health crises and to support federal assets deployed through the SNS. While some of these state plans have been rehearsed, most plans are untested and exist only on paper. Furthermore, the emergency simulations that test these plans may not portray the chaos of a real event. The federal government provides limited assistance to help state and local government develop their plans. For example, the federal government, through the CDC Division of the Strategic National Stockpile, provides resources for state and local emergency officials to assist with planning and implementation. Additionally, the federal government attempts to share any lessons learned.200

In 2004 Health and Human Services launched a pilot program called the Cities Readiness Initiative (CRI) in 21 metro areas to help them increase their capacity to deliver medicines and medical supplies (mostly from the SNS).²⁰¹ The following year, the program expanded to 15 additional metro areas. The CRI not only provides the necessary funding to increase the capacity of these mechanisms for a major public health emergency, but also helps communities share best practices developed during this nation-wide program.

Although the federal government is taking positive steps towards improving state and local capacity and distribution, criticism remains. In December 2005, The Trust for America's Health (TFAH), a non-profit, non-partisan organization, released its third annual report evaluating the preparedness of public health emergency response capabilities. They found most state plans lacking. TFAH scored each state based on ten key indicators developed with input from an advisory committee. 202 States received one point for achieving an indicator or zero points if they did not achieve the indicator. Zero was the lowest possible overall score and 10 the highest. Nearly 60 percent of states received a score of 5 or less of 10 possible indicators. Nearly 85 percent of states received a score of 6 or less. They gave the CRI a grade of C-. 203

While the federal government has a system for deployment, the capacity to effectively handle and manage nation-wide health crises does not exist. Additionally, the states are unprepared to receive these federal assets. State plans lack full vetting and many state capacities remain unknown. Even the best prepared localities note weaknesses and gaps in both their infrastructure capacity and transportation logistics. Thus significant problems still exist at all levels of government.

²⁰¹ CRI Fact Sheet Site. Centers for Disease Control and Prevention. June 2004.

http://www.bt.cdc.gov/cri/pdf/facts.pdf.

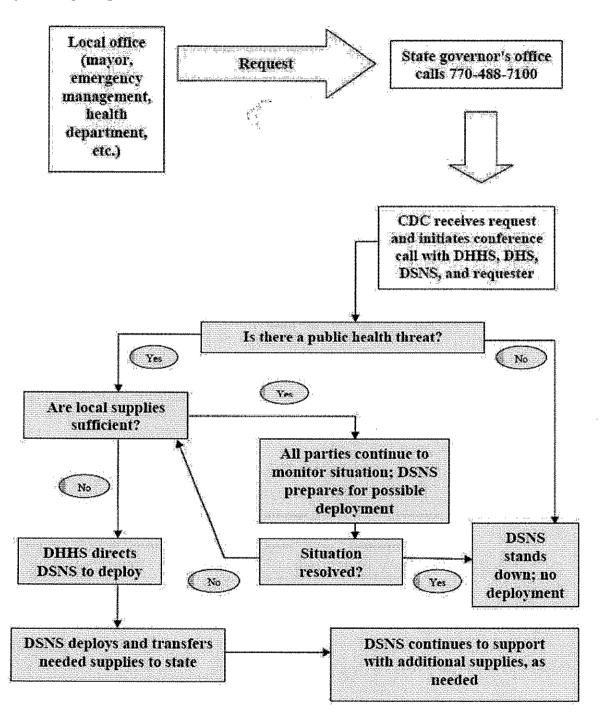
²⁰⁰ <u>Homeland Security Information Network Site</u>. Lessons Learned Information Sharing. <www.llis.dhs.gov>.

²⁰² Trust for America's Health. Ready or Not?: Protecting the Public's Health from Diseases, Disasters, and Bioterrorism. Dec 2005: 2. http://healthyamericans.org/reports/bioterror05/bioterror05Report.pdf.

203 Id. However, unlike the DSNS progress report, which came with internal expertise, their access to the specifics

of the program was limited, and their sample size, a mere nineteen experts.

Figure 1: Requesting SNS Assets



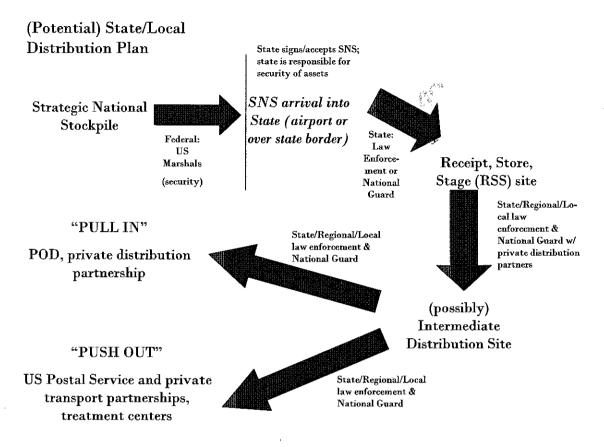
Source: Centers for Disease Control and Prevention Division of the Strategic National Stockpile. <u>Receiving.</u> <u>Distributing.</u> and <u>Dispensing Strategic National Stockpile Assets: A Guide for Preparedness.</u> Version 10.01 – Draft. May 2006: 3-3.

Salani Cenetiti i Sebera HEALTH 1-877-PA-HEALTH (1-877-724-3258) Strategic Notional Stockpile - Volunteer Application You wis on page 5 to 5. There are 20 questionarts assures on his sage. Scries e unbushing your voluntees application, please tead ever the information regarding the Studeyic Hadenad Steckpile, so well as the Busies and Responsibilities associated with each volunteer assignment, on our weighte. Last Stane" Snest Address I State" (Le. PA) Zip Code* (Le. 17600) Davies Phone Number" S.A. 71759512123 Email Address Do you passens a readfoal Oconse (Dt., RR, SMT, Flest Responder, etc.)? Would you like us to contact you to obtain the license number for milication? World you like us to contact you to obtain the license number for verification? C Yes C No Dulles and Respondibilities residency you are interested in columbering for? (check all that apply) Dispensing Site Supervisor Public Information Officer D Secrety Section Chief C Security Staff C Administration Section Chief C Does Every Clork C Logistica Section Chief Communications Unit Leader F: Communications Staff D Pharmacy Unit Leader C Pharmacy Technician C Logistics Staff C Operations Section Chief ☐ Greeten/Triage C Medical Screener C Dispensing Staff 🖺 Interpretar/Translator C Planning Section Chief

Figure 2: State Volunteer Form

Source: National Strategic Stockpile Volunteer Form Site. State of Pennsylvania Department of Health. <https://www.dsf.health.state.pa.us/health/webforms/survey.asp?s=C7CBCD83CECAC7&d=C6CBCE83CECAC7>.

Figure 3: (Potential) State/Local Distribution Model



Source: Illustration by Kerri Weir.

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