

ARE WE READY?

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

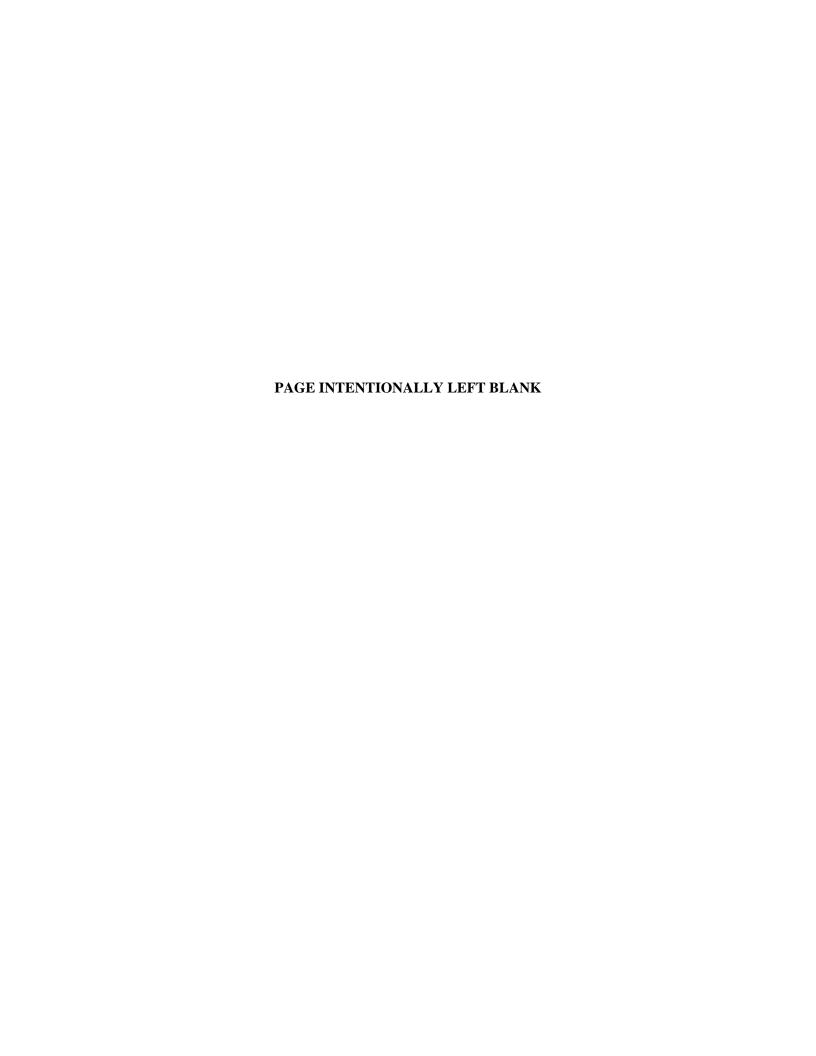
Executive Summary

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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.⁵ 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

http://www.dhs.gov/interweb/assetlibrary/Prep_NationwidePlanReview.pdf>.

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

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." 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..9 The following recommendations help to address this issue as well as concerns regarding liability, regulatory flexibility, and transparency.

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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. <u>Meet the Press Transcript</u>. http://www.msnbc.msn.com/id/10042399/.

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.¹⁰ Additionally, "if a pandemic occurs prior to licensure of a vaccine, the Food and Drug Administration (FDA) can use its 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."¹¹ However, despite these recent developments the threat of liability still remains a "major obstacle to developing a strong domestic vaccine industry."¹²

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 cellbased 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."¹⁴ 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

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

¹¹ *Id*.

¹² *Id*.

¹³ *Id*.
14 *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/>.

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.