

Testimony of Gregory Burel  
Committee on Homeland Security and Governmental Affairs  
June 24, 2020

Chairman Johnson, Ranking Member Peters and members of the Committee, thank you for the opportunity to testify on the Role of the Strategic National Stockpile in Pandemic Response. I am honored to continue to support the mission of this critical organization by testifying today before your committee. I had the privilege of serving as Director of the Strategic National Stockpile or SNS, for almost 13 years. My long-planned retirement from Federal Service was effective on January 3rd of this year. I remain a Fellow of the National Academy of Public Administration and am President of Hamilton Grace LLC.

For more than 20 years, the SNS has been the nation's repository of medical countermeasures, both drugs and devices, to protect our health security. SNS is a highly capable organization but its utility for certain responses, such as those for a nationwide pandemic event, are constrained by a lack of funding. I hope my testimony can provide better context for understanding the SNS response to COVID-19 in full view of its limitations.

In 1999, when SNS was established as the National Pharmaceutical Stockpile the design was to develop inventory to respond to Chemical Biological Radiological and Nuclear or CBRN threats. By December of 2019, the inventory was valued at around \$8 billion. SNS is more than its inventory and encompasses the skill and capability that support the unique needs of a civilian health and medical response. These unique and specialized capabilities of the SNS cannot be rapidly developed by some other organization in an event. While others can assist SNS, SNS must always manage the work of those providing assistance.

Over time, its highly specialized material and medical logistics capabilities became apparent, and it expanded to an all-hazards mission. All-hazards includes, among others, pandemic disease and natural events. Instead of 'mission creep', SNS experienced 'mission gallop'. Such a leap in expectation cannot occur, however, without commensurate increases in funding. Appropriations have not kept pace with the growing burden to expand inventory and capability to meet all hazards mission expectations.

SNS' inventory is its most visible component but as important are its capabilities to acquire, manage and distribute medical countermeasures to protect our nation's health security. There is no other federal department or agency more prepared and experienced in this field than the SNS. The dedicated federal and contract professionals are some of the best in the field of medical logistics.

SNS has vast experience in purchasing the correct, properly licensed, and effective drugs and devices to support any civilian health response. This ensures that funds are not unwisely invested in material that does not actually meet requirements. SNS material quality control is outstanding and always results in the most appropriate material being acquired and delivered for health and medical needs. In times of crisis, It is vital that the SNS is always the organization responsible for the purchase, either directly or through other agencies acting on its behalf. SNS uses many acquisition methods and procures products under several inventory management scenarios. We can be confident that the SNS experts will steer the federal family to buy the right things and get them to the right place at the right time all while assuring those products are managed in the most appropriate and cost effective manner. SNS can deploy inventory tailored to meet specific needs in many cases beginning within 4 to 6 hours of decision and completing deployment within 8 to 15 hours of decision.

SNS is uniquely qualified to address the large, usually regional threats, from the devastating impact of CBRN events. These same capabilities allow the SNS to be the best source of a response to other smaller regional outbreaks and national disasters that might require medical material intended for these threats but useful in other scenarios. The bottom line is that the capabilities of SNS to deploy its inventory are unmatched by any other organization.

The inventory of the SNS can save lives and greatly reduce illness caused by a variety of naturally occurring hazards, but again, preparing for and responding to CBRN threats has been its primary purpose. The specific threats are determined by the Department of Homeland Security and products to respond to these threats are determined by a robust, science-based governance process that brings together experts from across the executive branch.

SNS annually responds to a variety of illnesses that do not rise to the level of a national emergency, but that only its inventory can manage. Some of these involve a single patient and others involve a larger scale outbreak. As an example, a 2015 botulism outbreak in Ohio was far less deadly because the SNS mobilized to distribute a large quantity of antitoxin for those affected, many gravely ill. This antitoxin is available from no other source than the SNS.

Recent proposals questioning whether SNS should be moved to or its material and logistics be controlled by another department reflect a fundamentally flawed understanding of these issues and trouble me greatly. As part of ASPR, SNS is well integrated in the health and medical response framework and is ideally positioned to be supported by the science of all the operating divisions of HHS directly.

Statute requires a threat based annual review to drive decisions around funding which ultimately yields the available content of the SNS. This review is conducted under the auspices of the Public Health Emergency Management Countermeasures Enterprise (PHEMCE) governance process. PHEMCE is composed of experts in disease threats and other specialized medical and scientific areas and recommends the content to be held in SNS. Specialist groups make recommendations to an Executive Committee which provides final recommendations to a committee, including the highest ranks of the departments engaged in health and medical response. Led by the ASPR and including the Directors of CDC, NIH NIAID, and others, this body makes final decisions for the SNS formulary. PHEMCE experts use data from the required annual review in its regular work to determine the content requirements to meet contemporary needs.

Because available appropriations have been limited for the SNS, it is necessary to balance risk-based needs across threats to purchase the best mix of product. It is also notable that statute requires SNS prioritize products unavailable in the commercial market. Simply put, many things procured by the SNS, including the like the life-saving botulinum antitoxin deployed in the 2015 outbreak in Ohio, wouldn't be developed or manufactured otherwise because there is no or insufficient demand for the product outside of the Federal Government. Thus, it is important to remember that the SNS is the only source of a number of products that are often needed in healthcare, absent a declared disaster or emergency. SNS

has routinely deployed those products extremely rapidly, saving lives and reducing illness as a result.

In deciding what to hold in the SNS, the PHEMCE must consider matters such as:

1. If the government has invested in development of needed new MCM the SNS must continue to purchase them or we will lose access to the product and the investment of government funds for development will have been wasted;
2. Many products that have not been developed solely under government contracts are needed for CBRN defense but have no viable commercial market - meaning if the SNS does not invest in the continued manufacturing and delivery of those products, we will lose access to them;
3. General commercial availability of certain products and the capability of a normal supply chain to supply those products. That is to say, if the products needed for a specific event are normally available in the market, we would buy less of those products to assure that the material not available in the normal market yet vital for preparedness is not lost to the US.

Keeping the history and inventory requirements process in mind for context, We've all heard the disturbing accounts of brave doctors and nurses short on critical supplies treating COVID-19 patients at overcrowded hospitals. These initial shortages led to the logical question of why the United States was seemingly so unprepared for a pandemic. For many, there was an assumption that SNS should have been poised to immediately deliver everything needed, for all facets of a pandemic response. The truth is that, our lack of preparedness as a nation does not sit solely or predominantly with the SNS, but is instead the result of insufficient investment in public health at all levels of government. Our lack of capability to mount a swift, whole community response to such events also can be attributed to, among other things, limitations on manufacturing of important healthcare products in the United States. Finally, the SNS must rely on the very lean medical supply chain, optimized for the best value, but less than optimal for any crisis response.

As I have addressed already, the SNS was never envisioned to be the first stop in response to emerging infectious disease, particularly pandemics. The appropriations for SNS are far below a level that would enable it to be even close to a comprehensive source of every necessary supply in a pandemic.

SNS only began to invest in inventory to respond to pandemic influenza in response to special supplemental appropriations for that purpose in about 2006. In the early 2000s, Congress authorized funds for a minimal level of pandemic influenza supplies including PPE. Those items were largely depleted following a highly successful response to the 2009 H1N1 pandemic flu, and specific funds for replacement were never reauthorized. With no further appropriations to specifically restock and expand things such as PPE for a pandemic, SNS had little option but to carefully guard the remaining material and try to extend its usable life as best as possible. To that end, the SNS even commissioned a study by NIOSH to determine if this older, marked expired PPE was safe and effective for use. Ultimately, without increases in appropriations to rebuild, expand and maintain the old stock of pandemic influenza material the PHEMCE, was left with little recourse except to plan reliance on the commercial market for these commercial products, and focus on those that cannot be drawn from the market in an instant response to a CBRN event.

The SNS was designed to be just one piece of the public health preparedness puzzle. State, local, tribal and territorial or SLTT public health have a vital role to play. These levels of government are responsible for planning in their unique jurisdiction so that federal assets can be called upon when the options have run out, ideally enabling them to be more effective and efficient. However, the capabilities of the SLTT can only respond effectively when they are built and maintained through proper funding.

Public health generally and preparedness specifically must be consistently and robustly funded at all levels of government. We have a long history of heavily investing in public health when it is clear there is a problem, but as we move away from those significant adverse events, and the public's memory fades, funds for public health often decrease as well.

Just after 9/11 there was a large federal investment through various grants and cooperative agreements to fund and support states, locals, tribes and territories to be prepared for the next public health crisis. At the same time, federal investment in grants and cooperative agreements to assure state and local preparedness were declining. Funds for every aspect of public health preparedness have declined and negatively impact planning, exercising, stockpiling and daily operations.

Prior to H1N1, many states were invested in their own stockpiles that the SNS could supplement and replenish. As available funds from both the federal and state government for public health investment began to decline, these state stockpiles were some of the first programs to be slashed. Thus, when it was time to respond to a pandemic disease, states did not have material on hand themselves to support their requirements until either the federal government or the operating market could provide more material.

Commercially, as medical supply chains have become more just in time oriented, uncommitted material stocks have become more and more lean or non-existent. It is difficult for the operating market to shift and provide massive quantities of material exceeding the normal operating requirements of healthcare for these types of events.

There is a need for more robust investment at the federal level, at the SLTT level and in the commercial sector to be prepared for the next pandemic. Among considerations to be evaluated, are whether there should be mandatory federal funding for public health annually, whether there should be federal support to increase on-shore manufacturing and stock of material for the next pandemic, and whether we really expect the SNS to be solely responsible for all health and medical response material. The way forward must incorporate elements of all these considerations, and include a stronger partnership between federal, SLTT and the commercial healthcare manufacturing and distribution sector.

It is for good reason that the SNS has been the envy of the preparedness experts all over the world. Its record of achievement in accomplishing its intended mission is nothing short of exemplary. If we now want this critical strategic asset to

surpass prior expectations, we must invest in it and expand its authorities accordingly.

Our national health security suffered a blow from COVID-19 and the threat is far from over. At the same time, additional deadly threats against our nation, many which can only be addressed by the SNS, have not diminished. Unfortunately, this pandemic has illustrated the high cost of not making the necessary investments in public health. We wouldn't expect the US military to go into battle with half of its firepower. And we cannot expect the SNS to arm our nation for success against an invisible, yet ruthless enemy without the necessary resources to do so.