Attachment—Additional Questions for the Record

Subcommittee on Health
Hearing on
"Road to Recovery: Ramping Up COVID-19 Vaccines, Testing, and Medical Supply Chain"
February 3, 2021

Mr. Greg Burel, President and Principal Consultant, Hamilton Grace, Former Director, United States Strategic National Stockpile

The Honorable Frank Pallone, Jr. (D-NJ)

1. Mr. Burel, can you explain the history of preparedness funding? Has funding in this space been consistent over the years?

Funding for preparedness has not been consistent over the years. It is imperative that the SNS receive consistent funding to allow for appropriate investment in countermeasures of all types. SNS must be funded for both its Chemical Biological Radiological and Nuclear (CBRN) defense mission as well as for Emerging Infectious Disease (EID) threats. SNS funding has not kept pace with the requirements for just the CBRN mission. Based on my professional judgement and similar professional judgement budgets previously provided Congress, I believe that SNS needs a one time infusion of up to $1 billion to bring all stocks up to meet requirements and then approximately $800 million in annual appropriations to maintain those stocks. This amount would improve our posture for CBRN response. EID response should be funded in an amount I would defer to HHS for answer.

The following table shows the funds appropriated since 2000 in millions:

FY 2000	52.0
FY 2001	52.0
FY 2002	645.0
FY 2003	298.050
FY 2004	397.640
FY 2005	466.7
FY 2006	524.339
FY 2007	496.348
FY 2008	551.509
FY 2009	570.307
FY 2010	595.661

FY 2011	591.001
FY 2012	533.792
FY 2013	477.577
FY 2014	549.343
FY 2015	534.343
FY 2016	569.250
FY 2017	573.907
FY 2018	610.0
FY 2019	610.0
FY 2020	705.0
FY 2021	705.0

The Honorable Michael C. Burgess, M.D. (R-TX)

1. Mr. Burel, what currently happens if the Defense Production Act is invoked and we end up with too many of a particular medical item – for example, ventilators?

    a. What can the federal government do to better equip the Strategic National Stockpile to handle such a scenario?

    When the government holds material that is ultimately no longer required, that material may be declared "excess" and disposed of in accordance with statute that governs government property and its ultimate disposal. The General Services Administration (GSA) is charged with property disposal. Property may be declared as excess and offered through GSA sales authority with funds realized from sales being returned to the US Government but not to the "selling" agency. (https://www.gsa.gov/policy-regulations/regulations/federal-management-regulation/federal-property-management-regulation-fpmr-related-files).

    It is also permissible under statute for SNS and other government programs to offer excess property to other federal agencies directly when there is a known or potential requirement. For example, if SNS has medical material that may be of use to the Veterans Administration (VA), SNS can contact VA officials and offer to transfer that property to them. In practice, it is uncommon for SNS to find another agency that will accept such a property transfer. In these scenarios the receiving agency does not reimburse SNS for the value of the property.

    In normal operations, as it may be unclear immediately if such property may be needed in a future response, SNS will hold that property until the normal end of its useful life. When the property is no longer serviceable, or in the case of expiry dated product when it reaches its expiration date, it is destroyed in accordance with all applicable law and regulation. The disposal of such products also presents a cost to SNS.

To better equip the SNS to dispose of unrequired material, the Congress should provide SNS with authority to sell excess material and realize that income through an authorized Working Capital Fund. Such a fund would allow the SNS to use income realized from sales of unrequired property to purchase other required material.

It is my recommendation that the Congress authorize the SNS to sell excess property and further that the Congress authorize a Working Capital Fund for SNS to realize the income of such sales. Further, I would recommend Congress through the Department of Health and Human Services commission the National Academy of Public Administration (NAPA) to consider and propose the best way to implement such authorities for the SNS. I and other NAPA fellows have considered just such a scenario recently.

2. Access to COVID-19 testing is still an issue. A limiting factor has been access to swabs, viral transport medium, lateral flow membrane, and the raw materials for producing these essential components of testing. As Congress and the administration review and take actions to revitalize the Strategic National Stockpile (SNS) how can the SNS play a role in ensuring the medical supply chain has adequate supplies of raw materials necessary to produce necessary testing supplies and PPE?

   It is imperative that more manufacturing capability be available "on-shore" or "near-shore". The current medical supply chain has little flexibility to respond to large surge requirements due to its "just in time" nature. This operational norm is well designed for cost management but does not lend itself to any flexibility.

   I propose Congress enact authorities and appropriate funds to allow SNS to invest in manufacturing capabilities including the acquisition of raw materials held by manufacturers to increase manufacturing in surge need. Authorizing language in the Public Health Service Act to direct the SNS to undertake these investments should be coupled with the creation of an investment fund with "no-year" monies.

3. The current vaccine distribution chain only involves one distributor. Have there been capacity issues with distribution that could be solved by involving more private distribution companies? Are there certain areas, for example rural, that are more difficult to reach under the existing distribution channels?

   Limiting vaccine distribution to a single company and a limited number of dispensing sites creates barriers for vaccination. For example, in the case of pediatric patients and other vulnerable population members, there is significant trust in the regular healthcare providers with whom these individuals and families seek to provide care. With a single distributor and the accompanying challenges in requesting small packages of doses that may be administered to patients it is difficult if not impossible for these physicians to deliver vaccines. The normal supply chain that provides these professionals with vaccines and other medications for their patients should be used to the fullest extent so that persons seeking vaccines can be inoculated by their primary providers. Utilizing the existing supply chain will alleviate problems and barriers associated with having all vaccine flow through a single distributor.

The Honorable Gus M. Bilirakis (R-FL)

1. Today's lean manufacturing supply chains often operate "just in time" instead of "just in case" to reduce costs and maximize efficiency; however, this is a duel edge that can present challenges in the midst of a pandemic response – as we saw with personal protective equipment. How can supply chains balance resiliency with value moving forward?

   The government should provide incentives to manufacturers and distributors to hold more essential products than needed for just in time order fulfillment. A number of manufacturers made investments to provide on-shore manufacturing of material during COVID that have not seen good uptake on available products. FDA needs to move rapidly to grant full approval to these on-shore manufactured products. These manufacturers need incentives to continue their work and achieve pricing competitive with foreign made products.

   SNS should be provided funding and authority to enter into joint ventures or other financial arrangements with manufacturers to cover costs of new on-shore lines and to invest in margins for holding above immediately needed products.

The Honorable Billy Long (R-MO)

1. Mr. Burel, your testimony touches on the concept of increasing the flexibility of the supply chain through domestic production and a cushion with distributors to meet future surges. Can you share additional details on what that type of framework looks like?

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   Congress should create priorities for federal government purchase of medical supplies to favor US based manufacturing. These priorities, however, should not disallow purchase of non-US supplies when that presents a particularly favorable position for the government.

The Honorable Larry Bucshon, M.D. (R-IN)

1. Mr. Burel, with regard to ongoing PPE and other critical medical supply constraints, how can the public and private sector better cooperate to enhance last mile distribution?

   The major medical supply distributors and the SNS should work together to determine how best to accomplish a long term successful partnership during crisis. SNS has had success working with industry in exercises to help increase awareness of needs during public health emergencies of various types. I would propose a study to be conducted jointly by HHS/SNS, the National Academy of Science and the National Academy of Public Administration be sponsored to consider how best to create a routine partnership between government and industry to act immediately upon a public health emergency declaration.

2. Mr. Burel, I am hearing that the lack of visibility when critical medical supplies are shipped from the Strategic National Stockpile (SNS) to healthcare systems around the country has impeded private sector allocation efforts and has even led to duplicative shipments. How can we ensure greater transparency of shipments going from the SNS out to the States?

   This question is complex and the need to protect specific SNS material holding so as not to disclose potential weaknesses to determined actors can somewhat impede full transparency. I would defer this question to HHS for SNS and HHS Security Personnel for response based on current threat information.

3. Mr. Burel, I've heard concerns about states mandating that hospitals maintain 90-day stockpiles of PPE which, while well intended, distorts demand throughout the country and potentially siphons off needed PPE. Can (should) the Federal Government coordinate with the States to standardize these practices in a way that reflects the on the ground realities and true demand (i.e. based on the burn rate) for PPE?

   I would suggest rather than distorting demand, such requirements may effectively drive a higher demand to result in more manufacturing These stocks would allow these healthcare facilities to be self sufficient in certain scenarios without having to reach back to the supply chain for material. Combining marginal additional stocks at healthcare facilities, marginal additional stocks at distributors and manufacturers and stocks held at state and federal levels for the truly catastrophic need will better prepare the nation and spread that responsibility and cost logically.

   The Federal Government needs to engage in stronger coordination with states and localities for Public Health Preparedness overall. Additional funds are needed at the state and local level to be better prepared. These funds can be provided through the Public Health Emergency Preparedness Cooperative Agreements managed by CDC. SNS should be directed, funded and staffed to return to regular consultation with state and local preparedness professionals. This support from the federal government has become

fractured and inefficient after the responsibility was removed from the SNS. The SNS incorporates the public health preparedness expertise as well as supply chain and general medical logistics expertise required to support this consultative work.