



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Chair, Board of Scientific Counselors
Director and CEO
Center for Biosecurity of UPMC
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John S. Parker, MD, Major General (Retired)
Chair, National Biodefense Science Board
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Dear Drs. Inglesby and Parker,

Planning, building, and managing the Strategic National Stockpile (SNS) has taken a little over a decade worth of effort. In that time, increases in the number and types of threats and in the products and technologies available to manage those threats have broadened the scope and mission of the SNS program. Reductions in the resources necessary to support the SNS have, however, begun to constrain the ability of the program to deliver on its continued promise of countermeasure delivery in public health emergencies.

Because the imperatives to optimize the return on federal investments in health have never been greater, HHS must plan now for how it will support the SNS of the future (SNS 2020). At the same time, CDC needs to have access to the tools, processes, and mechanisms that will enable the SNS to efficiently anticipate and effectively meet novel challenges as they arise. Ideally, then, defining the mission of SNS 2020 will result from a calculated consideration and integration of current and future fiscal realities; an awareness of evolving and potential public health threats; and knowledge of available innovations – technological and otherwise – that permit efficiencies of economy, scale, and delivery of medical countermeasures. An SNS capable of responding to public health emergencies without compromise will require a combination of long-term investments – some financial, some strategic.

The Assistant Secretary for Preparedness and Response (ASPR) and the Director of the Office of Public Health Preparedness and Response (OPHPR), therefore, jointly charge the Chair of the National Biodefense Science Board (NBSB) and the Chair of the Office of Public Health Preparedness and Response (OPHPR) Board of Scientific Counselors (BSC) to form a joint review working group to:

- 1. Identify the anticipated responsibilities of the SNS in the year 2020;**
 - 2. Recommend approaches for meeting those responsibilities as efficiently as possible; and**
 - 3. Propose metrics for reporting program capability and informing improvement.**
1. **Identify the anticipated responsibilities of the SNS in the year 2020.** This charge is for both Federal Advisory Committees (FACs) – through the joint working group – to explore potential future responsibilities of the SNS by looking backward at past experience and forward to expected changes.

The evolving mission and response experiences of the SNS (and that of related programs such as those for vaccine storage and deployment) provide insight into the ways that decision-makers have viewed the role of the SNS over the past ten years. The SNS program has had to develop expertise in many capabilities, including: efficient procurement, transportation, and storage of products; quality control and management procedures to effect optimization of product lifespan; support for planning and exercising to optimally leverage every-day health systems while assuring back-up mechanisms to deliver and dispense products under crisis conditions to myriad diverse and vulnerable populations; and tracking the use, impact, and safety of deployed SNS products. Fluidity in the roles that the SNS program has been asked to play and in the responsibilities it has been required to assume is likely to continue. And while the capabilities of the SNS and its mission have expanded as it has been called upon to respond to an increasingly wider array of events and incidents, anticipation of roles and responsibilities has become ever more challenging. Input from senior government leaders needs to be elicited to identify the top anticipated responsibilities of the SNS.

Guidance concerning the responsibilities of SNS 2020 should also take into consideration the addition of other critical functions to its portfolio. Indeed, managing the emergency medical supply chain in a public health crisis – the sine qua non responsibility of the SNS – may only be one among several roles that the SNS could be asked to play 10 years into the future.

The impact that major developments in the Public Health and Emergency Medical Countermeasure Enterprise (PHEMCE) will have on what SNS will be asked to do (and how it will have to conduct its business) must also be considered. These developments may include – but are not

limited to – PHEMCE governance procedures, FDA regulatory changes, Biomedical Advanced Research and Development Authority (BARDA) Advanced Development and Manufacturing facilities and the Strategic Investor. An informed vision of SNS 2020 may also properly include knowledge of or a better than working familiarity with: advances in disease detection and diagnosis; faster and more flexible manufacturing technologies; innovations in countermeasure storage, distribution and dispensing practices; mandated requirements for safety and effectiveness monitoring; potential benefits from public-private partnerships and alliances; and available multi-use products.

2. Recommend approaches for meeting those anticipated responsibilities as efficiently as possible.

The FACs are charged with evaluating the relative merits and deficiencies of the different approaches used to meet the anticipated responsibilities of the SNS of the future.

Innovations in information systems, in manufacturing, and in supply chain management may change the options for SNS operations. The FACs are being asked here to evaluate and provide a relative hierarchy of the operational efficiencies of a stockpile managed inventory vs. a vendor managed inventory (VMI) vs. user managed inventory (UMI) or other approaches, to help the SNS program achieve maximal efficiency of the medical supply chain, both now and in the years ahead. Since it is expected that more than one approach may be needed to best manage the various responsibilities, products, and operating conditions of SNS 2020, we request that the FACs provide guidance and, where available, tools that can be used to identify different approaches, either singly or in combination, to create maximal efficiency. Given the critical mission of the SNS – to assure the American public’s access to appropriate medical countermeasures for identified key threats at the time they are needed – what approaches perform best and under what conditions? Where do proposed approaches underperform? And finally, what combination of approaches, if any, may be used to create maximal efficiency?

3. Propose metrics for reporting program capability and informing improvement.

Measurement is the currency of process improvement. While we have robust and well-tested measures of inventory management that have allowed the SNS to achieve remarkable performance capabilities, many other supply chain functions have no such reliable metrics as yet. Upon refining and prioritizing the critical capabilities for SNS 2020, the FACs are asked to provide guidance from the practice of science and industry for how we can measure performance to gauge program effectiveness, drive improvement,

and appropriately communicate the information with our partners in emergency preparedness and response.

Given the complexity of this task, the joint working group should consult with a wide range of experts within and outside the United States Government, to include the public health community, industry, subject matter experts in supply chain logistics and distribution, among other relevant stakeholders. The joint working group will present their findings to both FACS for their deliberation at a joint public meeting within a 7 – 10 month timeframe. It is vital that both Boards explore the broad range of options available for assuring the American Public's access to appropriate medical countermeasures for identified key threats, at the time they're needed.

The Department looks forward to the report with recommendations on behalf of both the BSC and the NBSB, and applaud the collaborative efforts of both FACs in taking a critical step towards improving and advancing our nation's resilience, preparedness, and response efforts.

Sincerely,

/s/ Nicole Lurie

Nicole Lurie, MD, MSPH
Assistant Secretary for Preparedness and Response

/s/

Ali S. Khan, MD, MPH
Director, Office of Public Health Preparedness and Response