



Shaping the Strategic National Stockpile in an Increasingly Global World

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Shaping the Strategic National Stockpile in an Increasingly Global World

Kevin F. Jura

A Thesis in the Field of International Relations
for the Degree of Master of Liberal Arts in Extension Studies

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Abstract

For the Strategic National Stockpile (SNS) to have a truly zero-failure rate in a world that faces an increasing number of international public health emergencies and global pandemics, it must be restructured and properly funded. Failure to make these necessary changes threatens not only the health of the US public, but also its overall domestic and national security.

Although the SNS failed to quickly and adequately respond to the COVID-19 pandemic, the SNS is still capable of being the successful lifesaving program it was designed to be. However, this requires the political will of both political parties as well as the executive and legislative branches working together to accomplish this. This thesis provides a roadmap to such success.

Author's Biographical Sketch

The Hon. Kevin F. Jura, FRSPH, FRSA, was born in Carmichael, California, and grew up in Gulf Breeze, Florida. He is an alumnus of both Harvard University and the Graduate Institute of International and Development Studies (*L'Institut de hautes études internationales et du développement*) in Geneva, Switzerland. Kevin will begin the Doctor of Public Health (DrPH) program at Tulane University School of Public Health and Tropical Medicine in New Orleans, Louisiana, starting August 2023. Kevin has more than 20 years of professional experience as a tactical paramedic, law enforcement lieutenant, and national and domestic security public health emergency management, preparedness, and response practitioner and responder.

Kevin has responded to more than 75 natural and man-made disasters, emergencies, and national special security events. Before returning to school, Kevin ran the then-Centers for Disease Control and Prevention's (CDC's) Strategic National Stockpile (SNS) Program for seven years for the State of Maryland.

He is an active member of the National Association of EMS Physicians (NAEMSP), serves on several NAEMSP national committees, and as a peer reviewer for multiple medical journals.

Kevin is an elected Fellow of the Royal Society for Public Health and a Lifetime Fellow (elected) of the Royal Society of Arts in the United Kingdom. He is a Massachusetts Justice of the Peace.

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Dedication

With tremendous gratitude and love, I dedicate this thesis to my close family and friends who have supported me in this journey and never gave up on me—they know who they are. Without their support, guidance, love, and, yes, even an occasional swift kick in the butt, I would not have accomplished this research and thesis, let alone attended and graduated from Harvard University. Thank you, with all my love.

It is also with a humble heart filled with immense gratitude, respect, and pride that I also dedicate this thesis to my fellow public health and healthcare practitioners who are on the frontline day in and day out, providing for the health and safety of every individual and community in the United States. I tell them, “Thank you for allowing me to serve alongside you and count myself among your heroic numbers.”

Acknowledgments

Is math an sgàthan sùil earaide.
(“A friend’s eye is a good looking-glass.”)

A Collection of Gaelic Proverbs and Familiar Phrases
—Alexander Nicolson, editor

First, I want to acknowledge the help, inspiration, and mentorship from my Research Advisor, Doug Bond, and Thesis Director, Paul Biddinger, who gave me their time, advice, and support throughout this process. With the guidance of both, I was able to write and defend my research and thesis successfully.

Second, I want to thank Al Romanosky, Medical Director and State Emergency Preparedness Coordinator at the Maryland Department of Health, Office of Preparedness and Response; also Judith Robinson, Public Health Advisor at the Centers for Disease Control and Prevention, each of whom has been my friend, colleague, and mentor for more than a decade. Without their guidance, friendship, and mentorship, I would not have succeeded in a field that I genuinely love, one that is a vocation and not just “a career.”

Finally, I must apologize to everyone whom I did not name. Over the years, I have been blessed to be guided and assisted on this journey by many wonderful friends, mentors, and colleagues. Properly acknowledging every one of them would fill a book. To each one, I sincerely thank you for everything you have done.

Mandatory Disclaimers

United States Government

Kevin F. Jura prepared this thesis in his personal capacity. The opinions expressed in this thesis are the author's own and do not reflect the views of the Centers for Disease Control and Prevention, the Administration for Strategic Preparedness and Response, the Department of Health and Human Services, or the United States Government.

Maryland State Government

Kevin F. Jura prepared this thesis in his personal capacity. The opinions expressed in this thesis are the author's own and do not reflect the views of the Office of Preparedness and Response, the Maryland Department of Health, or the Maryland State Government.

Epigraph

There's no harm in hoping for the best as long as you're prepared for the worst.

—Stephen King, *Different Seasons*

Tomorrow's unknown crisis is not something to avoid in fear. It requires our attention and deliberation. We just need to have the courage to face the truth of our future's uncertainty. We just need to be prepared.

—Christopher Manski

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Chapter I

Introduction

What's next is already here; we just haven't recognized it yet.

—Daniel Lucey, 2016¹

Over the last decade, the United States has watched how public health threats in an increasingly interconnected and global world have threatened the country's safety and security. The rise of international travel has magnified threats from terrorists wanting to use biological or chemical weapons, and the World Health Organization (WHO) has declared public health emergencies of international concern (PHEIC) and pandemics. The risk of rapid dissemination of infectious diseases, as well as emerging infectious disease, has never been greater in the history of the world. One resource the United States has to protect itself is the Strategic National Stockpile (SNS):

The SNS is the nation's repository of antibiotics, chemical antidotes, antitoxins, vaccines, antiviral drugs, and other medical material designed to supplement and resupply state and local public health agencies in the event of an emergency.²

1. Smithsonian Museum of Natural History, temporary exhibit. <https://naturalhistory.si.edu/exhibits/outbreak/digital-exhibit> and https://naturalhistory2.si.edu/vt3/misc/z_tour-m006.html; and Joshua Barajas, "I toured this exhibit on epidemics before the coronavirus pandemic shut it down," *PBS.org*, March 18, 2020, <https://www.pbs.org/newshour/arts/i-toured-this-exhibit-on-epidemics-before-the-coronavirus-pandemic-shut-it-down>.

2. National Academies of Sciences, Engineering, and Medicine, *The Nation's Medical Countermeasure Stockpile: Opportunities to Improve the Efficiency, Effectiveness, and Sustainability of the CDC Strategic National Stockpile: Workshop summary* (Washington, DC: National Academies Press, 2016), 1. <https://doi.org/10.17226/23532>.

The COVID-19 pandemic showed there is room for improvement in the SNS. Thus, the United States can prepare for the next public health emergency that requires medical countermeasures and overwhelms local and state resources, presenting an opportunity to begin preparing for the next major public health emergency. To do this, however, today's politicians must act. Among other things, they should:

- pass necessary legislation to update the Defense Production Act of 1950 (DPA) to include public health emergencies. The WHO declared “public health emergencies of international concern” as legitimate reasons for invoking the DPA.
- establish a permanent appropriation for the SNS
- help negotiate, then ratify the draft International Pandemic Treaty that is currently being negotiated at the WHO
- make necessary changes to the TRIPS Agreement³ to ensure that it will be successful.

Background

The approach taken toward the SNS, and lessons learned, should be applied by the WHO and other international organizations as they look at the SNS model and develop recommendations for their member states. Additionally, other nations can look at the model as they develop their respective national versions of the SNS. For its part, the U.S. SNS needs to be prepared to respond to any pandemic, public health emergency of international concern, or attack utilizing biological or chemical weapons.

3. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), April 15, 1994; Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.



Figure 1-1. Red Cross workers in Boston, MA, making anti-influenza masks for soldiers during 1918 influenza pandemic.

Source: National Archives, Identifier 45499341.

Global Pandemics and Public Health Emergencies of International Concern

With the rise of COVID-19 and Mpox (formerly known as monkeypox) over the last few years, the world has become more familiar with pandemics. No longer are they topics of discussion in medical and public health schools, but they are now dinner conversation. No longer is it something that happens only in history (e.g., the Black Death or the 1918 Influenza) but does not affect daily living. Millions have perished, and millions more have been hospitalized and sickened. One would be hard pressed to find someone who had not been directly affected by COVID-19, whether by being infected, knowing someone who was infected, or knowing someone who passed away. It would be just as difficult to find anyone who was not *indirectly* impacted by the effects of COVID-19.

During the SARS outbreak of 2002–2003, although multiple systems were in place to surveil and respond to early detection and effective responses to this infectious

disease and deadly outbreaks, those systems failed. This led the World Health Assembly, the highest decision-making body of the WHO, to adopt a new version of the International Health Regulations (IHR) in 2005 to address this failure. The new IHR resulted in the creation of the “public health emergency of international concern (PHEIC)”⁴ (see Figure 1-2). According to the IHRs, which every member state of the WHO is bound to observe under international law:

A “public health emergency of international concern” means an extraordinary event which is determined, as provided in these Regulations: (i) to constitute a public health risk to other States through the international spread of disease, and (ii) to potentially require a coordinated international response.⁵

Since the adoption of the new IHR, there have been seven PHEIC declarations. They are:

- 1) Swine flu (H1N1)⁶
- 2) 2014–Present: Polio⁷
- 3) 2014–2016: Ebola outbreak in Western Africa⁸
- 4) Zika virus epidemic⁹

4. Steven J. Hoffman and Sarah L. Silverberg, “Delays in Global Disease Outbreak Responses: Lessons from H1N1, Ebola, and Zika,” *American Journal of Public Health* 108, no. 3 (March 2018): 329–333, <https://doi.org/10.2105/AJPH.2017.304245>.

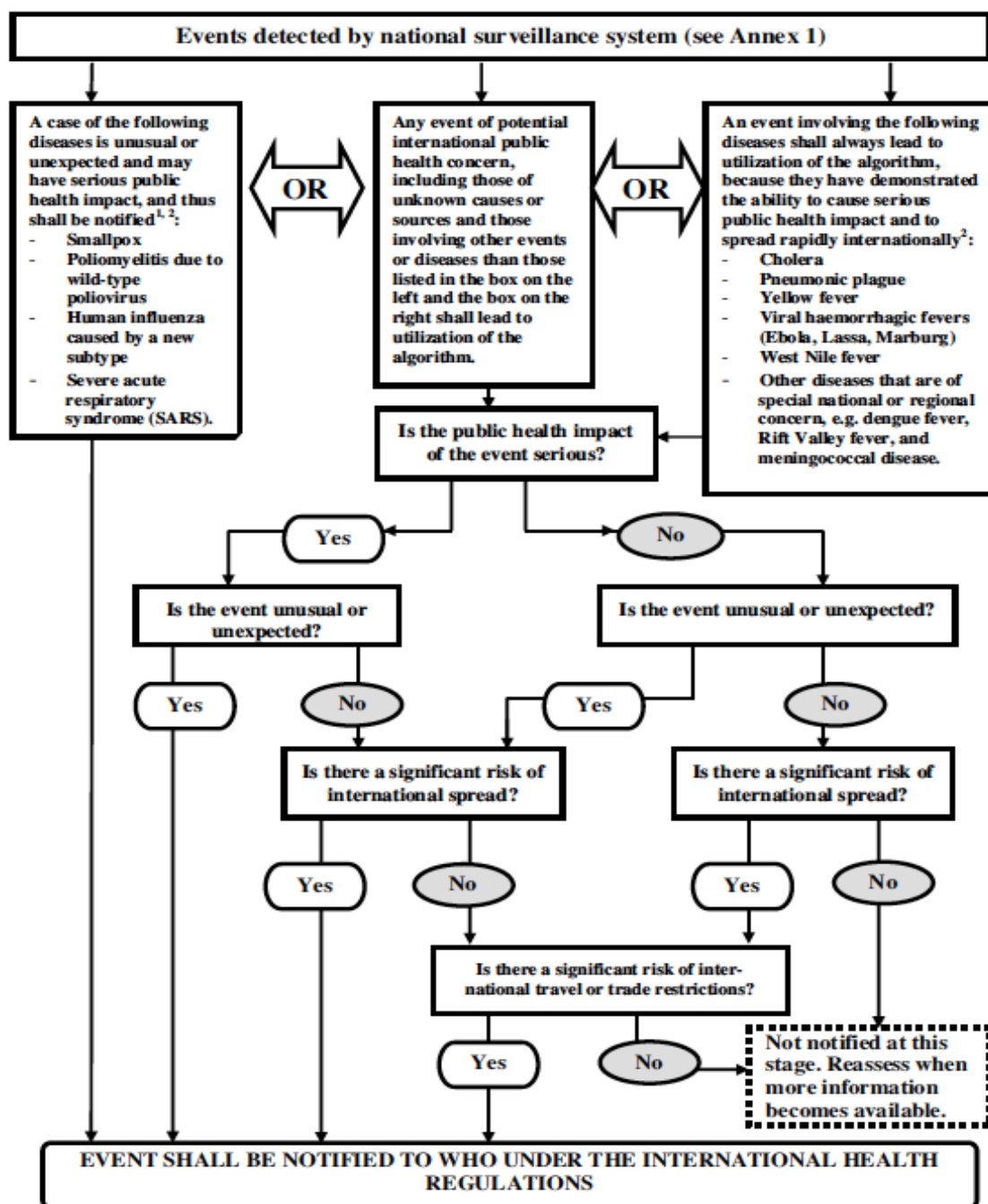
5 WHO, *International Health Regulations (2005)*, 2nd ed. (Geneva: WHO, 2008), 9.

6 WHO, “Implementation of the International Health Regulations (2005): Report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009: Report by the Director-General,” U.N. Doc. WHO/A64/10, May 5, 2011, 8. https://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_10-en.pdf.

7. WHO, “Implementation of the International Health Regulations (2005): Responding to public health emergencies: Report by the Director-General,” U.N. Doc. WHO/A68/22, May 15, 2015, 2-3, ¶ 3. https://web.archive.org/web/20221125114308/https://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_22-en.pdf?ua=121.

8. WHO, “Implementation of the International Health Regulations (2005).”

9. WHO, “WHO Director-General summarizes the outcome of the Emergency Committee regarding clusters of microcephaly and Guillain-Barré syndrome,” February 2016. <https://www.who.int/en/news-room/detail/01-02-2016-who-director-general-summarizes-the-outcome-of-the-emergency-committee-regarding-clusters-of-microcephaly-and-guillain-barr%C3%A9-syndrome>.



¹ As per WHO case definitions.

² The disease list shall be used only for the purposes of these Regulations.

Figure 1-2. Decision Instrument for the assessment and notification of events that may constitute a PHEIC.

Source: WHO, International Health Regulations, Annex 2: 43.

- 5) 2019–2020: Kivu Ebola epidemic¹⁰
- 6) 2020–Present: COIVD-19 (SARS-CoV-2)¹¹
- 7) 2022–Present: Mpox (formerly known as monkeypox)¹²

While the PHEIC is a technical public health decision made by the Director-General of the WHO with advice from the Emergency Committee, it is still a political decision due to the potential global ramifications of a PHEIC declaration. This was apparent in the interactions between the WHO and the People’s Republic of China (PRC) during the height of the COVID-19 pandemic. Because of the tepid response by the WHO when questioning the PRC’s official statements, as well as the delay in sending an independent team to Wuhan, China, to investigate the origins of COVID-19, the WHO’s independence has been called into questions by some.¹³

Furthermore, the WHO depends on member states to pay its annual operating assessments. That funding enables the WHO to fulfill its mission. It is surmised that a fear of financial retaliation by upset member states, especially one of the permanent five members of the UN Security Council (France, PRC, Russian Federation, UK, and US) which are critical funding sources, caused the WHO and its director-general to take an

10. WHO, “Ebola outbreak in the Democratic Republic of the Congo declared a Public Health Emergency of International Concern,” July 17, 2019. <https://www.who.int/news-room/detail/17-07-2019-ebola-outbreak-in-the-democratic-republic-of-the-congo-declared-a-public-health-emergency-of-international-concern>.

11. WHO, “Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV),” January 30, 2020. [https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-\(2019-ncov\)](https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)).

12. WHO, “Second meeting of the International Health Regulations (2005) (IHR) Emergency Committee regarding the multi-country outbreak of monkeypox,” July 23, 2022. [https://www.who.int/news/item/23-07-2022-second-meeting-of-the-international-health-regulations-\(2005\)-\(ihr\)-emergency-committee-regarding-the-multi-country-outbreak-of-monkeypox](https://www.who.int/news/item/23-07-2022-second-meeting-of-the-international-health-regulations-(2005)-(ihr)-emergency-committee-regarding-the-multi-country-outbreak-of-monkeypox).

13. James Griffiths, “The coronavirus crisis is raising questions over China’s relationship with the World Health Organization,” *CNN.com*, February 16, 2020. <https://www.cnn.com/2020/02/14/asia/coronavirus-who-china-intl-hnk/index.html>.

overly cautious approach when it comes to declaring a public health emergency of international concern, or pushing a state to answer difficult questions about the potential origins of an emerging infectious disease or public health threat.

Biological Weapons, Warfare, and Terrorism



Figure 1-3. Imperial Japanese Army scientists conduct a bacteriological trial on a test subject, Nov. 1, 1940.

Source: DarkTourist.com

Biological weapons have been used in warfare since time immemorial. Around 1335 BC, the Hittite plague affected Egypt and much of the Middle East. However, it is suspected that the spread of that plague was the first known use of biological warfare, which occurred during the Anatolian war of 1320-1318 BC. During this war, Arzawans and Neshites sent rams and their handlers, all infected with tularemia, into their

opponent's territories successfully infecting and killing most of the enemy.

Unfortunately, while that method was successful, it had the unintended consequence of creating and spreading a regional plague of tularemia.¹⁴

Biological warfare has continued throughout history, however. During the Siege of Caffa (1345-1347), the Black Death killed many of Khan Jani Beg's soldiers, eventually forcing him to lift the siege in 1347. Before departing Caffa, however, Beg utilized catapults to sling the infected corpses of his soldiers into Caffa, thus infecting the inhabitants with the Black Death, possibly beginning the European phase of the Black Death.¹⁵

Biological warfare was not limited to the Middle Ages, nor was it limited to the Middle East and Africa. It was used in the Americas (both deliberately and unintentionally) and in Europe. In 1763, the British Army intentionally sent blankets infected with smallpox to Native Americans, with the "hope [that] it will have the desired effect."¹⁶ During the American Civil War, Confederates soldiers sold Union troops clothing that was infected with yellow fever and smallpox.¹⁷

The first international prohibition against chemical and biological warfare, the Geneva Protocol of 1925,¹⁸ was enacted because Germany used anthrax and glanders

14. Siro Igino Trevisanato, "The 'Hittite plague', an epidemic of tularemia and the first record of biological warfare," *Medical Hypotheses* 69, no. 6 (December 2007): 1371-1374. <https://doi.org/10.1016/j.mehy.2007.03.012>.

15. Mark Wheelis, "Biological Warfare at the 1346 Siege of Caffa," *Historical Review* 8, no. 9 (September 2002): 971-975. <https://doi.org/10.3201/eid0809.010536>.

16. Vincent Barras and Gilbert Greub, "History of biological warfare and bioterrorism," *Clinical Microbiology and Infection* 20, no. 6 (June 2014): 498-499. <https://10.1111/1469-0691.12706>.

17. Barras & Greub, "History of biological warfare," 498.

18. Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare, June 17, 1925, 94 L.N.T.S. 66.

during the First World War.¹⁹ However, the Geneva Protocol was widely ignored, especially during World War II.

The most infamous use of biological weapons during World War II was by Imperial Japanese Army Unit 731, which used biological weapons on the Allies and prisoners of war. In 1942, Unit 731 used anthrax, typhoid, or paratyphoid on 3,000 Chinese POWs and their families. The Japanese gave the prisoners dumplings infected with typhoid or paratyphoid as a treat before releasing them to return to their families with chocolates infused with anthrax.²⁰

The Japanese were not the only ones to utilize biological warfare or have biological warfare programs. Nazi Germany conducted biological experiments on its war prisoners and concentration camp victims. Malaria experiments were conducted on prisoners in the Dachau concentration camp from approximately February 1942 to April 1945.²¹

Both the US and UK had active biological weapons programs during this time. The UK's *Operation Vegetarian* experimented with anthrax on Gruinard Island, which resulted in the island becoming contaminated and uninhabitable for either animals or

19. Roger Roffey, Anders Tegnell, and Fredrik Elgh, "Biological warfare in a historical perspective," *Clinical Microbiology and Infection* 8, no. 8 (August 2002): 450. <https://doi.org/10.1046/j.1469-0691.2002.00501.x>.

20. Sheldon H. Harris, *Factories of Death: Japanese Biological Warfare, 1932-45, and the American Cover-Up* (New York: Routledge, 1994), 77.

21. George J. Annas and Michael A. Grodin, eds., *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation* (New York: Oxford University Press, 1992), 98. Also: Nuremberg Military Tribunals, "The Medical Case," in *Trials of war criminals before the Nuremberg military tribunals under Control Council Law No. 10*, Volume II (Wash, DC: US GPO, October 1946–April 1949).

humans until 1990.²² During that time, the US tested and experimented with biological weapons at Fort Detrick, Maryland, and Dugway Proving Grounds.²³

Post September 11, 2001

The first year of President George W. Bush's Presidency was marked by a biological weapons attack against the United States Congress in October 2001, not even a month after the terrorist attacks of September 11th in New York City, the Pentagon, and Pennsylvania. The 2001 anthrax attacks terrorized the American public and the citizens of the four municipalities: Washington, DC; West Palm Beach, FL; New York City; and Oxford, CT. Millions were scared, 5 individuals were killed, and 17 were injured.



Figure 1-4. Responders holding possible anthrax-contaminated items in front of the US Capitol, Washington, DC.

Source: Kennigsberg, 2022.

22. Rosie George, "UK planned to wipe out Germany with anthrax" *Sunday Herald* (Glasgow, Scotland), October 14, 2001. <https://www.proquest.com/docview/331261246/83979AD2CA7C49B5PQ>.

23. George, "UK planned to wipe out Germany with anthrax."

Current Biological and Toxin Weapon Threats

Over the last century, there have been 11 serious viral outbreaks worldwide, of which the lethality of four were equal to or greater than COVID-19 (see Table 1-1). Most of these viruses could have posed a major public health threat if a rogue state or terrorist group were to weaponize them successfully. Before adopting the Biological Weapons Convention²⁴ in 1972, in which responsible states renounced biological and toxin weapons, many countries (including the US, former Soviet Union, UK, Northern Ireland) all possessed and produced biological and toxin weapons.

Table 1-1. Serious Viral Outbreaks, 1918–2019.

	Name	Virus Type	Year Began	Global Deaths	US Deaths
1	Spanish Flu	Orthomyxovirus	1918	50,000,000	675,000
2	Asian Flu (H2N2)	Orthomyxovirus	1957	1,100,000	116,000
3	Hong Kong Flu (H3N2)	Orthomyxovirus	1968	1,000,000	100,000
4	HIV	Retrovirus	1981	32,700,000	700,000
5	SARS-CoV-1	Coronavirus	2002	774	
6	Influenza (H1N1)	Orthomyxovirus	2009	284,000	12,469
7	MERS	Coronavirus	2012	875	
8	Ebola	Filovirus	2014	11,310	1
9	Zika	Flavivirus	2015	N/A	
10	Ebola	Filovirus	2018	2,300	
11	SARS-CoV-2	Coronavirus	2019	4,100,000+	620,000+

Source: Executive Office of the President of the United States, *American Pandemic Preparedness: Transforming Our Capabilities* (Washington, DC: The White House, 2021), 6.

24. Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, April 10, 1972, 1015 U.N.T.S. 163 (hereafter referred to as BWC).

In addition to the threat of these viruses being weaponized, there is also concern that other biological and toxin agents might be weaponized and used against the United States population. Each of the listed select agents and toxins in Table 1-2 poses a significant threat to the health and safety of the United States.

Table 1-2. HHS and USDA Select Agents and Toxins

HHS SELECT AGENTS			
01.	Abrin	19.	SARS-CoV/SARS-COV-2 chimeric
02.	<i>Bacillus cereus</i> Biovar <i>anthracis</i>		viruses resulting from any deliverable
03.	Botulinum neurotoxins		manipulation of SARS-CoV-2 to
04.	Botulinum neurotoxin producing species of <i>Clostridium</i>		incorporate nucleic acids coding for
05.	Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X ₁ CCX ₂ PACGX ₃ X ₄ X ₅ X ₆ CX ₇	21.	Saxitoxin
			South American Haemorrhagic Fever viruses:
06.	<i>Coxiella burnetii</i>	22.	Chapare
07.	Crimean-Congo haemorrhagic fever virus	23.	Guanarito
		24.	Junin
08.	Diacetoxyscirpenol	25.	Machupo
09.	Eastern Equine Encephalitis virus	26.	Sabia
10.	Ebola virus	27.	Staphylococcal enterotoxins (subtypes A, B, C, D, E)
11.	<i>Francisella tularensis</i>	28.	T-2 toxin
12.	Lassa fever virus	29.	Tetrodotoxin
13.	Lujo virus		Tick-borne encephalitis complex (flavi) viruses:
14.	Marburg virus		
15.	Mpox virus		
16.	Reconstructed replication component forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)	30.	Far Eastern subtype
		31.	Siberian subtype
17.	Ricin	32.	Kyasanur Forest disease virus
18.	<i>Rickettsia prowazekii</i>	33.	Omsk hemorrhagic fever virus
19.	SARS-associated coronavirus (SARS-CoV)	34.	Variola major virus (Smallpox virus)
		35.	Variola minor virus (Alastrim)
		36.	<i>Yersinia pestis</i>

OVERLAP SELECT AGENTS AND TOXINS	
37. <i>Bacillus anthracis</i>	43. <i>Burkholderia pseudomallei</i>
38. <i>Bacillus anthracis</i> Pasteur strain	44. Hendra virus
39. <i>Brucella abortus</i>	45. Nipah virus
40. <i>Brucella melitensis</i>	46. Rift Valley fever virus
41. <i>Brucella suis</i>	47. Venezuelan equine encephalitis virus
42. <i>Burkholderia mallei</i>	
USDA VETERINARY SERVICES (VS) SELECT AGENTS AND TOXINS	
48. African horse sickness virus	55. <i>Mycoplasma capricolum</i>
49. African swine fever virus	56. <i>Mycoplasma mycoides</i>
50. Avian influenza virus	57. Newcastle disease virus
51. Classical swine fever virus	58. Peste des petits ruminants virus
52. Foot-and-mouth disease virus	59. Rinderpest virus
53. Goat pox virus	60. Sheep pox virus
54. Lumpy skin disease virus	61. Swine vesicular disease virus
USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXIN	
62. <i>Coniothyrium glycines</i> (formerly <i>Phoma glycinicola</i> and <i>Pyrenochaeta glycines</i>)	64. <i>Ralstonia solanacearum</i>
	65. <i>Rathayibacter toxicus</i>
	66. <i>Sclerophthora rayssiae</i>
63. <i>Peronosclerospora philippinensis</i> (<i>Peronoscleropora sacchari</i>)	67. <i>Synchytrium endobioticum</i>
	68. <i>Xanthomonas oryzae</i>

Source: CDC, “List of HHS and USDA Select Agents and Toxins,” 2023.

Summary

The world faces a future of public health emergencies that threatens its domestic and national security. Global pandemics, public health emergencies of international concern, biological and chemical terrorism—taken all together, it is no wonder that the United States must have an *effective* and *efficient* method of preparing for and responding to health threats that can appear at any moment.

Chapter II

The Strategic National Stockpile

*For 75 years, CDC and Public Health have been preparing
for COVID-19, and in our big moment,
our performance did not reliably meet expectations.*

—Rochelle P. Walensky²⁵



Figure 2-1. Strategic National Stockpile warehouse.

Source: <https://www.flickr.com/photos/asprgov/49683881151/in/album-72157718487942018/>.

25. German Lopez, “America’s Pandemic Failures,” *New York Times*, August 18, 2022.
<https://www.nytimes.com/2022/08/18/briefing/monkeypox-cdc-walensky-covid.html>.

When the term “strategic national stockpile” is used, what is the first thing that most individuals think of? More than likely people will associate the term with nuclear weapons, and then to the United States’ stockpile of strategic nuclear weapons. Making that association might be logical, but it would be an incorrect assumption. Rather, the SNS is a nimble program that is scalable to meet any needed response, and it contains enough supplies to simultaneously respond to multiple large-scale events and emergencies.²⁶

Mission of the SNS

The current mission of the SNS is described as follows:

A health threat can appear at any moment, and the United States must be ready to respond. The Strategic National Stockpile (SNS) is part of the federal medical response infrastructure and can supplement medical countermeasures needed by states, tribal nations, territories and the largest metropolitan areas during public health emergencies. The supplies, medicines, and devices for lifesaving care contained in the stockpile can be used as a short-term, stopgap buffer when the immediate supply of these materials may not be available or sufficient.²⁷

Need for the SNS

Since the creation of the NPS and its evolution into the current SNS, the program has responded to 20 major public health emergencies, which will be discussed further in this chapter.²⁸ These include responding to: New York City following the 9/11 attacks; H1N1 (“Swine Flu”); the 2014 Ebola Outbreak; and COVID-19. After each response, lessons were learned by actors both within and outside the government.

26. HHS-ASPR, “Responses,” SNS Stockpile Responses, last updated August 11, 2022. <https://www.phe.gov/about/sns/Pages/responses.aspx>.

27. HHS/ASPR, Strategic National Stockpile.

28. HHS/ASPR, Strategic National Stockpile.

Unfortunately, many of the lessons learned were not heeded. One recurring theme among included the need for a properly funded PHEMCE, particularly the SNS. While Congress has been made aware, on multiple occasions, of the need to increase annual funding to the PHEMCE, and thus to the SNS, until COVID-19 Congress failed to act regularly. In the immediate crisis caused by COVID-19, however, the budgets for PHEMCE and SNS were nearly doubled. Regrettably, this influx of funds was a one-time event just as it had been in earlier years.²⁹ Since the FY2021 budget increase, funding to PHEMCE, and thus to SNS, has returned to the earlier status quo of small (if any) increases in the annual budgets.

History of the Strategic National Stockpile

The history of the NPS, and subsequently the SNS, begins with Richard Preston’s fictional novel *The Cobra Event*,³⁰ which tells the story of Kate Moran, a 17-year-old who lived on the edge of Greenwich Village. Kate mysteriously contracted a novel virus and died a few days later. Her virus was eventually identified and named the *Cobra* virus, a genetically engineered biological weapon used by a so-called “lone wolf” terrorist.

Fortunately for the US and the world, Kate Moran and the other individuals involved with the *Cobra* virus were not real. The story is described thus:

[*The Cobra Event*] is about biological weapons—the modern version of what were once known as germ-warfare weapons. . . . The characters and story developed here are fictional . . . but the historical background *is* real,

29. HHS/ASPR, “Fiscal Year 2023 Public Health and Social Services Emergency Fund: Justification of the Estimates for Appropriations Committee” (Washington, DC: DHS, 2022), 111.

30. Richard Preston, *The Cobra Event* (New York: Random House, 1997).

the government structures are real, and the science is real or based on what is possible.³¹

Bill Clinton Administration and Creation of the NPS

In 1977, when President Bill Clinton read Preston's book about Kate Moran and several other individuals who died painful deaths, he called together his national security, public health experts, and the National Security Council (NSC).³² One can only imagine Clinton's concern: "Could this actually happen here?" On May 5, 1998, Clinton received a briefing that had a major impact on him, and he directed his experts to brief senior officials at the DoD and HHS.³³ The senior officials quickly dropped the idea of stockpiling vaccines.³⁴ However, within six months, Congress rushed legislation through. On October 23, 1998, President Clinton signed the Omnibus Consolidated and Emergency Appropriations Act of 1999,³⁵ which created the NPS. The early idea that senior officials had dropped so quickly was picked up and came to fruition.

The speed with which President Clinton and the NSC pushed through the legislation was not without criticism. The *Washington Post* reported:

Some administration officials outside the White House expressed surprise at how fast the president and his National Security Council staff had

31. Preston, *Cobra*, xi.

32. Olivia B. Waxman, "Coronavirus Is Putting the U.S. Strategic National Stockpile to the Test. Here's the Surprising Story Behind the Stash.," *Time*, March 11, 2020. <https://time.com/5800393/coronavirus-national-stockpile-history/>.

33. David C. Rapoport, ed., *Terrorism Critical Concepts in Political Science: The Third or New Left Wave* Vol. III (London: Routledge, 2006), 186.

34. Rapoport, *Terrorism*, 186.

35. United States Congress, "Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999," Pub. L. No. 105-277, 112 Stat. 2681 (1998). <https://www.congress.gov/105/plaws/publ277/PLAW-105publ277.pdf>.

moved on the initiative this month, noting with some concern that it had not gone through the customary deliberative planning process.³⁶

However, their concerns turned out to be unfounded. President Clinton was already working toward establishing a special unit to deal with biological and chemical outbreaks, and the *Cobra* event simply accelerated his efforts. Clinton recalled:

It really accelerated my efforts to get the White House to set up a special unit on dealing with biological and chemical outbreaks. And especially in the biological area, both deliberate biological warfare and the possibility of pandemics. And we started working on this in about 1998. And that's – We hatched a lot of plans out. We did a lot of kind of war gaming I mean real efforts with security people all over America. And we set up the first stockpile. So, I've been waiting for what happened with COVID, and we were—look, with SARS, with MERS, with all this stuff, we were given plenty of advanced warning that something like this could happen.³⁷

George W. Bush Administration

It was during the George W. Bush Administration that the SNS experienced its first six major responses. The first two happened within weeks of each other—the attacks of September 11th followed shortly by the anthrax attacks on several US cities. Four years later, the SNS had to respond to Hurricanes Katrina and Rita. Finally, three years later, the SNS was also deployed to supplement local and state public health departments immediately following Hurricanes Gustav and Ike.

36. Bradley Graham, “Clinton to Order Reserves of Germ Weapon Antidotes,” *Washington Post*, May 21, 1998. <https://www.proquest.com/docview/1620171797/fulltextPDF/5399AC3495B94144PQ/1?accountid=11311>.

37. Interview with Seth Myers, *Late Night with Seth Meyers*, June 23, 2021, NBC video. <https://www.youtube.com/watch?v=zxjxPCMBdw4>, at 3:49 to 4:41.

Barack Obama Administration

It was during the Obama Administration that the SNS really came to the forefront of public health emergency preparedness and response. During the eight years Obama was in office, the SNS experienced the majority of its deployments: responses to multiple natural disasters, several pandemics, and public health emergencies of international concern, including the arrival of Ebola and Zika in the United States.

Donald Trump Administration

Since its creation, the mission of the SNS has changed over time. However, the most drastic (and, some would argue, politically motivated change³⁸) occurred on April 3, 2020, when the SNS mission statement changed. Presidential Advisor Jared Kushner made a statement denying that the SNS was meant to apply to State, Local, Tribal, and Territorial (SLTT) use during a White House press conference on April 2, 2020. Kushner stated: “The notion of the federal stockpile is it’s not supposed to be state stockpiles.”³⁹ This statement contradicted the long-time commitment made by the federal government to the SLTTs. The next day, the Trump Administration changed the mission of the SNS to comport with Kushner’s public remarks.⁴⁰

38. Courtney Bubl , “Trump Administration draws fire for new description of National Stockpile,” *Government Executive*, April 3, 2020. <https://www.govexec.com/oversight/2020/04/trump-administration-draws-fire-new-description-national-stockpile/164356/>.

39. “President Trump with Coronavirus Task Force Briefing,” White House, *C-SPAN*, video, at 01:48:31. <https://www.c-span.org/video/?470902-1/president-coronavirus-test-negative-defense-production-act-ventilators>.

40. Aaron Blake, “The Trump administration just changed its description of the national stockpile to jibe with Jared Kushner’s controversial claim,” *Washington Post*, April 3, 2020. <https://www.washingtonpost.com/politics/2020/04/03/jared-kushner-stands-trump-proceeds-offer-very-trumpian-claim-about-stockpiles/>; Quint Forgy, “Strategic National Stockpile description altered online after Kushner’s remarks,” *Politico*, April 3, 2020. <https://www.politico.com/news/2020/04/03/strategic-national-stockpile-description-altered-after-kushners-remarks-163181>.

Before Kushner made his remarks, the mission of the SNS was stated thus:

The Strategic National Stockpile is the nation's largest supply of life-saving pharmaceuticals and medical supplies for use in a public health emergency severe enough to cause local supplies to run out.

When state, local, tribal, and territorial responders request federal assistance to support their response efforts, the stockpile ensures that the right medicines and supplies get to those who need them most during an emergency. Organized for scalable response to a variety of public health threats, this repository contains enough supplies to respond to multiple large-scale emergencies simultaneously.⁴¹

After Kushner spoke at the press briefing, later that day the SNS mission was changed so as to remove support for local and state public health emergency responses, as seen below:

The Strategic National Stockpile's role is to supplement state and local supplies during public health emergencies. Many states have products stockpiled, as well. The supplies, medicines, and devices for life-saving care contained in the stockpile can be used as a short-term stopgap buffer when the immediate supply of adequate amounts of these materials may not be immediately available.⁴²

The importance of this change in response to Kushner's remarks cannot be overstated. A simple remark quickly and radically changed the policy and mission of the SNS.

41. HHS/ASPR, "Strategic National Stockpile," Strategic National Stockpile [Archived 1], Last updated December 12, 2018, Archival date December 14, 2018, at 22:21:30, <https://web.archive.org/web/20181215222130/https://www.phe.gov/about/sns/Pages/default.aspx>; HHS/ASPR, "Strategic National Stockpile," Strategic National Stockpile [Archived 2], Last updated April 01, 2020, Archival date April 03, 2020, at 13:44:14, <https://web.archive.org/web/20200403134414/https://www.phe.gov/about/sns/Pages/default.aspx>.

42. HHS/ASPR, "Strategic National Stockpile," Strategic National Stockpile [Archived 3], Last updated April 03, Archival date April 3, 2020, at 16:10:34, <https://web.archive.org/web/20200403161034/https://www.phe.gov/about/sns/Pages/default.aspx>.

Joseph Biden Administration

At the time of this writing, the Biden Administration has significantly increased funding and support for the SNS. Additionally, the SNS mission has changed once again.

Prior to the recent change, it stated:

The Strategic National Stockpile's role is to supplement state and local medical supplies and equipment during public health emergencies. The supplies, medicines, and devices for lifesaving care contained in the stockpile can be used as a short-term, stopgap buffer when the immediate supply of these materials may not be available or sufficient.⁴³

In its current form, on August 6, 2021,⁴⁴ it now reads:

A health threat can appear at any moment, and the United States must be ready to respond. The Strategic National Stockpile (SNS) is part of the federal medical response infrastructure and can supplement medical countermeasures needed by states, tribal nations, territories and the largest metropolitan areas during public health emergencies. The supplies, medicines, and devices for lifesaving care contained in the stockpile can be used as a short-term, stopgap buffer when the immediate supply of these materials may not be available or sufficient.⁴⁵

These changes show that the Biden administration takes public health emergency preparedness seriously.

Responses to Disasters

Since its creation, the SNS and its predecessor the NPS, have responded to more than 20 twenty major public health emergencies, terrorist events, and natural disasters (see Table 2-1).⁴⁶ These include the terrorist attacks on September 11, 2001, in which the

43. HHS/ASPR, "Strategic National Stockpile (Archived 4)," Strategic National Stockpile, January 13, 2021. <https://web.archive.org/web/20210113155542/https://www.phe.gov/about/sns/Pages/default.aspx>.

44. HHS/ASPR, "Strategic National Stockpile," [Archived 5], archival date August 6, 2021. <https://web.archive.org/web/20210806174515/https://www.phe.gov/about/sns/Pages/default.aspx>.

45. HHS/ASPR, Strategic National Stockpile, [Archived 5].

46. HHS-ASPR, SNS Stockpile Responses.

NPS deployed to New York City after the Twin Towers collapsed. It also responded to the 2001 Anthrax Attacks at the US Capitol and Washington, DC. It has responded to multiple hurricanes in various parts of the US, and major flooding in North Dakota. Finally, it has responded to several public health emergencies and pandemics inside the United States.

Table 2-1. 23 major SNS responses to date.

Component	Year	Emergency
NPS	2001	World Trade Center
		Anthrax Attacks
	2005	Hurricane Katrina
		Hurricane Rita
		Hurricane Gustav
	2008	Hurricane Hanna
		Hurricane Ike
	2009	H1N1 Pandemic Influenza
		North Dakota Flooding
	2010	North Dakota Flooding
Hurricane Alex		
SNS	2011	Hurricane Irene
	2012	Hurricane Isaac
		Hurricane Sandy
	2014 – 2015	Ebola
	2014	Botulism
	2016 – 2017	Zika Virus
		Hurricane Harvey
	2017	Hurricane Irma
		Hurricane Maria
2019	Hurricane Dorian	
2020 – Present	COVID-19	
2021 – Present	Unaccompanied Children	

Source: HHS-ASPR, SNS Stockpile Responses. See also Appendix G.



Figure 2-2. Historic responses of the NPS and SNS, 1999–2022.

Source: HHS-ASPR, SNS Stockpile Responses. See Appendix G for a more detailed listing and larger image.

History of the Organization of the SNS

While still part of HHS-ASPR, the SNS held a lower position within the HHS hierarchy as a division, and was previously known as the Division of Strategic National Stockpile (DSNS). It was located within the Office of Resource Management (ORM), which itself was located within the Office of Operations and Resources (OOR), which itself was an office within HHS-ASPR and was a direct report to the Principal Deputy Assistant Secretary for Preparedness and Response and not a direct report to ASPR herself.

Although the SNS is currently within HHS/ASPR, this was only sometimes the case. It was initially located within the CDC, which occurred with the passage of the Public Health Security and Bioterrorism Preparedness and Response (PHSBRP) Act of 2002,⁴⁷ which provided the SNS with its first enabling statute. The PHSBRP Act also explicitly directed the CDC to coordinate with the US Department of Veterans Affairs (VA). However, this changed some two years later with the passage of the Project BioShield Act (PBA) of 2004.⁴⁸ The PBA transferred the VA's responsibility to DHS, the renamed the National Pharmaceutical Stockpile as the Strategic National Stockpile, effective March 1, 2003.⁴⁹

Further, the PBA allowed the SNS to procure medical and security counter-measures against CBRN (Chemical, Biological, Radiological, and Nuclear) threats via

47 Public Health Security and Bioterrorism Preparedness and Response Act (PHSBRPA) of 2002, Pub. L. No. 107-188, 116 Stat. 594 (2002). <https://www.congress.gov/107/plaws/publ188/PLAW-107publ188.pdf>.

48. Project Bioshield Act of 2004, Pub. L. No. 108-276, 118 Stat 835 (2004). <https://www.congress.gov/108/plaws/publ276/PLAW-108publ276.pdf>; HHS, Radiation Emergency Medical Management, "SNS," Strategic National Stockpile (SNS), Last updated February 18, 2022. <https://remm.hhs.gov/sns.htm>.

49. Project Bioshield Act of 2004.

the PBA. The PBA also established a Special Reserve Fund⁵⁰ for Project BioShield. This fund included \$5.6 billion funded over a 10-year period starting in 2004. Once it expired, Project Bio Shield was funded with annual appropriations.

Although the SNS was now under the joint control of DHS and HHS, it still remained at the CDC. It was not until 2018 that the SNS was transferred from the CDC to HHS-ASPR. Finally, in July 2022, the SNS was promoted within the HHS hierarchy when the Office of the Assistant Secretary for Preparedness and Response became the Administration for Strategic Preparedness and Response (HHS/ASPR). Since then, HHS/ASPR (and previously HHS-ASPR) has been primarily responsible for five of the eight Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) mission components, with additional secondary responsibility for one additional PHEMCE mission component (FDA) and NIH primary responsibility for one of the eight PHEMCE mission components.

Current Organizational Structure of the SNS

The SNS is currently located within the Administration for Strategic Preparedness and Response (HHS/ASPR), and is led Deputy Assistant Secretary Steven Adams, who serves as Director of the SNS, and his Deputy Director Lisa Dillard. Both Adams and Dillard are senior, apolitical, career civil servants who oversee six offices, as shown in Figure 2-3:

- Office of Supply Chain Alliance and Development;
- Office of National Readiness and Response;

50. 42 U.S.C. § 247d-6b(c) .

- Office of Management and Business Operations;
- Office of Logistics;
- Office of Science; and
- Office of State, Tribal, and Territorial Preparedness.

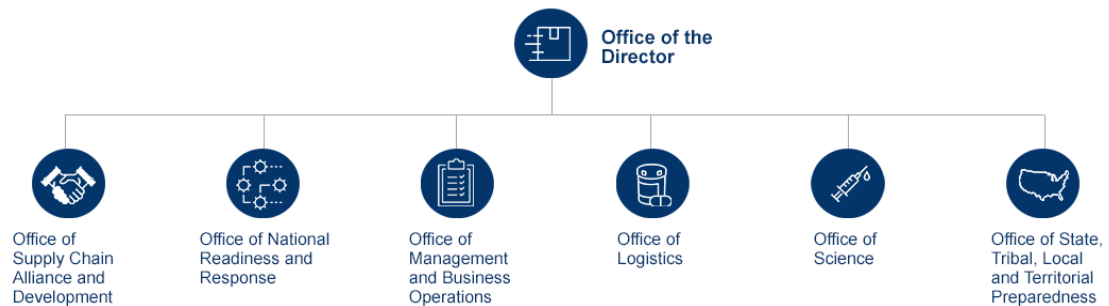


Figure 2-3. Organizational Chart of the SNS

Source: HHS/ASPR, “Who We Are,” n.d. <https://aspr.hhs.gov/SNS/Pages/Who-We-Are.aspx>.

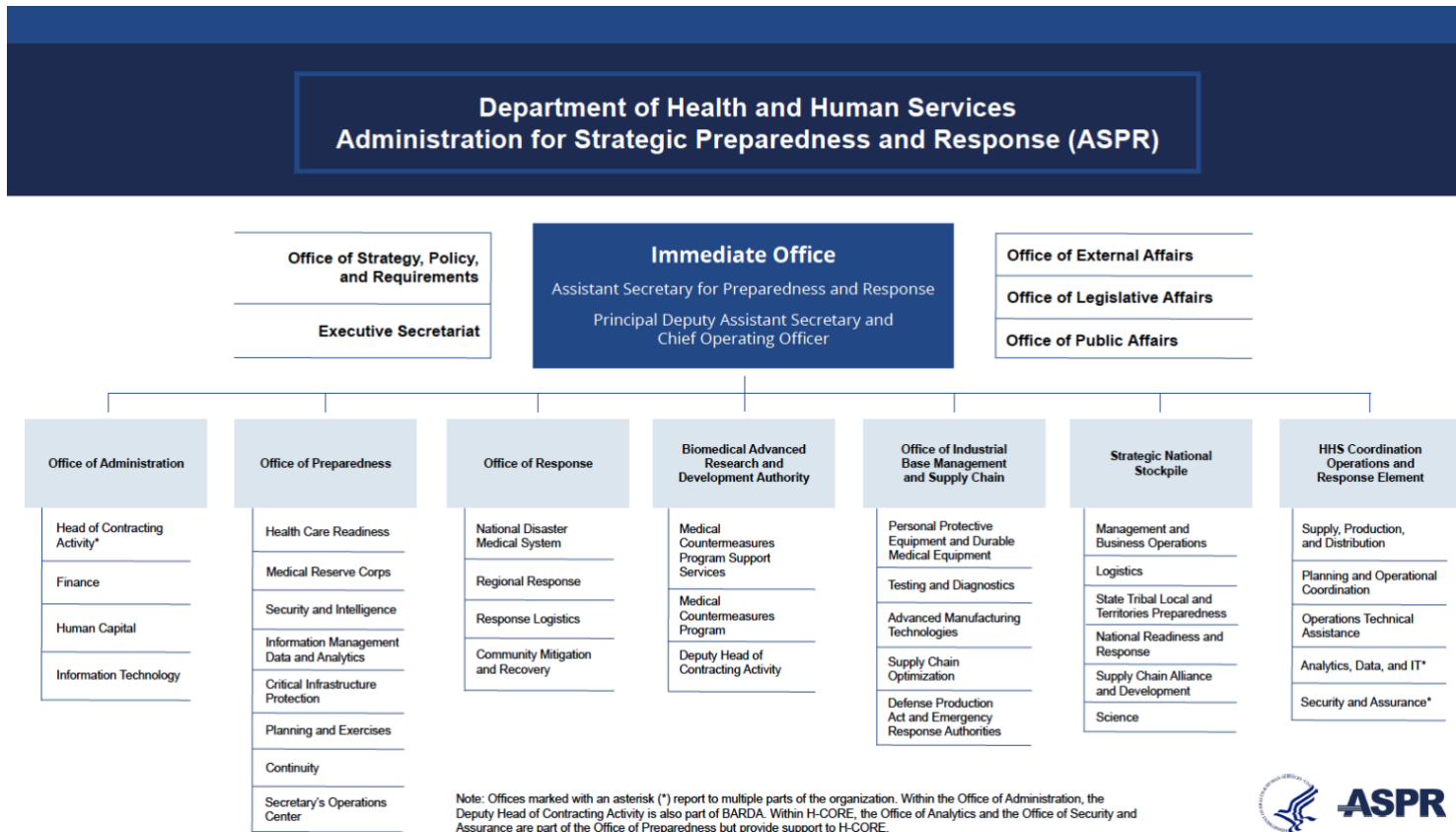


Figure 2-4. Organizational Chart for ASPR.

Source: HHS/ASPR Organization Chart, n.d. <https://aspr.hhs.gov/AboutASPR/ProgramOffices/Documents/ASPR%20-%20Organizational-Chart.pdf>.

Since HHS Secretary Xavier Becerra redesignated ASPR, Assistant Secretary O’Connell restructured her office and all the units within. Prior to reorganization in July 2022, O’Connell’s Office was an HHS Staff Division, not an Operating Division.

Public Health Emergency Medical Countermeasures Enterprise

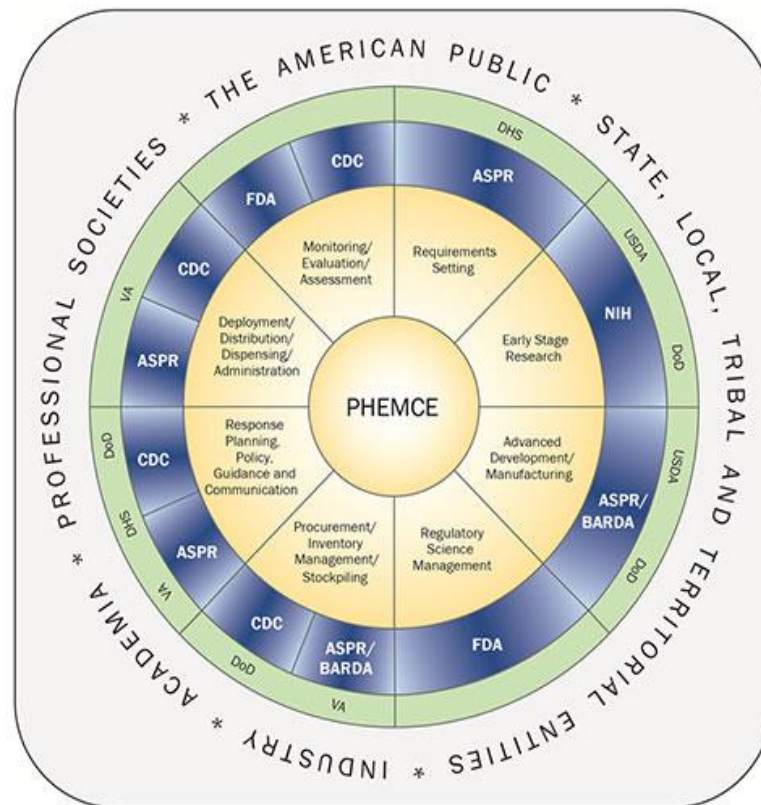
The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) coordinates federal efforts to enhance chemical, biological, radiological, and nuclear threats and emerging infectious diseases preparedness from a medical countermeasure perspective. The PHEMCE is led by the HHS Office of the Assistant Secretary for Preparedness and Response through the Administration for Strategic Preparedness and Response. In addition to HHS/ASPR, the PHEMCE includes three primary HHS internal agency partners: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH)

The PHEMCE also includes several interagency partners: the Department of Defense (DoD), the U.S. Department of Veterans Affairs (VA), the Department of Homeland Security (DHS), and the U.S. Department of Agriculture (USDA). Collectively, these Departments and agencies are referred to as the “PHEMCE statutory agencies.” As such, the PHEMCE is designed to “facilitate collaborative activities and inform federal decisions related to medical countermeasure preparedness.”⁵¹ To accomplish its mission, the PHEMCE brings together senior leaders and subject matter experts from the aforementioned statutory agencies.

51. HHS/ASPR, “PHEMCE.”

PHEMCE's Mission

The PHEMCE mission is to advance national preparedness for natural, accidental, and intentional threats by coordinating medical countermeasure-related efforts within HHS and cooperating with PHEMCE interagency partners.⁵²



Key:



Figure 2-5. PHEMCE Mission Components.

Source: HHS/ASPR, “PHEMCE Mission Components,” Last updated February 27, 2015. <https://www.phe.gov/Preparedness/mcm/phemce/Pages/mission.aspx>.

⁵². HHS/ASPR, “PHEMCE Mission Components,” Last updated February 27, 2015, <https://www.phe.gov/Preparedness/mcm/phemce/Pages/mission.aspx>.

PHEMCE Agency Lead Roles

The PHEMCE is comprised of eight mission components. These components fall under the direct responsibility of five different HHS Administrations, Centers, and Authorities, with the assistance of four other US executive departments, and non-federal stakeholders. The mission components are:

- Advanced Development / Manufacturing (ASPR/BARDA);
- Deployment / Distribution / Dispensing Administration;
- Early Stage Research;
- Monitoring / Evaluation / Assessment;
- Procurement / Inventory Management / Stockpiling;
- Regulatory Science Management;
- Requirements Setting; and,
- Response Planning, Policy, Guidance and Communication.

The different HHS units and external executive departments include:

- HHS Administrations, Authorities, Centers, and Institutes
 - Administration for Strategic Preparedness and Response (HHS-ASPR);
 - Biomedical Advanced Research and Development Authority (ASPR/BARDA);
 - Centers for Disease Control and Prevention (CDC);
 - Food and Drug Administration (FDA); and,
 - National Institutes of Health (NIH).
- US Executive Departments
 - US Department of Agriculture (USDA)
 - US Department of Defense (DoD)
 - US Department of Homeland Security (DHS)
 - US Veterans Administration (VA)

- Non-Federal Stakeholders
 - Academia;
 - Industry;
 - Professional Societies;
 - State, Local, Tribal, and Territorial Entities (SLTT); and,
 - The American Public.

Morphing into the PHEMCE

The transition from a collection of disparate components, agencies, and departments working on a different aspects of public health preparedness, response, and security, began with the release of *The National Health Security Strategy* in December 2009, but it was January 27, 2010, when efforts began in earnest. This was when President Barack Obama declared in his first State of the Union Address that the United States was “launching a new initiative that will give us the capacity to respond faster and more effectively to bioterrorism or an infectious disease—a plan that will counter threats at home and strengthen public health abroad.”⁵³ Since then, the PHEMCE has grown and helped usher in a new era of national and domestic security public health emergency preparedness and response. Now is the time for the lessons learned from previous responses and for those taken from the COVID-19 pandemic to be implemented.

53. Barack Obama, “Remarks by the President in State of the Union Address,” January 27, 2010. <https://obamawhitehouse.archives.gov/the-press-office/remarks-president-state-union-address>.

Funding

Because of the COVID-19 pandemic, the PHEMCE and each of its component parts, received an annual infusion of cash. For FY2023, Congress authorized \$610 million, which is only 62.56% of President Biden’s budget request of \$975 million for the SNS. However, as the tables and graph show, until the arrival of COVID-19 (FY 2021) the annual funding increases for the SNS did not keep pace with inflation, resulting in a net loss of funding in real dollar terms.

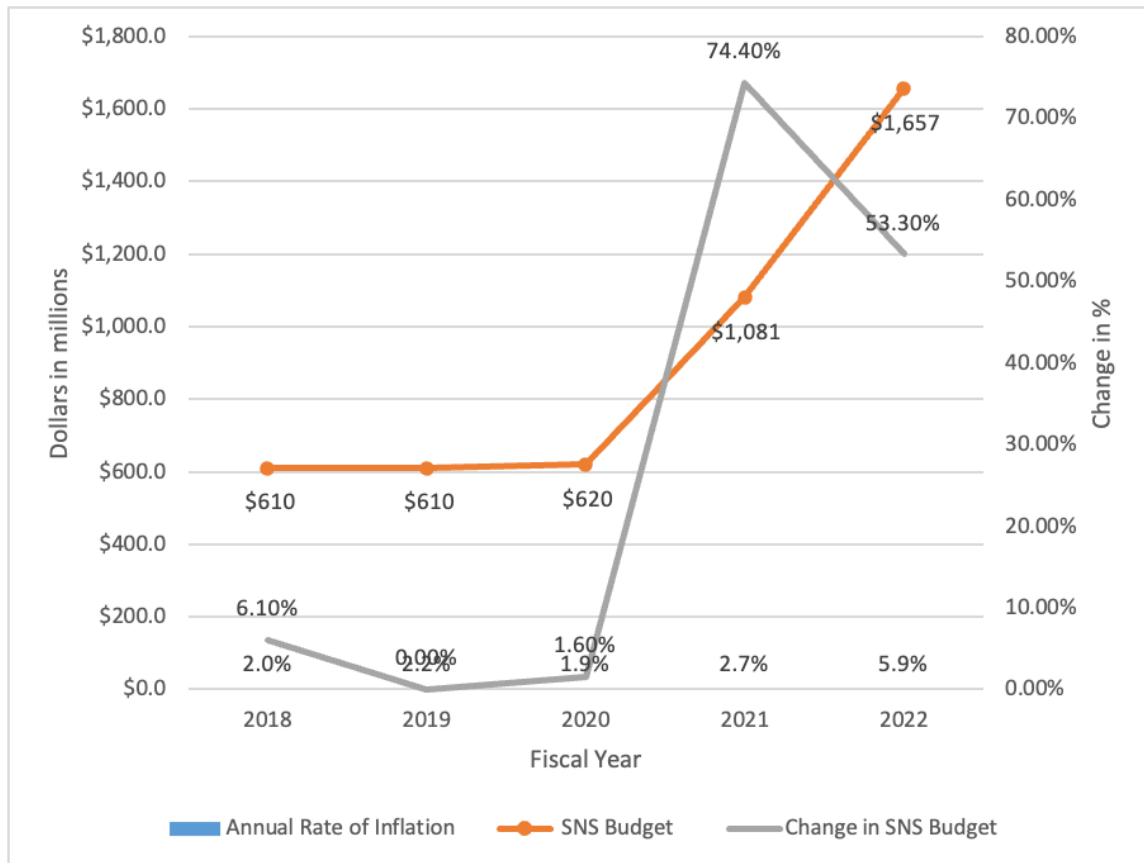


Figure 2-6. Rate of Inflation vs. Annual SNS Budget, 2018-2022

Note: Additional data and tables can be found in Appendix E: Important Tables.

Source: HHS-ASPR, “PHEMCE Multiyear Budget, Summary.”

<https://www.phe.gov/Preparedness/mcm/phemce/phemce-myb/FY2018-2022/Pages/exec-summary.aspx>

Table 2-2. Estimated Total PHEMCE Spending by HHS Division and Fiscal year (dollars, millions).

Division	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	Total	Change over FY 2017-2021
NIH	\$2,170	\$2,329	\$2,011	\$2,065	\$2,121	\$10,695	\$392
ASPR BARDA	\$1,514	\$1,653	\$1,698	\$4,217	\$3,671	\$12,753	\$2,778
ASPR SNS	\$610	\$610	\$620	\$1,081	\$1,657	\$4,578	\$803
FDA	\$142	\$141	\$154	\$173	\$178	\$787	\$12
Total	\$4,436	\$4,733	\$4,483	\$7,535	\$7,626	\$28,813	\$3,985

Source: HHS-ASPR, "PHEMCE Multiyear Budget, Summary."

<https://www.phe.gov/Preparedness/mcm/phemce/phemce-myb/FY2018-2022/Pages/exec-summary.aspx>

Table 2-3. Estimated Change in Total PHEMCE Spending by HHS division and fiscal year (2017-2022)

Division	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	Change over FY's 2017-2022	Pre-COVID Change over FY 2017 - 2020
NIH	8.122%	7.327%	-13.654%	2.685%	2.712%	-2.258%	-7.327%
ASPR BARDA	13.069%	9.181%	2.722%	148.351%	-12.948%	142.470%	12.153%
ASPR SNS	6.087%	0.000%	1.639%	74.355%	53.284%	171.639%	1.639%
FDA	4.412%	-0.704%	9.220%	12.338%	2.890%	25.352%	8.451%
Total	9.342%	6.695%	-5.282%	68.079%	1.208%	71.912%	1.060%

Source: HHS/ASPR, Public Health Emergency Medical Countermeasures Enterprise Multiyear Budget Fiscal Years 2017-2021, 2. <https://aspr.hhs.gov/AboutASPR/BudgetandFunding/Documents/PHEMCE%20Multiyear%20Budget%202017-2021/phemce-myb-2017-21.pdf>.

Table 2-4. US Annual Inflation Rates (2017 to 2023)

Yr	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Yr	1 st Half	2 nd Half
2017	2.3	2.2	2.0	1.9	1.7	1.7	1.7	1.7	1.7	1.8	1.7	1.8	1.8	2.0	1.7
2018	1.8	1.8	2.1	2.1	2.2	2.3	2.4	2.2	2.2	2.1	2.2	2.2	2.1	2.1	2.2
2019	2.2	2.1	2.0	2.1	2.0	2.1	2.2	2.4	2.4	2.3	2.3	2.3	2.2	2.1	2.3
2020	2.3	2.4	2.1	1.4	1.2	1.2	1.6	1.7	1.7	1.6	1.6	1.6	1.7	1.8	1.6
2021	1.4	1.3	1.6	3.0	3.8	4.5	4.3	4.0	4.0	4.6	4.9	5.5	3.6	2.6	4.5
2022	6.0	6.4	6.5	6.2	6.0	5.9	5.9	6.3	6.6	6.3	6.0	5.7	6.2	6.2	6.1

Source: US Bureau of Labor and Statistics, “Databases, Tables & Calculators by Subject.”

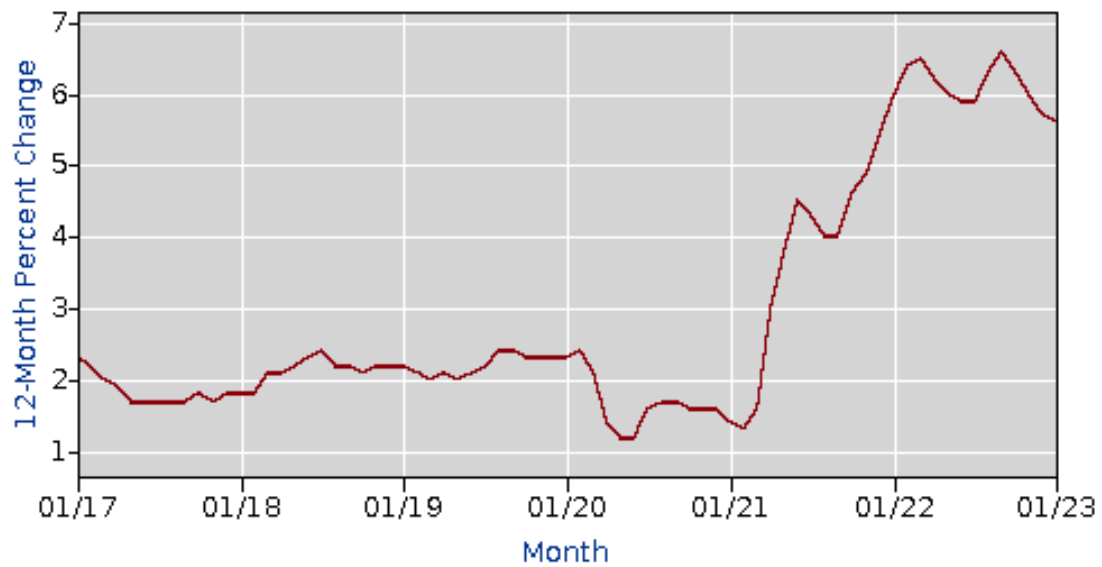


Figure 2-7. Percentage Change in the US Inflation Rate, January 2017 to January 2023.

Source: US Bureau of Labor and Statistics, “Databases, Tables & Calculators by Subject.”

Positive Changes for Fiscal Year 2023

For FY2023, President Biden has requested a 59.8% increase in funding compared to the amount authorized by the US Congress in 2022 for the SNS.⁵⁴ Additionally, Biden requested a 27.027% increase in staffing for the SNS in his proposed budget.⁵⁵ Combined with other requests, this represents a 34.062% increase in funding for bioterrorism and emergency preparedness at HHS.⁵⁶ Additionally, the budget calls for an additional 27.769% (366)⁵⁷ increase in staffing throughout all of HHS/ASPR, of which 19.126% (70) would go solely to the SNS.⁵⁸

Table 2-5. Strategic National Stockpile Budget Summary (Dollars, Millions)

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 ± FY 2022
Budget Activity	705.000	705.000	975.000	+270.000
FTE	259	259	329	+70

Source: HHS/ASPR, Fiscal Year 2023, 111.

54. HHS/ASPR, Fiscal Year 2023 Public Health and Social Services Emergency Fund: Justification of the Estimates for Appropriations Committee (Washington, DC: DHS, 2022), 111.
<https://www.hhs.gov/sites/default/files/fy-2023-phssef-cj.pdf>.

55. HHS/ASPR, Fiscal Year 2023, 11

56. HHS/ASPR, Fiscal Year 2023, 28.

57. HHS/ASPR, Fiscal Year 2022, 28.

58. HHS/ASPR, Fiscal Year 2023, 111.

Table 2-6. Budget Authority for Bioterrorism and Emergency Preparedness and Pandemic Influenza (Dollars, Millions)

Activity	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget
Bioterrorism and Emergency Preparedness	2,560.458	2,560.458	3,432.610
Pandemic Influenza	287.000	287.000	382.000
Total Budget Authority	2,847.458	2,847.458	3,814.610
FTE	1,079	1,318	1,684

Source: HHS/ASPR, Fiscal Year 2023, 28.

Table 2-7. Authorizing Legislation for FY2022 & FY2023 funding for ASPR divisions. (Dollars, Millions)

Activity	FY 2022 Amount Authorized	FY 2022 Amount Appropriated	FY 2023 Amount Authorized	FY 2023 President's Budget
ASPR				
National Disaster Medical System	57.404	63.404	57.404	130.030
Hospital Preparedness Program	385.00	280.555	385.000	291.777
Medical Reserve Corps	11.000	6.000	11.000	6.240
BARDA	611.700	597.700	611.700	823.380
Project BioShield	710.000	710.000	710.000	770.000
Strategic National Stockpile	610.000	705.000	610.000	975.000
Pandemic Influenza	250.00	287.00	250.00	374.991

Source: HHS/ASPR, Fiscal Year 2023, 29.

Chapter III

Literature Review

Very little information was available when I undertook the initial literature review for this thesis. Additionally, within the academic realm, little was known or published about the effects of COVID-19 on the SNS and its effectiveness.

During my review, I utilized the following search terms individually and in varying combinations:

- CDC
- Centers for Disease Control and Prevention
- CHEMPACK
- Coronavirus
- COVID
- COVID-19
- Medical Countermeasures
- MCM
- Pandemic
- PHEIC
- PHEMCE
- PHEP
- Public Health Emergency Preparedness
- Public Health Emergency Medical Countermeasures Enterprise
- Public Health Emergency of International Concern
- SARS-CoV-2
- SNS
- Strategic National Stockpile
- Supply Chain Management
- WHO
- World Health Organization

Databases Visited

The following databases and websites were explored:

- American Medical Association
- American Public Health Association
- Centers for Disease Control and Prevention
- Google (general searches)
- Google Scholar
- HOLLIS (Harvard On-Line Library Information Service)
- SLSP (Swiss Library Service Platform)
- *swisscovery plus*

Inclusion and Exclusion Criteria

The following exclusion criteria were used when evaluating the literature:

- It must have been published during or after 2010.
- Except for news articles, it must have been published by a government agency, or a peer-reviewed journal or text.
- It must directly deal with one or more of the following:
 - Assistant Secretary for Preparedness and Response
 - Centers for Disease Control and Prevention
 - COVID-19 or SARS-CoV-2
 - Medical Countermeasures
 - Pandemic Supply Chain Network
 - Public Health Emergency Medical Countermeasures Enterprise

- Strategic National Stockpile
- Supply Chain Management of Medical Countermeasures
- World Health Organization
- It must be germane to the thesis research questions.

What is Currently Known

What is currently known about the SNS and its pandemic responses predates the COVID-19 pandemic by decades. In conducting this literature review, I found two relevant peer-reviewed articles on the subject: “Impact of the Global Medical Supply Chain on SNS Operations and Communications,” published in 2018,⁵⁹ and “Ethical Questions Surrounding Health Care Resource Allocations for the Strategic National Stockpile,” published in 2011.⁶⁰ Neither publication was directly on point, and both were published prior to the existence of COVID-19. However, it was interesting that they were prescient in their evaluation of separate but highly important areas that impact the overall effectiveness of the SNS. I believe that had the information found in the Mack publication been acted on expeditiously (as was recommended), some—if not all—of the personal protective equipment (PPE) issues that the United States encountered in the first few months of COVID-19 might have been prevented. However, due to political conditions at the time (and still currently affecting the US government response), it seems impossible to prove or disprove this theory.

59. Alison Mack, ed., “Impact of the Global Medical Supply Chain on SNS Operations and Communications: Proceedings of a Workshop” (Washington, DC: The National Academies Press, 2018). <https://www.nap.edu/catalog/25149/impact-of-the-global-medical-supply-chain-on-sns-operations-and-communications>.

60. Ryan Meskimen and Brett Hicks, “Ethical Questions Surrounding Health Care Resource Allocations for the Strategic National Stockpile,” *Journal of Homeland Security and Emergency Management* 8, no. 1 (August 22, 2011). <https://doi.org/10.2202/1547-7355.1927>.

While I did review additional literature, most of it was not relevant due to its age and/or tangential application. Some of the information dated back to the early and mid-2000s, and none was helpful in answering the original research question. That said, these articles did provide important historical context that helped build the foundation on which further research into this subject will rely. However, at the time of my literature review, I was unable to find any information that directly related to my research question.

What is Currently Unknown

There is much that is currently unknown, and will remain so into the near-term future. Questions about how the US response to COVID-19 was framed, why it was conducted in that manner, and by whom, will undoubtedly consider the structural responses and capabilities of the SNS, and the US response as a whole. It will also focus on the politics behind the decisions and actions taken by elements of the US government. Unfortunately, answers to such questions are currently shrouded in secrecy and obfuscation.

However, with the installation of the Biden Administration in 2021, combined with the Democratic Party in control of the US House of Representatives and the US Senate for the 117th Congress, it is likely that multiple investigations will be conducted by the several House, Senate, and joint Congressional committees. As the outcomes of these investigations are published, I have incorporated that information into the writing of this thesis.

Grey Literature

Although there is a decent amount of “grey literature”⁶¹ on this subject, it was not included due to its lack of peer review. Additionally, some of the grey literature found related to political issues surrounding the US response to COVID-19. As such, some of the information was biased conjuncture at best, with some misinformation if not outright disinformation. Because of the dubious nature of the political information, it was not utilized as part of the literature review.

Tangential Information

The remaining literature reviewed was at best tangential to the research question. Most of the recent literature dealt with optimizing the use of limited SNS resources⁶² (including approximately 8,500 ventilators⁶³ found in SNS warehousing). However, it must also be said that much of the tangential literature is applicable, and was beneficial in researching and answering the newly modified research questions, found in the “Research Questions” section of this proposal.

61. Defined as materials and research produced by organizations outside of the traditional commercial or academic publishing and distribution channels. Common grey literature publication types include reports (annual, research, technical, project, etc.), working papers, government documents, white papers and evaluations. Organizations that produce grey literature include government departments and agencies, civil society or non-governmental organizations, academic centres and departments, and private companies and consultants.

62. Martin I. Meltzer, et al., “Estimates of the Demand for Mechanical Ventilation in the United States During an Influenza Pandemic,” *Clinical Infectious Diseases* 60, no. suppl_1 (May 1, 2015): S52–57. <https://doi.org/10.1093/cid/civ089>; also, Justin J. O’Hagan, et al., “Estimating the United States Demand for Influenza Antivirals and the Effect on Severe Influenza Disease During a Potential Pandemic,” *Clinical Infectious Diseases* 60, no. suppl_1 (May 1, 2015): S30–41. <https://doi.org/10.1093/cid/civ084>.

63. Mack, “Impact of Global Medical Supply Chain,” 2.

Review of Current Literature

Over 300 unique pieces of literature⁶⁴ (including videos and data sets) were reviewed during the course of researching and writing this thesis. I found that the majority of the literature I reviewed was not germane; the rest could be separated into three themes: (1) ventilators, (2) supply chain management (including production and distribution of vaccines), and (3) government or government-requested reports.

The production and distribution of vaccines is not germane to the research questions that this thesis seeks to answer. Further, politically themed literature constituted most of what I found and reviewed. Since this thesis is meant to be something other than a political science discussion, I did not address these articles.

Ventilators

More than two dozen articles dealt in some manner with ventilators at the height of COVID-19, primarily the lack of ventilators in or via the SNS. Additionally, a significant quantity of literature called for invoking the Defense Production Act of 1950 to quickly meet the growing demand for ventilators in hospitals and nursing homes throughout the US.

Additional literature dealt with the issues arising from non-standardization of ventilators in general and in the SNS. This caused issues for the receiving facilities to utilize and adapt to the ventilators they received. Furthermore, there were concerns about how the government handled the situation surrounding ventilators.

64. Not all of the 300 items are listed in the Bibliography.

Government or Government-Requested Reports

Besides various Congressional Committee hearings that produced voluminous amounts of literature (again, most political in nature), I believe the key report was one issued by the National Academies of Science, Engineering, and Medicine, titled *Ensuring an Effective Public Health Emergency Medical Countermeasure Enterprise*.⁶⁵ While extremely beneficial to this research, it did have the negative consequence of usurping several of my originally planned suggestions. However, the Biden Administration has adopted several suggestions similar to those I originally planned to write about, and it has entered a path toward strengthening the Strategic National Stockpile.

65. National Academies of Science, *Ensuring an Effective Public Health Emergency Medical Countermeasure Enterprise* (Washington, DC: National Academies Press, 2021). <https://doi.org/10.17226/26373>.

Chapter IV

Methodology

*For great doesn't happen through impulse alone,
it is a succession of little things that are brought together.*

—Vincent Van Gogh⁶⁶

I utilized qualitative methods for my approach to the thesis research. This included a detailed literature review, followed by an anonymous logic-based survey on the specific topic.

Near the end of 2019, COVID-19 began affecting the entire world population, bringing with it lethal outcomes. The United States began to feel these effects by the beginning of 2020. However, it was not until December 2020 that an approved COVID-19 vaccine was first administered to the US public. Unfortunately, politicians, competing work groups, task forces, and individuals without appropriate scientific background or education made policy decisions and offered suggestions that affected response efforts in the US. Soon multiple question began to arise:

- How did these factors affect the mass distribution of a lifesaving vaccine?
- Are the previous pandemic and mass distribution and vaccinations still in effect?
- Have they been updated or modified? Are they even still in existence?
- “What went wrong?”

66. Vincent van Gogh, Letter to Theo van Gogh, 22 October 1882, *The Letters* (Letter 274), Van Gogh Museum. <http://vangoghletters.org/vg/letters/let274/letter.html>.

- “What went right?”
- “What do we do to improve?”

This thesis seeks to answer these questions and offer potential corrective steps.

Research Objective

The objective of this research is to explore steps that need to be taken in order to improve the response capabilities of the SNS following the COVID-19 pandemic.

Additionally, I will address what steps or solutions should be taken to resolve any issues or problems identified during the research and writing of this thesis.

Research Questions

As the research and literature review were being conducted, I realized that the original research questions in this thesis were overly ambitious and too wide-ranging. Therefore, I redefined the research questions to focus solely on the SNS. The revised questions are as follows:

- RQ 1: What are the strengths and challenges in the current design and structure of the SNS that will enable it to meet the nation’s actual and realistic predicated medical countermeasure needs in response to emergency events that may overwhelm local and state healthcare capabilities?
- RQ 2: What are key lessons learned from using the SNS for the COVID-19 response that should inform future planning?
- RQ 3: What additional statutory, regulatory, programmatic, and other changes need to be taken, and by whom, to improve the ability of

the SNS to meet its all-hazard goals and responsibilities in the short, medium, and long term?

Sampling Bias

In the course of this research, I recognized that sampling bias would be a key concern due to the low response rate (5.78%). However, I sought to avoid this bias to the extent possible. I utilized a computer-generated random number to identify which local health departments would be selected in each SNS project area.

Further, I wanted to obtain the widest possible survey distribution by utilizing direct and indirect communication methods (e.g., contacting professional and trade organizations). In the end, however, I recognized the potential for sampling bias in the results, so I also included extensive written comments provided by the research study participants.

Research Ethics

This study was approved by the Harvard University Committee on the Use of Human Subjects, the Institutional Review Board for the Harvard University Area. It was assigned research project number IRB22–0783. All participants provided written informed consent before commencing the online survey.

Survey

This research utilized a qualitative survey sent to public health and emergency management subject matter experts and professionals at the federal, state, territorial, local, and private industry levels.

The final version of the survey was significantly changed from its original version due to concerns from Harvard University's Committee on the Use of Human Subjects. As originally designed, a Certificate of Confidentiality would be sought from the National Institutes of Health. However, despite my objections, the Committee's representative did not feel that a Certificate of Confidentiality was either necessary or appropriate for a master's thesis; it would only be appropriate for a doctoral dissertation, as a master's thesis should not be that extensive. This resulted in a significant delay in conducting the necessary research while negotiations were ongoing with the Committee, and eventually I redesigned the survey to obtain the Committee's approval.

Originally, I planned to interview public health, emergency management, and law enforcement personnel at the federal, territorial, state, and local levels to determine their perceptions of and concerns with the SNS, the Public Health Emergency Medical Countermeasures Enterprise, and the government's response to the COVID-19 public health emergency. I believed the NIH Certificate of Confidentiality was needed to ensure the anonymity of the interviewees and to protect my research materials and discovery notes. I believe this anonymity is necessary because of policies and regulations at all levels of government that restrict when and to whom government employees can talk or provide data, especially when discussing a sensitive program such as the SNS.

Design

The survey was designed as a qualitative survey utilizing multiple logic-based questions based on the respondent's answers. See Appendix D for the survey questions and logic. The survey consisted of single, multiple, and matrix multiple-choice questions. It also included a few questions utilizing a Likert scale of 1 through 10, with 1 being lowest and 10 being highest on the scale. Several questions allowed the participant to provide a longer written answer in his/her own words.

The survey sought to collect information that would support the research question using a constructivist approach. It was designed and deployed through Harvard's academic license on the Qualtrics© platform.⁶⁷ Distribution was through direct emails, including a link⁶⁸ to participate in the survey anonymously. The survey was open for responses over a 61-day period (August 1–September 30, 2022).

Vetting of Questions

The survey questions were vetted by a select group of public health and medical experts, inside and outside of government, that did not participate in the research or have any direct or indirect conflicts of interest. The individuals chosen to vet the questions are personally known to me, and are senior state and federal public health officials, including a deputy secretary of health and a state medical director.

Selected Audiences

The survey was distributed directly to 3,579 email addresses (see Table 2-8). There was a bounce rate of 10.617% (380) and a duplication rate of 20.928% (749). That

67. Qualtrics, Prov, UT, United States of America. <https://www.qualtrics.com/>.

68. https://harvard.az1.qualtrics.com/jfe/form/SV_1z9YK8H29eUprPE.

left a successful delivery rate to unique email addresses of 68.455% (2,450). From the 2,450 successful email deliveries, there was a response rate of 7.633% (187). Of the 187 recipients that responded, 87.166% (163) completed the survey. Of the 163 respondents who completed the survey, only one participant (0.613% of the sample population; 0.028% of the population) refused to consent to participate and did not provide any responses.

Table 4-1. Survey Target Audience and Number of Emails Sent.

Target Audience	Number of Participants Emailed
SNS Project Area Coordinators	104
SNS Project Area Senior Public Health Officials	
Local Health Department SNS/MCM Coordinators	3386
Local Health Department Directors	
Hospital Emergency Management Directors and/or Medical Directors for Emergency Preparedness	0
SNS Project Area Senior Emergency Management Official	79
Other PHEP/SNS Subject Matter Experts	10
Total	3,579

Source: thesis author

The contacted 62 SNS Project Areas (which are coterminous with the Public Health Emergency Preparedness (PHEP) Cooperative Agreement Program Areas) are:

- All 50 U.S. States
- Five (5) U.S. Territories

- American Samoa
- Guam
- Northern Mariana Islands (Commonwealth of)
- Puerto Rico (Commonwealth of)
- US Virgin Islands
- Four (4) Directly Funded Local Jurisdictions
 - Chicago, IL
 - Los Angeles County, CA (which includes the City of Los Angeles)
 - New York, NY
 - Washington, DC
- Three (3) Freely Associated States
 - Marshall Islands (Republic of)
 - Micronesia (Federated States of)
 - Palau (Republic of)

The original survey population was approximately 9,276 public health emergency preparedness and response professionals. My original intention was to obtain the assistance of the Association of State and Territorial Health Officers (ASTHO), the National Association of County and City Health Officers (NACCHO), the American Hospital Association (AHA), and the International Association of Emergency Managers (IAEM). However, due to internal policies and procedures, these organizations could not forward the survey to its membership.

The original target audience was as follows:

- Funded state, territorial, and major metropolitan area SNS Project Area Coordinators (62 each).
- Senior state/territorial/metropolitan public health official responsible for public health preparedness/response (62 each)

- Local health department MCM coordinators (1,500 members from local health departments who belong to NACCHO)
- Local health department directors (1,500 local health departments who belong to NACCHO)
- Hospital emergency management directors and/or medical directors for emergency preparedness (6,090 hospitals in the US per the AHA)
- Senior state/territorial/metropolitan emergency management official (62 each)

This would have resulted in the survey being sent to approximately 9,726 unique individual recipients. Unfortunately, the identified professional and trade organizations could not provide their members with a link to the survey, resulting in it being successfully sent to only 25.2% (2,450) of the original sample population.

An analysis of the data obtained is discussed in Chapter V. Raw data can be found in Appendix E.

Political Context

One significant limitation that manifested during the writing of this thesis was the hyper-partisan political environment in which the United States finds itself, which makes the likelihood of significant legislative fixes improbable during the current 118th United States Congress. Public health has been hyper-politicized on a partisan basis since the beginning of COVID-19 in the United States. One such consequence has led to the creation of the US House of Representatives Select Subcommittee on the Coronavirus Crisis, within the Committee on Oversight and Accountability, which has been

authorized and directed to conduct a full and complete investigation and study and, not later than January 2, 2025, issue a final report to the House

of its findings (and such interim reports as it may deem necessary) regarding—

- (i) the origins of the coronavirus pandemic, including but not limited to the Federal Government’s funding of gain-of-function research;
- (ii) the efficiency, effectiveness, and transparency of the use of taxpayer funds and relief programs to address the coronavirus pandemic, including any reports of waste, fraud, or abuse;
- (iii) the implementation or effectiveness of any Federal law or regulation applied, enacted, or under consideration to address the coronavirus pandemic and prepare for future pandemics;
- (iv) the development of vaccines and treatments, and the development and implementation of vaccination policies for Federal employees and members of the armed forces;
- (v) the economic impact of the coronavirus pandemic and associated government response on individuals, communities, small businesses, health care providers, States, and local government entities;
- (vi) the societal impact of decisions to close schools, how the decisions were made and whether there is evidence of widespread learning loss or other negative effects as a result of those decisions;
- (vii) executive branch policies, deliberations, decisions, activities, and internal and external communications related to the coronavirus pandemic;
- (viii) the protection of whistleblowers who provide information about waste, fraud, abuse or other improper activities related to the coronavirus pandemic; and
- (ix) cooperation by the executive branch and others with Congress, the Inspectors General, the Government Accountability Office, and others in connection with oversight of the preparedness for and response to the coronavirus pandemic.⁶⁹

69. H.R. Res. 5, 118th Cong. § 4(a)(2)(A) (2023).

Chapter V

Discussion

*To be frank, we are responsible for some
pretty dramatic, pretty public mistakes,
from testing to data to communications.*

—Rochelle P. Walensky⁷⁰

The major takeaway from the survey results is that local health departments feel they do not know enough about the SNS or how it operates. Specifically, they feel the program at the federal level lacks transparency, especially as to what can or cannot be found in the stockpile itself, and how to request different medical countermeasures.

In addition, the health departments believed that the SNS programming should be focus more on local needs rather than state or federal needs; as one respondent noted, “disasters are local and the SNS process is based mostly on state resources.” Another respondent felt that

based on the experience with covid-19 response, as soon as the disaster was declared, the SNS was overwhelmed with requests and healthcare facilities were forced to locate their own supplies. Price elevations to astronomical levels resulted, and the SNS remained inept until supplies returned to pre-pandemic levels.

70. Sharon LaFraniere and Noah Weiland, “Walensky, Citing Botched Pandemic Response, Calls for C.D.C. Reorganization,” *New York Times*, August 17, 2022.
<https://www.nytimes.com/2022/08/17/us/politics/cdc-rochelle-walensky-covid.html>.

Statements like this may imply that the SNS at the federal level and the state level coordinators need to provide clearer and more transparent communications with to the local health departments and their respective local SNS coordinators.

Changed Circumstances

The organizational structure of the SNS, as well as the priority placed on it, changed considerably during the research and writing of this thesis. In turn, this shifted the focus of the thesis from a discussion of restructuring the entire PHEMCE to focusing primarily on the SNS.

Some of my conclusions, suggestions, and next steps became moot due to actions by the current Biden Administration. For instance, one suggestion was to move the then-DSNS from a fifth- or sixth-level division to become a direct report to the Assistant Secretary of Health and Human Services for ASPR. As noted in Chapter II, in July 2022, HHS Secretary Xavier Becerra redesignated the HHS-ASPR from a Headquarters Staff Division to an HHS Operational Division and renamed and transformed it into the HHS/ASPR.

In another instance, the Division of Strategic National Stockpile became a direct report to ASPR. This resulted in the Director of the DSNS being promoted from a Division Chief to a Deputy Assistant Secretary of Health and Human Services for Preparedness Response and concurrently the Director of the Strategic National Stockpile, with a direct line to ASPR and the Principal Deputy Assistant Secretary for Preparedness and Response. Moreover, then-*Acting* Division Chief Steven Adams received a significant promotion to Deputy Assistant Secretary of HHS for the SNS.

This restructuring shows how seriously the Biden Administration takes public health emergency preparedness and response. The promotion of the SNS and its director from division chief to a deputy assistant secretary elevated the SNS's stature and the director's authority not only within HHS/ASPR but throughout HHS and the executive branch of the government.

These changes, which I believe were for the better, affected the conclusions of this thesis, the proposed solutions, and suggested next steps forward, all of which are reflected in this chapter and in the conclusion.

Solutions

For the SNS to have a zero-failure rate in a world faced with an increasing number of public health emergencies, international concerns, and global pandemics, it must be restructured and properly funded. Failure to do so threatens the public health of the United States as well as its domestic and national security. Such a failure also threatens humanity's public health and security writ large.

Below are a series of proposed solutions based on research conducted for this thesis, categorized in the following three themes: (1) legislative, (2) administrative, and (3) supply chain management. These solutions are the first of several steps that need to be addressed to place the SNS and domestic and international public health and security on a strong footing for the remainder of this decade and beyond.

Proposed Legislative Solutions⁷¹

1. Legislation

- a. Amend 31 U.S.C. § 1305 to add a subsection providing for a ringed-fenced permanent appropriation for SNS operations (as described in Paragraph 3.b. of this section below), including but not limited to:
 - i. SNS operations;
 - ii. SNS Emergency Operations;
 - iii. SNS Deployments;
 - iv. SNS Warehouse Operations;
 - v. SNS Medical Countermeasure Purchasing;
 - vi. Shelf Life Extension Program (SLEP) Expenses;
 - vii. Funding for the 62 SNS Project Areas; and,
 - viii. SNS Project Area Advisory Council Operations (including travel) (See paragraph 3.a. in the “Administrative” section below).
- b. Enact the “Public Health Emergency Production Act of 202__” which would amend several different current Acts of Congress (e.g., the Defense Production Act of 1950⁷²).

71. See Appendix H for proposed draft legislation.

72. Defense Production Act of 1950, 50 U.S.C. §§ 4501 *et seq.* (2018), Pub. L. No. 81-774, 64 Stat. 798 (1950).

- c. Require the Secretary of HHS (except in the case of a Presidentially declared disaster, emergency, or public health emergency) to:
 - i. ensure that the SNS's physical inventory of medical countermeasures maintains a level greater than or equal to ($\geq$) 85% of the minimum required inventory;⁷³ and,
 - ii. in the case of a Presidential declaration, where the inventory drops below the 85% threshold, require the inventory be returned to the minimum 85% level within 90 days following the last day the Presidential declaration is in effect.
- d. Designating all SNS staff as "Emergency Essential Personnel" for purposes of government shutdowns and other operational necessities, which would ensure that the SNS would remain operational throughout any government shutdowns or defaults.

2. Authorities

- a. Delegate authority to authorize the release and deployment of the Strategic National Stockpile from the President of the United States and Secretary of Health and Human Services to the Deputy Assistant Secretary for the Strategic National Stockpile. This will allow for a quicker response by the SNS and the release of its assets.

73. This number was chosen based on my previous experience running the SNS in the State of Maryland, with secondary responsibility for Washington, DC.

- b. Expand the authority to utilize the Food and Drug Administration's (FDA's) Shelf Life Extension Program (SLEP) to all 59 of the 62 SNS Project Areas (excluding Chicago, Los Angeles County, and New York City).
- c. Codify the current recommendation⁷⁴ within the SNS program that all 62 SNS Project Area Coordinators receive and maintain a security clearance at the Secret level at a minimum, preferably at the Top Secret (or higher) level.
- d. Mutual-Aid Mechanisms.
 - i. Establish a mutual-aid mechanism to allow the 62 SNS Project Areas to pre-position or send their SNS assets (including the CHEMPACK) to another SNS Project Area without prior approval or coordination of the HHS/ASPR or the SNS.
 - ii. The mutual-aid mechanisms would be based on the one currently entered into by the States of California, Oregon, Arizona, and Nevada.
 - iii. The SNS Project Areas would still be required to notify the SNS but not obtain prior approval.
 - iv. By establishing a nationwide mutual-aid mechanism, the 62 PHEP cooperative agreement project areas would not need to obtain approval from their respective Governors (or

74. This information is personally known to me based on my previous experience running the SNS in the State of Maryland, with secondary responsibility for Washington, DC.

mayors), the receiving Governors (or mayors), the US Secretary of Health and Human Services or their designee, or the Deputy Assistant Secretary for the Strategic National Stockpile. This would save valuable time (potentially hours) during a crisis where minutes (in the case of accessing the CHEMPACK) may mean the difference between saving lives or the mass loss of life.

- v. Furthermore, it will prevent the significant difficulties that individual Project Area SNS Coordinators face when attempting to negotiate such agreements amongst themselves.⁷⁵

3. Funding

- a. Establishing a ring-fenced permanent non-lapsing appropriation for the Strategic National Stockpile with a ring-fenced perpetual triple lock in line with the highest of the following:
 - i. personal consumption expenditures (PCE) price index determined by the United States Department of Conference Bureau of Economic Analysis;
 - ii. Average wage growth during the previous US Government Fiscal Year (October – September); and,
 - iii. Four point five percent (4.5%).

75. This information is personally known to me based on my previous experience running the SNS in the State of Maryland, with secondary responsibility for Washington, DC.

- b. Establish a ring-fenced trust fund to maintain an appropriate level of medical and non-medical countermeasures throughout the Strategic National Stockpile, including the CHEMPACK, 12-hours Push Packs, Federal Medical Stations, personal protective equipment (PPE), and ventilators.
- c. Provide a 20% increase each year over five (5) years⁷⁶ to the Strategic National Stockpile portion of the Public Health Emergency Preparedness (PHEP) Cooperative Agreement provided to each of the 62 PHEP jurisdictions. This recommendation should hopefully make up some of the money that has been lost over the years by cuts to the PHEP Cooperative Agreement.
- d. Increase the size of the CHEMPACK to ensure a minimum of 90% of the counties in each of the 59 of the 62 SNS Project Areas (excluding Chicago, Los Angeles County, and New York City) have an *adequate* supply of CHEMPACK containers readily available.
- e. Increase funding to offer the 62 SNS Project Area Coordinators, their respective staffs, and the local health department SNS Coordinators the opportunity to attend at US Government expense trainings, table top exercises, and full scale exercises on the following SNS specific topics:

76. This would result in an approximately 250% total increase from the base year. This number was based on my previous experience running the SNS in the State of Maryland, with secondary responsibility for Washington, DC.

- i. SNS (basic and advanced level);
- ii. crisis communications and public affairs;
- iii. supply chain management;
- iv. warehouse operations; and,
- v. Train-the-Trainer for each of the courses so the 62 SNS Project Area Coordinators (and their staffs) can provide these courses to local and state officials and agencies within their respective jurisdictions.

4. Senate Ratification of International Treaties and Agreements

- a. Once it has been finalized, ratify the International Treaty on Pandemic Prevention, Preparedness and Response (“International Pandemic Treaty”).
- b. Once it has been finalized, ratify the necessary amendments to the TRIPS Agreement necessary for the International Pandemic Treaty to be effective.

Proposed Administrative Solutions

1. Communications

- a. Establish clearer lines of communication from the SNS to the 62 SNS Project Area Coordinators and the 62 PHEP Project Area Coordinators.
- b. Establish a means for the 62 SNS Project Area Coordinators to communicate directly to each other without first having to contact the SNS and request they contact the SNS Project Area

Coordinator first and request permission to provide the requesting SNS Project Area Coordinator with the other SNS Project Area Coordinator's contact information (e.g., listserv, secure online community, etc.).

- c. Provide each of the 62 SNS Project Area Coordinators with the contact information of the other SNS Project Area Coordinators and SNS Leadership and Staff.
- d. Clearly articulate to the 62 SNS Project Area Coordinators and the 62 PHEP Project Area Coordinators that the respective SNS Coordinators do not need the permission of their respective PHEP Coordinator to contact SNS staff or leadership.

2. Security Clearances

- a. Enforce the current mandate that all 62 SNS Project Area Coordinators receive and maintain a security clearance at the Secret level at a minimum, preferably at the Top Secret level with authorization to access all relevant "Law Enforcement Sensitive" materials.⁷⁷ This change is due to most of the details surrounding the SNS (e.g., warehouse locations, security plans, transportation plans, etc.) being classified at the Secret or Top Secret levels or designated as "Law Enforcement Sensitive."
- b. Provide (as needed) classified briefings/updates to the 62 SNS Project Area Coordinators on current and emerging threats.

77. This is because most of the details surrounding the SNS (e.g., warehouse locations, security plans, transportation plans, etc.) are classified at the Secret or Top Secret levels, or designated as "Law Enforcement Sensitive."

c. Law Enforcement Coordination

- i. Ensure that all 62 SNS Project Areas are fully integrated into their respective jurisdictions' security planning and procedures, the SNS-controlled warehouses within their respective jurisdictions, and the national security/law enforcement procedures and plans as they pertain to their respective jurisdictions.
- ii. Work with the US Department of Justice to ensure that the SNS program and the 62 SN Project Areas are integrated into the Domestic Security Task Forces, Joint Terrorism Task Forces, and Intelligence Fusion Centers in their respective jurisdictions as it relates to medical intelligence, public health, and weapons of mass destruction related concerns, issues, and threats.

3. Coordination with the 62 SNS Project Areas

- a. Establish an Advisory Council of the 62 SNS Project Areas consisting of a primary and alternate representative from each HHS Region and representatives from the United States Marshals Service.
- b. Meet collectively with all 62 SNS Project Areas twice a year, in a SCIF for a classified briefing and to meet with SNS leadership and key staff at:

- i. the annual Preparedness Summit (usually held in Atlanta, GA); and,
 - ii. HHS/ASPR
- c. Increase funding to the SNS budget to send the appropriate SNS Project Area Coordinators at US Government expense to the necessary meetings and briefings listed subparagraphs a and b above.

4. Request Procedures

- a. Allow the 58 US State/Territorial/Free Associated State Secretaries/Commissioners of (Public) Health (and Human Services) to request the deployment of the Strategic National Stockpile and not limit it to only the respective Governors.
- b. Increase transparency among state and local SNS/MCM Coordinators on what is currently stockpiled within the SNS and the appropriate steps to request deployment of the SNS assets.

5. Training

- a. offer the 62 SNS Project Area Coordinators, their respective staffs, and the local health department SNS Coordinators the opportunity to attend at US Government expense trainings, table top exercises, and full scale exercises on the following SNS specific topics:
 - i. SNS (basic and advanced level);
 - ii. crisis communications and public affairs;
 - iii. supply chain management;

- iv. warehouse operations; and,
- v. Train-the-Trainer for each of the courses so the 62 SNS Project Area Coordinators (and their staffs) can provide these courses to local and state officials and agencies within their respective jurisdictions.
- b. Provide online asynchronous trainings on a variety of SNS, medical countermeasures, HHS/ASPR operations, disaster management, and other topics.

Proposed Supply Chain Management Solutions

1. Direct the Secretaries of Commerce, Labor, Health and Human Services, Transportation, and Treasury to:
 - a. coordinate with the manufacturing and pharmaceutical industries and corporations that produce the items maintained in the SNS;
 - b. develop a *realistic* and executable plan to return manufacturing of the SNS physical inventory to the continental United States; and,
 - c. Develop a nationwide transportation policy and mechanism for the rapid transport of medical countermeasures and other supplies in a declared emergency or SNS deployment.
2. Designate certain products as critical and mandate their production within the continental United States.
3. Pre-designate critical items of the SNS for immediate implementation of the “Public Health Emergency Production Act” to ensure enough supplies are in the stockpile and in production when emerging or current threats are identified as

posing a public health emergency to the United States or a public health emergency of international concern.

Next Steps

In normal circumstances, next steps would likely present a reasonable and *realistic* path to accomplish proposed solutions. However, these are not normal times, and the solutions I have proposed require the cooperation of three distinctly different institutions, two of which are under the control of two opposing political parties: (1) the Executive Branch (Democrats); (2) the House of Representatives (Republicans); and (3) the United States Senate, which is nominally under the control of Democrats but subject to Republican filibuster. Thus, the path forward is fraught with hyper-partisan political landmines. Notwithstanding this, the next steps lay with the Biden Administration as well as the majority and minority leaders of the House of Representatives and the Senate.

Future Research

This thesis is not, nor was it intended to be, a definitive solution to the issues that plague the SNS. Rather, it is a first step, and additional research is required. Proposed areas of future research include, but are not limited to:

- methods for improving communication and coordination with all 62 SNS Project Areas, 1,500 local health departments, and 6,000 hospitals in the United States, its Territories, and Freely Associated States;
- domestic, regional, and international supply chain management as it relates to the SNS and its stockpile of medical countermeasures; and

- domestic, regional, and international supply chain routes and transportation as it relates to the SNS and its stockpile of medical countermeasures.

Proposed Future Research Questions (FRQ)

- FRQ 1: How can the SNS improve the quality, quantity, and transparency of its communications with the 62 project area SNS coordinators?
- FRQ 2: What inventory management system can the SNS implement that would provide transparency to the 62 project area SNS coordinators on what is currently in the Stockpile Managed Inventory (SMI) and Vendor Managed Inventory (VMI) and are available to be requested?
- FRQ 3: What type of consolidated transportation systems or agreements can the SNS enter into that would maximize the efficiency, efficacy, cost, and security associated with transporting SNS SMI and VMI to the 62 project areas and internally within the 62 project areas?
- FRQ 4: How can the United States improve its domestic (continental US) supply chain management for public health emergency and medical countermeasure materials to prevent future disruptions like those seen during the height of covid-19 in the short, medium, and long term?

Chapter VI

Conclusion

Our world is interconnected more than ever before—
by global travel and trade, technology, and even our viruses.

—Outbreak: Epidemics in a Connected World Exhibit⁷⁸

The Strategic National Stockpile has played an important role in this nation's security, public health (domestic, and national) for over 20 years. There is no reason this should ever change. But as we saw with responses to the covid-19 pandemic, there is a need for significant improvements in the SNS operations, stockpiling, and important funding. This cannot happen, however, through sheer will or the desire of SNS staff. Rather, it requires the commitment and buy-in of leadership in the US Department of Health and Human Services, the Executive Office of the President, the US House of Representatives, and the US Senate. Additionally, it needs the support and buy-in of professional and industry organizations responsible for public health, emergency management, pharmaceuticals, and industry. More importantly, it needs the support of the public.

Now is the time for these changes to occur. However, they will not happen overnight, nor will they happen between now and the end of the year. Rather, it will take time to achieve. Part of this is the realities of legislative and budget processes in the

78. Temporary exhibit at the Smithsonian Museum of Natural History.

federal government, the Executive Office of the President, Office of Budget and Management, Congressional Budget Office, and most importantly the several committees and subcommittees of the House of Representatives and Senate.

Another critical obstacle is the current partisan political environment that not only Washington, DC, but the entire nation finds itself in. It will take time, the patience of Job, the wisdom of Solomon, tenacity, perseverance, and a bit of luck to achieve this change, but it is possible.

Although it has been over 20 years since the anthrax attack on the US Congress, and significant improvements have been made in postal security, it should not take another attack to convince our elected leaders to act. Nor should it take another September 11th, Hurricane Katrina, or pandemic to prompt such action. However, politics being what they are, that is exactly what it might take. Let us hope that is not the case. Let us hope that through the hard work of all concerned, both inside and outside of “official Washington,” the country can achieve this noble goal of improving the nation’s public health safety and security and, by extension, the domestic and national security of the United States.

As Niccolò Machiavelli wrote in *The Prince*:

There is nothing more difficult to take in hand, more perilous to conduct, or more uncertain in its success, then to take the lead in the introduction of a new order of things. Because the innovator has for enemies all those who have done well under the old conditions, and lukewarm defenders in those who may do well under the new. This coolness arises partly from fear of the opponents, who have the laws on their side, and partly from the incredulity of men, who do not readily believe in new things until they have had a long experience of them.⁷⁹

79. Niccolò Machiavelli, “Chapter 6: Concerning new Principalities Which Are Acquired By One’s Own Arms and Ability,” *The Prince*, Lit2Go Edition, (1916). <https://etc.usf.edu/lit2go/217/the-prince/5586/chapter-6-concerning-new-principalities-which-are-acquired-by-ones-own-arms-and-ability/>.

Now is the time to take that risk. The United States cannot suffer more than 1.1 million⁸⁰ fatalities from a pandemic again. Instead, the nation must be proactive in preparing for the next pandemic and other public health emergencies it will face in the future. As Dr. Lucey said in 2016, *before* the arrival of COVID-19: “What’s next is already here; we just haven’t recognized it yet.”⁸¹

However, it is not all doom and gloom. We have seen positive steps already being taken. For the 2023 budget, President Biden requested an increase of \$270 million and 70 full-time equivalent positions for the SNS—an increase of 38.3% in the budget and a 27% increase in the number of SNS personnel.⁸² This is a positive change that will have a significant improvement on the overall operations of the SNS.

Furthermore, in July 2022, the HHS Secretary transformed the Headquarters Staff Division of the Office of the Assistant Secretary for Preparedness and Response to an Operational Division as the Administration of Strategic Preparedness and Response. Additionally, the Director of the SNS was promoted from a division chief to a Deputy Assistant Secretary with a direct line or report to the Assistant Secretary for Preparedness and Response and her Principal Deputy Assistant Secretary, instead of having several intermediate supervisors between them.

There is hope. Let us hope that this thesis and the suggestions and road map it lays out will reach those who need to read it, and those who have the authority to act on the suggestions and, more importantly, *will* act on them. Additionally, there is light at the

80. As of February 14, 2023, at 5:12 pm ET. CDC, “Daily Update for the United States.” Last updated February 14, 2023. <https://www.cdc.gov/globalhealth/healthprotection/errb/global-rrt.htm>.

81. Temporary exhibit at the Smithsonian Museum of Natural History.

82. HHS/ASPR, *Fiscal Year 2023 Public Health and Social Services Emergency Fund: Justification of the Estimates for Appropriations Committee* (Washington, DC: Department of Health and Human Services, 2022), 111.

end of the tunnel regarding the COVID-19 public health emergency that the United States continues to deal with. Yes, it is probable that COVID-19 will never be eradicated from the face of the Earth. However, it will (hopefully) soon, if it has not already done so, become endemic, like the annual flu, instead of the epidemic (pandemic) that it so recently has been.

Finally, it is heartening to see all the hard work that the nation's public health practitioners perform day in and day out. Their efforts may have become politicized in today's partisan political environment, but the personnel still carry on. These dedicated professionals still go to work every day to help and support the public and ensure their health and safety. It is truly appreciated, and while it may never be fully recognized, they and the many healthcare providers they work with have made an innumerable and heroic contribution to the health and safety of every individual, community, state, territory, and region of the United States.

Appendix A

Legal Authorities

Executive Orders

Executive Order 13526. 3 C.F.R. § 13526 (2010). “Classified National Security Information.” *Federal Register* 75, no. 2 (January 5, 2010): 707-31.
<https://www.govinfo.gov/content/pkg/FR-2010-01-05/pdf/E9-31418.pdf>.

Legislation

Defense Production Act of 1950, as amended, Pub. L. No. 81-774, 64 Stat. 798 (1950), 50 U.S.C. §§ 4501 *et seq.* (2018). https://www.fema.gov/sites/default/files/2020-03/Defense_Production_Act_2018.pdf.

Disaster Relief Act of 1974, as amended, Pub. L. 93-288, 88 Stat. 143 (1974),
<https://www.govinfo.gov/link/statute/88/143?link-type=pdf>.

Drug Quality and Security Act, Pub. L. 113-54, 127 Stat. 587 (2013).

Federal Food, Drug, and Cosmetic Act, as amended, Pub. L. 75-717, 52 Stat. 1040 (1938), *See* 42 U.S.C. § 360bbb-3.

Homeland Security Act of 2002, Pub. L. No. 107-296, 116 Stat. 2135 (2002).
<https://www.congress.gov/107/plaws/publ296/PLAW-107publ296.pdf>.

National Emergencies Act, as amended, 50 U.S.C. §1601 *et seq.* (2018), Pub. L. 94-412, 90 Stat. 1255 (1976).

Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999, Pub. L. No. 105-277, 112 Stat. 2681 (1998).
<https://www.congress.gov/105/plaws/publ277/PLAW-105publ277.pdf>.

Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006, 42 U.S.C. §§ 300hh *et seq.* (2018), Pub. L. No. 109-417, 120 Stat. 2831 (2006).
<https://www.congress.gov/109/plaws/publ417/PLAW-109publ417.pdf>.

Pandemic and All-Hazards Preparedness and Advancing Innovation (PAHPAIA) Act of 2019, 42 U.S.C. §§ 347d-3a – 347d-3c, Pub. L. No. 116-22, 133 Stat. 905 (2019).
<https://www.congress.gov/116/plaws/publ22/PLAW-116publ22.pdf>.

Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) of 2013, 42 U.S.C. §§ 300hh *et seq.* (2018), Pub. L. No. 113-5, 127 Stat. 161 (2013). <https://www.congress.gov/113/plaws/publ5/PLAW-113publ5.pdf>.

Project Bioshield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835 (2004). <https://www.congress.gov/108/plaws/publ276/PLAW-108publ276.pdf>.

Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (2002), *See* 42 U.S.C. §§ 247d-6b and 300hh-10 (2018). <https://www.congress.gov/107/plaws/publ188/PLAW-107publ188.pdf>.

Public Health Service Act, as amended, Pub. L. 78-410, 58 Stat. 682, ch. 373 (1944), *See* 42 U.S.C. § 247d *et seq.* (2018). <https://www.govinfo.gov/content/pkg/USCODE-2019-title42/pdf/USCODE-2019-title42-chap6A-subchapII-partB-sec247d.pdf>.

Public Readiness and Emergency Preparedness Act, 42 U.S.C. §§ 247d-6d – 247d-6e (2018), Pub. L. No. 109-148, 119 Stat. 2680 (2005). <https://www.congress.gov/109/plaws/publ148/PLAW-109publ148.pdf>.

Robert T. Stafford Disaster Relief and Emergency Assistance Act, Pub. L. 100-707, 102 Stat. 4689 (1988), 42 U.S.C. § 5121 *et seq.* (2018). <https://www.govinfo.gov/content/pkg/STATUTE-102/pdf/STATUTE-102-Pg4689.pdf>.

Social Security Act of 1935, Pub. L. 74-271, 49 Stat. 620 (1935), *See* 42 U.S.C. § 1320b-5 (2018).

International Agreements

Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [commonly known as the TRIPS Agreement].

Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, April 10, 1972, 1015 U.N.T.S. 163.

Appendix B

List of Acronyms and Key Words

Acronyms

ASPR	Assistant Secretary for Preparedness and Response
ASPR	Administration for Strategic Preparedness and Response, US Department of Health and Human Services (<i>See</i> HHS-ASPR)
ASPR	(Office of the) Assistant Secretary for Preparedness and Response, US Department of Health and Human Services (<i>See</i> HHS/ASPR)
ASTHO	Association of State and Territorial Health Officials
BARDA	Biomedical Advanced Research and Development Authority
CBRN	Chemical, Biological, Radiological, and Nuclear [Threats / Weapons]
CBRNE	Chemical, Biological, Radiological, Nuclear and high-yield Explosive [Threats / Weapons]
CDC	Centers for Disease Control and Prevention
CRI	Cities Readiness Initiative
DHS	US Department of Homeland Security
DoD	US Department of Defense
DPA	Defense Production Act of 1950
DSNS	Division of Strategic National Stockpile
EID	Emerging Infectious Diseases
EUA	Emergency Use Authorization
EUI	Emergency Use Instructions
FEMA	Federal Emergency Management Agency

FDA	US Food and Drug Administration
HHS	US Department of Health and Human Services
HHS/ASPR	US Department of Health and Human Services, Administration for Strategic Preparedness and Response
HHS-ASPR	US Department of Health and Human Services, (Office of the) Assistant Secretary for Preparedness and Response
HSPD	Homeland Security Presidential Decision
MCM	Medical Countermeasures
NAE	National Academy of Engineering
NAM	National Academy of Medicine
NAS	National Academy of Sciences
NASEM	National Academies of Sciences, Engineering, and Medicine
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NORTHCOM	US Northern Command
NPS	National Pharmaceutical Stockpile
NSC	National Security Council
OPHPR	Office of Public Health Preparedness and Response
OWS	Operation Warp Speed
PAHPA	Pandemic and All-Hazards Preparedness Act of 2006
PAHPRA	Pandemic and All-Hazards Preparedness Reauthorization Act of 2013
PAHPAIA	Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019
PBA	Project Bioshield Act of 2004
PBS	Project BioShield
PHE	Public Health Emergency

PHEIC	Public Health Emergency of International Concern
PHEMCE	Public Health Emergency Medical Countermeasure Enterprise
PHEP	Public Health Emergency Preparedness
PHS Act	Public Health Services
PHSBPRA	Public Health Security and Bioterrorism Preparedness and Response Act of 2002
POD	Point of Dispensing
PPE	Personal Protective Equipment
PREP Act	Public Readiness and Emergency Preparedness Act
PSCN	Pandemic Supply Chain Network
R&D	Research and Development
SLTT	State, Local, Tribal, and Territorial
SNS	Strategic National Stockpile
USDA	US Department of Agriculture
USPHS	US Public Health Service
VA	US Department of Veterans Affairs
WHO	World Health Organization
WMD	Weapons of Mass Destruction

NB: The word “CHEMPACK” appears throughout this thesis. However, it is *not* an acronym, but a project name and a metonym for its containers.

Keywords

Countermeasures

COVID-19

Disaster Management

Emergency Management

Emergency Preparedness and Response

Logistics

Pandemic

SARS-CoV-19

Supply Chain

Supply Chain Management

Appendix C

Glossary

Administration for Strategic Preparedness and Response. The Administration for Strategic Preparedness and Response (HHS-ASPR), was created as an operational unit of the US Department of Health and Human Services (HHS), on July 22, 2022. It replaced the HHS Staff Division of the Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR).⁸³ HHS-ASPR leads the nation’s medical and public health preparedness for, response to, and recovery from disasters and public health emergencies. ASPR collaborates with hospitals, healthcare coalitions, biotech firms, community members, state, local, tribal, and territories governments, and other partners across the country to improve readiness and response capabilities.⁸⁴

Assistant Secretary for Preparedness and Response. The US Department of Health and Human Services’ Assistant Secretary for Preparedness and Response (ASPR) is a Presidentially appointed, with the advice and consent of the United States Senate, who typically holds the grade of Vice Admiral in the US Public Health Service. ASPR oversees the US Department of Health and Human Services operational unit Administration for Strategic Preparedness and Response (HHS-ASPR).

Assistant Secretary for Preparedness and Response, Office of the. The Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR) was an HHS Staff Division that was disestablished on July 22, 2022. It was replaced by the Administration for Strategic Preparedness and Response.

CHEMPACK. CHEMPACK is not an acronym, but rather the name of a project and a metonym for its containers. CHEMPACK consists of containers of nerve agent antidotes placed in secure locations in local jurisdictions around the country to allow rapid response to a chemical incident. These medications treat the

83. US Department of Health and Human Services, Administration for Strategic Preparedness and Response (HHS-ASPR), “Introducing the Administration for Strategic Preparedness and Response,” *ASPR Blog*, July 22, 2022, at 19:33:00 UTC.
<https://aspr.hhs.gov/ASPRBlog/Lists/Posts/CustomView.aspx?ID=439>.

84. HHS-ASPR, “Mission and Key Priorities,”
<https://aspr.hhs.gov/AboutASPR/WorkingwithASPR/BoardsandCommittees/Pages/Mission-and-Key-Priorities.aspx>.

symptoms of nerve agent exposure and can be used even when the actual agent is unknown.⁸⁵

Cities Readiness Initiative. The Cities Readiness Initiative (CRI) is a federally funded program designed to enhance preparedness in the nation's largest population centers, where nearly 60% of the population resides, to effectively respond to large public health emergencies needing life-saving medicines and medical supplies. State and large metropolitan public health departments use CRI funding to develop, test, and maintain plans to quickly receive medical countermeasures from the Strategic National Stockpile and distribute them to local communities.⁸⁶

Division of Strategic National Stockpile. The Division of Strategic National Stockpile (DSNS) is organized to support any public health threat. Stockpile staff represent a variety of specialties, including pharmacy, clinical care, emergency management, medical logistics and operations, quality control, public health, procurement and financial management, information technology, strategic planning, training, policy and communications. All work together to ensure the right resources are ready and can get to the right place at the right time.⁸⁷

Emergency Use Authorization. The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological, and nuclear (CBRN) threats including infectious diseases, by facilitating the availability and use of medical countermeasures (MCMs) needed during public health emergencies.⁸⁸

Emergency Use Instructions. The EUI [Emergency Use Instructions] authority allows [the] CDC to facilitate the availability of streamlined information about the use of eligible, approved MCMs needed during public health emergencies without FDA needing to issue an Emergency Use Authorization.⁸⁹

Emerging Infectious Diseases. Emerging infectious diseases (EIDs) are infectious diseases that have newly appeared in a population or have existed but are rapidly increasing in incidence or geographic range, or that are caused by one of the

85. HHS/ASPR, "CHEMPACK," last updated August 09, 2021. <https://www.phe.gov/about/sns/Pages/CHEMPACK.aspx>.

86. Centers for Disease Control and Prevention, Cities Readiness Initiative. Last updated April 4, 2022. <https://www.cdc.gov/cpr/readiness/mcm-readiness.html>.

87. HHS/ASPR, About Who We Are. Last updated March 28, 2022. <https://www.phe.gov/about/sns/Pages/about.aspx>.

88. Food and Drug Administration, "Emergency Use Authorization." Last updated August 26, 2022. <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

89. Food and Drug Administration, "Emergency Dispensing Orders and Emergency Use Instructions EUI." Last updated November 17, 2021. <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-dispensing-orders-and-emergency-use-instructions-eui>.

NIAID Category A, B, or C priority pathogens.⁹⁰ See “NIAID Category A priority pathogen,” “NIAID Category B priority pathogens,” and “NIAID Category C priority pathogens” below.

Homeland Security Presidential Decision. Homeland Security Presidential Decisions (HSPDs) are directives “that shall record and communicate presidential decisions about the homeland security policies of the United States.”⁹¹

Infective. Capable of transmitting an infection.⁹²

Medical Countermeasures. Medical countermeasures (MCMs) are medicines and medical supplies regulated by the U.S. Food and Drug Administration (FDA) that can be used to diagnose, prevent, or treat diseases related to chemical, biological, radiological, or nuclear (CBRN) threats, emerging infectious diseases, or a natural disaster.⁹³ MCMs can include: biological products (vaccines, blood products, and antibodies); drugs (antimicrobial or antiviral drugs); or devices (diagnostic tests to identify threat agents and personal protective equipment (PPE)).⁹⁴

NIAID Category A priority pathogens. Category A pathogens are those organisms/biological agents that pose the highest risk to national security and public health because they: can be easily disseminated or transmitted from person to person; result in high mortality rates and have the potential for major public health impact; might cause public panic and social disruption; and require special action for public health preparedness.⁹⁵

NIAID Category B priority pathogens. Category B pathogens are the second highest priority organisms/biological agents. They: are moderately easy to disseminate; result in moderate morbidity rates and low mortality rates; and require specific enhancements for diagnostic capacity and enhanced disease surveillance.⁹⁶

NIAID Category C priority pathogens. Category C pathogens are the third highest priority and include emerging pathogens that could be engineered for mass

90. National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIAID), “Emerging Infectious Diseases Pathogens.” Last updated July 26, 2018. <https://www.niaid.nih.gov/research/emerging-infectious-diseases-pathogens>.

91. US Library of Congress, Congressional Research Service, *Presidential Directives: Background and Overview*, Harold C. Relyea, Order No. 98-611 GOV, 2008.

92. Thomas Lanthrop Stedman, *Stedman’s Medical Dictionary*, 28th ed. (Philadelphia: Lippincott: 2006) see “infective,” 970.

93. CDC, “MCM Readiness,” Medical Countermeasure Readiness. Last updated April 29, 2022. <https://www.cdc.gov/cpr/readiness/mcm-readiness.html>.

94. CDC, “mcm2-508,” Medical Countermeasures. Last updated October 5, 2020. <https://www.cdc.gov/cpr/readiness/mcm2-508.html>.

95. NIAID, NIAID Emerging Infectious Diseases / Pathogens.

96. NIAID, NIAID Emerging Infectious Diseases / Pathogens.

dissemination in the future because of: availability, ease of production and dissemination, and potential for high morbidity and mortality rates and major health impact.⁹⁷

National Pharmaceutical Stockpile. The National Pharmaceutical Stockpile (NPS) was the forerunner to the SNS. The SNS replaced it in 2004.

National Security Council. The National Security Council (NSC) is the President's principal forum for considering national security and foreign policy matters with his or her senior advisors and cabinet officials. Since its inception under President Truman, the Council's function has been to advise and assist the President and coordinate national security matters among government agencies.⁹⁸

Operation Warp Speed. Operation Warp Speed was a partnership between the Departments of Health and Human Services (HHS) and Defense (DOD) that aimed to help accelerate the development of a COVID-19 vaccine.⁹⁹

Pandemic Supply Chain Network. The Pandemic Supply Chain Network (PSCN) is a public-private initiative that seeks to increase supply chain and logistics capacities and develop an information platform to more equitably match supplies with demand. By focusing on supply chain logistics to support the response to large-scale health emergencies, the partnership complements other efforts that are underway to strengthen national and international systems that prevent and manage future pandemics.¹⁰⁰

Project BioShield. Project BioShield (PBS) was created by the Project BioShield Act (PBA) of 2004. Its purpose is to accelerate the research, development, purchase, and availability of effective medical countermeasures against biological, chemical, radiological, and nuclear (CBRN) threats.¹⁰¹

Public Health Emergency. A public health emergency is defined as “an occurrence or imminent threat of an illness or health condition, caused by bioterrorism, epidemic or pandemic disease, or an infectious agent or biological toxin, that

97. NIAID, NIAID Emerging Infectious Diseases / Pathogens.

98. White House, National Security Council. Last updated September 2, 2022, <https://www.whitehouse.gov/nsc/>.

99. U.S. GAO-21-319, “Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing (2021).” <https://www.gao.gov/assets/gao-21-319.pdf>.

100. World Food Programme, “Innovative Supply Chain Information Platform Will Help Prepare Next Pandemic.” Last updated March 9, 2017. <https://www.wfp.org/news/innovative-supply-chain-information-platform-will-help-prepare-next-pandemic>.

101. BARDA, “Project BioShield,” Project BioShield, n.d. <https://www.medicalcountermeasures.gov/barda/cbrn/project-bioshield>.

poses a substantial risk to humans by either causing a significant number of human fatalities or permanent or long-term disability.”¹⁰²

Public Health Emergency Medical Countermeasure Enterprise. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) coordinates Federal efforts to enhance chemical, biological, radiological and nuclear threats (CBRN) and emerging infectious diseases (EID) preparedness from a medical countermeasure (MCM) perspective.¹⁰³

Public Health Emergency of International Concern. An extraordinary event which is determined, as provided in these Regulations: (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response.¹⁰⁴

Strategic National Stockpile. The Strategic National Stockpile (SNS) is part of the federal medical response infrastructure and can supplement medical countermeasures needed by states, tribal nations, territories and the largest metropolitan areas during public health emergencies. The supplies, medicines, and devices for lifesaving care contained in the stockpile can be used as a short-term, stopgap buffer when the immediate supply of these materials may not be available or sufficient.¹⁰⁵ It replaced the NPS in 2004.

Weapons of Mass Destruction. A weapon of mass destruction is a nuclear, radiological, chemical, biological, or other device that is intended to harm a large number of people.¹⁰⁶

102. Center for Law and the Public’s Health at Georgetown and Johns Hopkins Universities, The Model State Emergency Health Powers Act, October 23, 2001. <https://biotech.law.lsu.edu/blaw/bt/MSEHPA.pdf>.

103. HHS/ASPR, “Default,” Public Health Emergency Medical Countermeasures Enterprise. Last updated: March 26, 2021, <https://www.phe.gov/Preparedness/mcm/phemce/Pages/default.aspx>.

104 World Health Organization (hereafter referred to as WHO), *International Health Regulations* (2005), 2nd ed. (Geneva: WHO, 2008), 9.

105. HHS/ASPR, “Strategic National Stockpile.” Last updated August 09, 2021. <https://web.archive.org/web/20200403134414/https://www.phe.gov/about/sns/Pages/default.aspx>.

106 US Department of Homeland Security, “Weapons of Mass Destruction.” Last updated November 1, 2022, <https://www.dhs.gov/topics/weapons-mass-destruction>.

Appendix D

Survey Questions and Logic

Last Updated: 31 July 2022
Version: 10
IRB Approval No.: IRB22-0783

Note: All scales are from 1 to 10, with 1 being the lowest and 10 being the highest.

SECTION I CONSENT STATEMENT

Statement: Mandatory IRB Consent Statement

Key Information

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are currently, or have previously, worked in/with the Strategic National Stockpile program, at the local, state, tribal, and/or federal level(s).

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- Your participation is completely voluntary.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- Your refusal to participate will not result in any consequences or any loss of benefits that you are otherwise entitled to receive.
- You can ask all the questions you want before you decide.

Why is this research being done?

This research is being done to identify improvements needed to the nation's Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and Strategic National Stockpile (SNS) programs, looking at lessons learned from COVID-19 and from the opinions of experts around the US.

PHEMCE

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) coordinates Federal efforts to enhance chemical, biological, radiological and nuclear threats (CBRN) and emerging infectious diseases (EID) preparedness from a medical countermeasure (MCM) perspective. The PHEMCE is led by the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) and includes three primary HHS internal agency partners: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and the National Institutes of Health (NIH), as well as several interagency partners: the Department of Defense (DoD), the U.S. Department of Veterans Affairs (VA), the Department of Homeland Security (DHS) and the U.S. Department of Agriculture (USDA).

SNS

The Strategic National Stockpile (SNS) is part of the federal medical response infrastructure and can supplement medical countermeasures needed by states, tribal nations, territories and the largest metropolitan areas during public health emergencies. The supplies, medicines, and devices for lifesaving care contained in the stockpile can be used as a short-term, stopgap buffer when the immediate supply of these materials may not be available or sufficient.

The SNS team works every day to prepare and respond to emergencies, support state and local preparedness activities, and ensure availability of critical medical assets to protect the health of Americans. The role of the SNS is to supplement state and local supplies during public health emergencies. Many states have products stockpiled, as well. The supplies, medicines, and devices for life-saving care contained in the stockpile can be used as a short-term stopgap buffer when the immediate supply of adequate amounts of these materials may not be immediately available.

CHEMPACK

CHEMPACKs are containers of nerve agent antidotes placed in secure locations in local jurisdictions around the country to allow rapid response to a chemical incident. These medications treat the

symptoms of nerve agent exposure and can be used even when the actual agent is unknown.

How long will the research last and what will I need to do?

You are being asked to complete a research survey. We expect that the time requested of you to participate in a survey as part of this research will be less than one (1) hour.

If you would like to indicate that you are interested in possibly having a follow-up conversation with the study investigator about the topics addressed in the survey, you will be given the opportunity to tell us when you complete the survey. This is completely optional and you are not required to participate in any additional conversations or efforts as a part of this study. If you do indicate that you are interested in possibly having a follow up conversation, that conversation, if it occurs, will be less than one hour.

Is there any way being in this study could be bad for me?

At this time, we do not see foresee any risks associated with participating in this survey.

More detailed information about the study procedures can be found under “*What can I expect if I take part in this research*”.

Will being in this study help me in any way?

There are no direct benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include helping improve the United States’ Public Health Medical Countermeasures Enterprise (including its participation in the Pandemic Supply Chain Network (PSCN), and the Strategic National Stockpile program) going forward.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

What is the purpose of this research?

The purpose of this research is to improve the nation’s Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), including its Strategic National Stockpile (SNS) and CHEMPACK operations, including but not limited to: distribution, dispensing, logistics, operations, security, and training. This research is intended to find long-term solutions in structuring,

funding, and operating the PHEMCE to ensure its suitability and operational capability to respond to any emergency.

How long will I take part in this research?

Participation in this research is not expected to last longer than 45-minutes, unless you indicate that you may be willing to speak more with the study investigator to provide additional detail about your free text responses to questions.

What can I expect if I take part in this research?

The research will be conducted online, through a single research survey questionnaire, which should not take you more than one (1) hour to complete. As part of the survey, you will be given the option to opt-in to participate in a further interview. If you opt-in, the study investigator may contact you to obtain additional detail about your free text responses to questions. By opting-in to participate in a follow-up interview, your responses will become identifiable. If you do *not* opt-in, then your responses will remain anonymous.

If you participate in any follow-up interviews, the length will depend on your responses to the follow-up question, but should not exceed ninety (90) minutes. The interviews will be conducted by using mainly open-ended questions, with a few clarifying close-ended questions. Any follow-up interviews you participate in will be audio and/or video recorded to ensure accuracy. You will have the right to end the interview at any time.

What happens if I say yes, but I change my mind later?

If you withdraw your permission, you will no longer be able to participate in the study. No new information will be collected about you or from you by the study team and you will not be contacted further. Your withdrawal has no effect on the lawfulness of the data processing that occurred prior to your withdrawal.

Your Personal Information that has already been collected to the time of your withdrawal will be used to guarantee the integrity of the study and/or for any other purposes permitted under applicable data protection and privacy laws.

Your Personal Information will not be used for further research. However, if permitted by applicable law, your Personal Information may be anonymized so that the information does not identify you personally, and such anonymized information may be used for further research.

*If I take part in this research, how will my privacy be protected?
What happens to the information you collect?*

All reasonable efforts will be made to limit the use and disclosure of your Personal Information, including research study records to study staff, the IRB and possibly other representatives of this organization.

See “*What can I expect if I take part in this research?*” above for steps taken to protect your privacy and personal information.

Researcher Financial Interests in this Study

The researcher and faculty advisors have no financial interests in this study.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at:

- Kevin F. Jura, Principal Investigator, kej044@g.harvard.edu
- Doug Bond, PhD, Faculty Advisor & Research Director, dougbond@fas.harvard.edu
- Paul D. Biddinger, MD, FACEP, Faculty Advisor & Thesis Director, pbidding@hsph.harvard.edu

This research has been reviewed and approved by the Harvard University Area Institutional Review Board (“IRB”). You may talk to them at (617) 496-2847 or cuhs@harvard.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Submission of this survey constitutes your written consent to participate in this research.

Statement:

If you check the “Yes” answer, you are declaring that you have read and understood this consent form, have had the chance to ask any questions, and have freely given your consent to participate in this research.

If you check the “No” answer, you will not be able to participate in this survey.

- Question I-01: Having read all of the information provided, do you voluntarily consent to participate in this survey?
- Yes – *go to Section II*
 - No – *go to Section XXIX*

[NEXT BUTTON]

SECTION II DEMOGRAPHICS

- Question II-01: What is your gender?
- Female
 - Male
 - Non-Binary
 - I do not wish to identify at this time

- Question II-02: What is your age?
- 18 – 20 years old
 - 21 – 29 years old
 - 30 – 39 years old
 - 40 – 49 years old
 - 50 – 59 years old
 - 60 – 69 years old
 - 70 or older

- Question II-03: What is your highest level of education?
- High School Diploma or GED
 - Some college
 - Associate’s Degree (A.A., A.S., or A.A.S.)
 - Bachelor’s Degree
 - Master’s Degree
 - Research Doctorate
 - Professional Doctorate
 - Other

[NEXT BUTTON – *GO TO SECTION III*]

SECTION III AGENCY & EMPLOYMENT INFORMATION

- Question III-01: What HHS/FEMA Region are you located in?
- Region 1 (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont)
 - Region 2 (New Jersey, New York, Puerto Rico, and the Virgin Islands)
 - Region 3 (Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia)

- Region 4 (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee)
- Region 5 (Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin)
- Region 6 (Arkansas, Louisiana, New Mexico, Oklahoma, and Texas)
- Region 7 (Iowa, Kansas, Missouri, and Nebraska)
- Region 8 (Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming)
- Region 9 (Arizona, California, Hawaii, Nevada, American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Republic of the Marshall Islands, and the Republic of Palau)
- Region 10 (Alaska, Idaho, Oregon, and Washington)

Question III-02: How long have you been in your *current* position?

- Less than 1 year
- 1 – 5 years
- 6 – 10 years
- 11 – 15 years
- 16 – 20 years
- 21 – 25 years
- 26 – 30 years
- Over 30 years

Question III-03: Do you work for a governmental agency?

- Yes – *go to Section IV*
- No – *go to Section V*

[NEXT BUTTON]

SECTION IV

GOVERNMENTAL AGENCY

Question IV-01: At what level of government do you work at?

- Federal Government
- Military
- USPHS
- State Government
- Local Government
- Tribal Government
- Other

Question IV-02: What type of governmental agency do you work for?

- Department of (Public) Health (and Human Services)
- Hospital or Healthcare Organization

- Emergency Management
- Law Enforcement
- Fire Department
- EMS Department
- Other

[NEXT BUTTON – *GO TO SECTION VI*]

SECTION V

NON-GOVERNMENTAL AGENCY

Question V-01: What type of *non-governmental* agency do you work for?

- Hospital or Healthcare Organization
- Private EMS Agency
- Non-Profit Organization
- Trade Association
- Other

[NEXT BUTTON – *GO TO SECTION VI*]

SECTION VI

FAMILIARITY OF THE PHEMCE, SNS, AND CHEMPACK

Definitions

CHEMPACK – CHEMPACKs are containers of nerve agent antidotes placed in secure locations in local jurisdictions around the country to allow rapid response to a chemical incident. These medications treat the symptoms of nerve agent exposure and can be used even when the actual agent is unknown.¹⁰⁷

Familiar(-ity) – Having personal or intimate knowledge —used with “with.”¹⁰⁸ *C.f.* “Knowledgeable”: The fact or condition of knowing something with familiarity gained through experience or association; acquaintance with or understanding of a science, art, or technique; the fact or condition of being aware of something; the range of one’s information or understanding; the circumstance or condition of apprehending truth or fact through reasoning; the fact or condition of having information or of being learned.¹⁰⁹

Fit for Purpose – Appropriate; of a necessary standard; for its intended use.¹¹⁰

107. ASPR, “CHEMPACK,” <https://www.phe.gov/about/sns/Pages/CHEMPACK.aspx>.

108. Merriam-Webster, “Merriam-Webster Online Dictionary,” s.v. “knowledgeable,” <https://www.merriam-webster.com/dictionary/familiar>.

109. Merriam-Webster, “Merriam-Webster Online Dictionary,” s.v. “knowledgeable,” <https://www.merriam-webster.com/dictionary/knowledge>.

110. Wordhippo.com, “What is another word for ‘fit for purpose’,” https://www.wordhippo.com/what-is/another-word-for/fit_for_purpose.html.

Involvement – Active responsibility in/for planning, exercising, operations, mobilization or administration of PHEMCE, SNS, and/or CHEMPACK resources.

Participate(-ion) – To have a part or share in something.

PHEMCE – The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) coordinates Federal efforts to enhance chemical, biological, radiological and nuclear threats (CBRN) and emerging infectious diseases (EID) preparedness from a medical countermeasure (MCM) perspective. The PHEMCE is led by the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) and includes three primary HHS internal agency partners: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and the National Institutes of Health (NIH), as well as several interagency partners: the Department of Defense (DoD), the U.S. Department of Veterans Affairs (VA), the Department of Homeland Security (DHS) and the U.S. Department of Agriculture (USDA).¹¹¹

SNS – The Strategic National Stockpile (SNS) is part of the federal medical response infrastructure and can supplement medical countermeasures needed by states, tribal nations, territories and the largest metropolitan areas during public health emergencies. The supplies, medicines, and devices for lifesaving care contained in the stockpile can be used as a short-term, stopgap buffer when the immediate supply of these materials may not be available or sufficient. The SNS team works every day to prepare and respond to emergencies, support state and local preparedness activities, and ensure availability of critical medical assets to protect the health of Americans.¹¹²

Question VI-01: How familiar are you with the PHEMCE
Scale of 1 to 10

Question VI-02: How familiar are you with the Strategic National Stockpile (SNS)
Scale of 1 (I have never heard of it) to 10 (I am a Subject Matter Expert)

111. US Department of Health and Human Service Assistant Secretary for Preparedness and Response (“ASPR”), “Public Health Emergency Medical Countermeasures Enterprise,” from <https://www.phe.gov/Preparedness/mcm/phemce/Pages/default.aspx>.

112. ASPR, “Strategic National Stockpile,” <https://www.phe.gov/about/sns/Pages/default.aspx>.

- Question VI-03: How familiar are you with the CHEMPACK Program
Scale of 1 to 10
- Question VI-04: Does your organization participate in the PHEMCE Program
(including the SNS or CHEMPACK Program)?
Yes – *Go to Section VII*
No – *Go to Section XXV*
I’m not sure – *Go to Section XXV*

[NEXT BUTTON]

SECTION VII ORGANIZATIONAL PARTICIPATION – SNS (PART 1)

- Question VII-01: Does your organization participate in the SNS?
Yes – *Go to Section VII*
No – *Go to Section IX*
I’m not sure – *Go to Section IX*

[NEXT BUTTON]

SECTION VIII ORGANIZATIONAL PARTICIPATION – SNS (PART 2)

- Question VIII-01: How involved is your agency’s participation in the SNS Program?
Scale of 1 (It is NOT involved in the SNS Program) to 10 (It is extremely involved with the SNS Program)
- Question VIII-02: How involved are you in your agency’s participation in the SNS Program?
Scale of 1 (I am NOT involved in the SNS Program) to 10 (I am extremely involved with the SNS Program)

[NEXT BUTTON – GO TO SECTION IX]

SECTION IX ORGANIZATIONAL PARTICIPATION – CHEMPACK (PART 1)

- Question IX-01: Does your agency participate in the CHEMPACK Program?
Yes – *Go to Section X*
No – *Go to Section XI*
I am not sure – *Go to Section XI*

[NEXT BUTTON]

SECTION X ORGANIZATIONAL PARTICIPATION – CHEMPACK (PART 2)

- Question X-01: How involved is your agency’s participation in the CHEMPACK Program?

Scale of 1 (It is NOT involved in the CHEMPACK Program) to 10 (It is extremely involved with the CHEMPACK Program)

Question X-02: How involved are you in your agency's participation in the CHEMPACK Program?
Scale of 1 (I am NOT involved in the CHEMPACK Program) to 10 (I am extremely involved with the CHEMPACK Program)

[NEXT BUTTON – GO TO SECTION XI]

SECTION XI SECURITY

Question XI-01: How familiar are you with your organization's PHEMCE security procedures?
Scale of 1 (I have never heard of it) to 10 (I am a subject matter expert)

Question XI-02: How familiar are you with your organization's SNS security procedures?
Scale of 1 (I have never heard of it) to 10 (I am a subject matter expert)

Question XI-03: How familiar are you with your agency's CHEMPACK security procedures?
Scale of 1 (I have never heard of it) to 10 (I am a subject matter expert)

[NEXT BUTTON – GO TO SECTION XII]

SECTION XII PRESSURE

Question XII-01: In your *current* position, with(in) the PHEMCE, SNS, or CHEMPACK programs, have you ever been pressured to take a certain action or make a certain decision that you did not agree with?

- Yes – go to Section XIII
- No – go to Question XV

[NEXT BUTTON]

SECTION XIII PRESSURED – FOLLOW-UP QUESTIONS (PART 1)

Question XIII-01: In your experience, has the utilization of PHEMCE, SNS or CHEMPACK Program resources been influenced by factors other than scientific or medical needs of the disaster event?
Yes – Go to Section XIV

No – *Go to Section XV*
I'm not sure – *Go to Section XV*

[NEXT BUTTON]

SECTION XIV PRESSURED – FOLLOW-UP QUESTIONS (PART 2)

Question XIV-01: What factors do you think may have influence the utilization of PHEMCE, SNS, or CHEMPACK Program resources in this case?
Select all that apply

- Budgetary reasons
- Non-Medical/Scientific reasons
- Legal reasons
- Political reasons
- Unknown reasons
- Other [manual entry of description]

Question XIV-02 Please feel free to expand on your answer, in your own words. All information provided is anonymized and kept confidential.
Long answer field

[NEXT BUTTON – *GO TO SECTION XV*]

SECTION XV FIT FOR PURPOSE – PHEMCE

Question XV-01: Do you feel the current designs of the Public Health Medical Countermeasure Enterprise (PHMCE), which includes Strategic National Stockpile (SNS) and the CHEMPACK Program, are properly structured to adequately meet anticipatable real-world disaster needs for healthcare emergency responses / events?

- Yes – *Go to Section XX*
- No – *Go to Section XVI*
- I don't know – *Go to Section XVI*

[NEXT BUTTON]

SECTION XVI FIT FOR PURPOSE – SNS (PART 1)

Explanatory Paragraph Since you said “no” to whether or not the PHEMCE is fit for purpose, we are now going to ask you questions about both the SNS and CHEMPACK Programs.

Question XVI-01: Do you feel the current designs of the Strategic National Stockpile (SNS) (*not* including the CHEMPACK Program), is properly structured to meet and respond to actual predicted disaster needs for healthcare emergency responses / events?

- Yes – Go to Section XVIII
- No – Go to Section XVII
- I don't know – Go to Section VII

[NEXT BUTTON]

SECTION XVII FIT FOR PURPOSE – SNS (PART 2)

Question XVII-01: In your own words, describe why you do not feel the SNS (*NOT* including the CHEMPACK Program) is not properly structured to respond to actual predicted disaster needs for healthcare emergency responses or events? (*Please do not offer suggestions for improvement. You will be able to provide those in the next questions*)
Long answer field

Explanatory Paragraph The following questions are for suggestions for improvements in the short-, medium-, and long-term time periods.

Question XVII-02: In your own words, describe what improvements or restructuring needs to be taken, and by whom, in order for the SNS (*NOT* including the CHEMPACK Program) to be properly structured to respond to actual predicted disaster needs for healthcare emergency responses or events in the *short-term*? (*This may include statutory, regulatory, or programmatic changes*)
Long answer field

Question XVII-03: In your own words, describe what improvements or restructuring needs to be taken, and by whom, in order for the SNS (*NOT* including the CHEMPACK Program) to be properly structured to respond to actual predicted disaster needs for healthcare emergency responses or events in the *mid-term*? (*This may include statutory, regulatory, or programmatic changes*)
Long answer field

Question XVII-04: In your own words, describe what improvements or restructuring needs to be taken, and by whom, in order for the SNS (*NOT* including the CHEMPACK Program) to be properly structured to respond to actual predicted disaster needs for healthcare emergency responses or events in the *long-term*? (*This may include statutory, regulatory, or programmatic changes*)
Long answer field

[NEXT BUTTON – GO TO SECTION XVIII]

SECTION XVIII FIT FOR PURPOSE – CHEMPACK (PART 1)

Explanatory Paragraph: Since you said “no” or “I am not sure” to whether or not the PHEMCE is fit for purpose, we are now going to ask you questions about the CHEMPACK Program.

Question XVIII-01: Do you feel the current designs of the CHEMPACK Program, is properly structured to meet and respond to actual predicted disaster needs for healthcare emergency responses / events?

- Yes – *Go to Section XX*
- No – *Go to Section XIX*
- I don’t know – *Go to Section XIX*

[NEXT BUTTON]

SECTION XIX FIT FOR PURPOSE – CHEMPACK (PART 2)

Question XIX-01 In your own words, describe why you do not feel the CHEMPACK Program is not properly structured to respond to actual predicted disaster needs for healthcare emergency responses or events? (*Do not offer suggestions for improvement. You will be able to provide those in the next questions*)
Long answer field

[NEXT BUTTON – *GO TO SECTION XX*]

SECTION XX FIT FOR PURPOSE – SECURITY

Question XX-01: Do you feel the current designs of the federal security procedures for the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which includes the Strategic National Stockpile (SNS) and the CHEMPACK Program, are properly structured to adequately meet anticipatable real-world disaster needs for healthcare emergency responses / events?

- Yes – *Go to Section XXV*
- No – *Go to Section XXI*
- I don’t know – *Go to Section XXI*

[NEXT BUTTON]

SECTION XXI FIT FOR PURPOSE – SECURITY – SNS (PART 1)

Explanatory Paragraph: Since you said “no” or “I am not sure” to whether or not the security procedures for the PHEMCE (including the SNS and CHEMPACK Program) are fit for purpose, we are

not going to ask you questions about the security procedures for the SNS.

- Question XXI-01: Do you feel the current designs of the security procedures for the Strategic National Stockpile (SNS) are properly structured to meet and respond to actual or predicted disaster needs for healthcare emergency responses / events?
- Yes – Go to Section XXIII
 - No – Go to next Section XXII
 - I don't know – Go to Section XXII

[NEXT BUTTON]

SECTION XXII FIT FOR PURPOSE – SECURITY – SNS (PART 2)

- Question XXII-01: In your own words, describe why you do not feel the security procedures for the SNS are properly structured to respond to actual predicted disaster needs for healthcare emergency responses or events? *(Please do not offer suggestions for improvement. You will be able to provide those in the following questions.)*
Long answer field

Explanatory Paragraph: The following questions are suggestions for improvements in the short-, medium, and long-term time periods.

- Question XXII-02: In your own words, describe what improvements or restructuring needs to be taken, and by whom, in order for the security procedures for the SNS Program to be properly structured to respond to actual or predicted disaster needs, for healthcare emergency responses or events in the SHORT-term?
Long answer field

- Question XXII-03: In your own words, describe what improvements or restructuring needs to be taken, and by whom, in order for the security procedures for the SNS Program to be properly structured to respond to actual or predicted disaster needs, for healthcare emergency responses or events in the MEDIUM-term?
Long answer field

- Question XXII-04: In your own words, describe what improvements or restructuring needs to be taken, and by whom, in order for the security procedures for the SNS Program to be properly structured to respond to actual or predicted disaster needs, for healthcare emergency responses or events in the LONG-term?
Long answer field

[NEXT BUTTON – GO TO SECTION XXIII]

SECTION XXIII FIT FOR PURPOSE – SECURITY – CHEMPACK (PART 1)

Explanatory Paragraph: Since you said “no” or “I am not sure” to whether or not the security procedures for the PHEMCE (including the SNS and CHEMPACK Program) are fit for purpose, we are not going to ask you questions about the security procedures for the CHEMPACK.

Question XXIII-01: Do you feel the current designs of the security procedures for the CHEMPACK Program are properly structured to meet and respond to actual or predicted disaster needs for healthcare emergency responses / events?

- Yes – Go to Section XXV
- No – Go to next Section XXIV
- I don’t know – Go to Section XXIV

[NEXT BUTTON]

SECTION XXIV FIT FOR PURPOSE – SECURITY – CHEMPACK (PART 2)

Question XXIV-01: In your own words, describe why you do not feel the security procedures for the CHEMPACK Program are properly structured to respond to actual predicted disaster needs for healthcare emergency responses or events? *(Please do not offer suggestions for improvement. You will be able to provide those in the following questions.)*

Long answer field

Explanatory Paragraph: The following questions are suggestions for improvements in the short-, medium, and long-term time periods.

Question XXIV-02: In your own words, describe what improvements or restructuring needs to be taken, and by whom, in order for the security procedures for the CHEMPACK Program to be properly structured to respond to actual or predicted disaster needs, for healthcare emergency responses or events in the SHORT-term?

Long answer field

Question XXIV-03: In your own words, describe what improvements or restructuring needs to be taken, and by whom, in order for the security procedures for the CHEMPACK Program to be properly structured to respond to actual or predicted disaster needs, for healthcare emergency responses or events in the MEDIUM-term?

Long answer field

Question XXIV-04: In your own words, describe what improvements or restructuring needs to be taken, and by whom, in order for the security procedures for the CHEMPACK Program to be properly structured to respond to actual or predicted disaster needs, for healthcare emergency responses or events in the LONG-term?
Long answer field

[NEXT BUTTON – GO TO SECTION XXV]

SECTION XXV ADDITIONAL COMMENTS

Question XXV-01: Do you have any additional comments for the research team?
Long answer field

[NEXT BUTTON – GO TO SECTION XXVI]

SECTION XXVI FUTURE RESEARCH

Question XXVI-01: Are you willing to be contacted by the Research Team with any follow-up questions or further research projects on this topic or other PHEMCE, SNS, or CHEMPACK related research projects?

- Yes – *Go to Section XXVI*
- No – *go to Section XXVIII*

[NEXT BUTTON]

SECTION XXVII FUTURE RESEARCH – PARTICIPANT INFORMATION

Statement: By providing this information, you are agreeing to be contacted by the investigator for a follow-up interview. You are also acknowledging that your responses will no longer be anonymous.

Question XXVII-01: What is your first and last (family) names?
Short answer

Question XXVII-02: What is your email address?
Short answer

Question XXVII-03: What is your phone number? (Please include your country code – if you are in the United States, American Samoa, Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, or the U.S. Virgin Islands your country code is “+1”) (Optional answer)
Short answer

[NEXT BUTTON – GO TO SECTION XXVIII]

SECTION XXVIII CLOSING

Statement: Thank you for participating in this research survey. Your answers will help in improving the PHEMCE, including the SNS and CHEMPACK Program going forward.

Statement: If you have any questions about this research survey or research project, please contact the research team at kej044@g.harvard.edu.

Statement: Please click on the submission below to complete this survey.

[SUBMISSION BUTTON]

SECTION XXIX REJECT CONSENT FORM CLOSING

Statement: Thank you for participating in this research survey. However, you must choose the “yes” answer to the consent question in order to continue with research survey.

Statement: If you have any questions about this research survey or research project, please contact the research team at kej044@g.harvard.edu.

Question: Do you wish to go back to the consent question?

- Yes – *go to Section I*
- No – *Submits the survey*

[NEXT BUTTON – *GO TO SECTION I*] / [SUBMISSION BUTTON]

Appendix E

Raw Data Results from the Survey

Section I: Consent

Question I-01: Having read all of the information provided, do you voluntarily and knowingly consent to participate in this survey?

Table E-1. Survey Question I-01 Responses

Response	Responses	Percentage (%)
Yes	162	99.387
No	1	0.613
Total	163	100.00

Section II: Demographics

Question II-01: What is your gender?

Table E-2. Survey Question II-01 Responses

Response	Responses	Percentage (%)
Male	53	35.099
Female	97	64.238
Non-Binary / third gender	0	0.000
Prefer not to say	1	0.662
Total	151	100.00

Question II-02: What is your age?

Table E-3. Survey Question II-02 Responses

Answer	Responses	Percentage (%)
18 – 19 years old	0	0.000
20 – 29 years old	10	6.623
30 – 39 years old	23	15.232
40 – 49 years old	48	31.788
50 – 59 years old	34	22.517
60 – 69 years old	31	20.530
70 or older	5	3.311
Total	151	100.00

Question II-03: What is your highest level of education?

Table E-4. Survey Question II-03 Responses

Answer	Responses	Percentage (%)
High School Diploma or GED	2	1.325
Some College	3	1.987
Associate's Degree	6	3.974
Bachelor's Degree	55	36.424
Master's Degree	70	46.358
Professional Doctorate	10	6.623
Research Doctorate	1	0.662
Other	4	2.649
Total	151	100.00

Table E-5. Survey Question II-03 Responses (Answer: Other)

Entered Information	Responses	Percentage (%)
Technical School	1	0.662
Diploma in Nursing	1	0.662
Certificate in Public Health	1	0.662
Certificate (Unknown Type)	1	0.662
Total	4	2.649

Section III: Agency & Employment Information

Question III-01: What HHS/FEMA Region are you located in?

Table E-6. Survey Question III-01 Responses

Answer	Responses	Percentage (%)
Region 1 (CT, ME, MA, NH, RI, VT)	14	9.396
Region 2 (NJ, NY, PR, VI)	10	6.711
Region 3 (DE, DC, MD, PA, VA, WV)	9	6.040
Region 4 (AL, FL, GA, KY, MS, NC, SC, TN)	13	8.725
Region 5 (IL, IN, MI, MN, OH, WI)	32	21.477
Region 6 (AR, LA, NM, OK, TX)	17	11.409
Region 7 (IA, KS, MO, NE)	24	16.107
Region 8 (CO, MT, ND, SD, UT, WY)	18	12.081
Region 9 (AZ, CA, HI, NV, AS, MP, MN, GU, MH, PW)	9	6.040
Region 10 (AK, ID, OR, WA)	3	2.013
Total	149	100.00

Question III-02: Is your agency considered a “state” level agency for purposes of the SNS program (e.g., a state health agency, a territorial health agency, or a directly funded city (Chicago, IL; Los Angeles County, CA; New York City, NY; or Washington, DC))?

Table E-7. Survey Question III-02 Responses

Answer	Responses	Percentage (%)
Yes	38	25.503
No	111	74.497
Total	149	100.00

Question III-03: How long have you been in your current position?

Table E-8. Survey Question III-03 Responses

Answer	Responses	Percentage (%)
Less than 1 year	17	11.409
1 – 5 years	66	44.295
6 – 10 years	29	19.463
11 – 15 years	11	7.383
16 – 20 years	16	10.738
21 – 25 years	7	4.698
26 – 30 years	2	1.342
Over 30 years	1	0.671
Total	149	100.00

Question III-04: Do you work for a governmental agency?

Table E-9. Survey Question III-04 Responses

Answer	Responses	Percentage (%)
No	7	4.698
Yes	142*	95.302
Total	149	100.00

* Note: Three respondents accidentally marked themselves under non-governmental agency (Question V-01). The number of responses and percentages reflect what their actual written responses of working for local governments and have been corrected to address the discrepancy.

Section IV: Governmental Agency

Question IV-01: At what level of government do you work at?

Table E-10. Survey Question IV-01 Responses

Answer	Responses	Percentage (%)
Federal Government (Civilian)	0	0.000
US Military (Enlisted, Warrant Officer, Commissioned Officer)	0	0.000
US Public Health Service Commissioned Officer	0	0.000
State Government	21	14.894
Territorial Government	0	0.000
Local Government	118*	83.688
Tribal Government	0	0.000
US National Guard (Enlisted, Warrant Officer, Commissioned Officer)	0	0.000
Other	2**	1.418
Total	141	100.00

* *Ibid*; plus two respondents accidentally marked themselves as “Other” and then wrote “Local Health Department.” The number of responses and percentages reflect what their actual written responses of working for local health departments and have been corrected to address the discrepancy.

** Two respondents accidentally marked themselves as “Other” and then wrote “Local Health Department.” The number of responses and percentages reflect what their actual written responses of working for local health departments and have been corrected to address the discrepancy.

Table E-11. Survey Question IV-01 Responses (Answer: Other)

Entered Information	Responses	Percentage (%)
Federal Government <i>and</i> Local Government	1	0.750
Regional Office of Public Health	1	0.750
Total	2	1.500

Question IV-02: What type of government agency do you work for?

Table E-12. Survey Question IV-02 Responses

Answer	Responses	Percentage (%)
Department of (Public) Health (and Human Services)	139*	92.053
Hospital or Healthcare Organization	4	2.649
Emergency Management	7	4.636
Law Enforcement	1	0.662
EMS Department	0	0.000
Other	0	0.000
Total	151	100.00

* Three respondents accidentally marked themselves under non-governmental agency (Question V-01). The number of responses and percentages reflect what their actual written responses of working for local governments and have been corrected to address the discrepancy

Section V: Non-Governmental Agency

Question V-01: What type of non-governmental agency do you work for?

Table E-13. Survey Question V-01 Responses

Answer	Responses	Percentage (%)
Hospital or Healthcare Organization	4	57.143
Private EMS Agency	0	0.000
Non-Profit Organization	3	42.857
Trade Association	0	0.000
Other	0	0.000
Total	7	100.00

Section VI: Familiarity of the PHEMCE, SNS, and CHEMPACK

Questions VI-01 through VI-03: What is your familiarity with the following? With 1 being, “I have never heard of it” and 10 being “I am a subject expert.”

Table E-14. Survey Questions VI-01 through VI-03 Responses

Answer	Min.	Max.	Mean	Std. Dev.	Variance	Count
PHEMCE	1.000	10.000	5.007	2.798	7.828	145
SNS	1.000	10.000	7.283	2.237	5.003	145
CHEMPACK	1.000	10.000	2.894	2.894	8.376	145

Question VI-04: Does your organization participate in the PHEMCE Program (including the SNS or CHEMPACK Programs)?

Table E-15. Survey Question VI-04 Responses

Answer	Responses	Percentage (%)
Yes	89	61.379
No	20	13.793
I am not sure	36	24.828
Total	145	100.00

Section VII: Organizational Participation – SNS (Part 1)

Question VII-01: Does your organization participate in the SNS?

Table E-16. Survey Question VII-01 Responses

Answer	Responses	Percentage (%)
Yes	86	96.629
No	2	2.247
I am not sure	1	1.124
Total	89	100.00

Section VIII: Organizational Participation – SNS (Part 2)

Questions VIII-01 and VIII-02: Participation in the SNS Program – With 1 being “not at all involved” and 10 being “extremely involved.”

Table E-17. Survey Question VIII-01 and VIII-02 Responses

Answer	Min.	Max.	Mean	Std. Dev.	Variance	Count
How involved is your agency’s participation in the SNS Program?	2.000	10.000	7.221	2.403	5.777	86
How involved are you in your agency’s participation in the SNS Program?	1.000	10.000	7.581	2.691	7.243	86

Section IX: Organizational Participation – CHEMPACK (Part 1)

Question IX-01: Does your organization participate in the CHEMPACK Program?

Table E-18. Survey Question IX-01 Responses

Answer	Responses	Percentage (%)
Yes	57	64.045
No	23	25.843
I am not sure	9	10.112
Total	89	100.00

Section X: Organizational Participation – CHEMPACK (Part 2)

Questions X-01 and X-02: Participation in the CHEMPACK Program – With 1 being “not at all involved” and 10 being “extremely involved.”

Table E-19. Survey Questions X-01 and X-02 Responses

Answer	Min.	Max.	Mean	Std. Dev.	Variance	Count
How involved is your agency’s participation in the CHEMPACK Program?	1.000	10.000	7.088	2.755	7.589	57
How involved are you in your agency’s participation in the CHEMPACK Program?	1.000	10.000	7.053	2.768	7.664	57

Section XI: Security

Questions XI-01 through XI-03: How familiar are you with your organization’s security procedures for the PHEMCE, SNS, and CHEMPACK Programs? With 1 being, “I have never heard of it” and 10 being “I am a subject expert.”

Table E-20. Survey Questions XI-01 through XI-03 Responses

Answer	Min.	Max.	Mean	Std. Dev.	Variance	Count
PHEMCE	0.000	100.000	61.261	30.768	946.648	88
SNS	1.000	100.000	77.795	22.487	505.663	88
CHEMPACK	0.000	100.000	56.636	35.358	1250.209	88

Section XII: Pressure

Question XXII-01: In your current position, with(in) the PHEMCE, SNS, or CHEMPACK programs, have you ever been pressured to take certain actions or make a certain decision that you did not agree with?

Table E-21. Survey Question XII-01 Responses

Answer	Responses	Percentage (%)
Yes	10	11.494
No	77	88.506
Total	87	100.00

Section XIII: Pressured – Follow-up Questions (Part 1)

Question XIII-01: In your experience, has the utilization of PHEMCE, SNS or CHEMPACK Program resources been influenced by factors other than scientific or medical needs of the disaster event?

Table E-22. Survey Question XIII-01 Responses

Answer	Responses	Percentage (%)
Yes	8	80.000
No	2	20.000
Total	10	100.00

Section XIV: Pressured – Follow-up Questions (Part II)

Question XIV-01: What factors do you think may have influenced the utilization of PHEMCE, SNS, or CHEMPACK Program resources in this case? Select all that apply.

Table E-23. Survey Question XIV-01 Responses

Answer	Responses	Percentage (%)
Budgetary reasons	5	26.316
Non=Medical/Scientific reasons	5	26.316
Legal reasons	0	0.000
Political reasons	8	42.105
Unknown reasons	0	0.000
Other	1	5.263
Total	19	100.00

Question XIV-02: Please feel free to expand on your answer, in your own words. All information provided is anonymized and kept confidential.

Responses to Question XIV-02:

- “Political people pressuring us to purchase from or rent space from particular associates not vetted.”
- “The roll-out and utilization of covid vaccines in NYS appeared to be managed in such a way that would highlight the actions and words of certain people, and was unevenly distributed in a manner that I still do not comprehend.”
- “Specific to SNS: 1) limited visibility on the overall structure and contents of SNS (pre-COVID) posed significant challenges as a result of size/scope of [the] response, 2) political positioning among elected officials created skewed the balance of resources provided, those distributed within the state and possibly [the] nation, and 3) federal contracts prohibited state level procurement of materiel (intubation medications, PPE, vents/PAPRs, etc.)”

Section XV: Fit for Purpose - PHEMCE

Question XV-01: Do you feel the current designs of the Public Health Medical Countermeasure Enterprise (PHMCE), which includes the Strategic National Stockpile (SNS) and the CHEMPACK Program, are properly structured to adequately meet anticipatable real-world disaster needs for healthcare emergency responses/events?

Table E-24. Survey Question XV-01 Responses

Answer	Responses	Percentage (%)
Yes	26	30.233
No	39	45.349
I am not sure	21	24.419
Total	86	100.00

Section XVI: Fit for Purpose – SNS (Part 1)

Question XVI-01: Do you feel the current design of the Strategic National Stockpile (SNS) (not including the CHEMPACK Program) is properly structured to meet and respond to actual predicted disaster needs for healthcare emergency responses/events?

Table E-25. Survey Question III-01 Responses

Answer	Responses	Percentage (%)
Yes	8	13.333
No	40	66.667
I am not sure	12	20.000
Total	60	100.00

Section XVII-01: Fit for Purpose – SNS (Part 2)

Question XVII-01: In your own words, describe why you do not feel the SNS (not including the CHEMPACK Program) is not properly structured to respond to actual predicted disaster needs for healthcare emergency responses or events? (Please do not offer suggestions for improvement. You will be able to provide those in the next questions.)

Responses to Question XVII-01:

- “Takes too long, too many processes and red tape.”
 - “Disasters are local and the SNS process is based mostly on state resources.”
 - “It is a stock pile that just sits there. Decisions for allocation are not made with any regard for local health authorities who are dealing with issues. It is typically too much too little too late.”
 - “MCM is lacking and outdated, not enough to spread to all areas in need if a nationwide response is necessary. Many products are manufactured outside the US making us vulnerable to shortages.”
- “Recent events since 2020 - including COVID and monkeypox - support that the SNS is not properly equipped for the scope of some emergencies, and is too slow to respond to needs nationally.”
- “Separation from locals to the feds makes the process confusing. Communication between state and local is also challenging.”
 - “Rural counties are not given enough product and the distance takes so long to deploy.”
 - “Based upon the experience with COVID-19 response, as soon as the disaster was declared, the SNS was overwhelmed with requests and healthcare facilities were forced to locate their own supplies. Price elevations to astronomical levels resulted, and the SNS remained inept until supplies returned to prepandemic levels.”
 - “Program Leadership are not professional logisticians. Design is inappropriate for the Threat / Risk analyses”
 - “Being new to this position, there seems to be quite a bit of confusion and no clear answers in this area. We have numerous new people in these positions.”
 - “I believe the concepts surrounding the SNS are sound. However, the processes they use do not follow their own plans. By doing this, they have rendered state and local planning (and previous exercises) useless.”

- “Resources in the SNS did not adequately meet our needs. Other states with higher population densities received the majority of the SNS resources during the covid 19 pandemic, when they also had theoretically more healthcare infrastructure.”
- “The instructions we, at the Local Health Department, were trained on prior to the COVID pandemic were not followed during the pandemic.”
- “We had trouble getting PPE during COVID. LTC also worked without PPE because of the shortage.”
- “COVID proved that the long standing plans at the local level were too specific and narrow and didn’t fully meet the ongoing need of the response. Additionally, we have way overthought what is a reality of an MCM operation.”
- “I do not know if the SNS is properly structured.”
- “In past experience when we had the H1N1 pandemic, and had an outbreak in our county, the vaccine supplies from the SNS were severely short to take care of our citizens”
- “There is not enough product to provide everyone what they need if the entire country is at risk (i.e., pandemic). SNS is better suited to smaller scale emergencies.”
- “It takes way to much time to actually get supplies to agencies for distribution.”
- “We do not have enough trained human resources (staff/volunteers) at the State or local levels to realistically meet the needs of deploying the SNS within 24-48 hours. We have plans to do deploy the resources, but the time of day, time of year, weather/roads and a host of other factors both human and environmental will significantly impact our ability to do so.”
- “The decision to NOT use any existing SNS measures in the COVID response shows the SNS plans are not sound. Nothing in COVID PPE or vaccine distribution aligned with SNS processes. NOTHING!”
- “Covid-19 was a good indication that the SNS and the country is not prepared to address shortages in PPE and medical supplies when there is worldwide interruption in supply during major pandemics. The SNS was clearly not sufficient and there was a long delay before manufacturing was able to be mobilized.”
- “We do not currently have adequate stock piles of vaccine, or the ability to mass produce vaccine quick enough to supply the country within a timeframe acceptable to reduce mass casualties.”

- “1. The SNS was not able to meet the requirement for masks early on in the pandemic, along with other PPE items. It seems illogical that it will meet the requirements of the next national health emergency. 2. Current SNS plans and Public Health Asset Distribution Plans developed and maintained by LHDs do not reflect how assets were delivered and disbursed to end use entities during the Covid response.”
- “Vaccines for H1N1 and COVID-19 were handled through the vaccine program. H1N1 antivirals were handled through SNS. It would seem medications could be managed differently.”
- “Too dependent on scale of event response. For national event such as COVID, doubtful. For large-scale but regional or relatively local event, possibly.”
- “On the local level, we know very little about the structure of the SNS. The State department of Health is the direct link to the SNS.”
- “SNS cannot provide the needs and requirements during large scale events (i.e., COVID-19 outbreak). Supply/resupply lines rely on overseas suppliers (China) who are not always friendly actors towards the US. SNS is only equipped to assist up to a regional level. Cannot meet the demands of even a single state, let alone the entire United States.”
- “There is too much of a disconnect between the state and local units of government. I’m supposed to be the link between our government and state government in these areas but I couldn’t tell you the last time I received an update email about either program from our state partners.”
- “Failure to restock with N95 masks after H1N1 created a mass shortage of them throughout the COVID Pandemic.”
- “In my observations, the SNS is not fit to respond to nation-wide public health incidents. The structure of distribution methods and the step-down structure prevents local entities from collecting materials quickly and efficiently.”
- “1) Since 2018, the shift to ASPR has greatly taken the visibility from state/local public health, 2) direct line communication from ASPR/SNS and CDC regarding medical countermeasures is not clear.”
- “The distribution is slower than optimal.”
- “The push packs contain controlled substances and most PH plans state the PH will sign for these. However, federal law prohibits redistribution by a provider such as myself. We don’t have a pharmacist and have never solved this issue.”
- “There is a lack of communication still between Public Health and Emergency Management as for the use of the SNS program where decisions are made both at

state and local level without PH being involved even when it relates to PH matters.”

- “Did not follow procedures that had been in place for dispensing/distribution.”
- “Lack of clarity to local from state health department.”
- “The landscape for emergency response in public health has changed so much over the past two and a half years, I’m not sure what will be tolerated by the politicians.”
- “What I have learned from COVID-19 and now MPX is that these robust federal structures are not hugely helpful in a real-time emergency. They are not designed to be quickly responsive to changing needs, and often policy/practice seems to be not informed by on-the-ground staff.”
- “Lack of supply chain, coordination, distribution hub and communications. Will not meet the time restrictions to adequately make decisions. Lack of confidence in government that expired medications are adequate. Conspiracy theories regarding government medication. Civil unrest if certain organizations put their staff in the front of the line for distribution.”
- “I am not sure the SNS can be ready for all emergencies as COVID demonstrated.”
- “During COVID, the SNS was not able to provide the necessary items for a proper response. Many of the products were expired. A good number of requests were bounced back to the states to resolve and source.”
- “Insufficient reserves and rotation of stock.”

Question XVII-02: In your own words, describe what improvements or restructuring needs to be taken, and by whom, in order for the SNS (NOT including the CHEMPACK Program) to be properly structured to respond to actual predicted disaster needs for healthcare emergency responses or events in the short-term? (This may include statutory, regulatory, or programmatic changes.)

Responses to Question XVII-02:

- “Reduce the red tape.”
- “I don’t have suggestions
- “I don’t know how to fix this. It is reflective of a lack of leadership and vision on the national level.”

- “Efforts should be made to build up the SNS using American manufacturers and keeping those relationships alive even in dormant periods.”
- “Make it more response oriented. Appropriately stock with necessary supplies that are consistently rotated to avoid expiration. Make the resources.”
- “More deployable quicker to meet needs of local public health and healthcare systems.”
- “More training. should be required for all folks doing this work taking the SNS course in Anniston and then more follow up and direct communication with local government.”
- “Look at rural counties and what their needs are.”
- It is impossible to prepare for every disaster; however, I would have secured PPE and other non-pharmaceutical materials from multiple suppliers and purchased or earmarked supplies in their store houses to be released to the SNS immediately upon request. I would have made compliance with the request and participation in this program a non negotiable aspect of the NIOSH or OSHA certification or other agreements to be a supplier of PPE or non pharmaceutical material supplier.”
- “Hire professional logisticians. Turn to states for immediate, mid and long term requirements Turn non drug stockpile contents to FEMA; focus on drug/pharm materials.”
- “Need to have logistics and the plan on the same page.”
- “Stick to your plans and training. This keeps everyone on the same page. It allows for action to be taken during a response that is consistent with the training and exercises done.”
- “Evaluate resource distribution criteria to factor in the states that do not have more robust healthcare infrastructures.”
- “The process should definitely be reviewed from the top down and updated, based on the process during the COVID-19 pandemic.”
- “Understanding the rural set up of Illinois and how to effectively distribute to those areas. They do NOT have the same resources as Chicago and are much harder to reach.”
- “Any recent changes to the SNS program federally need to be disseminated to the states and local health departments, not just held in reserve until the next CDP SNS course is open. When medical countermeasures are released due to a new public health threat (such as Monkeypox) states need to be told immediately what the process will look like and how to plan for it.”

- “SNS guidance should be formatted more as a guideline or recommendation rather than a black and white standard.”
- “More supplies when considering the average age of the citizens of each county. We had a high percentage of our population at risk.”
- “Should be easier for LPH to make direct requests for SNS, without going through a state agency, although I think its important the state agency should be aware of the request.”
- “Be ready to move faster and get things out faster to protect and treat people.”
- “Additional funding should be provided to the rural areas/states to bolster their training and exercise efforts. Right now, the lion’s share of the funding goes to the Urban (UASI) areas, but terrorists are just as likely to strike the “heartland” areas because they know we are most vulnerable and it will take longer to mount effective response and countermeasures in rural areas. Big cities have big resources, rural areas have to wait for all that stuff to arrive.”
- “I have no idea as I do not know who, during COVID, made the decisions to or why to ignore the years worth of work done at the local level. If I don’t know where it broke down, I don’t know what to recommend.”
- “Expand the stockpile and the locations.”
- “Taking a look at regulations, and cutting away the excess to speed processes.”
- “This question probably cannot be answered. No 2 events are alike. I’ve been involved with events where vaccine was dropped shipped directly to the LHD. State and Local entities sited in plans that are supposed to facilitate delivery were not involved. This was true of medications delivered during the early days of the Covid Pandemic. In my county, they were delivered directly to hospitals. My LHD and Emergency Management Office were not even in the communications for these deliveries. This might have been a more efficient means of getting the medications where needed. But it violated all planning up to that point. I believe more flexible plans need to be developed on the federal level that recognize there is no “One Size Fits All” model for the provision of emergency assets to entities. The entire SNS/PHAD concept would benefit from a reboot.”
- “Public Health only deals with Preventive medications. It may be helpful If preventive medications were managed separately from other SNS resources.”
- “Federal funding/management at scale sufficient for large-scale response unsure ASPR should notify our partners of the limitations of the SNS program, and outline in DETAIL what regions, states, and the country can expect from the SNS program in terms of assistance and equipment.”

- “I think there needs to be two or three liaisons appointed at the state level who’s sole responsibility would be to make sure the locals are up to date on everything SNS and CHEMPACK.”
- “Ensure that the President (at the time Obama) signs the order to restock the SNS.”
- “In the short-term, I feel the SNS should receive a review of effectiveness by a third-party to prevent bias on the effectiveness, and contents represented within the SNS.”
- “1) front line communication with planners reflecting limitations of existing structure by scale (isolated v. large scale).”
- “The rural states need a more streamlined approach to distribution.”
- “There has to be some changes to controlled substance inclusion either redistribution (justice dept) or not including them routinely.”
- “State Level leaders need to work to establish a plan to include SNS/MCM coordinators in planning even within the LHD.”
- “Utilize known and tested programs for distribution.”
- “Clarity provided.”
- “The regulatory and/or statutory framework must be changed or bolstered so the use of the SNS is not different in each state.”
- “Direct conduit of feedback from the bottom up. The top needs input from people who are “in the weeds” and experiencing the actual workflow.”
- “Map supply chain, update stockpile so medications and supplies are not expired. Convene subject matter expert groups so you understand the correct supplies that need to accompany the medication.”
- “Improved communications with state stake holders.”
- “Consolidate control of the SNS under one agency. Develop a more flexible, JIT supply chain, utilizing suppliers in various regions.”
- “Ensuring adequate reserves and rotation of stock, by ASPER in partnership with states.”

Question XVII-03: In your own words, describe what improvements or restructuring needs to be taken, and by whom, in order for the SNS (NOT including the CHEMPACK Program) to be properly structured to respond to actual predicted disaster needs for healthcare emergency responses or events in the medium-term? (This may include statutory, regulatory, or programmatic changes.)?

Responses to Question XVII-03:

- “Programmatic changes”
- “Supply-chain management”
- “CDC & HHS should take the lead in coordination with other response entities like ASPR and FEMA.”
- “The SNS program needs to have a network of suppliers who will immediately fill request orders from the SNS and have contingency plans consistent with the FEMA COOP.”
- “ASPR: Develop a roles & missions continuum with DHS / FEMA. Form a state / locality based Advisory Committee. Bring in Commercial supply chain expertise.”
- “Have those involved in the distribution met and work out the logistics.”
- “This is a leadership issue.”
- “Evaluate resource distribution criteria to factor in the states that do not have more robust healthcare infrastructures.”
- “Update current platforms to align with each other, and including all relevant partners access to those platforms.”
- “Establish a plan for direct ships to LTCs and hospitals before the disaster happens, not months in.”
- “ASPR needs to finish (or publish) the ESF-8 playbooks that their website says were coming several years ago, including what the expected SNS process for each specified event is expected to look like. ASPR also needs to publish guides for state, regional (within large states), and local health departments for all-hazards SNS planning.”
- “There has to be additional flexibility around program principals and implementation. Exercises of the SNS need to be more realistic and varied for the threats that we deal with.”

- “I’d rather see the Defense Production Act instated in a timely manner to meet demands rather than have products wasted (if they expire) in a SNS warehouse.”
- “Have more stockpiles in more areas for easier distribution by local entities.”
- “The federal government should identify and train quick response teams that could deploy to rural areas that do not have enough people to manage the effort on their own. They could use the DMORT, USAR, or even Wildland Fire teams as a model and develop regional QRFs that could deploy within hours of an event to help augment local response.”
- “I have no idea as I do not know who, during COVID, made the decisions to or why to ignore the years worth of work done at the local level. If I don’t know where it broke down, I don’t know what to recommend.”
- “Improve an increase prepositioning and adjust the stockpile to emerging threats.”
- “It may be helpful If preventive medications were managed separately from other SNS resources.”
- “Federal funding/management at scale sufficient for large-scale response”
- “Training programs need to be developed for those of us who deal with the SNS on a regular basis so that we have more knowledge of the program and what we are able to promise to our partners.”
- “Both entities ... DHSS and local entities”
- “Ensure supplies are restocked.”
- “In the medium-term, actions should be taken to improve distribution schemes/models to ensure quick access at every level of government for distribution.”
- “1) federal contracting with distributors for direct distribution of MCM to states/territories.”
- “SAA. Not sure the process for justice dept to change. It is unclear is an emergency declaration/proclamation would allow flexibility. I think the penalties are so stiff for controlled substances that I personally will refuse to sign for the SNS. A huge barrier.”
- “Flexibility from the top created delays and bureaucratic layers.”
- “Need to contract with pharmacies, Amazon, US Postal Service so people can answer medical questionnaires and have medicine distributed to them via mail or lockers. Need to re-think role of CRI (Cities Readiness Initiative) since many long

term care facilities already have access to medication from suppliers. Need to concentrate ESF8 and ESF 6 in assisting vulnerable populations (seniors, houseless, low literacy).”

- “Always a question of allocation of resources.”
- “Better knowledge of where supplies are and making sure there is a good inventory control system in place, taking into account the expiration date of products.”
- “Structurally, not much. But ensuring reserves is a challenge.”

Question XVII-04: In your own words, describe what improvements or restructuring needs to be taken, and by whom, in order for the SNS (NOT including the CHEMPACK Program) to be properly structured to respond to actual predicted disaster needs for healthcare emergency responses or events in the long-term? (This may include statutory, regulatory, or programmatic changes.)

Responses to Question XVII-04:

- “Each state should establish their own SNS since state’s needs vary depending on how disease may spread in their region, vulnerability index, and how aggressive state and local health officials plan to mitigate threats.”
- “Walmart and Amazon rarely have out of stock items and are usually able to fill orders quickly. Develop a system that is similar to that of the retail giants like Walmart, Amazon, and Alibaba.”
- “Need comprehensive training and education in the logistics of these programs.”
- “Proper planning and exercising leads to a successful mission outcome.”
- “Evaluate resource distribution criteria to factor in the states that do not have more robust healthcare infrastructures.”
- “Ensure all entities are aware of the available resources and how to access them.”
- “Better availability and larger supply.”
- “SNS planning at all levels needs to be more all-hazards and less Anthrax-centric, and all ASPR/CDC training materials, guides, and plans need to reflect this so that state and local plans can support good federal plans.”
- “There has to be better integration between local, state, and federal. COVID highlighted to amount to which the feds don’t trust local agencies to fully

implement plans and programs that have been developed and improved for well over a decade.”

- “I’d rather see the Defense Production Act instated in a timely manner to meet demands rather than have products wasted (if they expire) in a SNS warehouse.”
- “More stockpiles in more places with more people to be able to get things out quickly and efficiently.”
- “After Regional QRF Teams are identified, staffed and trained, they should then train and exercise regularly with local jurisdictions and responders.”
- “This could be done using a similar model to how the Civil Support Teams (CST) operate. Naturally, funding would need to be allocated to the QRF teams as well as the local responders so they could afford the costs of training and exercising together.”
- “Expand domestic manufacturing capabilities.”
- “Federal funding/management at scale sufficient for large-scale response.”
- “Eliminate (or at least reduce as far as possible) the reliance on overseas suppliers. Particularly those with competing agendas with the US.”
- “Again, the appointing of two or three liaisons to monitor and push out information to their counties of concern about SNS or CHEMPACK updates.”
- “Ensure supplies are restocked by not leaving this decision up to one person who can refuse to sign the order to restock it.”
- “In the long-term, policy should be changed after assessment and testing of potential policy change(s) has occurred.”
- “1) separate funding (cooperative agreement) from PHEP and HPP for MCM.”
- “Communication break downs were common from Federal to State to Locals.”
- “Clarity provided.”
- “The CDC is no longer trusted by a large segment of the population. It should be moved to Health and Human Services.”
- “Fundamental changes in communication and not just having policy experts at the table, but real live on the ground staff who come up with many “what if” scenarios that can’t be seen from the 30,000 foot level.”
- “The Immunization Information System is a statewide immunization registry. Immunization registries should be standardized and access across the USA so no

matter where someone is coming from we have the ability to know which vaccine was administered. In the long-long run this should include Mexico. In the long-long-long run this should be worldwide compatible.”

- “Not sure that model is the most efficient one. A de-centralized model might be better.”
- “Decrease dependence on foreign suppliers.”
- “Ensuring adequate reserves and rotation of stock, by ASPER in partnership with states.”

Section XVIII: Fit for Purpose – CHEMPACK (Part 1)

Question XVIII-01: Do you feel the current designs of the CHEMPACK Program, is properly structured to meet and respond to actual predicted disaster needs for healthcare emergency responses / events?

Table E-26. Survey Question III-01 Responses

Answer	Responses	Percentage (%)
Yes	21	39.623
No	4	7.547
I am not sure	28	52.830
Total	53	100.00

Section XIX: Fit for Purpose – CHEMPACK (Part 2)

Question XIX-01: In your own words, describe why you do not feel the CHEMPACK Program is not properly structured to respond to actual predicted disaster needs for healthcare emergency responses or events? (Do not offer suggestions for improvement. You will be able to provide those in the next questions.)

Responses to Question XIX-01:

- “I am a public health official in a county that is ringed by refineries, toxic waste and petrochemical industry. That I don’t know enough to comment says it all.”
- “I do not have enough experience with CHEMPACK for input.”

- “Not enough product for rural settings and distances for deployment.”
- “Numerous new employees in position.”
- “Although I, on behalf of my organization, can request to activate a CHEMPACK, I have not had enough training/experience to determine if the current process is effective or not.”
- “We don’t deal with CHEMPACK. That is handled by state health in coordination with our healthcare facilities.”
- “I have heard of the CHEMPACK program but know very little about it. I don’t even know if there are packs in our area.”
- “We do not have enough trained human resources (staff/volunteers) at the State or local levels to realistically meet the needs of deploying the CHEMPACK within 24-48 hours. We have plans to deploy the resources, but the time of day, time of year, weather/roads and a host of other factors both human and environmental will significantly impact our ability to do so.”
- “I am not completely familiar with CHEMPACK, but based on how hospital preparedness coalitions and HSEM were engaged in COVID, I highly doubt Public Health, especially at the County level, will be engaged at all in a CHEMPACK distribution. Again, if SNS was not honored/used in COVID, why should one expect anything in that process would be used for a CHEMPACK situation.”
- “Very few people are aware of it’s [sic] existence. Most doctors and medical personnel in our area would not even know that there are CHEMPACK containers and antidotes available to them.”
- “Well, the CHEMPACK link on our state’s page is busted as of this writing and they didn’t know it when I called them at the state to report it not working. That kind of tells me there’s no oversight so makes me wonder about response level activity.”
- “CHEMPACK location is too far away from our jurisdiction.”
- “Not clearly communicated from state to LHD.”
- “It’s very ‘need to know’ so I don’t have access to information regarding amount, location or usage even though I am a primary planner for local public health.”
- “Ensuring adequate reserves and rotation of stock, by ASPER in partnership with states. For example, we needed to access CHEMPACK for sedatives for the COVID response.”

Section XX: Fit for Purpose - Security

Question XX-01: Do you feel the current designs of the federal security procedures for the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which includes the Strategic National Stockpile (SNS) and the CHEMPACK Program, are properly structured to adequately meet anticipatable real-world disaster needs for healthcare emergency responses / events??

Table E-27. Survey Question III-01 Responses

Answer	Responses	Percentage (%)
Yes	43	54.430
No	11	13.924
I am not sure	25	31.646
Total	79	100.00

Section XXI: Fit for Purpose – Security – SNS (Part 1)

Question XXI-01: Do you feel the current designs of the security procedures for the Strategic National Stockpile (SNS) are properly structured to meet and respond to actual or predicted disaster needs for healthcare emergency responses / events?

Table E-28. Survey Question XXI-01 Responses

Answer	Responses	Percentage (%)
Yes	8	22.222
No	12	33.333
I am not sure	16	44.4444
Total	36	100.00

Section XXII: Fit for Purpose – Security – SNS (Part 2)

Question XXII-01: In your own words, describe why you do not feel the security procedures for the SNS are properly structured to respond to actual predicted disaster needs for healthcare emergency responses or events? (Please do not offer suggestions for improvement. You will be able to provide those in the following questions.)

Responses to Question XXII-01:

- “Again, takes too long to get material.”
- “Rural county has more needs.”
- “I don’t have experience with the security aspect to provide feedback.”
- “There is a high reliance on local and state law enforcement. Depending on the type of event, those resources might not be available There I do not know the security procedures for the SNS.”
- “All of the SNS and CHEMPACK plans suggest using local law enforcement to provide security. Our rural police and Sheriff’s departments are too small to respond to whatever incident scene there is as well as peel off officers to provide security for distribution of countermeasures. We’ve looked at State resources, but they are few and literally far between (Montana is a huge state, some of the State LEOs cover hundreds of square miles by themselves.) National Guard resources are the same, spread across a huge geographic area and often filling responder roles in their own community already. It takes days to pull them together to mount any kind of response, plus, many of our state units are often deployed to places like Iraq and not even available. We simply don’t have enough people to pull off an effective countermeasure response in the timeframes (24-48 hours) called for in SNS and CHEMPACK deployments.”
- “I have not been engaged in any actual use of SNS distribution nor have I been provided any information on the process and therefore cannot comment on the existing security protocols.”
- “Security was not a real consideration when Covid assets were delivered. This is my only recent reference point. In 2014 I took receipt for a medical countermeasure as a volunteer for the county receiving the asset. There were no security considerations when this occurred.”
- “Again, very little is known at the local level, regarding the SNS system.”
- “Good availability of medical supplies but the supplies are substandard and difficult to get ahold of.”
- “Too complicated and convoluted.”

- “I’m not sure there is enough communication flowing between local and state authorities and the national government at this time. Getting bogged down in the red tape that usually accompanies federal programs.”
- “I feel that there are always improvements to security. Furthermore, I feel as though during an actual response, security could be overwhelmed resulting in failures.”
- “Delays in response from the SNS during COVID-19 response created safety concerns for healthcare workers needed the supplies from the SNS.”
- “Clarity not provided from state to LHD.”
- “The medication flow to the state and then to medical hubs and those areas are secure. Once the medication is on-site at local distribution centers there is not adequate security measures to protect staff, there is low involvement in discouraging protesters, there is no help in addressing the death threats or threats of harm from parents or the public against the school board, staff and administration where many of our distribution sites are located. This has caused some sites to no longer allow us to do distribution on their property.”
- “There needs to be maximal flexibility in the system, which is not currently the case.”
- “Difficult to predict all types of disasters that would require SNS push. Therefore, the answering of this question is purely speculative on my part and not of true relevance.”

Question XXII-02: In your own words, describe what improvements or restructuring needs to be taken, and by whom, in order for the security procedures for the SNS Program to be properly structured to respond to actual or predicted disaster needs, for healthcare emergency responses or events in the short-term?

Responses to Question XXII-02:

- “Reduce the red tape.”
- “There has to be allowances for other law enforcement agencies to participate in a response.”
- “Additional funding should be provided to the rural areas/states to bolster their training and exercise efforts.”
- “I have not been engaged in any actual use of SNS distribution nor have I been provided any information on the process, and therefore cannot comment on the existing security protocols.”

- “I am not familiar with security procedures.”
- “There is no one size fits all answer to this question. The need for security is too dependent upon other considerations.”
- “Localize supplies to be better accessed by everyone. County EMA should be able to have a small supply on hand and be able to access the larger supply without difficulty/having to access requests through technology.”
- “Provide training and instructions for those involve so that they can have a better understanding of the security procedures.”
- “Need to set up an email update that goes out at least monthly on changes with distribution, trainings available and changes in personnel at SNS.”
- “In the short-term, I feel an evaluation should be conducted on the effectiveness of security measures.”
- “Restructuring to deploy items in a timely manner needs to take place.”
- “Clarity provided.”
- “Schools that receive Federal money should be required to have a medical countermeasure distribution plan with their local public health agency in place and certified by the State Department of Education and State Department of Health. Counties that receive Federal money should be required for their Sheriff’s office to have a surge staffing plan in place for security of Points of Distribution.”
- “Decentralization.”

Question XXII-03: In your own words, describe what improvements or restructuring needs to be taken, and by whom, in order for the security procedures for the SNS Program to be properly structured to respond to actual or predicted disaster needs, for healthcare emergency responses or events in the medium-term?

Responses to Question XXII-03:

- “Reduce the red tape.”
- “The federal government should identify and train quick response teams that could deploy to rural areas that do not have enough people to manage the effort on their own.”
- “I have not been engaged in any actual use of SNS distribution nor have I been provided any information on the process, and therefore cannot comment on the existing security protocols.”

- Answered above
- “Better access of adequate supplies that are standard use (many of the supplies obtained during COVID were not usable due to lack of safety i.e., needles that did not have safety features needed to protect staff).”
- “I think the security is acceptable with the program from the state and local level. Not sure about the federal security program. Maybe a bi-yearly review of all is needed.”
- “In the medium-term, security staffing should be increased and the evaluation should be used to determine increased standards.”
- “Restructuring to deploy items in a timely manner needs to take place.”
- “Clarity provided.”
- “I did not have any involvement/awareness of security procedures.”
- “Federal level organizations and federal key leaders should have ‘one-voice’. Confusion and dissention at the top makes it confusing in local jurisdictions.”
- “Sustained communication with stake holders.”

Question XXII-04: In your own words, describe what improvements or restructuring needs to be taken, and by whom, in order for the security procedures for the SNS Program to be properly structured to respond to actual or predicted disaster needs, for healthcare emergency responses or events in the long-term?

Responses to Question XXII-04:

- “Reduce the amount of red tape.”
- “After Regional QRF Teams are identified, staffed and trained, they should then train and exercise regularly with local jurisdictions and responders.”
- “I have not been engaged in any actual use of SNS distribution nor have I been provided any information on the process, and therefore cannot comment on the existing security protocols.”
- “Answered above.”
- “Better access to supplies that are useable in short period of time.”
- “ASPR needs to review its procedures and streamline them where possible.”

- “Again, not sure about the federal level security response. Know the state and local level security is looked at regularly.”
- “In the long-term, a test should be conducted of the security measures with an AAR-IP being created.”
- “Restructuring to deploy items in a timely manner needs to take place.”
- “Clarity provided.”
- “Have more points of distribution for medications such as antibiotics through pharmacies, postal service, Amazon, and UPS. This will help limit the number of people that need to flow through Public Health PODs. This would increase security by not concentrating product at too few locations.”
- “Perhaps a de-centralized model with computer integration.”

Section XXIII: Fit for Purpose – Security – CHEMPACK (Part 1)

Question XXIII-01: Do you feel the current designs of the security procedures for the CHEMPACK Program are properly structured to meet and respond to actual or predicted disaster needs for healthcare emergency responses/events?

Table E-29. Survey Question XXIII-01 Responses

Answer	Responses	Percentage (%)
Yes	10	33.333
No	0	0.000
I am not sure	20	66.667
Total	30	100.00

Section XXIV: Fit for Purpose – Security – CHEMPACK (Part 2)

Question XXII-01: In your own words, describe why you do not feel the security procedures for the CHEMPACK are properly structured to respond to actual predicted disaster needs for healthcare emergency responses or events? (Please do not offer suggestions for improvement. You will be able to provide those in the following questions.)

Responses to Question XXIV-01:

- “New employees and numerous administration overturn.”
- “We don’t handle CHEMPACK at our agency.”
- “Clarity is needed.”
- “There is not enough discussion at the local level to know about distribution.”

Question XXII-02: In your own words, describe what improvements or restructuring needs to be taken, and by whom, in order for the security procedures for the CHEMPACK Program to be properly structured to respond to actual or predicted disaster needs, for healthcare emergency responses or events in the short-term?

Responses to Question XXIV-02:

- “Education on the process.”
- “I would like some training on this so I could be prepared in the event CHEMPACKS would need to be used in our area.”
- “Same as previous. We need more funding to train the people we do have and to possibly hire more. We also need the Federal government to augment our resources with federal teams, like they do for FEMA and Wildland Fire. Fund them, train them, equip them and have them ready to deploy within hours. That’s more likely to be successful than expecting every rural town to be prepared on their own.”
- “Clarity provided.”
- “Additional awareness for local jurisdictions regarding roles and responsibilities.”

Question XXIV-03: In your own words, describe what improvements or restructuring needs to be taken, and by whom, in order for the security procedures for the CHEMPACK Program to be properly structured to respond to actual or predicted disaster needs, for healthcare emergency responses or events in the medium-term?

Responses to Question XXIV-03:

- “Those involved need to meet and work plans in place and/or update them.”
- “More training by people in charge.”
- “Same as previous for SNS. We need Federal QRFs ready to go. The local jurisdictions cannot all do this alone.”
- “Clarity provided.”
- “Additional CHEMPACK locations.”

Question XXIV-04: In your own words, describe what improvements or restructuring needs to be taken, and by whom, in order for the security procedures for the SNS Program to be properly structured to respond to actual or predicted disaster needs, for healthcare emergency responses or events in the LONG-term?

Responses to Question XXIV-04:

- “Training and education in this process.”
- “More training of locals that would need to respond.”
- “Same as previous for SNS. We need Federal QRFs ready to go. The local jurisdictions cannot all do this alone.”
- “Clarity provided.”
- “Additional exercises and public communications readily deployable content about the incident, medication, expectations in multiple languages and for low/no literacy.”

Section XXV: Additional Comments

Question XXV-01: Do you have any additional comments for the research team?

Responses to Question XXV-01:

- “SNS program is a great concept and a major flaw in this system is the fact that it is controlled by the government. Governments run on exclusive contracts which runs exactly counter to Continuity of Operations Plans which state to have contingencies. Have exclusive contracts prevents entities from having contingencies. The SNS seems that it was designed for the localized or controlled disasters. For some reason, the Cities of Readiness Initiative plan was not followed. Had it been followed, I am fairly certain the response would have been better controlled and better managed. Instead, the response was to cast a wide net. This concept works well when gathering, but fails when used in a distribution campaign.”
- “Consider forward basing/staging stockpile contents. Use a single supply chain model vice switching for each response (H1N1, Ebola, Zika, COVID, Monkeypox). Consider turning the entire enterprise to a vendor, DOD, or FEMA. HHS does not have the chops for this type response.”
- “I feel that the SNS process worked well during COVID-19, but the supplies had not been updated or rotated since H1N1. I fear that decline in SNS/Public Health Emergency Preparedness will again happen, and we will be doomed to repeat the issues again.”
- “I would definitely like more information on CHEMPACKS and trainings for the use and distribution of those.”
- “The people way out in DC and working in the Federal Government have for years now misunderstood the reality of living in not just rural, but “frontier” areas. States like Montana are huge geographically, but tiny in terms of population and resources. Preparedness funding alone is not going to change that reality. Our towns are not going to suddenly grow and have larger police forces. Most of our responders in Fire and EMS are always going to be volunteers. Most Health departments have less than a dozen staff. We only have a few dozen critical access hospitals for the whole state and less than half a dozen Trauma Centers. That is not going to change anytime soon and is true for dozens of rural states, not just Montana. The only way the Nation is going to have the ability to respond anywhere quickly is to have those teams ready to deploy at the Federal level. Again, the models exist. We have QRF for USAR, DMAT/DMORT, FEMA, Wildland Fire and others. The CST’s have tremendous capability for identifying agents, but they don’t have enough people to staff and manage a POD. We need federal “POD” teams that can come in, like a Wildland Type 1 Team, and take over the incident and we need to train our locals on how to support that effort rather than try to manage it themselves. We will never have enough local

resources, so let's fund and train efforts to augment those resources effectively and appropriately instead of throwing money and effort at ineffective and unrealistic models for rural response."

- "I think the whole concept of SNS/CHEMPACK needs to be honestly reassessed. When the country was faced with an actual Public Health Emergency absolutely nothing previously planned was even attempted to be executed. Based on the COVID response I now treat any SNS / CHEMPACK planning as an exercise in 'check the box' because it has been demonstrated that our work on local plans are not and will not be honored."
- "Although the processes in place are adequate, there is a need for the exercising and testing of the processes to ensure new staff are familiar with the process and to avoid duplication of efforts between local, state and federal partners."
- "The COVID-19 pandemic and the current Monkeypox outbreak have both demonstrated the need for SNS; however, politics kept Monkeypox vaccine from being distributed for weeks. Unfortunately, with the SNS being a government asset, it falls victim to manipulation by political agendas."
- "The responses for both COVID-19 and Monkeypox show severe need for the rapid deployment of critical resources."
- "Communication during the current emergency has not been effective. Several times I requested assets and would have to wait at least a month for a response of yes or no."
- "I was a participant in a NACCHO team making recommendations back to CDC on the Emergency Preparedness programs which included sections especially on the SNS. Contact at NACCHO = Emily Boyle, MS (Pronouns: she/her) Senior Program Analyst, Preparedness National Association of County & City Health Officials 1201 Eye Street NW, Fourth Floor Washington, DC 20005 Phone: 202-507-4256 www.naccho.org."
- "We are not privy to the security plans."
- "No. Thank you for the opportunity to fill out this research information."
- "Recently each time something happens (COVID, Monkeypox), the SNS comes up short. I think a reassessment of what's included and amounts is appropriate. We've always understood that it's not enough for a national emergency but maybe that isn't the correct model for the SNS."
- "The biggest obstacle for the SNS after COVID is being included in planning with Emergency Management teams. During COVID the decisions were handled by many different channels in every state causing some dysfunction to what should have been a smooth response."

- “SNS was not stocked for a national disaster. It may have met the needs if only one region had been effected, but not the entire nation.”
- “There is a lot of confusion at the state level; and lack of clarity to the LHDs.”
- “The positives of these programs is that resources are federally owned and state managed. These programs do not include everything that would be needed for All Hazard BT threats however, they provide the basics. Through Big Cities Coalition and working with NACCHO state and local governments can work with federal partners to make these resources compatible with emerging threats. High cost to maintain this capability is significant barrier to state and local governments, sustainment of capabilities. When items are removed from SNS such as DTPA then we gradually lose capability to treat population impacted by this hazard specific threat.”
- “More can always be done to improve these programs, but COVID-19 response showed me how these relationships and partnerships really did work in a real-life event. Yes, we could use more funding and more training, but overall, it does work.”
- “It is almost impossible to plan for future events when the situation changes so drastically all the time. The COVID response was a perfect example.”
- “It took weeks to catch up with events. Supply chains failed, transportation failed, human resources failed.”
- “There is confusion out there regarding the SNS/MCM items, and how COVID vaccine and therapeutics supplies were managed/distributed vs. standing procedures for SNS/CHEMPACK.”
- “Making sure there is a liquid supply chain and being aware of inventory and expiration dates are extremely important in making sure we have a stockpile that will meet the needs of future emergency response scenarios. Having been on the healthcare side during COVID made me see some of the shortcomings of the SNS.”
- “During the Trump administration, rather than relying on a well-planned system, where many people are well trained and exercised (table top exercises, functional and full scale exercises) a corporate model was used, with businesses that had no clue about this type of response. We are still trying to recover from these horrible decisions made during a global event.”

Appendix F

Important Tables

Table F-1. Summary of EUAs Issued (2005-2015)

EUAs Issued by FDA

Year	MCM	Requester	Status
Anthrax (<i>Bacillus anthracis</i>)			
2005	Anthrax Vaccine Adsorbed (AVA)	DoD	Terminated
2008 (reissued in 2009, 2010, and 2011)	Doxycycline hyclate 100 mg oral tablets (in National Postal Model home/workplace kits)	HHS (ASPR/ BARDA)	Current (2011 version)
2011	All oral formulations of doxycycline (mass dispensing	HHS (CDC)	Current
2009 H1N1 Influenza Pandemic			
2009-2010	Antivirals (3)	HHS (CDC)	Terminated (all H1N1 EUAs)
	IVDs (18)	Various	
	Disposable N95 respirators	HHS (CDC)	
Novel Influenza A (H7N9) Virus			
2013	CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay	HHS (CDC)	Current
2014	Lyra Influenza A Subtype H7N9 Assay	Quidel Corporation	Current
2014	A/H7N9 Influenza Rapid Test	Arbor Vita Corporation	Current
Middle East Respiratory Syndrome Coronavirus (MERS-CoV)			
2013 (reissued in 2014)	CDC Novel Coronavirus 2012 Real-time RT-PCR Assay	HHS (CDC)	Current
2015	RealStar MERS-CoV RT-PCR Kit U.S.	Altona Diagnostics, GmbH	Current
Enterovirus D68 (EV-D68)			
2015	CDC EV-D68 2014 rRT-PCR Assay	HHS (CDC)	Current

NOTE: IVD = in vitro diagnostics; PCR = polymerase chain reaction; rRT-PCR = real-time reverse transcription polymerase chain reaction; RT-PCR = reverse transcription polymerase chain reaction. Source: NASEM, “The Nation’s Medical Countermeasure Stockpile,” 28-29.

Table F.02. Summary of Ebola EUAs Issued (2014-2015)

Ebola EUAs Issued by FDA			
Year	MCM	Requester	Status
2014 (reissued in 2014)	DoD EZ1 Real-time RT-PCR Assay	DoD	Current
2014 (reissued in 2015)	CDC Ebola VP40 rRT-PCR Assay	HHS (CDC)	Current
2014 (reissued in 2015)	CDC Ebola NP rRT-PCR Assay	HHS (CDC)	Current
2014 (reissued in 2015)	FilmArray NGDS BT-E Assay	BioFire Defense, LLC	Current
2014	FilmArray Biothreat-E test	BioFire Defense, LLC	Current
2014 (reissued in 2014)	RealStar Ebolavirus RT-PCR Kit 1.0	Altona Diagnostics, GmbH	Current
2014	LightMix Ebola ailer RT-PCR Test	Roche Molecular Systems, Inc.	Current
2015 (reissued in 2015)	Xpert Ebola Assay	Cepheid	Current
2015	OraQuick Ebola Rapid antigen Test	Ora Sure Technologies, Inc.	Current

NOTE: IVD = in vitro diagnostics; PCR = polymerase chain reaction; rRT-PCR = real-time reverse transcription polymerase chain reaction; RT-PCR = reverse transcription polymerase chain reaction.

Source: NASEM, “The Nation’s Medical Countermeasure Stockpile,” 28-29.

Table F-3. PHEMCE Multiyear Spend Plan Table (dollars in millions).

Division	Funding Source	Portfolio	Sub Portfolio	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2018 to FY 2022 Total
ASPR BARDA	Project BioShield SRF, No-Year	Anthrax	Therapeutics	\$8.8	\$0.0	\$0.0	\$0.0	\$0.0	\$8.8
ASPR BARDA	Project BioShield SRF, No-Year	Anthrax	Vaccine	\$113.9	\$254.1	\$170.0	\$250.0	\$250.0	\$1,038.0
ASPR BARDA	Project BioShield SRF, No-Year	Biodiagnostic		\$0.0	\$0.0	\$0.0	\$0.0	\$40.0	\$40.0
ASPR BARDA	Project BioShield SRF, No-Year	Botulinum	Botulinum Antitoxin	\$11.3	\$50.0	\$0.0	\$0.0	\$0.0	\$61.3
ASPR BARDA	Project BioShield SRF, No-Year	Broad Spectrum Antimicrobials		\$0.0	\$60.0	\$100.0	\$140.0	\$150.0	\$450.0
ASPR BARDA	Project BioShield SRF, No-Year	Chemical	Chemical Countermeasures	\$0.6	\$0.0	\$40.0	\$200.0	\$200.0	\$440.6
ASPR BARDA	Project BioShield SRF, No-Year	Filoviruses	Ebola	\$254.6	\$194.0	\$200.0	\$250.0	\$270.0	\$1,168.6
ASPR BARDA	Project BioShield SRF, No-Year	Radiological / Nuclear	ARS - Skin/ Lung/GI	\$154.9	\$80.0	\$80.0	\$100.0	\$100.0	\$514.9
ASPR BARDA	Project BioShield SRF, No-Year	Radiological / Nuclear	Biodosimetry	\$1.8	\$3.2	\$45.0	\$25.0	\$25.0	\$100.0
ASPR BARDA	Project BioShield SRF, No-Year	Radiological / Nuclear	Thermal Burns	\$25.2	\$20.7	\$30.0	\$75.0	\$75.0	\$225.9
ASPR BARDA	Project BioShield SRF, No-Year	Smallpox	Antivirals	\$101.9	\$25.0	\$20.0	\$0.0	\$0.0	\$146.9
ASPR BARDA	Project BioShield SRF, No-Year	Smallpox	Vaccine	\$37.0	\$48.0	\$50.0	\$0.0	\$0.0	\$135.0
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual Appropriations	Pandemic Influenza	International MCM and Sample Testing Initiative	\$0.0	\$0.0	\$0.0	\$10.0	\$10.0	\$20.0
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual	Pandemic Influenza	Vaccine Stockpile, Storage, Stability,	\$2.1	\$28.0	\$28.0	\$117.0	\$117.0	\$292.1

Division	Funding Source	Portfolio	Sub Portfolio	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2018 to FY 2022 Total
	Appropriations		and Testing						
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual Appropriations	Pandemic Influenza	Vx AD (Universal, Cell and Recomb)	\$25.9	\$0.0	\$0.0	\$0.0	\$0.0	\$25.9
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Ventilators/ Respirators/ Diagnostics AD	\$0.0	\$20.0	\$20.0	\$220.7	\$220.7	\$481.4
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Facilities, Infrastructure Readiness, and Sustainability	\$12.0	\$130.0	\$90.0	\$264.2	\$172.2	\$668.4
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Fill/Finish Network	\$2.7	\$0.0	\$0.0	\$0.0	\$0.0	\$2.7
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Infrastructure	\$83.2	\$0.0	\$0.0	\$0.0	\$0.0	\$83.2
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Therapeutics Advanced Development	\$49.3	\$42.0	\$55.0	\$233.9	\$203.8	\$584.0
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Vx AD (Improved vaccines incl. cell and recombinant technologies)	\$48.7	\$33.0	\$60.0	\$661.4	\$525.1	\$1,328.2
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	Vaccine Stockpile, Storage, Stability, and Testing	\$9.1	\$0.0	\$0.0	\$29.3	\$12.0	\$50.4
ASPR BARDA	Pandemic Influenza - PHSSEF, Annual No-Year	Pandemic Influenza	MCM Innovation	\$10.0	\$0.0	\$0.0	\$5.0	\$5.0	\$20.0
ASPR BARDA	Pandemic Influenza -	Pandemic Influenza	Diagnostics AD	\$24.0	\$0.0	\$0.0	\$0.0	\$0.0	\$24.0

Division	Funding Source	Portfolio	Sub Portfolio	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2018 to FY 2022 Total
	PHSSEF, Sup Bal No-Year								
ASPR BARDA	Pandemic Influenza - PHSSEF, Sup Bal No-Year	Pandemic Influenza	Vx AD (Improved vaccines including cell and recombinant technologies)	\$0.0	\$9.6	\$0.0	\$0.0	\$0.0	\$9.6
ASPR BARDA	Pandemic Influenza - PHSSEF, Sup Bal No-Year	Pandemic Influenza	Vaccine Stockpile, Storage, Stability, and Testing	\$0.0	\$38.0	\$0.0	\$0.0	\$0.0	\$38.0
ASPR BARDA	Pandemic Influenza - PHSSEF, Sup Bal No-Year	Pandemic Influenza	Therapeutics Advanced Development	\$0.0	\$56.0	\$0.0	\$0.0	\$0.0	\$56.0
ASPR BARDA	Pandemic Influenza - PHSSEF, Sup Bal No-Year	Pandemic Influenza	Facilities, Infrastructure Readiness, and Sustainability	\$0.0	\$0.0	\$148.4	\$0.0	\$0.0	\$148.4
ASPR BARDA	Direct Appropriation, Multiyear	Anthrax	Therapeutics	\$1.2	\$4.0	\$0.0	\$0.0	\$0.0	\$5.2
ASPR BARDA	Direct Appropriation, Multiyear	Anthrax	Vaccine	\$14.2	\$21.7	\$10.0	\$35.0	\$50.0	\$130.9
ASPR BARDA	Direct Appropriation, Multiyear	Botulinum	Next generation candidates	\$0.0	\$0.0	\$0.0	\$25.0	\$25.0	\$50.0
ASPR BARDA	Direct Appropriation, Multiyear	BARDA EID		\$0.0	\$0.0	\$0.0	\$200.0	\$200.0	\$400.0
ASPR BARDA	Direct Appropriation, Multiyear	BARDA MCIP	Medical Countermeasures Innovation	\$7.0	\$39.0	\$55.0	\$150.0	\$150.0	\$401.0
ASPR BARDA	Direct Appropriation, Multiyear	BARDA Mgt & Admin		\$92.0	\$93.6	\$60.0	\$85.0	\$85.0	\$415.6
ASPR BARDA	Direct Appropriation, Multiyear	Broad Spectrum Antimicrobials	BARDA CARB	\$107.0	\$107.0	\$107.0	\$107.0	\$107.0	\$535.0
ASPR BARDA	Direct Appropriation, Multiyear	Broad Spectrum Antimicrobials		\$109.3	\$33.0	\$73.0	\$123.0	\$123.0	\$461.3
ASPR BARDA	Direct Appropriation, Multiyear	Chemical		\$50.5	\$35.7	\$60.0	\$115.0	\$115.0	\$376.2
ASPR	Direct	Chemical	Pharmaceutical-	\$0.0	\$0.0	\$0.0	\$350.0	\$0.0	\$350.0

Division	Funding Source	Portfolio	Sub Portfolio	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2018 to FY 2022 Total
BARDA	Appropriation, Multiyear		Based Agents						
ASPR BARDA	Direct Appropriation, Multiyear	CIADM	Operations	\$0.0	\$0.0	\$0.0	\$75.0	\$50.0	\$125.0
ASPR BARDA	Direct Appropriation, Multiyear	Cross-Cutting Science	Animal Models	\$14.0	\$15.1	\$0.0	\$40.0	\$45.0	\$114.1
ASPR BARDA	Direct Appropriation, Multiyear	Cross-Cutting Science	Clinical Services Network	\$1.0	\$1.1	\$12.0	\$5.0	\$20.0	\$39.1
ASPR BARDA	Direct Appropriation, Multiyear	Filoviruses		\$19.0	\$58.3	\$32.0	\$40.0	\$75.0	\$224.3
ASPR BARDA	Direct Appropriation, Multiyear	Other Threats	Vaccine Development	\$0.0	\$0.0	\$0.0	\$75.0	\$0.0	\$75.0
ASPR BARDA	Direct Appropriation, Multiyear	Radiological / Nuclear	ARS - Neutropenia/Skin/Lung/GI	\$75.2	\$66.4	\$60.0	\$100.0	\$120.0	\$421.6
ASPR BARDA	Direct Appropriation, Multiyear	Radiological / Nuclear	Biodosimetry and Biodiagnostics	\$23.9	\$40.0	\$48.0	\$30.0	\$40.0	\$181.9
ASPR BARDA	Direct Appropriation, Multiyear	Radiological / Nuclear	Thermal Burn Products	\$13.4	\$28.7	\$30.0	\$50.0	\$50.0	\$172.1
ASPR BARDA	Direct Appropriation, Multiyear	Smallpox	Vaccine/ Antivirals	\$9.0	\$18.0	\$15.0	\$30.0	\$40.0	\$112.0
Subtotal (non-add)				\$1,514	\$1,653	\$1,698	\$4,217	\$3,671	\$12,753
NIH	Direct Appropriation, Annual	Anthrax	Basic/Other Research	\$7.2	\$7.5	\$6.5	\$6.6	\$6.8	\$34.6
NIH	Direct Appropriation, Annual	Anthrax	Vaccines	\$5.5	\$5.7	\$4.9	\$5.0	\$5.1	\$26.2
NIH	Direct Appropriation, Annual	Botulinum	Basic/Other Research	\$0.9	\$0.9	\$0.8	\$0.8	\$0.8	\$4.1
NIH	Direct Appropriation, Annual	Botulinum	Vaccines	\$0.6	\$0.7	\$0.6	\$0.6	\$0.6	\$3.1
NIH	Direct Appropriation, Annual	Botulinum	Antitoxins	\$2.8	\$2.9	\$2.5	\$2.6	\$2.7	\$13.5
NIH	Direct	Broad	Antibiotics	\$362.1	\$413.6	\$356.1	\$365.7	\$375.6	\$1,873.0

Division	Funding Source	Portfolio	Sub Portfolio	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2018 to FY 2022 Total
	Appropriation, Annual	Spectrum Antimicrobials							
NIH	Direct Appropriation, Annual	Broad Spectrum Antimicrobials	Antivirals	\$77.7	\$80.8	\$69.6	\$71.4	\$73.4	\$372.8
NIH	Direct Appropriation, Annual	Cross-Cutting Science	Basic/Other Research	\$285.7	\$296.1	\$255.0	\$261.9	\$268.9	\$1,367.5
NIH	Direct Appropriation, Annual	Cross-Cutting Science	Product Development	\$142.8	\$148.6	\$133.8	\$137.4	\$141.1	\$703.7
NIH	Direct Appropriation, Annual	Cross-Cutting Science	Translational	\$128.2	\$133.3	\$114.8	\$117.9	\$121.0	\$615.1
NIH	Direct Appropriation, Annual	Cross-Cutting Science	Animal Model	\$22.2	\$23.1	\$19.9	\$20.4	\$21.0	\$106.5
NIH	Direct Appropriation, Annual	Filoviruses	Basic/Other Research	\$58.0	\$60.3	\$51.9	\$53.4	\$54.8	\$278.4
NIH	Direct Appropriation, Annual	Filoviruses	Vaccines	\$44.8	\$46.6	\$40.1	\$41.2	\$42.3	\$214.9
NIH	Direct Appropriation, Annual	Pandemic Influenza	Basic/Other Research	\$98.4	\$102.3	\$88.1	\$90.4	\$92.9	\$472.0
NIH	Direct Appropriation, Annual	Pandemic Influenza	Vaccines	\$149.7	\$195.7	\$168.5	\$173.0	\$177.7	\$864.7
NIH	Direct Appropriation, Annual	Multiplex Diagnostics	Diagnostics	\$101.9	\$106.0	\$91.3	\$93.7	\$96.3	\$489.1
NIH	Direct Appropriation, Annual	Other Threats	Basic/Other Research	\$433.5	\$450.9	\$388.2	\$398.7	\$409.4	\$2,080.7
NIH	Direct Appropriation, Annual	Other Threats	Vaccines	\$104.8	\$109.0	\$93.9	\$96.4	\$99.0	\$503.1
NIH	Direct Appropriation, Annual	Smallpox	Basic/Other Research	\$10.2	\$10.6	\$9.1	\$9.4	\$9.6	\$48.9
NIH	Direct Appropriation, Annual	Smallpox	Vaccines	\$1.0	\$1.0	\$0.9	\$0.9	\$0.9	\$4.6
NIH	Direct Appropriation, Annual	Plague/Tularemia	Basic/Other Research	\$5.9	\$6.2	\$5.3	\$5.4	\$5.6	\$28.4
NIH	Direct Appropriation,	Plague/Tularemia	Vaccines	\$2.7	\$2.8	\$2.4	\$2.5	\$2.5	\$12.9

Division	Funding Source	Portfolio	Sub Portfolio	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2018 to FY 2022 Total
	Annual								
NIH	Direct Appropriation, Annual	Broad Spectrum Antimicrobials	Antibiotics	\$1.5	\$1.5	\$1.3	\$1.3	\$1.4	\$7.0
NIH	Direct Appropriation, Annual	Multiplex Diagnostics	Diagnostics	\$1.4	\$1.4	\$1.2	\$1.3	\$1.3	\$6.5
NIH	Direct Appropriation, Annual	Other Threats	Basic/Other Research	\$21.6	\$22.8	\$18.7	\$19.2	\$19.8	\$102.1
NIH	Direct Appropriation, Annual	Other Threats	Vaccines	\$2.0	\$2.1	\$1.8	\$1.9	\$1.9	\$9.8
NIH	Direct Appropriation, Annual	Chemical	Chemical Countermeasures Research	\$49.2	\$49.2	\$42.4	\$43.5	\$44.7	\$228.9
NIH	Direct Appropriation, Annual	Radiological / Nuclear	Nuclear/ Radiological Countermeasures	\$47.9	\$47.9	\$41.3	\$42.4	\$43.5	\$223.1
Subtotal (non-add)				\$2,170	\$2,329	\$2,011	\$2,065	\$2,121	\$10,695
FDA	Direct Appropriation, Annual	FDA Regulatory Science	Antimicrobial Resistance MCM	\$22.6	\$22.2	\$22.0	\$22.6	\$23.3	\$112.7
FDA	Direct Appropriation, Annual	FDA Regulatory Science	CBRN MCM Base Funding (pre-MCMi)	\$48.4	\$48.6	\$57.2	\$58.9	\$60.7	\$273.8
FDA	Direct Appropriation, Annual	FDA Regulatory Science	MCMi Annual	\$24.6	\$24.6	\$31.6	\$46.1	\$47.5	\$174.3
FDA	Direct Appropriation, Annual	FDA Regulatory Science	Pandemic Influenza MCM	\$40.5	\$41.1	\$43.7	\$45.0	\$46.3	\$216.6
FDA	Ebola Emergency Funding, Multiyear, Direct	FDA Regulatory Science	Ebola Emergency	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
FDA	Transfer from No-Year PI Funding	FDA Regulatory Science	Transfer from No-Year Pandemic Influenza	\$1.7	\$0.0	\$0.0	\$0.0	\$0.0	\$1.7
FDA	Direct Appropriation, Multiyear	FDA Regulatory Science	MCMi Multiyear	\$4.1	\$4.1	\$0.0	\$0.0	\$0.0	\$8.2

Division	Funding Source	Portfolio	Sub Portfolio	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2018 to FY 2022 Total
Subtotal (non-add)				\$142	\$141	\$154	\$173	\$178	\$787
ASPR SNS	Direct Appropriation, No-Year	Ancillary	Other supportive (incl. antimicrobials)	\$17.0	\$0.0	\$10.9	\$36.5	\$27.6	\$92.1
ASPR SNS	Direct Appropriation, No-Year	Ancillary	Therapeutic	\$0.0	\$5.0	\$0.0	\$0.0	\$0.0	\$5.0
ASPR SNS	Direct Appropriation, No-Year	Anthrax	Antibiotic	\$126.2	\$11.0	\$37.7	\$79.0	\$79.2	\$333.0
ASPR SNS	Direct Appropriation, No-Year	Anthrax	Therapeutic	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
ASPR SNS	Direct Appropriation, No-Year	Anthrax	Vaccine	\$115.8	\$145.0	\$0.0	\$0.0	\$0.0	\$260.8
ASPR SNS	Direct Appropriation, No-Year	Burkholderia	Antibiotic	\$0.7	\$0.7	\$2.3	\$2.3	\$2.3	\$8.4
ASPR SNS	Direct Appropriation, No-Year	Chemical	Anticonvulsant	\$0.2	\$2.2	\$10.4	\$0.2	\$1.9	\$14.9
ASPR SNS	Direct Appropriation, No-Year	Chemical	Nerve agent antidote	\$29.3	\$14.7	\$97.1	\$3.5	\$6.4	\$150.8
ASPR SNS	Direct Appropriation, No-Year	FMS	Antibiotic	\$0.1	\$0.1	\$0.2	\$0.2	\$0.2	\$0.7
ASPR SNS	Direct Appropriation, No-Year	Pandemic Influenza	Antiviral	\$47.5	\$25.5	\$9.0	\$222.7	\$222.7	\$527.3
ASPR SNS	Direct Appropriation, No-Year	Radiological / Nuclear	Antibiotic	\$0.0	\$0.0	\$0.0	\$0.3	\$0.0	\$0.3
ASPR SNS	Direct Appropriation, No-Year	Radiological / Nuclear	Antiviral	\$1.5	\$0.0	\$0.0	\$0.8	\$0.8	\$3.0
ASPR SNS	Direct Appropriation, No-Year	Radiological / Nuclear	Decorporation	\$6.4	\$0.0	\$3.2	\$3.2	\$3.2	\$16.1
ASPR SNS	Direct Appropriation, No-Year	Radiological / Nuclear	Other supportive (incl. antimicrobials)	\$2.1	\$5.0	\$4.1	\$7.1	\$7.4	\$25.6
ASPR	Direct	Smallpox	Antiviral	\$1.6	\$1.6	\$1.1	\$0.8	\$1.1	\$6.2

Division	Funding Source	Portfolio	Sub Portfolio	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2018 to FY 2022 Total
SNS	Appropriation, No-Year								
ASPR SNS	Direct Appropriation, No-Year	Smallpox	Uricosuric	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.1
ASPR SNS	Direct Appropriation, No-Year	Smallpox	Vaccine	\$78.4	\$136.4	\$143.7	\$248.2	\$263.4	\$870.1
ASPR SNS	Direct Appropriation, No-Year	SNS Non-Procurement	Operating	\$15.0	\$28.1	\$28.9	\$29.8	\$30.7	\$132.5
ASPR SNS	Direct Appropriation, No-Year	SNS Non-Procurement	Sustainment	\$91.0	\$148.9	\$122.5	\$126.2	\$130.0	\$618.6
ASPR SNS	Direct Appropriation, No-Year	SNS Non-Procurement	Program Support	\$77.6	\$85.5	\$87.8	\$90.5	\$93.2	\$434.6
ASPR SNS	Direct Appropriation, No-Year	Smallpox	Vaccine	\$0.0	\$0.0	\$0.0	\$0.0	\$196.0	\$196.0
ASPR SNS	Direct Appropriation, No-Year	Chemical	Nerve agent antidote	\$0.0	\$0.0	\$0.0	\$22.4	\$19.2	\$41.6
ASPR SNS	Direct Appropriation, No-Year	Radiological / Nuclear	Antineutropenic	\$0.0	\$0.0	\$0.0	\$67.0	\$67.0	\$134.0
ASPR SNS	Direct Appropriation, No-Year	Anthrax	Vaccine	\$0.0	\$0.0	\$0.0	\$0.0	\$287.0	\$287.0
ASPR SNS	Direct Appropriation, No-Year	Anthrax	Therapeutic	\$0.0	\$0.0	\$0.0	\$136.0	\$17.9	\$153.9
ASPR SNS	Direct Appropriation, No-Year	Radiological / Nuclear	Thermal Burn Products	\$0.0	\$0.0	\$4.0	\$4.0	\$4.0	\$12.0
ASPR SNS	Direct Appropriation, No-Year	Smallpox	Antiviral	\$0.0	\$0.0	\$57.1	\$0.0	\$196.0	\$253.1
Subtotal (non-add)				\$610	\$610	\$620	\$1,081	\$1,657	\$4,578

Source: HHS-ASPR, "PHEMCE Multiyear Budget, Appendix A – Spend Plan Tables."
<https://www.phe.gov/Preparedness/mcm/phemce/phemce-myb/FY2018-2022/Pages/appendixA.aspx>.

Appendix G

Strategic National Stockpile Response Details¹¹³

2001 – World Trade Center and Anthrax Attacks

- Deployed pharmaceuticals and medical supplies to New York City within 7 hours on September 11, 2001.
- Responded to the anthrax crisis of 2001 by delivering vaccines and medicines for oral prophylaxis to more than 50 sites in 11 states and Washington, DC, within 5 hours.

2005 – Hurricanes Katrina and Rita

In response to requests from Louisiana and Mississippi related to Hurricane Katrina, the stockpile:

- Sent 3,500 beds and critical medications for conditions such as diabetes, heart disease, high blood pressure, pain, anxiety, and diarrhea.
- Delivered more than 130,000 tetanus/diphtheria vaccines; close to 145,000 hepatitis A, and hepatitis B vaccines to Louisiana; and a host of other childhood vaccines to Louisiana; and a host of other childhood vaccines for measles/mumps/rubella, chickenpox, etc. to treat children in shelters.
- Delivered 10,000 vials of insulin to Mississippi and 20,000 to Louisiana
- Launched three special flights early in the response for expedited delivery of controlled substance pain medications, intravenous (IV) re-hydration fluids, insulin, and stockpile experts to Louisiana
- Shipped 28 ventilator kits to the New Orleans airport to aid in evacuation of patients with critical health concerns.

In response to Hurricane Rita, the stockpile sent medical supplies and Federal Medical Stations (totaling 2,000 beds) to assist in local response efforts. Beds were set up at Texas A&M University in College Station, Texas, as well as in Waco and Marlin, Texas.

2008 – Hurricanes Gustav, Hanna, and Ike

- Responded to Hurricanes Gustav, Hanna, and Ike by deploying 24 Federal Medical Stations to support the states of Florida, Kentucky, Louisiana, Mississippi, and Texas with approximately 6,000 beds over a 30-day period.

113. HHS-ASPR, SNS Stockpile Responses.

2009 – H1N1 Pandemic Influenza and North Dakota Flooding

- Supported a coordinated response to the initial phase of H1N1 “swine flu”¹¹⁴ outbreak by shipping 25 percent of its total influenza antiviral medications to 62 areas in 7 days. The stockpile also responded to the outbreak by delivering peramivir IV,¹¹⁵ based on more than 1,300 requests from doctors treating H1N1 patients.
- Deployed two Federal Medical Stations – one to Bismarck and the other to Grand Forks – in response to North Dakota flooding in 2009.

2010 – North Dakota Flooding and Hurricane Alex

- Deployed two Federal Medical Stations – one to Bismarck, North Dakota, and the other to National Guard Armory – for preparedness.
- Deployed two Federal Medical Stations in response to Hurricane Alex.

2011 – Hurricane Irene

- Deployed one Federal Medical Station to Camp Hartwell, Connecticut for preparedness.

2012 – Hurricanes Isaac and Sandy

- Deployed staff and seven Federal Medical Stations to New Jersey and New York.
- Deployed Commissioned Corps Officers to staff the Federal Medical Stations in response to Hurricane Sandy.
- Deployed two Federal Medical Stations to Louisiana – one to Baton Rouge and the other to New Orleans – in response to Hurricane Isaac.

2014–2015 – Ebola and Botulism

- Coordinated with supply chain partners to identify gaps between commercial supply of personal protective equipment¹¹⁶ and existing inventory at U.S. hospitals designated as Ebola Treatment Centers. The hospitals were prioritized for orders and the rapid delivery of key products such as gowns, coveralls, aprons, boot covers, gloves, face shields and disinfecting wipes in the event the hospitals received an Ebola patient.
- Established a small stockpile of Ebola-specific personal protective equipment to meet urgent, short-term needs until commercial sources could respond to the demand.
- Deployed 54 staff to support the Ebola response with 61 assignments in the CDC Emergency Operations Center, 5 major U.S. airports, and West Africa.

114. Centers for Disease Control and Prevention (CDC), 2009 H1N1 Flu (“Swine Flu”) and You, Last updated February 10, 2010 at 5:00 PM ET. <https://www.cdc.gov/h1n1flu/qa.htm>.

115. CDC, Influenza Antiviral Medications: Summary for Clinicians, Last updated August 16, 2022. <https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm>.

116. CDC, Personal Protective Equipment (PPE). <https://www.cdc.gov/vhf/ebola/healthcare-us/ppe/index.html>.

- Provided 50 vials of Botulism Antitoxin Heptavalent¹¹⁷ to Ohio for the largest botulism¹¹⁸ outbreak in the United States in the past 40 years.

2016–2017 – Zika

In the midst of the Zika virus outbreak, the stockpile:

- Collaborated with the CDC Foundation to help obtain Zika prevention products, including insect repellent, larvicides, mosquito netting, and condoms, to prevent sexual transmission of Zika, as well as educational materials.
- Activated staff to rapidly assemble and deliver approximately 31,000 Zika Prevention Kits¹¹⁹ for distribution to pregnant women in affected areas.
- Initiated contracts for mosquito control efforts.
- Sprayed more than 9,000 homes, hospitals, schools and churches to prevent the spread of the virus in U.S. territories and island jurisdictions.
- Deployed 22 stockpile personnel to U.S. territories, including Puerto Rico, the U.S. Virgin Islands, Guam, and the Republic of the Marshall Islands.

2017 – Hurricanes Harvey, Irma

- Deployed 6 Federal Medical Stations, 12 strike team members, 1 liaison to the Incident Response Coordination Team in Texas and 3 liaisons to the Department of Health and Human Services (HHS) Secretary’s Operations Center in Washington, D.C.
- Set up two Federal Medical Stations in Houston – one at the George R. Brown Convention Center and the other at the NRG Center. Four were ready on standby – two in Texas and two in Louisiana – so they could be set up immediately.
- Assigned approximately 45 staffers to serve in the stockpile’s team room.

2017 – Hurricane Maria

- Arrived in Puerto Rico with Federal Medical Stations and staff within 48 hours of receiving orders from HHS.
- Shipped six Federal Medical Stations to Puerto Rico and set up in Manati, Bayamón, Ponce, and Arecibo.
- Engaged 120 personnel, including strike team members, supply chain experts, and other responders at stockpile facilities and in the field.
- Deployed liaisons to the HHS Secretary’s Operations Center in Washington, D.C., and the Incident Response Coordination Team in San Juan.
- Coordinated delivery of four refrigerators, 42,000 meals ready to eat, 177,000 bottles of water, and ancillary vaccine supplies.
- Established warehouse service and ground transportation in Puerto Rico, specifically a 10,000-square-foot medical distribution center supporting all

117. CDC, “Formulary,” December 29, 2021.
<https://www.cdc.gov/laboratory/drugservice/formulary.html#bat>.

118. CDC, Botulism, Last updated June 8, 2022. <https://www.cdc.gov/botulism/index.html>.

119. CDC, Build a Zika Prevention Kit, Last updated March 14, 2019.
<https://www.cdc.gov/zika/prevention/prevention-kit.html>.

medical supplies for the Disaster Medical Assistance Teams and Federal Medical Stations across the island of Puerto Rico.

- Restocked Federal Medical Station operations with a new shipment of medicines and supplies.
- Purchased and deployed vaccines for hepatitis A and B, tetanus, pneumococcal, rabies and influenza, and surplus medical supplies to assist in USVI [U.S. Virgin Islands] and Puerto Rico's public health needs.

Overall, \$4.5 million in supplies were purchased and deployed on 26 flights carrying more than 347 tons of cargo to support public health needs in Puerto Rico and USVI.

2019 – Hurricane Dorian

- Deployed medical supplies to support responders with ASPR's National Disaster Medical System.¹²⁰
- Deployed two liaisons to the Department of Health and Human Services (HHS) Secretary's Operations Center in Washington, D.C.
- Assigned approximately 50 staffers to serve in the stockpile's operations center.

2020–2022 – COVID-19

* AS of August 3, 2022:

- 27,535 tons of cargo shipped to support U.S. repatriation efforts and state PPE needs.
 - 748 flights transporting supplies; and
 - 5,745 trucks transporting supplies.
- Assigned more than 200 staffers to serve in the stockpile's operation center.
- Engaged 411 private industry partners for medical supply chain and delivery.
- Supporting the National Vaccination Campaign¹²¹ with vaccine ancillary supply and mixing kits to support 1.32 billion COVID-19 vaccine and booster doses and with epinephrine autoinjectors to support the potential treatment of allergic reactions.
- Expanded and enhanced SNS capabilities¹²² to respond to nationwide emerging infectious diseases, now and in the future.

2021 – Unaccompanied Children

SNS provides critical PPE and medical supplies to multiple National Disaster Medical System and U.S. Public Health Service teams, which provide medical support and case management at emergency intake sites for unaccompanied children at the U.S. southern border.

120. HHS-ASPR, National Disaster Medical System. <https://aspr.hhs.gov/ndms/Pages/default.aspx>.

121. HHS/ASPR, "COVID-19 Vaccine Supplies." <https://www.phe.gov/about/sns/COVID/Pages/covid19-vaccine-supplies.aspx>.

122. HHS/ASPR, "Expanding SNS Capabilities." <https://www.phe.gov/about/sns/COVID/Pages/expanding-sns-capabilities.aspx>.

Appendix H

Draft Legislation

A Bill

Making improvements to the Strategic National Stockpile, public health security and preparedness of the United States, and amendments to the Defense Production Act of 1950 as amended other statutes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE

This Act, divided into titles, may be referred to as the “Public Health Emergency Production Act of 20___” or the “PHEP Act”.

SEC. 2. TABLE OF CONTENTS

Sec. 1. Short Title

Sec. 2. Table of Contents

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Sec. 5. Adjustment to Compensation.

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Sec. 101. Title I – Priorities and Allocations

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Title II — Appropriations

Sec. 201. Ring-Fenced Protection of Appropriations

Sec. 202. Triple Lock Protection of Appropriations

Sec. 203. Strategic National Stockpile

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Sec. 301. Protection of this Act

Sec. 302. Suspension of the Provisions of this Act

Sec. 303. Repealing Provisions of this Act

Title IV — General Provision

Sec. 401. Permanent Appropriations

Sec. 402. PHEP Project Area SNS Coordinators

Sec. 403. Security Clearances

Sec. 404. Shelf-Life Extension Program

Sec. 405. Delegation of Authority

Sec. 406. Effective Date

SEC. 3. DECLARATION OF POLICY

(a) Findings

Congress finds that—

- (1) the security of the United States is dependent on the ability of the domestic pharmaceutical and medical countermeasure industrial base to supply materials and services for the national public health, national defense, and to respond to military conflicts, natural or man-caused disasters, public health emergencies, World Health Organization declared “public health emergencies of international concern,” or acts of terrorism within the United States;
- (2) to ensure the vitality of the domestic industrial bases, actions are needed—
 - (A) to promote industrial resources preparedness in the event of domestic or foreign threats to the security of the United States;
 - (B) to support continuing improvements in industrial efficiency and responsiveness;
 - (C) to provide for the protection and restoration of domestic critical infrastructure operations under emergency conditions; and
 - (D) to respond to actions taken outside of the United States that could result in reduced supplies of strategic and critical materials, including energy, necessary for national defense and the general economic well-being of the United States;
- (3) in order to provide for the national security, the national defense preparedness effort of the United States Government requires—
 - (A) preparedness programs to respond to both domestic emergencies and international threats to national defense;
 - (B) measures to improve the domestic industrial base for national defense;
 - (C) the development of domestic productive capacity to meet—
 - (i) essential national defense needs that can result from emergency conditions; and
 - (ii) unique technological requirements; and
 - (D) the diversion of certain materials and facilities from ordinary use to national defense purposes, when national defense needs cannot otherwise be satisfied in a timely fashion;
- (4) to meet the requirements referred to in this subsection, this Act provides the President with an array of authorities to shape national defense preparedness programs and to take appropriate steps to maintain and enhance the domestic industrial base;
- (5) in order to ensure national defense preparedness, it is necessary and appropriate to assure the availability of domestic energy supplies for national defense needs;
- (6) to further assure the adequate maintenance of the domestic industrial base, to the maximum extent possible, domestic energy supplies should be augmented through reliance on renewable energy sources (including solar, geothermal, wind, and biomass sources), more efficient energy storage and distribution technologies, and energy conservation measures;
- (7) much of the industrial capacity that is relied upon by the United States Government for military production and other national defense purposes is deeply and directly influenced by—
 - (A) the overall competitiveness of the industrial economy of the United States; and

- (B) the ability of industries in the United States, in general, to produce internationally competitive products and operate profitably while maintaining adequate research and development to preserve competitiveness with respect to military and civilian production; and
 - (8) the inability of industries in the United States, especially smaller subcontractors and suppliers, to provide vital parts and components and other materials would impair the ability to sustain the Armed Forces of the United States in combat for longer than a short period.
- (b) Statement of policy
- It is the policy of the United States—
- (1) to ensure the adequacy of productive capacity and supply, Federal departments and agencies that are responsible for national defense acquisition should continuously assess the capability of the domestic industrial base to satisfy production requirements under both peacetime and emergency conditions, specifically evaluating the availability of adequate production sources, including subcontractors and suppliers, materials, skilled labor, and professional and technical personnel;
 - (2) every effort should be made to foster cooperation between the defense and commercial sectors for research and development and for acquisition of materials, components, and equipment;
 - (3) plans and programs to carry out the purposes of this Act should be undertaken with due consideration for promoting efficiency and competition;
 - (4) in providing United States Government financial assistance under this Act [sections 4501 to 4568 of 50 U.S.C.] to correct a domestic industrial base shortfall, the President should give consideration to the creation or maintenance of production sources that will remain economically viable after such assistance has ended;
 - (5) authorities under this Act should be used to reduce the vulnerability of the United States to terrorist attacks, and to minimize the damage and assist in the recovery from terrorist attacks that occur in the United States;
 - (6) in order to ensure productive capacity in the event of an attack on the United States, the United States Government should encourage the geographic dispersal of industrial facilities in the United States to discourage the concentration of such productive facilities within limited geographic areas that are vulnerable to attack by an enemy of the United States;
 - (7) to ensure that essential national defense requirements are met, consideration should be given to stockpiling strategic materials, to the extent that such stockpiling is economical and feasible; and
 - (8) in the construction of any industrial facility owned by the United States Government, in the rendition of any financial assistance by the United States Government for the construction, expansion, or improvement of any industrial facility, and in the production of goods and services, under this Act [sections 4501 to 4568 of 50 U.S.C.] or any other provision of law, each department and agency of the United States Government should apply, under the coordination of the Federal Emergency Management Agency, when practicable and consistent with existing law and the desirability for

maintaining a sound economy, the principle of geographic dispersal of such facilities in the interest of national defense.

SEC. 4. STATEMENT OF APPROPRIATIONS

Except as expressly provided otherwise, the following sums in this Act are appropriated, out of any money in the Treasury not otherwise appropriated, for the fiscal year ending September 30, 20____.

SEC. 5. ADJUSTMENTS TO COMPENSATION

Notwithstanding any other provision of law, no adjustment shall be made under section 601(a) of the Legislative Reorganization Act of 1946 (2 U.S.C. 4501) relating to the cost of living adjustments for Members of Congress) during fiscal year 20____.

TITLE I — AMENDMENTS TO THE DEFENSE PRODUCTION ACT OF 1950
The Defense Production Act of 1950 [50 U.S.C. §§ 4501 *et seq.*] is hereby amended as follows—

SEC. 101. TITLE I – PRIORITIES AND ALLOCATIONS

Section 4513 of title 50, United States Code is amended by—

- (a) striking “\$10,000” and inserting “\$100,000”; and
- (b) striking “one year” and inserting “ten years”.

SEC. 102. TITLE VII – GENERAL PROVISIONS

Title VII – General Provisions of the Defense Production Act of 1950 is amended as follows:

- (a) Section 4552 of title 50, United States Code is amended as follows:

- (1) Paragraph 14 is amended by striking the second sentence in its entirety and inserting:

“Such term includes emergency preparedness activities conducted pursuant to title VI of The Robert T. Stafford Disaster Relief and Emergency Assistance Act [42 U.S.C. 5195 *et seq.*], critical infrastructure protection and restoration, public health emergencies, public health emergencies of international concern, emergency preparedness and response activities of the Public Health Emergency Medical Countermeasures Enterprise (42 U.S.C. 300hh–10a) including the Strategic National Stockpile, and the emergency preparedness and response activities and operations of the Administration for Preparedness and Response and the Centers for Disease Control and Prevention located within the Department of Health and Human Services.”

- (2) Inserting a new Paragraph 15 entitled “Public Health Emergency” and adding the following:

“A public health emergency shall have the same meaning as that found in 42 U.S.C. § 247d.”

- (3) Inserting a new Paragraph 16 entitled “Public Health Emergency of International Concern” and adding the following:

“‘public health emergency of international concern’ means an extraordinary event which is determined as provided in the International Health Regulations:

- (i) to constitute a public health risk to other States through the international spread of disease and
 - (ii) to potentially require a coordinated international response.”

- (4) Renumbering the current paragraphs 15 *et seq.* accordingly.
- (b) Section 4567 of title 50, United States Code is amended by—
 - (1) striking the word “and” at the end of Paragraph (1) Subsection (A);
 - (2) striking the “.” at the end of Paragraph (1) Subsection (B) and replacing it with a “;”;
 - (3) inserting a new Subparagraph (C) and adding the following:
 - (4) “the Secretary of Health and Human Services;
 - (5) inserting a new Subparagraph (D) and adding the following:
 - “the Assistant Secretary [of Health and Human Services] for Preparedness and Response; and”
 - (6) inserting a new Subparagraph (E) and adding the following:
 - “the Deputy Assistant Secretary [of Health and Human Services] for the Strategic National Stockpile.”

TITLE II — APPROPRIATIONS

SEC. 201. RING-FENCED PROTECTION OF APPROPRIATIONS

- (a) Notwithstanding any other provision of current or future law, upon enactment of this Act, all appropriations listed in this Title and Sec. 501 of this Act are ring-fenced protected and shall not be reduced or eliminated.
- (b) For purposes of this Act, ring-fenced shall mean:
 - (1) an appropriation that is separate from all other appropriations to the US Departments of Health and Human Services, and Homeland Security;
 - (2) notwithstanding any other statutes, shall not be subject to reduction or sequestering; and,
 - (3) notwithstanding any other statutes shall not be subject to a lapse of funding or appropriation.

SEC. 202. TRIPLE LOCK PROTECTION OF APPROPRIATIONS

- (a) Notwithstanding any other provisions of current or future law, all appropriations listed in this Title or Sec. 501 of this Act shall not be reduced.
- (b) Notwithstanding any other provisions of current or future law, all appropriations listed in this Title shall be increased annually at a rate no less than the greater of the following three conditions:
 - (1) personal consumption expenditures (PCE) price index determined by the United States Department of Conference Bureau of Economic Analysis;
 - (2) the average wage growth during the previous US Government Fiscal Year (October – September); or,
 - (3) four point five percent (4.5%).

SEC. 203. STRATEGIC NATIONAL STOCKPILE

For the five fiscal years following the enactment of this Act, the following appropriations will be increased by no less than fifteen percent (15%) per year for:

- (a) the US Department of Health and Human Services, Administration for Strategic Preparedness and Response:
 - (1) Strategic National Stockpile;
 - (2) Preparedness and Emergency Operations;
 - (3) Preparedness and Response Innovation;

- (4) Public Health Emergency Social Services Emergency Fund, not including the Strategic National Stockpile, Preparedness and Emergency Operations, and Preparedness and Response Innovation.
- (b) Public Health Emergency Medical Countermeasures Enterprise;
- (c) Project BioShield;
- (d) Public Health Emergency Preparedness (PHEP) cooperative agreement; and,
- (e) Cities Readiness Initiative.

TITLE III — PROTECTION OF THIS ACT

SEC. 301. PROTECTION OF THIS ACT

Notwithstanding any current or future legislation, the provisions of this Act may not be repealed or suspended except as provided for by the provision found within this Title of this Act.

SEC. 302. SUSPENSION OF THE PROVISIONS OF THIS ACT

Notwithstanding any current or future legislation, the provisions of this Act may not be suspended except by an absolute three-fourths vote of the total number members of the US House of Representatives as authorized by the Reapportionment Act of 1929 (ch. 28, 46 Stat. 21, 2 U.S.C. 2a) and the total number of US Senators authorized by the United States Constitution (U.S. CONST. art I, § 3, cl. 1).

SEC. 303. REPEALING PROVISIONS OF THIS ACT

Notwithstanding any current or future legislation, the provisions of this Act may not be repealed except by an absolute three-fourths vote of the total number of members of both the US House of Representatives as authorized by the Reapportionment Act of 1929 (ch. 28, 46 Stat. 21, 2 U.S.C. 2a) and the US Senate as authorized by the United States Constitution (U.S. CONST. art I, § 3, cl. 1).

TITLE IV — GENERAL PROVISIONS

SEC. 401. PERMANENT APPROPRIATIONS

Section 1305 of title 31, United States Code is amended adding the following new paragraphs:

- (a) “(10) to make payments required under contracts and orders made under the Defense Production Act of 1950, as amended (50 U.S.C. 4501 *et seq.*).”
- (b) “(11) to make payments required under contracts made under sections 247d, 247d–6a, 247d–6b, and 247d–6e of title 42, United States Code.”
- (c) “(12) to make payments required under the Public Health Emergency Production Act of ____ (____ U.S.C. ____).”
- (d) “(13) to make payments required under contracts and orders made under the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) (42 U.S.C. 300hh-10a).”

SEC. 402. PHEP PROJECT AREA SNS COORDINATORS

- (a) No later than the fifth fiscal year following enactment of this Act, all 62 Public Health Emergency Preparedness Cooperative (PHEP) cooperative agreement project areas’ Strategic National Stockpile (SNS) or Medical Countermeasures (MCM) Coordinators shall receive a salary no less than the current fiscal year’s General Schedule grade 13, step 3 and no more than level IV of the Executive Schedule (5 U.S.C. 5304 (g)(1)) with the appropriate locality pay adjustment.

- (b) All 62 PHEP SNS/MCM Coordinators shall be paid out of their respective PHEP cooperative agreements.
- (c) The PHEP cooperative agreement shall include this section as a required provision for acceptance.

SEC. 403. SECURITY CLEARANCES

- (a) This section applies to all federal, state, and local government employees, contractors, and partners working on or with the Strategic National Stockpile and its programs.
- (b) All individuals identified in subsection (a) above shall maintain at a minimum the following:
 - (1) Single Scope Background Investigation (SSBI) with a positive adjudication;
 - (2) a minimum of a Secret security clearance; and,
 - (3) a Department of Energy issued L or Q clearance if required by, or their current position is designated as such by the Director of the Strategic National Stockpile, Assistant Secretary for Preparedness and Response, Secretary of Health and Human Services, or the Secretary of Energy.
- (c) The Director of the Strategic National Stockpile, or his designee, may grant interim security clearances while the required background investigation is being conducted, provided that the individual receiving the interim security clearance has not previously had a security clearance revoked for cause.
- (d) Original Classifying and Declassifying Authority.
 - (1) The Director and Deputy Director of the Strategic National Stockpile shall have Original Classifying Authority and declassification authority for classified materials related to the Strategic National Stockpile.
 - (2) The following are authorized to override the decision of the Director and Deputy Director of the Strategic National Stockpile as it relates to their respective Original Classifying and Declassifying Authority and as it relates to this subsection only:
 - (i) The President of the United States;
 - (ii) The Vice President of the United States;
 - (iii) Executive Office of the President of the United States
 - (aa) Assistant to the President and Chief of Staff;
 - (bb) Assistant to the President for National Security Affairs;
 - (cc) Assistant to the President for Homeland Security and Counterterrorism;
 - (dd) Assistant to the President and Deputy National Security Advisor;
 - (ee) Deputy Homeland Security Advisor
 - (iv) US Department of Defense
 - (aa) Secretary of Defense;
 - (bb) Deputy Secretary of Defense;
 - (cc) Under Secretaries and Deputy Under Secretaries of Defense for:
 - (AA) Intelligence;
 - (BB) Policy;

- (CC) Research and Engineering;
- (dd) Deputy Under Secretaries of Defense
- (ee) Assistant Secretary of Defense for:
 - (AA) Health Affairs;
 - (BB) Homeland Defense;
 - (CC) Nuclear, Chemical & Biological Defense Programs;
- (ff) Chairman of the Joint Chiefs of Staff;
- (gg) Vice Chairman of the Joint Chiefs of Staff;
- (hh) Director, National Security Agency;
- (ii) Deputy Director, National Security Agency;
- (jj) Director, National Reconnaissance Office;
- (kk) Deputy Director, National Reconnaissance Office;
- (ll) Director, Defense Intelligence Agency
- (mm) Deputy Director. Defense Intelligence Agency;
- (nn) Director, National Geospatial-Intelligence Agency;
- (oo) Deputy Director, National Geospatial-Intelligence Agency;
- (pp) Department of the Air Force
 - (AA) Secretary of the Air Force;
 - (BB) Under Secretary of the Air Force;
 - (CC) Chief of Staff of the Air Force;
 - (DD) Vice Chief of Staff of the Air Force;
 - (EE) Chief of Space Operations;
 - (FF) Vice Chief of Space Operations;
 - (GG) Commander, Sixteenth Air Force
 - (HH) Deputy Commander, Sixteenth Air Force;
 - (II)
- (qq) Department of the Army
 - (AA) Secretary of the Army;
 - (BB) Under Secretary of the Army;
 - (CC) Chief of Staff of the Army;
 - (DD) Vice Chief of Staff of the Army;
 - (EE) Deputy Chief of Staff for Intelligence;
 - (FF) Chief of the Military Intelligence Corps;
- (rr) Department of the Navy
 - (AA) Secretary of the Navy;
 - (BB) Under Secretary of the Navy;
 - (CC) Chief of Naval Operations;
 - (DD) Vice Chief of Naval Operations;
 - (EE) Commandant of the Marine Corps;
 - (FF) Assistant Commandant of the Marine Corps;
 - (GG) Director of Intelligence, US Marine Corps;
 - (HH) Assistant Director of Intelligence, US Marine Corps;
- (v) US Department of Energy:
 - (aa) Secretary of Energy;
 - (bb) Deputy Secretary of Energy;
 - (cc) Under Secretary of Energy for Nuclear Security;

- (dd) Deputy Under Secretary of Energy for Nuclear Security;
- (vi) US Department of Health and Human Services:
 - (aa) Secretary of Health and Human Services;
 - (bb) Deputy Secretary of Health and Human Services;
 - (cc) Assistant Secretary of Health;
 - (dd) Assistant Secretary of Preparedness and Response;
 - (ee) Principal Deputy Assistant Secretary of Preparedness and Response;
- (vii) US Department of Homeland Security:
 - (aa) Secretary of Homeland Security;
 - (bb) Deputy Secretary of Homeland Security;
 - (cc) Under Secretaries and Principal Deputy Under Secretaries of Homeland Security for:
 - (AA) Intelligence and Analysis;
 - (BB) Strategy, Policy, and Plans;
 - (dd) Assistant Secretary for Countering Weapons of Mass Destruction;
 - (ee) Principal Assistant Secretary for Countering Weapons of Mass Destruction;
 - (ff) United States Coast Guard:
 - (AA) Commandant;
 - (BB) Vice Commandant;
 - (CC) Assistant Commandant for Intelligence;
 - (DD) Deputy Assistant Commandant for Intelligence
- (viii) US Department of Justice:
 - (aa) Attorney General;
 - (bb) Deputy Attorney General;
 - (cc) Drug Enforcement Administration:
 - (AA) Administrator;
 - (BB) Principal Deputy Administrator;
 - (CC) Assistant Administrator for Intelligence;
 - (DD) Director, Office of National Security Intelligence;
 - (EE) Principal Deputy Director, Office of National Security Intelligence;
 - (dd) Federal Bureau of Intelligence:
 - (AA) Director;
 - (BB) Deputy Director;
 - (CC) Executive Assistant Director, Intelligence Branch;
 - (DD) Assistant Director, Directorate of Intelligence;
- (ix) US Department of State:
 - (aa) Secretary of States;
 - (bb) Deputy Secretary of State;
 - (cc) Assistant Secretary of State for Intelligence and Research;
 - (dd) Principal Deputy Assistant Secretary of State for Intelligence and Research;
- (x) US Department of the Treasury:

- (aa) Secretary of the Treasury;
- (bb) Deputy Secretary of the Treasury;
- (cc) Assistant Secretary of the Treasury for Intelligence and Analysis;
- (dd) Principal Deputy Assistant Secretary of the Treasury for Intelligence and Analysis;
- (xi) United States Intelligence Community:
 - (aa) Director of National Intelligence;
 - (bb) Principal Director of National Intelligence;
 - (cc) Director, Central Intelligence Agency;
 - (dd) Deputy Director, Central Intelligence Agency.

SEC. 404. SHELF-LIFE EXTENSION PROGRAM

- (a) All 62 PHEP cooperative agreement project areas' health departments shall have access to and the authority to utilize the Food and Drug Administration's Shelf-Life Extension Program (SLEP) at their own cost.
- (b) Funding provided by the PHEP cooperative agreement may be utilized to pay any associated SLEP costs.

SEC. 405. DELEGATION OF AUTHORITY

- (a) Except as provided for in this section, no authority granted in this Act may be delegated.
- (b) Authority to authorize the following actions is delegated to the Deputy Assistant Secretary for the Strategic National Stockpile or his designee:
 - (1) Response of the Strategic National Stockpile;
 - (2) Release of Strategic National Stockpile assets, including but not limited to:
 - (i) Stockpile Managed Inventory;
 - (ii) Vendor Managed Inventory;
 - (iii) CHEMPACK;
 - (iv) Federal Medical Stations;
 - (v) Personal Protective Equipment; and,
 - (vi) Ventilators.
 - (3) Request assistance from any:
 - (i) Executive, Judicial, or Legislative Branch department or agency of the:
 - (aa) United States Government;
 - (bb) United States Territorial Governments;
 - (cc) State Governments; and,
 - (dd) Freely Associated State Governments;
 - (ii) Notwithstanding section 303 of the National Defense Production Act [50 U.S.C. § 4533 (2018)] enter into any contracts, not exceeding \$20,000,000 individually or \$250,000 collectively, necessary to fulfill its statutory and regulatory obligations.

SEC. 406. EFFECTIVE DATE

This Act shall take effect on the earlier date of the following:

- (a) ninety (90) days following enactment; or
- (b) the first day of October immediately following enactment of this Act.

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