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STRENGTHENING AMERICA'S STRATEGIC NATIONAL STOCKPILE ACT OF 2020

SEPTEMBER 18, 2020.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. PALLONE, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 7574]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 7574) to amend the Public Health Service Act with respect to the Strategic National Stockpile, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Strengthening America's Strategic National Stockpile Act of 2020".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Reimbursable transfers.
Sec. 3. Equipment maintenance.
Sec. 4. Supply chain flexibility manufacturing pilot.
Sec. 5. GAO study on the feasibility and benefits of a user fee agreement.
Sec. 6. Grants for State strategic stockpiles.
Sec. 7. Action reporting.
Sec. 8. Improved, transparent processes.
Sec. 9. Authorization of appropriations.

SEC. 2. REIMBURSABLE TRANSFERS.

Section 319F–2(a) of the Public Health Service Act (42 U.S.C. 247d–6b(a)) is amended by adding at the end the following:

"(6) TRANSFERS AND REIMBURSEMENTS.—

"(A) IN GENERAL.—Without regard to chapter 5 of title 40, United States Code, the Secretary may transfer to any Federal department or agency, on a reimbursable basis, any drugs, vaccines and other biological products, medical devices, and other supplies in the stockpile if—

"(i) the transferred supplies are less than one year from expiry;

"(ii) the stockpile is able to replenish the supplies, as appropriate; and

"(iii) the Secretary decides the transfer is in the best interest of the United States Government.

"(B) USE OF REIMBURSEMENT.—Reimbursement derived from the transfer of supplies pursuant to subparagraph (A) may be used by the Secretary, without further appropriation and without fiscal year limitation, to carry out this section.

"(C) RULE OF CONSTRUCTION.—This paragraph shall not be construed to preclude transfers of products in the stockpile under other authorities.

"(D) REPORT.—Not later than September 30, 2022, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on each transfer made under this paragraph and the amount received by the Secretary in exchange for that transfer.

"(E) SUNSET.—The authority to make transfers under this paragraph shall cease to be effective on September 30, 2023.".

SEC. 3. EQUIPMENT MAINTENANCE.

Section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) is amended—

(1) in subsection (a)(3)—

(A) in subparagraph (I), by striking "; and" and inserting a semicolon;

(B) in subparagraph (J), by striking the period at the end and inserting a semicolon; and

(C) by inserting the following new subparagraph at the end:

"(K) ensure contents of the stockpile remain in good working order and, as appropriate, conduct maintenance services on contents of the stockpile; and"; and

(2) in subsection (c)(7)(B), by adding at the end the following new clause:

"(ix) EQUIPMENT MAINTENANCE SERVICE.—In carrying out this section, the Secretary may enter into contracts for the procurement of equipment maintenance services.".

SEC. 4. SUPPLY CHAIN FLEXIBILITY MANUFACTURING PILOT.

(a) IN GENERAL.—Section 319F–2(a)(3) of the Public Health Service Act (42 U.S.C. 247d–6b(a)(3)), as amended by section 3, is further amended by adding at the end the following new subparagraph:

"(L) enhance medical supply chain elasticity and establish and maintain domestic reserves of critical medical supplies (including personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, and other medical devices (including diagnostic tests)) by—

"(i) increasing emergency stock of critical medical supplies;

"(ii) geographically diversifying domestic production of such medical supplies, as appropriate;

"(iii) entering into cooperative agreements or partnerships with respect to manufacturing lines, facilities, and equipment for the domestic production of such medical supplies; and

"(iv) managing, either directly or through cooperative agreements with manufacturers and distributors, domestic reserves established under this subparagraph by refreshing and replenishing stock of such medical supplies.".

(b) REPORTING; SUNSET.—Section 319F–2(a) of the Public Health Service Act (42 U.S.C. 247d–6b(a)), as amended by section 2, is further amended by adding at the end the following:

"(7) REPORTING.—Not later than September 30, 2022, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report on the details of each cooperative agreement or partnership entered into under paragraph (3)(L), including the amount expended by the Secretary on each such cooperative agreement or partnership.

"(8) SUNSET.—The authority to enter into cooperative agreements or partnerships pursuant to paragraph (3)(L) shall cease to be effective on September 30, 2023.".

(c) FUNDING.—Section 319F–2(f) of the Public Health Service Act (42 U.S.C. 247d–6b(f)) is amended by adding at the end the following:

"(3) SUPPLY CHAIN ELASTICITY.—

"(A) IN GENERAL.—For the purpose of carrying out subsection (a)(3)(L), there is authorized to be appropriated $500,000,000 for each of fiscal years 2020 through 2023, to remain available until expended.

"(B) RELATION TO OTHER AMOUNTS.—The amount authorized to be appropriated by subparagraph (A) for the purpose of carrying out subsection (a)(3)(L) is in addition to any other amounts available for such purpose.".

SEC. 5. GAO STUDY ON THE FEASIBILITY AND BENEFITS OF A USER FEE AGREEMENT.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study to investigate the feasibility of establishing user fees to offset certain Federal costs attributable to the procurement of single-source materials for the Strategic National Stockpile under section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) and distributions of such materials from the Stockpile. In conducting this study, the Comptroller General shall consider, to the extent information is available—

(1) whether entities receiving such distributions generate profits from those distributions;

(2) any Federal costs attributable to such distributions;

(3) whether such user fees would provide the Secretary with funding to potentially offset procurement costs of such materials for the Strategic National Stockpile; and

(4) any other issues the Comptroller General identifies as relevant.

(b) REPORT.—Not later than February 1, 2023, the Comptroller General of the United States shall submit to the Congress a report on the findings and conclusions of the study under subsection (a).

SEC. 6. GRANTS FOR STATE STRATEGIC STOCKPILES.

Title III of the Public Health Service Act is amended by inserting after section 319F–4 of such Act (42 U.S.C. 247d–6e) the following new section:

"SEC. 319F–5. GRANTS FOR STATE STRATEGIC STOCKPILES.

"(a) IN GENERAL.—The Secretary may establish a pilot program consisting of awarding grants to States to expand or maintain a strategic stockpile of commercially available drugs, medical equipment, personal protective equipment, and other products deemed by the State to be essential in the event of a public health emergency.

"(b) ALLOWABLE USE OF FUNDS.—

"(1) USES.—A State receiving a grant under this section may use the grant funds to—

"(A) acquire commercially available products listed pursuant to paragraph (2) for inclusion in the State's strategic stockpile;

"(B) store, maintain, and distribute products in such stockpile; and

"(C) conduct planning in connection with such activities.

"(2) LIST.—The Secretary shall develop and publish a list of the products that are eligible, as described in subsection (a), for inclusion in a State's strategic stockpile using funds received under this section.

"(3) CONSULTATION.—In developing the list under paragraph (2) and otherwise determining the allowable uses of grant funds under this section, the Secretary shall consult with States and relevant stakeholders, including public health organizations.

"(c) FUNDING REQUIREMENT.—The Secretary may not obligate or expend any funds to award grants or fund any previously awarded grants under this section for a fiscal year unless the total amount made available to carry out section 319F–2 for such fiscal year is equal to or greater than the total amount of funds made available to carry out section 319F–2 for fiscal year 2020.

"(d) MATCHING FUNDS.—

"(1) IN GENERAL.—With respect to the costs of expanding and maintaining a strategic stockpile through a grant under this section, as a condition on receipt of the grant, a State shall make available (directly) non-Federal contributions in cash toward such costs in an amount that is equal to not less than the amount of Federal funds provided through the grant.

"(2) WAIVER.—The Secretary may waive the requirement of paragraph (1) with respect to a State for the first two years of the State receiving a grant under this section if the Secretary determines that such waiver is needed for the State to establish a strategic stockpile described in subsection (a).

"(e) TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance to States in establishing, expanding, and maintaining a stockpile described in subsection (a).

"(f) DEFINITION.—In this section, the term 'drug' has the meaning given to that term in section 201 of the Federal Food, Drug, and Cosmetic Act.

"(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $3,500,000,000 for each of fiscal years 2020 through 2023, to remain available until expended.

"(h) SUNSET.—The authority vested by this section terminates at the end of fiscal year 2023.".

SEC. 7. ACTION REPORTING.

(a) IN GENERAL.—The Assistant Secretary for Preparedness and Response (in this section referred to as the "Assistant Secretary"), in coordination with the Administrator of the Federal Emergency Management Agency, shall—

(1) not later than 30 days after the date of enactment of this Act, issue a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate regarding all State, local, Tribal, and territorial requests for supplies from the Strategic National Stockpile related to COVID–19; and

(2) not less than every 30 days thereafter through the end of the emergency period (as such term is defined in section 1135(g)(1)(B) of the Social Security Act (42 U.S.C. 1320b–5(g)(1)(B))), submit to such committees an updated version of such report.

(b) REPORTING PERIOD.—

(1) INITIAL REPORT.—The initial report under subsection (a) shall address all requests described in such subsection made during the period—

(A) beginning on January 31, 2020; and

(B) ending on the date that is 30 days before the date of submission of the report.

(2) UPDATES.—Each update to the report under subsection (a) shall address all requests described in such subsection made during the period—

(A) beginning at the end of the previous reporting period under this section; and

(B) ending on the date that is 30 days before the date of submission of the updated report.

(c) CONTENTS OF REPORT.—The report under subsection (a) (and updates thereto) shall include—

(1) the details of each request described in such subsection, including—

(A) the specific medical countermeasures, devices, personal protective equipment, and other materials requested; and

(B) the amount of such materials requested; and

(2) the outcomes of each request described in subsection (a), including—

(A) whether the request was wholly fulfilled, partially fulfilled, or denied;

(B) if the request was wholly or partially fulfilled, the fulfillment amount; and

(C) if the request was partially fulfilled or denied, a rationale for such outcome.

SEC. 8. IMPROVED, TRANSPARENT PROCESSES.

(a) IN GENERAL.—Not later than January 1, 2021, the Secretary of Health and Human Services, in collaboration with the Assistant Secretary for Preparedness and Response and the Director of the Centers for Disease Control and Prevention, shall develop and implement improved, transparent processes for the use and distribution of drugs, vaccines and other biological products, medical devices, and other supplies (including personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests) in the Strategic National Stockpile under section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) (in this section referred to as the "Stockpile").

(b) PROCESSES.—The processes developed under subsection (a) shall include—

(1) the form and manner in which States, localities, Tribes, and territories are required to submit requests for supplies from the Stockpile;

(2) the criteria used by the Secretary of Health and Human Services in responding to such requests, including the reasons for fulfilling or denying such requests;

(3) what circumstances result in prioritization of distribution of supplies from the Stockpile to States, localities, Tribes, or territories;

(4) clear plans for future, urgent communication between the Secretary and States, localities, Tribes, and territories regarding the outcome of such requests; and

(5) any differences in the processes developed under subsection (a) for geographically related emergencies, such as weather events, and national emergencies, such as pandemics.

(c) CLASSIFICATION.—The processes developed under subsection (a) shall be unclassified to the greatest extent possible consistent with national security. The Secretary of Health and Human Services may classify portions of such processes as necessary to protect national security.

(d) REPORT TO CONGRESS.—Not later than January 1, 2021, the Secretary of Health and Human Services shall—

(1) submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate regarding the improved, transparent processes developed under this section;

(2) include in such report recommendations for opportunities for communication (by telebriefing, phone calls, or in-person meetings) between the Secretary and States, localities, Tribes, and territories regarding such improved, transparent processes; and

(3) submit such report in unclassified form to the greatest extent possible, except that the Secretary may include a classified appendix if necessary to protect national security.

SEC. 9. AUTHORIZATION OF APPROPRIATIONS.

Section 319F–2(f)(1) of the Public Health Service Act (42 U.S.C. 247d-6b(f)(1)) is amended by striking "$610,000,000 for each of fiscal years 2019 through 2023" and inserting "$705,000,000 for each of fiscal years 2020 through 2023".

I. PURPOSE AND SUMMARY

H.R. 7574, the "Strengthening America's Strategic National Stockpile Act of 2020", was introduced on July 13, 2020, by Representatives Elissa Slotkin (D–MI), Susan Brooks (R–IN), Anna G. Eshoo (D–CA), Earl "Buddy" L. Carter (R–GA), Debbie Dingell (D–MI), Jackie Walorski (R–IN), Diana DeGette (D–CO), David McKinley (R–WV), G.K. Butterfield (D–NC), Jeff Van Drew (R–NJ), Darren Soto (D–FL), Fred Upton (R–MI), Tom Malinowski (D–NJ), Richard Hudson (R–NC), Kim Schrier (D–CA), Greg Gianforte (R–MT), Gil Cisneros (D–CA), Joe Neguse (D–CO), and Michael C. Burgess (R–TX).

H.R. 7574 amends the Public Health Service Act to enhance the capabilities of the Strategic National Stockpile (SNS) in order to ensure the Federal Government can sufficiently respond to the ongoing coronavirus disease of 2019 (COVID–19) pandemic and prepare for future public health emergencies that require distributions of drugs, devices, vaccines, or other ancillary medical supplies from the SNS.

In order to ensure all supplies within the SNS are operational and to prevent expired items from remaining in the stockpile, the legislation authorizes the SNS to transfer to other Federal agencies for reimbursement supplies within the stockpile that are less than one year from expiry and requires that the SNS ensure the contents of the stockpile remain in good working order. Additionally, H.R. 7574 establishes a supply chain manufacturing pilot to en-

hance supply chain elasticity and build up the domestic reserves of critical medical supplies. This pilot would be intended to ensure manufacturing supply chains of critical supplies could be expanded when needed to meet demand, and then appropriately reduced once demand has been fulfilled.

The bill also requires the Government Accountability Office (GAO) to study the feasibility of user fees for certain supplies within the SNS and authorizes grants to States to expand or maintain State strategic stockpiles of commercially available medical supplies and countermeasures for use in the event of a public health emergency. H.R. 7574 increases transparency of SNS medical countermeasure (MCM) allocation by requiring ongoing action reporting in response to the COVID–19 pandemic, as well as the development of improved, transparent processes for the use and distribution of MCMs moving forward. Finally, the legislation increases the annual authorization of appropriations for the SNS to $705 million for each of the fiscal years 2020 through 2023.

Based on lessons learned from the ongoing COVID–19 pandemic, H.R. 7574 provides the SNS with the necessary tools and transparent processes that will ultimately strengthen its ability to better prepare for and respond to future public health emergencies.

II. Background and Need for Legislation

Established in 1998 as the National Pharmaceutical Stockpile, Congress appropriated funds to the Department of Health and Human Services (HHS) to create a national stockpile of pharmaceuticals and other medical supplies that may be needed for rapid deployment in response to an emergency.[1] In 2002, the stockpile was renamed and first authorized as the Strategic National Stockpile (SNS) in the Public Health Security and Bioterrorism Preparedness Act of 2002.[2] Historically, the SNS has largely contained materials relevant to chemical, biological, radiological, and nuclear (CBRN) events, including antibiotics, ancillary medical supplies, equipment, antidotes, antitoxins, antivirals, vaccines, and other medical countermeasures (MCMs) that are strategically located throughout the United States that can be distributed quickly after State and local authorities request such assets from the stockpile.[3] The SNS also has limited quantities of personal protective equipment (PPE), including N95 respirators, face masks, face shields, gowns, coveralls, and gloves. With respect to what are typically widely-available supplies such as PPE, the SNS was designed to serve as a source of medical supplies and medicines for use during domestic public health emergencies in which adequate amounts of State and local supplies may be depleted and not immediately

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[1] Strategic National Stockpile, Overview, Association of State and Territorial Health Officials, available at https://astho.org/Programs/Preparedness/Public-Health-Emergency-Law/Emergency-Use-Authorization-Toolkit/Strategic-National-Stockpile-Fact-Sheet/. See also *Strategic National Stockpile: Origin, Policy Foundations, and Federal Context*, available at https://www.ncbi.nlm.nih.gov/books/NBK396378/; Strategic National Stockpile (SNS) Radiation Emergency Medical Management, U.S. Dep't of Health & Human Services, available at https://www.remm.nlm.gov/sns.htm.

[2] Id.

[3] About the Strategic National Stockpile, Office of the Assistant Secretary for Preparedness and Response, available at https://www.phe.gov/about/sns/Pages/about.aspx. See also National Stockpiles: Background and Issues for Congress, Congressional Research Service, available at https://www.crs.gov/Reports/IF11574?source=search&guid9b97faf5767f4cb6bf0f65c69216cfae&index=0.

available.[4] Since the initial authorization of the SNS, the stockpile has been continually reauthorized, most recently as part of the Pandemic All-Hazards Preparedness and Advancing Innovation Act of 2019.[5]

Since the emergence of the novel coronavirus, known as SARS–CoV–2, the SNS has been utilized throughout the country to provide PPE, medical devices such as ventilators, and other medical supplies to health care workers and other first responders in order to meet the needed demand to respond to COVID–19. On January 31, 2020, HHS Secretary Alex Azar declared a public health emergency in response to the emergence of COVID–19[6] and six weeks later, on March 13, 2020, President Trump issued a proclamation declaring a national emergency concerning the COVID–19 outbreak.[7] The proclamation noted that the spread of COVID–19 within the United States "threatens to strain our Nation's healthcare system"[8] and in the weeks and months following the national emergency declarations, this strain on the Nation's healthcare system continues. This was the first time the President had declared a nationwide Stafford Act emergency in response to a public health emergency.[9]

In response to COVID–19, the SNS has deployed PPE, including N95 respirators, surgical and face masks, face shields, gloves, and disposable gowns to help prevent COVID–19 transmission in all 50 States, the Nation's four largest cities, as well as in U.S. territories.[10] The SNS has also deployed ventilators to areas in need.[11] However, COVID–19 "presented an unusual set of circumstances involving nearly simultaneous requests from all 56 [State, local, Tribal, and territorial] SLTT authorities."[12] As the pandemic has continued, the stockpile's supplies have been exhausted as a result of the simultaneous, widespread, and ongoing demand from across the country and around the world.[13] The COVID–19 pandemic has been an unprecedented experience for the SNS as compared with

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[4] U.S. Department of Health and Human Services, Public Health Emergency, Inventory Management and Tracking System (IMATS), Sustaining the Stockpile (Mar. 12, 2020), available at https://www.phe.gov/about/sns/Pages/imats.aspx.

[5] P.L.116–22.

[6] Secretary Azar Declares Public Health Emergency for United States for 2019 Novel Coronavirus, Jan. 31, 2020, available at https://www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html#:~:text=Health%20and%20Human%20Services%20Secretary%20Alex%20M.%20Azar,healthcare%20community%20in%20responding%20to%202019%20novel%20coronavirus.

[7] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak, March 13, 2020, available at https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

[8] Id.

[9] Congressional Research Service, Presidential Declarations of Emergency for COVID–19: NEA and Stafford Act, INSIGHT IN11264 (Mar. 19, 2020), available at https://crsreports.congress.gov/product/pdf/IN/IN11264.

[10] HHS/ASPR Strategic National Stockpile, Response to the COVID–19 Pandemic, Office of the Assistant Secretary for Preparedness and Response, available at https://www.phe.gov/emergency/events/COVID19/SNS/Pages/default.aspx.

[11] Id.

[12] The Strategic National Stockpile and COVID–19, Testimony of Daniel M. Gerstein, The RAND Corporation, June 24, 2020, available at https://www.rand.org/content/dam/rand/pubs/testimonies/CTA500/CTA530-1/RAND_CTA530-1.pdf.

[13] *See Protective gear in national stockpile is nearly depleted, DHS officials say*, April 1, 2020, Washington Post, available at https://www.washingtonpost.com/national/coronavirus-protective-gear-stockpile-depleted/2020/04/01/44d6592a-741f-11ea-ae50-7148009252e3_story.html.

previous public health emergencies in which the SNS and relevant supplies in inventory were utilized for more targeted purposes.[14]

Additionally, some supplies within the SNS, including ventilators, were found to be inoperative when deployed based on lack of previous use and maintenance.[15] Other supplies, such as respirators and face masks, were deployed from the stockpile despite having surpassed their manufacturer-designated expiration for use.[16] Some States and cities reported receiving masks and respirators with dry rot and faulty elastics.[17] In one case discovered by the HHS Office of the Inspector General, certain masks distributed to a health system from the Federal and State governments were designed for children and therefore unusable for adult medical providers.[18] In a statement, the CDC acknowledged that some items had indeed exceeded their manufacturer-designated shelf life, but were nevertheless sent to hospitals "due to the potential urgent demand caused by the COVID–19 public health emergency." [19] The urgent demand also strained State-based stockpiled resources, which in some cases also contained expired supplies, compounding broader medical supply access throughout the country. For example, Missouri had a left-over supply of 663,920 N95 respirator masks, 253,800 surgical masks, 154,000 gloves, 17,424 face shields, and 14,048 gowns provided by CDC after the 2009 H1N1 influenza pandemic.[20] Stockpiles in California, Colorado, Connecticut, Illinois, Michigan, Nevada, New Hampshire, New Mexico, Ohio, Pennsylvania, Virginia, Vermont, Washington, and West Virginia all included at least some leftovers from the H1N1 pandemic as well.[21]

The background of the supply shortfall would be incomplete without mention of how supply needs were compounded by failings of global medical supply chains, which were completely disrupted by the pandemic.[22] Long standing declines in public health funding at the Federal and State levels and the growth of "just in time" inventory models, also contributed to nationwide shortages of critical supplies.[23]

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[14] COVID–19: Opportunities to Improve Federal Response and Recovery Efforts, Report to the Congress, Government Accountability Office, June 25, 2020, available at https://www.gao.gov/reports/GAO-20-625/.

[15] *See A ventilator Stockpile, With One Hitch: Thousands Do Not Work*, April 1, 2020, New York Times, available at https://www.nytimes.com/2020/04/01/us/politics/coronavirus-ventilators.html.

[16] *Health care workers using expired gear during pandemic and 'hoping for the best'* March 30, 2020, NC Policy Watch, available at http://www.ncpolicywatch.com/2020/03/30/health-care-workers-using-expired-gear-during-pandemic-and-hoping-for-the-best/.

[17] *Some states receive masks with dry rot, broken ventilators,* April 4, 2020, AP News, available at https://apnews.com/f43781b64bacd6aa094d9404f4ab91a4.

[18] *See Protective gear in national stockpile is nearly depleted, DHS officials say*, April 1, 2020, Washington Post, available at https://www.washingtonpost.com/national/coronavirus-protective-gear-stockpile-depleted/2020/04/01/44d6592a-741f-11ea-ae50-7148009252e3_story.html. *See also*, Hospital Experiences Responding to the COVID–19 Pandemic: Results of a National Pulse Survey March 23–27, 2020, Dep't of Health and Human Services, Office of Inspector General, available at https://oig.hhs.gov/oei/reports/oei-06-20-00300.pdf

[19] Supra n. 17.

[20] David Lieb, Cuneyt Dil, AP Review: State supply stocks sparse and dated before virus, THE ASSOCIATED PRESS (Apr. 23, 2020), available at https://apnews.com/1f123d323b4089a6f7b242abcceb6d08.

[21] Id.

[22] We Need a Stress Test for Critical Supply Chains, David Simchi-Levi and Edith Simchi-Levi, Harvard Business Review, April 28, 2020, available at https://hbr.org/2020/04/we-need-a-stress-test-for-critical-supply-chains?ab=hero-subleft-1

[23] State Public Health Resources and Capacity, Association of State and Territorial Health Officials, March 23, 2020, available at https://www.astho.org/Research/Data-and-Analysis/Data-Brief-on-State-Public-Health-Resources-and-Capacity/. *See also Why don't hospitals have enough masks? Because coronavirus broke the market.* May 21, 2020, Washington Post, available at

H.R. 7574 authorizes several important initiatives to address the challenges experienced during the COVID–19 pandemic by providing the SNS with new tools and flexibilities that will help address domestic supply chain shortfalls, ultimately strengthening the ability of the SNS to prepare for and respond to major public health emergencies in the future. Section 2 of H.R. 7574 allows the SNS to pilot the reimbursable transfer of supplies within the stockpile that are near expiration to other Federal agencies for more immediate usage, which will permit the SNS to use the reimbursement towards the purchase of new supplies for the stockpile that will be readily available for deployment and will not be at risk of imminent expiration. Additionally, section 3 of the legislation requires that items within the stockpile be maintained in "good working order" to prevent deployment of any devices or equipment that would not be operational as a result of lack of use or lack of maintenance. Further, this section clarifies that the Secretary may enter into contracts for purposes of equipment maintenance services.

Section 4 of the bill is intended to increase the domestic reserves of critical medical supplies, including PPE, ancillary medical supplies, medical devices including diagnostic tests, and other supplies required for the administration of vaccines or treatments, which have been in significant shortage and extremely high demand since the emergence of COVID–19. This manufacturing pilot would support increasing emergency stock of medical supplies, diversification of medical supply production, and entering into cooperative agreements or partnerships for domestic production of medical supplies. This pilot will be in effect until September 30, 2023. Section 5 of H.R. 7574 directs the Comptroller General to conduct a study to investigate the feasibility of establishing user fees to offset Federal costs associated with the procurement of certain materials for the SNS. The study should examine whether the user fees would augment Congressional appropriations to the SNS for purposes of procurement.

Section 6 authorizes the creation of a pilot grant program for the enhancement and maintenance of independent State-managed medical stockpiles to help States and localities maintain reserve supplies. These State-managed reserves would be intended to supplement supplies deployed from the SNS, ultimately contributing additional resources in the event of an emergency and helping States be better prepared to manage critical shortages of medical resources in the future. Grants under this program can only be funded if the SNS's fiscal year funding is maintained at fiscal year 2020 funding levels or greater.

In order to increase transparency with regards to SNS operations, section 7 of H.R. 7574 requires the Secretary, in consultation with the Administrator of the Federal Emergency Management Agency (FEMA), to submit monthly reports to Congress regarding all requests made by States, localities, Tribes and territories for supplies from the SNS during the COVID–19 public health emergency. This action reporting is intended to better inform Congress about the needs and nature of requests of State and local health officials responding to COVID–19, and the allocations

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https://www.washingtonpost.com/outlook/2020/05/21/why-dont-hospitals-have-enough-masks-because-coronavirus-broke-market/.

deployed from the SNS to fulfill those needs and requests. Additionally, section 8 of H.R. 7574 requires the Secretary to develop and implement an improved, transparent process for the use and distribution of supplies from the SNS in the future. Given the critical and vast needs identified during the COVID–19 public health emergency, a more transparent process by which States, localities, Tribes, and territories can request supplies from the SNS will help enhance the stockpile's response capabilities, potentially shorten deployment timeframes, and improve the allocation of resources.

Finally, to ensure resource limitations do not contribute to shortages or delays for maintaining and deploying supplies from the SNS, H.R. 7574 also strengthens the stockpile's financial security by increasing the annual authorization of appropriations from $610 million to $705 million for each of the fiscal years 2020 through 2023. This reflects the enacted funding level for the SNS for fiscal year 2020.

Together, the provisions of H.R. 7574 will strengthen the capabilities of the SNS to better prepare for and respond to public health emergencies in the future that require the deployment of critical medical supplies throughout the country. The legislation will also ensure the SNS has the ability to build better domestic manufacturing supply capacity as the Nation continues to respond to the COVID–19 pandemic.

III. Committee Hearings

For the purposes of section 103(i) of H. Res. 6 of the 116th Congress, the following hearing was used to develop or consider H.R. 7574:

The Committee on Energy and Commerce held a hearing on June 23, 2020, entitled, "Oversight of the Trump Administration's Response to the COVID–19 Pandemic." The full Committee received testimony from the following witnesses:

- Anthony Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health
- Adm. Brett P. Giroir, M.D., Assistant Secretary for Health, U.S. Department of Health and Human Services
- Stephen M. Hahn, M.D., Commissioner, U.S. Food and Drug Administration
- Robert R. Redfield, M.D., Director, Centers for Disease Control and Prevention

IV. Committee Consideration

H.R. 7574, the "Strengthening America's Strategic National Stockpile Act of 2020", was introduced by Representatives Slotkin (D–MI) and other members on July 13, 2020, and referred to the Committee on Energy and Commerce. The bill was then referred to the Subcommittee on July 14, 2020, to the Subcommittee on Health. The bill was discharged from the subcommittee on July 15, 2020, when it was called up for consideration and markup by the full Committee. During committee consideration, a manager's amendment was offered by Mrs. Dingell of Michigan, on behalf of herself and Mrs. Brooks of Indiana. The Dingell/Brooks amendment to H.R. 7574 was agreed to by a voice vote. Consideration of the bill having concluded, the full Committee agreed to a motion

on final passage by Mr. Pallone, Chairman of the committee, to order H.R. 7574 reported favorably to the House, amended, by a voice vote, a quorum being present.

V. Committee Votes

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion to report legislation and amendments thereto. The Committee advises that there were no record votes taken on H.R. 7574, including the motion for final passage of the bill.

VI. Oversight Findings

Pursuant to clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the oversight findings and recommendations of the Committee are reflected in the descriptive portion of the report.

VII. New Budget Authority, Entitlement Authority, and Tax Expenditures

Pursuant to 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate of new budget authority, entitlement authority, or tax expenditures or revenues contained in the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

The Committee has requested but not received from the Director of the Congressional Budget Office a statement as to whether this bill contains any new budget authority, spending authority, credit authority, or an increase or decrease in revenues or tax expenditures.

VIII. Federal Mandates Statement

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

IX. Statement of General Performance Goals and Objectives

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to strengthen the Strategic National Stockpile for preparation in the event of future public health emergencies and for the continued response to the COVID–19 pandemic.

X. Duplication of Federal Programs

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 7574 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

XI. Committee Cost Estimate

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

XII. Earmarks, Limited Tax Benefits, and Limited Tariff Benefits

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 7574 contains no earmarks, limited tax benefits, or limited tariff benefits.

XIII. Advisory Committee Statement

No advisory committee within the meaning of section 5(b) of the Federal Advisory Committee Act was created by this legislation.

XIV. Applicability to Legislative Branch

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

XV. Section-by-Section Analysis of the Legislation

Section 1. Short title; table of contents

Section 1 designates that the short title may be cited as the "Strengthening America's Strategic National Stockpile Act of 2020" and provides the table of contents for the legislation.

Sec. 2. Reimbursable transfers

Section 2 amends section 319F–2(a) of the Public Health Service Act to permit the Strategic National Stockpile to transfer to any Federal department or agency, on a reimbursable basis, any drugs, vaccines or other biological products, medical devices, and other supplies in the stockpile if the supplies are less than one year from expiry; the stockpile is able to replenish the supplies, as appropriate; and the Secretary decides the transfer is in the best interest of the United States Government. A report shall be submitted to the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor and Pensions on each transfer made and the amount received in exchange for that transfer no later than September 30, 2022. The authority to make transfers under this section shall cease to be effective on September 30, 2023.

Sec. 3. Equipment maintenance

Section 3 further amends Section 319F–2 of the Public Health Service Act to require that the contents of the stockpile remain in good working order and, as appropriate, have maintenance services conducted on the contents of the stockpile. Section 3 also permits the Secretary to enter into contracts for the procurement of equipment maintenance services.

Sec. 4. Supply chain flexibility manufacturing pilot

Section 4 amends Section 319F–2(a)(3) of the Public Health Service Act to establish a supply chain flexibility manufacturing pilot in order to enhance medical supply chain elasticity and maintain domestic reserves of critical medical supplies. Such supplies include PPE, ancillary medical supplies, and other supplies required for the administration of drugs, vaccines, and other biological products, and other medical devices, including diagnostic tests. Such enhancements to domestic medical supply capacity may be done by increasing emergency stock of critical medical supplies diversifying domestic production of medical supplies, entering into cooperative agreements or partnerships with respect to manufacturing lines, facilities, and equipment for domestic production of medical supplies, and managing domestic reserves by refreshing and replenishing stock of such medical supplies. A report shall be submitted to the Committee on Energy and Commerce and the Committee on Health, Education, Labor and Pensions of the Senate on each cooperative agreement or partnership entered into under the manufacturing pilot and the amount expended by the Secretary on each cooperative agreement or partnership transfer no later than September 30, 2022. The authority to enter into cooperative agreements or partnerships under this section shall cease to be effective on September 30, 2023. To carry out this manufacturing pilot, section 4 authorizes $500,000,000 for each of fiscal years 2020 through 2023.

Sec. 5. GAO study on the feasibility and benefits of a user fee agreement

Section 5 requires the Comptroller General of the United States to conduct a study to investigate the feasibility of establishing user fees to offset certain Federal costs attributable to the procurement of single-source materials for the SNS and distributions of such materials from the stockpile. In conducting this study, the Comptroller General shall consider, to the extent information is available: whether entities receiving such distributions generate profits from those distributions; any Federal costs attributable to such distributions; whether such user fees would provide the Secretary with funding to potentially offset procurement costs of such materials for the Strategic National Stockpile; and any other issues the Comptroller General identifies as relevant. The report shall be submitted to Congress not later than February 1, 2023.

Sec. 6. Grants for state strategic stockpiles

Section 6 adds a new section 319F–5 to the Public Health Service Act to establish a pilot program that awards grants to States to expand or maintain a strategic stockpile of commercially available drugs, medical equipment, personal protective equipment, and other products deemed by the State to be essential in the event of a public health emergency. The Secretary shall develop and publish a list of products that are eligible for inclusion in a State's strategic stockpile using funds received through this pilot program. The Secretary may not obligate or expend any funds to award grants or fund any previously awarded grants under this section unless the total amount made available for the SNS under section 319F–2 is equal to or greater than the total amount of funds made available

in fiscal year 2020. States shall make available non-Federal contributions in cash toward such costs in an amount that is equal to and not less than the amount of Federal funds provided under this pilot program. However, the Secretary may waive this matching fund requirement for the first two years of a State receiving a grant if the Secretary determines that such waiver is needed for a State to establish a strategic stockpile. To carry out this section, there is $3,500,000,000 authorized to be appropriated for each of the fiscal years 2020 through 2023. The authority vested by this section terminates at the end of fiscal year 2023.

Sec. 7. Action reporting

Section 7 requires the Secretary, in consultation with the FEMA Administrator, to issue a report to the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor and Pensions regarding all State, local, Tribal, and territorial requests for supplies from the SNS related to COVID–19. This report is required to be issued not later than 30 days after the date of enactment of H.R. 7574 and shall be updated every 30 days thereafter for the duration of the emergency period. Section 7 requires that the report include the specific medical countermeasures, devices, personal protective equipment, and other materials requested and the amount of such materials requested, as well as the outcomes of each request.

Sec. 8. Improved, transparent processes

Section 8 requires the Secretary to develop and implement improved, transparent processes for the use and distribution of drugs, vaccines and other biological products, medical devices, and other supplies in the SNS. The processes developed shall include: the form and manner in which States, localities, Tribes, and territories are required to submit requests for supplies from the Stockpile; the criteria used by the Secretary in responding to such requests; the circumstances that result in prioritization of distribution to States, localities, Tribes, and territories; clear plans for future, urgent communication between the Secretary and States, localities, Tribes, and territories regarding the outcome of such requests; and any differences in the processes developed for geographically related emergencies and national emergencies.

The processes developed shall be unclassified to the greatest extent possible consistent with national security. This report shall be submitted to the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor and Pensions no later than January 1, 2021.

Sec. 9. Authorization of appropriations

Section 9 amends section 319F–2(f)(1) of the Public Health Service Act to increase the annual authorization of appropriations from $610,000,000 to $705,000,000 for each of the fiscal years 2020 through 2023.

XVI. Changes in Existing Law Made by the Bill, as Reported

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omit-

ted is enclosed in black brackets, new matter is printed in italics, and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

* * * * * * *

PART B—FEDERAL-STATE COOPERATION

* * * * * * *

SEC. 319F–2. STRATEGIC NATIONAL STOCKPILE AND SECURITY COUNTERMEASURE PROCUREMENTS.

(a) STRATEGIC NATIONAL STOCKPILE.—

(1) IN GENERAL.—The Secretary, in collaboration with the Assistant Secretary for Preparedness and Response and the Director of the Centers for Disease Control and Prevention, and in coordination with the Secretary of Homeland Security (referred to in this section as the "Homeland Security Secretary"), shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies (including personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests in the stockpile) in such numbers, types, and amounts as are determined consistent with section 2811 by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for and optimize the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency and, as informed by existing recommendations of, or consultations with, the Public Health Emergency Medical Countermeasure Enterprise established under section 2811–1, make necessary additions or modifications to the contents of such stockpile or stockpiles based on the review conducted under paragraph (2).

(2) THREAT-BASED REVIEW.—

(A) IN GENERAL.—The Secretary shall conduct an annual threat-based review (taking into account at-risk individuals) of the contents of the stockpile under paragraph (1), including non-pharmaceutical supplies, and, in consultation with the Public Health Emergency Medical Countermeasures Enterprise established under section 2811–1, review contents within the stockpile and assess whether such contents are consistent with the recommendations made pursuant to section 2811–1(c)(1)(A). Such review shall be submitted on June 15, 2019, and on March 15 of each year thereafter, to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and

Commerce and the Committee on Appropriations of the House of Representatives, in a manner that does not compromise national security.

(B) ADDITIONS, MODIFICATIONS, AND REPLENISHMENTS.—Each annual threat-based review under subparagraph (A) shall, for each new or modified countermeasure procurement or replenishment, provide—

(i) information regarding—

(I) the quantities of the additional or modified countermeasure procured for, or contracted to be procured for, the stockpile;

(II) planning considerations for appropriate manufacturing capacity and capability to meet the goals of such additions or modifications (without disclosing proprietary information), including consideration of the effect such additions or modifications may have on the availability of such products and ancillary medical supplies in the health care system;

(III) the presence or lack of a commercial market for the countermeasure at the time of procurement;

(IV) the emergency health security threat or threats such countermeasure procurement is intended to address, including whether such procurement is consistent with meeting emergency health security needs associated with such threat or threats;

(V) an assessment of whether the emergency health security threat or threats described in subclause (IV) could be addressed in a manner that better utilizes the resources of the stockpile and permits the greatest possible increase in the level of emergency preparedness to address such threats;

(VI) whether such countermeasure is replenishing an expiring or expired countermeasure, is a different countermeasure with the same indication that is replacing an expiring or expired countermeasure, or is a new addition to the stockpile;

(VII) a description of how such additions or modifications align with projected investments under previous countermeasures budget plans under section 2811(b)(7), including expected lifecycle costs, expenditures related to countermeasure procurement to address the threat or threats described in subclause (IV), replenishment dates (including the ability to extend the maximum shelf life of a countermeasure), and the manufacturing capacity required to replenish such countermeasure; and

(VIII) appropriate protocols and processes for the deployment, distribution, or dispensing of the countermeasure at the State and local level, including plans for relevant capabilities of State and

local entities to dispense, distribute, and administer the countermeasure; and

(ii) an assurance, which need not be provided in advance of procurement, that for each countermeasure procured or replenished under this subsection, the Secretary completed a review addressing each item listed under this subsection in advance of such procurement or replenishment.

(3) PROCEDURES.—The Secretary, in managing the stockpile under paragraph (1), shall—

(A) consult with the working group under section 319F(a) and the Public Health Emergency Medical Countermeasures Enterprise established under section 2811–1;

(B) ensure that adequate procedures are followed with respect to such stockpile for inventory management and accounting, and for the physical security of the stockpile;

(C) in consultation with Federal, State, and local officials, take into consideration the timing and location of special events, and the availability, deployment, dispensing, and administration of countermeasures;

(D) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered and that the potential depletion of countermeasures currently in the stockpile is identified and appropriately addressed, including through necessary replenishment;

(E) devise plans for effective and timely supply-chain management of the stockpile, in consultation with the Director of the Centers for Disease Control and Prevention, the Assistant Secretary for Preparedness and Response, the Secretary of Transportation, the Secretary of Homeland Security, the Secretary of Veterans Affairs, and the heads of other appropriate Federal agencies; State, local, Tribal, and territorial agencies; and the public and private health care infrastructure, as applicable, taking into account the manufacturing capacity and other available sources of products and appropriate alternatives to supplies in the stockpile;

(F) deploy the stockpile as required by the Secretary of Homeland Security to respond to an actual or potential emergency;

(G) deploy the stockpile at the discretion of the Secretary to respond to an actual or potential public health emergency or other situation in which deployment is necessary to protect the public health or safety;

(H) ensure the adequate physical security of the stockpile;

(I) ensure that each countermeasure or product under consideration for procurement pursuant to this subsection receives the same consideration regardless of whether such countermeasure or product receives or had received funding under section 319L, including with respect to whether the countermeasure or product is most appropriate to meet

the emergency health security needs of the United States[; and]*;*

(J) provide assistance, including technical assistance, to maintain and improve State and local public health preparedness capabilities to distribute and dispense medical countermeasures and products from the stockpile, as appropriate[.]*;*

(K) ensure contents of the stockpile remain in good working order and, as appropriate, conduct maintenance services on contents of the stockpile; and

(L) enhance medical supply chain elasticity and establish and maintain domestic reserves of critical medical supplies (including personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, and other medical devices (including diagnostic tests)) by—

(i) increasing emergency stock of critical medical supplies;

(ii) geographically diversifying domestic production of such medical supplies, as appropriate;

(iii) entering into cooperative agreements or partnerships with respect to manufacturing lines, facilities, and equipment for the domestic production of such medical supplies; and

(iv) managing, either directly or through cooperative agreements with manufacturers and distributors, domestic reserves established under this subparagraph by refreshing and replenishing stock of such medical supplies.

(4) UTILIZATION GUIDELINES.—The Secretary shall ensure timely and accurate recommended utilization guidelines for qualified countermeasures (as defined in section 319F–1), qualified pandemic and epidemic products (as defined in section 319F–3), and security countermeasures (as defined in subsection (c)), including for such products in the stockpile.

(5) GAO REPORT.—

(A) IN GENERAL.—Not later than 3 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, and every 5 years thereafter, the Comptroller General of the United States shall conduct a review of any changes to the contents or management of the stockpile since January 1, 2015. Such review shall include—

(i) an assessment of the comprehensiveness and completeness of each annual threat-based review under paragraph (2), including whether all newly procured or replenished countermeasures within the stockpile were described in each annual review, and whether, consistent with paragraph (2)(B), the Secretary conducted the necessary internal review in advance of such procurement or replenishment;

(ii) an assessment of whether the Secretary established health security and science-based justifications, and a description of such justifications for procure-

ment decisions related to health security needs with respect to the identified threat, for additions or modifications to the stockpile based on the information provided in such reviews under paragraph (2)(B), including whether such review was conducted prior to procurement, modification, or replenishment;

(iii) an assessment of the plans developed by the Secretary for the deployment, distribution, and dispensing of countermeasures procured, modified, or replenished under paragraph (1), including whether such plans were developed prior to procurement, modification, or replenishment;

(iv) an accounting of countermeasures procured, modified, or replenished under paragraph (1) that received advanced research and development funding from the Biomedical Advanced Research and Development Authority;

(v) an analysis of how such procurement decisions made progress toward meeting emergency health security needs related to the identified threats for countermeasures added, modified, or replenished under paragraph (1);

(vi) a description of the resources expended related to the procurement of countermeasures (including additions, modifications, and replenishments) in the stockpile, and how such expenditures relate to the ability of the stockpile to meet emergency health security needs;

(vii) an assessment of the extent to which additions, modifications, and replenishments reviewed under paragraph (2) align with previous relevant reports or reviews by the Secretary or the Comptroller General;

(viii) with respect to any change in the Federal organizational management of the stockpile, an assessment and comparison of the processes affected by such change, including planning for potential countermeasure deployment, distribution, or dispensing capabilities and processes related to procurement decisions, use of stockpiled countermeasures, and use of resources for such activities; and

(ix) an assessment of whether the processes and procedures described by the Secretary pursuant to section 403(b) of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 are sufficient to ensure countermeasures and products under consideration for procurement pursuant to subsection (a) receive the same consideration regardless of whether such countermeasures and products receive or had received funding under section 319L, including with respect to whether such countermeasures and products are most appropriate to meet the emergency health security needs of the United States.

(B) SUBMISSION.—Not later than 6 months after completing a classified version of the review under subparagraph (A), the Comptroller General shall submit an un-

classified version of the review to the congressional committees of jurisdiction.

(6) TRANSFERS AND REIMBURSEMENTS.—

(A) IN GENERAL.—Without regard to chapter 5 of title 40, United States Code, the Secretary may transfer to any Federal department or agency, on a reimbursable basis, any drugs, vaccines and other biological products, medical devices, and other supplies in the stockpile if—

(i) the transferred supplies are less than one year from expiry;

(ii) the stockpile is able to replenish the supplies, as appropriate; and

(iii) the Secretary decides the transfer is in the best interest of the United States Government.

(B) USE OF REIMBURSEMENT.—Reimbursement derived from the transfer of supplies pursuant to subparagraph (A) may be used by the Secretary, without further appropriation and without fiscal year limitation, to carry out this section.

(C) RULE OF CONSTRUCTION.—This paragraph shall not be construed to preclude transfers of products in the stockpile under other authorities.

(D) REPORT.—Not later than September 30, 2022, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on each transfer made under this paragraph and the amount received by the Secretary in exchange for that transfer.

(E) SUNSET.—The authority to make transfers under this paragraph shall cease to be effective on September 30, 2023.

(7) REPORTING.—Not later than September 30, 2022, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report on the details of each cooperative agreement or partnership entered into under paragraph (3)(L), including the amount expended by the Secretary on each such cooperative agreement or partnership.

(8) SUNSET.—The authority to enter into cooperative agreements or partnerships pursuant to paragraph (3)(L) shall cease to be effective on September 30, 2023.

(b) SMALLPOX VACCINE DEVELOPMENT.—

(1) IN GENERAL.—The Secretary shall award contracts, enter into cooperative agreements, or carry out such other activities as may reasonably be required in order to ensure that the stockpile under subsection (a) includes an amount of vaccine against smallpox as determined by such Secretary to be sufficient to meet the health security needs of the United States.

(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the private distribution, purchase, or sale of vaccines from sources other than the stockpile described in subsection (a).

(c) ADDITIONAL AUTHORITY REGARDING PROCUREMENT OF CERTAIN COUNTERMEASURES; AVAILABILITY OF SPECIAL RESERVE FUND.—

(1) IN GENERAL.—

(A) USE OF FUND.—A security countermeasure may, in accordance with this subsection, be procured with amounts in the special reserve fund as defined in subsection (h).

(B) SECURITY COUNTERMEASURE.—For purposes of this subsection, the term "security countermeasure" means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as that term is defined by section 351(i) of this Act (42 U.S.C. 262(i))), or device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))) that—

(i)(I) the Secretary determines to be a priority (consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002) to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(ii), or to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent;

(II) the Secretary determines under paragraph (2)(B)(ii) to be a necessary countermeasure; and

(III)(aa) is approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act; or

(bb) is a countermeasure for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing within 10 years after the date of a determination under paragraph (5); or

(ii) is authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act.

(2) DETERMINATION OF MATERIAL THREATS.—

(A) MATERIAL THREAT.—The Homeland Security Secretary, in consultation with the Secretary and the heads of other agencies as appropriate, shall on an ongoing basis—

(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and

(ii) determine which of such agents present a material threat against the United States population sufficient to affect national security.

(B) PUBLIC HEALTH IMPACT; NECESSARY COUNTERMEASURES.—The Secretary shall on an ongoing basis—

(i) assess the potential public health consequences for the United States population of exposure to agents identified under subparagraph (A)(ii); and

(ii) determine, on the basis of such assessment, the agents identified under subparagraph (A)(ii) for which

countermeasures are necessary to protect the public health.

(C) NOTICE TO CONGRESS.—The Secretary and the Secretary of Homeland Security shall send to Congress, on an annual basis, all current material threat determinations and shall promptly notify the Committee on Health, Education, Labor, and Pensions and the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Energy and Commerce and the Committee on Homeland Security of the House of Representatives that a determination has been made pursuant to subparagraph (A) or (B).

(D) ASSURING ACCESS TO THREAT INFORMATION.—In making the assessment and determination required under subparagraph (A), the Homeland Security Secretary shall use all relevant information to which such Secretary is entitled under section 202 of the Homeland Security Act of 2002, including but not limited to information, regardless of its level of classification, relating to current and emerging threats of chemical, biological, radiological, and nuclear agents.

(3) ASSESSMENT OF AVAILABILITY AND APPROPRIATENESS OF COUNTERMEASURES.—

(A) IN GENERAL.—The Secretary, in consultation with the Homeland Security Secretary, shall assess on an ongoing basis the availability and appropriateness of specific countermeasures to address specific threats identified under paragraph (2).

(B) INFORMATION.—The Secretary shall institute a process for making publicly available the results of assessments under subparagraph (A) while withholding such information as—

(i) would, in the judgment of the Secretary, tend to reveal public health vulnerabilities; or

(ii) would otherwise be exempt from disclosure under section 552 of title 5, United States Code.

(4) CALL FOR DEVELOPMENT OF COUNTERMEASURES; COMMITMENT FOR RECOMMENDATION FOR PROCUREMENT.—

(A) PROPOSAL TO THE PRESIDENT.—If, pursuant to an assessment under paragraph (3), the Homeland Security Secretary and the Secretary make a determination that a countermeasure would be appropriate but is either currently not developed or unavailable for procurement as a security countermeasure or is approved, licensed, or cleared only for alternative uses, such Secretaries may jointly submit to the President a proposal to—

(i) issue a call for the development of such countermeasure; and

(ii) make a commitment that, upon the first development of such countermeasure that meets the conditions for procurement under paragraph (5), the Secretaries will, based in part on information obtained pursuant to such call, and subject to the availability of appropriations, make available the special reserve fund

as defined in subsection (h) for procurement of such countermeasure, as applicable.

(B) COUNTERMEASURE SPECIFICATIONS.—The Homeland Security Secretary and the Secretary shall, to the extent practicable, include in the proposal under subparagraph (A)—

(i) estimated quantity of purchase (in the form of number of doses or number of effective courses of treatments regardless of dosage form);

(ii) necessary measures of minimum safety and effectiveness;

(iii) estimated price for each dose or effective course of treatment regardless of dosage form; and

(iv) other information that may be necessary to encourage and facilitate research, development, and manufacture of the countermeasure or to provide specifications for the countermeasure.

(C) PRESIDENTIAL APPROVAL.—If the President approves a proposal under subparagraph (A), the Homeland Security Secretary and the Secretary shall make known to persons who may respond to a call for the countermeasure involved—

(i) the call for the countermeasure;

(ii) specifications for the countermeasure under subparagraph (B); and

(iii) the commitment described in subparagraph (A)(ii).

(5) SECRETARY'S DETERMINATION OF COUNTERMEASURES APPROPRIATE FOR FUNDING FROM SPECIAL RESERVE FUND.—

(A) IN GENERAL.—The Secretary, in accordance with the provisions of this paragraph, shall identify specific security countermeasures that the Secretary determines, in consultation with the Homeland Security Secretary, to be appropriate for inclusion in the stockpile under subsection (a) pursuant to procurements made with amounts in the special reserve fund as defined in subsection (h) (referred to in this subsection individually as a "procurement under this subsection").

(B) REQUIREMENTS.—In making a determination under subparagraph (A) with respect to a security countermeasure, the Secretary shall determine and consider the following:

(i) The quantities of the product that will be needed to meet the stockpile needs.

(ii) The feasibility of production and delivery within 10 years of sufficient quantities of the product.

(iii) Whether there is a lack of a significant commercial market for the product at the time of procurement, other than as a security countermeasure.

(6) RECOMMENDATIONS FOR PROCUREMENT.—

(A) NOTICE TO APPROPRIATE CONGRESSIONAL COMMITTEES.—The Secretary shall notify the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of

the House of Representatives of each decision to make available the special reserve fund as defined in subsection (h) for procurement of a security countermeasure, including, where available, the number of, the nature of, and other information concerning potential suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons for each such rejection.

(B) SUBSEQUENT SPECIFIC COUNTERMEASURES.—Procurement under this subsection of a security countermeasure for a particular purpose does not preclude the subsequent procurement under this subsection of any other security countermeasure for such purpose if the Secretary has determined under paragraph (5)(A) that such countermeasure is appropriate for inclusion in the stockpile and if, as determined by the Secretary, such countermeasure provides improved safety or effectiveness, or for other reasons enhances preparedness to respond to threats of use of a biological, chemical, radiological, or nuclear agent. Such a determination by the Secretary is committed to agency discretion.

(7) PROCUREMENT.—

(A) PAYMENTS FROM SPECIAL RESERVE FUND.—The special reserve fund as defined in subsection (h) shall be available for payments made by the Secretary to a vendor for procurement of a security countermeasure in accordance with the provisions of this paragraph.

(B) PROCUREMENT.—

(i) IN GENERAL.—The Secretary shall be responsible for—

(I) arranging for procurement of a security countermeasure, including negotiating terms (including quantity, production schedule, and price) of, and entering into, contracts and cooperative agreements, and for carrying out such other activities as may reasonably be required, including advanced research and development, in accordance with the provisions of this subparagraph; and

(II) promulgating such regulations as the Secretary determines necessary to implement the provisions of this subsection.

(ii) CONTRACT TERMS.—A contract for procurements under this subsection shall (or, as specified below, may) include the following terms:

(I) PAYMENT CONDITIONED ON DELIVERY.—The contract shall provide that no payment may be made until delivery of a portion, acceptable to the Secretary, of the total number of units contracted for, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment, partial payment for significant milestones, or payment to increase

manufacturing capacity is necessary to ensure success of a project, the Secretary shall pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The Secretary shall, to the extent practicable, make the determination of advance payment at the same time as the issuance of a solicitation. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform by the vendor under the contract. The contract may also provide for additional advance payments of 5 percent each for meeting the milestones specified in such contract, except that such payments shall not exceed 50 percent of the total contract amount. If the specified milestones are reached, the advanced payments of 5 percent shall not be required to be repaid. Nothing in this subclause shall be construed as affecting the rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to the termination of contracts for the convenience of the Government.

(II) DISCOUNTED PAYMENT.—The contract may provide for a discounted price per unit of a product that is not licensed, cleared, or approved as described in paragraph (1)(B)(i)(III)(aa) at the time of delivery, and may provide for payment of an additional amount per unit if the product becomes so licensed, cleared, or approved before the expiration date of the contract (including an additional amount per unit of product delivered before the effective date of such licensing, clearance, or approval).

(III) CONTRACT DURATION.—The contract shall be for a period not to exceed five years, except that, in first awarding the contract, the Secretary may provide for a longer duration, not exceeding 10 years, if the Secretary determines that complexities or other difficulties in performance under the contract justify such a period. The contract shall be renewable for additional periods, none of which shall exceed five years. The Secretary shall notify the vendor within 90 days of a determination by the Secretary to renew, extend, or terminate such contract.

(IV) STORAGE BY VENDOR.—The contract may provide that the vendor will provide storage for stocks of a product delivered to the ownership of the Federal Government under the contract, for such period and under such terms and conditions as the Secretary may specify, and in such case amounts from the special reserve fund as defined in subsection (h) shall be available for costs of shipping, handling, storage, and related costs for such product.

(V) PRODUCT APPROVAL.—The contract shall provide that the vendor seek approval, clearance, or licensing of the product from the Secretary; for a timetable for the development of data and other information to support such approval, clearance, or licensing; and that the Secretary may waive part or all of this contract term on request of the vendor or on the initiative of the Secretary.

(VI) NON-STOCKPILE TRANSFERS OF SECURITY COUNTERMEASURES.—The contract shall provide that the vendor will comply with all applicable export-related controls with respect to such countermeasure.

(VII) SALES EXCLUSIVITY.—The contract may provide that the vendor is the exclusive supplier of the product to the Federal Government for a specified period of time, not to exceed the term of the contract, on the condition that the vendor is able to satisfy the needs of the Government. During the agreed period of sales exclusivity, the vendor shall not assign its rights of sales exclusivity to another entity or entities without approval by the Secretary. Such a sales exclusivity provision in such a contract shall constitute a valid basis for a sole source procurement under section 303(c)(1) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1)).

(VIII) WARM BASED SURGE CAPACITY.—The contract may provide that the vendor establish domestic manufacturing capacity of the product to ensure that additional production of the product is available in the event that the Secretary determines that there is a need to quickly purchase additional quantities of the product. Such contract may provide a fee to the vendor for establishing and maintaining such capacity in excess of the initial requirement for the purchase of the product. Additionally, the cost of maintaining the domestic manufacturing capacity shall be an allowable and allocable direct cost of the contract.

(IX) CONTRACT TERMS.—The Secretary, in any contract for procurement under this section—

(aa) may specify—

(AA) the dosing and administration requirements for the countermeasure to be developed and procured;

(BB) the amount of funding that will be dedicated by the Secretary for advanced research, development, and procurement of the countermeasure; and

(CC) the specifications the countermeasure must meet to qualify for procurement under a contract under this section; and

(bb) shall provide a clear statement of defined Government purpose limited to uses related to a security countermeasure, as defined in paragraph (1)(B).

(iii) AVAILABILITY OF SIMPLIFIED ACQUISITION PROCEDURES.—

(I) IN GENERAL.—If the Secretary determines that there is a pressing need for a procurement of a specific countermeasure, the amount of the procurement under this subsection shall be deemed to be below the threshold amount specified in section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11)), for purposes of application to such procurement, pursuant to section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a)), of—

(aa) section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A)) and its implementing regulations; and

(bb) section 302A(b) of such Act (41 U.S.C. 252a(b)) and its implementing regulations.

(II) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding subclause (I) and the provision of law and regulations referred to in such clause, each of the following provisions shall apply to procurements described in this clause to the same extent that such provisions would apply to such procurements in the absence of subclause (I):

(aa) Chapter 37 of title 40, United States Code (relating to contract work hours and safety standards).

(bb) Subsections (a) and (b) of section 7 of the Anti-Kickback Act of 1986 (41 U.S.C. 57(a) and (b)).

(cc) Section 304C of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254d) (relating to the examination of contractor records).

(dd) Section 3131 of title 40, United States Code (relating to bonds of contractors of public buildings or works).

(ee) Subsection (a) of section 304 of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254(a)) (relating to contingent fees to middlemen).

(ff) Section 6002 of the Solid Waste Disposal Act (42 U.S.C. 6962).

(gg) Section 1354 of title 31, United States Code (relating to the limitation on the use of appropriated funds for contracts with entities not meeting veterans employment reporting requirements).

(III) INTERNAL CONTROLS TO BE ESTABLISHED.—The Secretary shall establish appropriate internal

controls for procurements made under this clause, including requirements with respect to documentation of the justification for the use of the authority provided under this paragraph with respect to the procurement involved.

(IV) AUTHORITY TO LIMIT COMPETITION.—In conducting a procurement under this subparagraph, the Secretary may not use the authority provided for under subclause (I) to conduct a procurement on a basis other than full and open competition unless the Secretary determines that the mission of the BioShield Program under the Project BioShield Act of 2004 would be seriously impaired without such a limitation.

(iv) PROCEDURES OTHER THAN FULL AND OPEN COMPETITION.—

(I) IN GENERAL.—In using the authority provided in section 303(c)(1) of title III of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1)) to use procedures other than competitive procedures in the case of a procurement under this subsection, the phrase "available from only one responsible source" in such section 303(c)(1) shall be deemed to mean "available from only one responsible source or only from a limited number of responsible sources".

(II) RELATION TO OTHER AUTHORITIES.—The authority under subclause (I) is in addition to any other authority to use procedures other than competitive procedures.

(III) APPLICABLE GOVERNMENT-WIDE REGULATIONS.—The Secretary shall implement this clause in accordance with government-wide regulations implementing such section 303(c)(1) (including requirements that offers be solicited from as many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered), as such regulations apply to procurements for which an agency has authority to use procedures other than competitive procedures when the property or services needed by the agency are available from only one responsible source or only from a limited number of responsible sources and no other type of property or services will satisfy the needs of the agency.

(v) PREMIUM PROVISION IN MULTIPLE AWARD CONTRACTS.—

(I) IN GENERAL.—If, under this subsection, the Secretary enters into contracts with more than one vendor to procure a security countermeasure, such Secretary may, notwithstanding any other provision of law, include in each of such contracts a provision that—

(aa) identifies an increment of the total quantity of security countermeasure required, whether by percentage or by numbers of units; and

(bb) promises to pay one or more specified premiums based on the priority of such vendors' production and delivery of the increment identified under item (aa), in accordance with the terms and conditions of the contract.

(II) DETERMINATION OF GOVERNMENT'S REQUIREMENT NOT REVIEWABLE.—If the Secretary includes in each of a set of contracts a provision as described in subclause (I), such Secretary's determination of the total quantity of security countermeasure required, and any amendment of such determination, is committed to agency discretion.

(vi) EXTENSION OF CLOSING DATE FOR RECEIPT OF PROPOSALS NOT REVIEWABLE.—A decision by the Secretary to extend the closing date for receipt of proposals for a procurement under this subsection is committed to agency discretion.

(vii) LIMITING COMPETITION TO SOURCES RESPONDING TO REQUEST FOR INFORMATION.—In conducting a procurement under this subsection, the Secretary may exclude a source that has not responded to a request for information under section 303A(a)(1)(B) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253a(a)(1)(B)) if such request has given notice that the Secretary may so exclude such a source.

(viii) FLEXIBILITY.—In carrying out this section, the Secretary may, consistent with the applicable provisions of this section, enter into contracts and other agreements that are in the best interest of the Government in meeting identified security countermeasure needs, including with respect to reimbursement of the cost of advanced research and development as a reasonable, allowable, and allocable direct cost of the contract involved.

(ix) EQUIPMENT MAINTENANCE SERVICE.—In carrying out this section, the Secretary may enter into contracts for the procurement of equipment maintenance services.

(8) INTERAGENCY COOPERATION.—

(A) IN GENERAL.—In carrying out activities under this section, the Homeland Security Secretary and the Secretary are authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative undertakings with other agencies of the United States Government. Such agreements may allow other executive agencies to order qualified and security countermeasures under procurement contracts or other agreements established by the Secretary. Such ordering process (including transfers of appropriated funds between an agency and the Department of Health and Human Services as reimbursements for such orders for countermeasures) may be conducted under the authority of section 1535 of title 31,

United States Code, except that all such orders shall be processed under the terms established under this subsection for the procurement of countermeasures.

(B) LIMITATION.—An agreement or undertaking under this paragraph shall not authorize another agency to exercise the authorities provided by this section to the Homeland Security Secretary or to the Secretary.

(d) DISCLOSURES.—No Federal agency may disclose under section 552 of title 5, United States Code any information identifying the location at which materials in the stockpile described in subsection (a) are stored, or other information regarding the contents or deployment capability of the stockpile that could compromise national security.

(e) DEFINITION.—For purposes of subsection (a), the term "stockpile" includes—

(1) a physical accumulation (at one or more locations) of the supplies described in subsection (a); or

(2) a contractual agreement between the Secretary and a vendor or vendors under which such vendor or vendors agree to provide to such Secretary supplies described in subsection (a).

(f) AUTHORIZATION OF APPROPRIATIONS.—

(1) STRATEGIC NATIONAL STOCKPILE.—For the purpose of carrying out subsection (a), there are authorized to be appropriated ⟦$610,000,000 for each of fiscal years 2019 through 2023⟧ *$705,000,000 for each of fiscal years 2020 through 2023*, to remain available until expended. Such authorization is in addition to amounts in the special reserve fund referred to in subsection (h).

(2) SMALLPOX VACCINE DEVELOPMENT.—For the purpose of carrying out subsection (b), there are authorized to be appropriated $509,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

(3) SUPPLY CHAIN ELASTICITY.—

(A) IN GENERAL.—For the purpose of carrying out subsection (a)(3)(L), there is authorized to be appropriated $500,000,000 for each of fiscal years 2020 through 2023, to remain available until expended.

(B) RELATION TO OTHER AMOUNTS.—The amount authorized to be appropriated by subparagraph (A) for the purpose of carrying out subsection (a)(3)(L) is in addition to any other amounts available for such purpose.

(g) SPECIAL RESERVE FUND.—

(1) AUTHORIZATION OF APPROPRIATIONS.—In addition to amounts appropriated to the special reserve fund prior to the date of the enactment of this subsection, there is authorized to be appropriated, for the procurement of security countermeasures under subsection (c) and for carrying out section 319L (relating to the Biomedical Advanced Research and Development Authority), $7,100,000,000 for the period of fiscal years 2019 through 2028, to remain available until expended.

(2) USE OF SPECIAL RESERVE FUND FOR ADVANCED RESEARCH AND DEVELOPMENT.—The Secretary may utilize not more than 50 percent of the amounts authorized to be appropriated under paragraph (1) to carry out section 319L (related to the Bio-

medical Advanced Research and Development Authority). Amounts authorized to be appropriated under this subsection to carry out section 319L are in addition to amounts otherwise authorized to be appropriated to carry out such section.

(3) RESTRICTIONS ON USE OF FUNDS.—Amounts in the special reserve fund shall not be used to pay costs other than payments made by the Secretary to a vendor for advanced development (under section 319L) or for procurement of a security countermeasure under subsection (c)(7).

(4) REPORT ON SECURITY COUNTERMEASURE PROCUREMENT.—Not later than March 1 of each year in which the Secretary determines that the amount of funds available for procurement of security countermeasures is less than $1,500,000,000, the Secretary shall submit to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives a report detailing the amount of such funds available for procurement and the impact such amount of funding will have—

(A) in meeting the security countermeasure needs identified under this section; and

(B) on the annual Public Health Emergency Medical Countermeasures Enterprise and Strategy Implementation Plan (pursuant to section 2811(d)).

(5) CLARIFICATION ON CONTRACTING AUTHORITY.—The Secretary, acting through the Director of the Biomedical Advanced Research and Development Authority, shall carry out the programs funded by the special reserve fund (for the procurement of security countermeasures under subsection (c) and for carrying out section 319L), including the execution of procurement contracts, grants, and cooperative agreements pursuant to this section and section 319L.

(h) DEFINITIONS.—In this section:

(1) The term "advanced research and development" has the meaning given such term in section 319L(a).

(2) The term "special reserve fund" means the "Biodefense Countermeasures" appropriations account, any appropriation made available pursuant to section 521(a) of the Homeland Security Act of 2002, and any appropriation made available pursuant to subsection (g)(1).

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SEC. 319F–5. GRANTS FOR STATE STRATEGIC STOCKPILES.

(a) IN GENERAL.—The Secretary may establish a pilot program consisting of awarding grants to States to expand or maintain a strategic stockpile of commercially available drugs, medical equipment, personal protective equipment, and other products deemed by the State to be essential in the event of a public health emergency.

(b) ALLOWABLE USE OF FUNDS.—

(1) USES.—A State receiving a grant under this section may use the grant funds to—

(A) acquire commercially available products listed pursuant to paragraph (2) for inclusion in the State's strategic stockpile;

(B) store, maintain, and distribute products in such stockpile; and

(C) conduct planning in connection with such activities.

(2) LIST.—The Secretary shall develop and publish a list of the products that are eligible, as described in subsection (a), for inclusion in a State's strategic stockpile using funds received under this section.

(3) CONSULTATION.—In developing the list under paragraph (2) and otherwise determining the allowable uses of grant funds under this section, the Secretary shall consult with States and relevant stakeholders, including public health organizations.

(c) FUNDING REQUIREMENT.—The Secretary may not obligate or expend any funds to award grants or fund any previously awarded grants under this section for a fiscal year unless the total amount made available to carry out section 319F–2 for such fiscal year is equal to or greater than the total amount of funds made available to carry out section 319F–2 for fiscal year 2020.

(d) MATCHING FUNDS.—

(1) IN GENERAL.—With respect to the costs of expanding and maintaining a strategic stockpile through a grant under this section, as a condition on receipt of the grant, a State shall make available (directly) non-Federal contributions in cash toward such costs in an amount that is equal to not less than the amount of Federal funds provided through the grant.

(2) WAIVER.—The Secretary may waive the requirement of paragraph (1) with respect to a State for the first two years of the State receiving a grant under this section if the Secretary determines that such waiver is needed for the State to establish a strategic stockpile described in subsection (a).

(e) TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance to States in establishing, expanding, and maintaining a stockpile described in subsection (a).

(f) DEFINITION.—In this section, the term "drug" has the meaning given to that term in section 201 of the Federal Food, Drug, and Cosmetic Act.

(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $3,500,000,000 for each of fiscal years 2020 through 2023, to remain available until expended.

(h) SUNSET.—The authority vested by this section terminates at the end of fiscal year 2023.

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