117TH CONGRESS
1ST SESSION

S. 1604

To codify the successes of rapid development of safe vaccines through Operation Warp Speed, for the next administration to use as a guide in the event of another pandemic.

IN THE SENATE OF THE UNITED STATES

MAY 13, 2021

Mr. COTTON introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To codify the successes of rapid development of safe vaccines through Operation Warp Speed, for the next administration to use as a guide in the event of another pandemic.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Operation Warp Speed Act of 2021''.

SEC. 2. FINDINGS.

Congress finds as follows:

(1) COVID–19 has infected more than 32,000,000 people in the United States and taken the lives of more than 550,000.

(2) The Trump Administration's creation of Operation Warp Speed, on May 15, 2020, and the development of 3 COVID–19 vaccines, in less than a year, was the greatest success in getting the COVID–19 pandemic under control, and one of the greatest public health programs in history.

(3) As a result of the Trump Administration's partnership with the private sector, more than 150,000,000 doses of authorized vaccines have been administered in the United States.

(4) The unprecedented rapid deployment of COVID–19 vaccines and therapeutics, thanks to the public-private partnership of Operation Warp Speed, has helped the United States combat the spread of COVID–19, protect at-risk populations, save millions of lives, and return to normal life.

SEC. 3. CODIFYING SUCCESSES.

(a) ADDRESSING THE STRATEGIC NATIONAL STOCKPILE.—

(1) ANNUAL THREAT-BASED REVIEW.—In conducting the annual threat-based review with respect to the Strategic National Stockpile under section

319F–2(a)(2)(A) of the Public Health Service Act (42 U.S.C. 247d–6b(a)(2)(A)), the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall ensure that such review considers, and the report to Congress includes, information about the supply levels in such stockpile and any materials that may be missing. The review described in the previous sentence shall include a supply chain assessment of materials in the Strategic National Stockpile that considers whether the United States could procure such materials in the event of a pandemic that limits trade and access to international supply chains.

(2) PROCURING SUPPLIES FOR THE SNS.—In procuring supplies for the Strategic National Stockpile under section 319F–2(a) of the Public Health Service Act (42 U.S.C. 247d–6b(a)), the Secretary shall—

(A) give priority to manufacturers of such supplies, including vaccines, that are manufactured by companies located in the United States;

(B) in the case that no domestic manufacturer is available for certain supplies, including vaccines, assess ways to ramp up domestic

manufacturing of such supplies, including vaccines; and

(C) in the case that no domestic manufacturer is available for certain supplies, including vaccines, and it is determined that domestic manufacturing cannot be ramped up in an appropriate amount of time, give priority to companies that are located in countries other than the People's Republic of China.

(b) INCREASING SPEED FOR SAFE EUA.—Section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) is amended—

(1) in subsection (c)—

(A) in the matter preceding paragraph (1)—

(i) by inserting ''the Commissioner of Food and Drugs,'' before ''the Assistant Secretary for''; and

(ii) by striking ''the Secretary concludes'' and inserting ''not fewer than 3 of such Commissioner, such Assistant Secretary, and such Directors, vote in favor of such authorization after concluding'';

(B) in paragraph (4), by striking ''; and'' and inserting a semicolon;

(C) by redesignating paragraph (5) as paragraph (6); and

(D) by inserting after paragraph (4) the following:

''(5) that the product complies with standards for clinical trials established by the Secretary, in consultation with such Commissioner, such Assistant Secretary, and such Directors; and''; and

(2) by adding at the end the following:

''(n) CONSIDERATION OF DATA.—The Secretary, and the heads of agencies described in subsection (c), shall consider the data submitted with respect to a product for which authorization is being sought under this section, on a rolling basis, as such data becomes available to such Secretary and heads of agencies.''.

(c) GAPS IN CLINICAL TRIALS.—The Director of the National Institutes of Health shall assess any geographical gaps in clinical trial sites for drugs or biological products and shall develop a plan for increasing the number of such sites across broad geographic areas.

(d) REQUIRING ASPR TO IMPROVE MANUFACTURING CAPABILITIES UNDER CONDITIONS OF PRESSURE.—

(1) VACCINE PRODUCTION.—The Secretary is authorized to use amounts made available to the De-

partment of Health and Human Services for purposes of producing vaccines in response to a public health emergency prior to emergency use authorization of such vaccine under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) or licensure of such vaccine under section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) OPERATION WARP SPEED DIRECTOR.—Section 2811 of the Public Health Service Act (42 U.S.C. 300hh–10) is amended by adding at the end the following:

''(g) OPERATION WARP SPEED DIRECTOR.—There is established within the Office of the Assistant Secretary for Preparedness and Response an Office of Operation Warp Speed, for purposes of responding to public health emergencies by ensuring timely and sufficient development of vaccines and other medical countermeasures (including vaccines, therapeutics, and diagnostics), as well as domestic manufacturing, through preparation in advance of any such public health emergency. Such Office shall be headed by a Director who has substantial relevant private sector experience and is appointed by the President, by and with the advice and consent of the Senate.''.

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