AMENDMENT NO. 3 Calendar No._____

Purpose: To amend the Public Health Service Act to provide for medical supply reserves to strengthen the United States medical supply chain and ensure that Americans have access to needed medical products.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

S. 3799

To prepare for, and respond to, existing viruses, emerging new threats, and pandemics.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

At the appropriate place in title V, insert the following:

SEC. ___. PILOT PROGRAM ON ENSURING MEDICATION SUPPLY STABILITY.

Part D of the Public Health Service Act (42 U.S.C. 254b et seq.) is amended by adding at the end the following new subpart:

"Subpart XIII—Ensuring Medication Supply Stability

"SEC. 340J. ENSURING MEDICATION SUPPLY STABILITY.

"(a) AWARD OF CONTRACTS.—Beginning not later than 9 months after the date of enactment of this subpart,

the Secretary, acting through the Assistant Secretary for Preparedness and Response, shall award contracts to eligible entities to develop, build, or increase capacity and capability to acquire, maintain, manage, and distribute, as appropriate, a reserve supply of medical products that consists of a balance of—

"(1) generic drugs of significant importance to respond to public health emergencies; and

"(2) personal protective equipment of significant importance to respond to public health emergencies.

"(b) SELECTION OF MEDICAL PRODUCTS.—

"(1) IN GENERAL.—The Secretary shall —

"(A) maintain an up-to-date list of medical products eligible for reserve pursuant to subsection (a); and

"(B) make such list publicly available.

"(2) CHOICE OF ELIGIBLE ENTITIES.—A contract awarded to an eligible entity under this section need not require the inclusion of all eligible medical products listed pursuant to paragraph (1) in such reserve supply of medical products.

"(c) SUFFICIENT MEDICAL SUPPLY RESERVE.—An eligible entity shall acquire, maintain, and manage, for purposes of distribution and commercial sale, an appro-

priate quantity of medical products listed pursuant to subsection (b)(1), as determined appropriate by the Secretary to increase the reserve supply of eligible medical products, including for purposes of responding to a public health emergency response.

"(d) DURATION.—A contract awarded under this section shall be for a term of no more than 3 years.

"(e) PERFORMANCE REQUIREMENTS FOR ELIGIBLE ENTITIES.—

"(1) IN GENERAL.—With respect to eligible entities awarded a contract under this section, the Secretary shall require certain milestone or performance requirements, including—

"(A) that collectively, such eligible entities will, not later than 6 months following the date set in such contracts, develop, build, or otherwise increase capacity to provide for the acquisition, maintenance, and management of eligible medical products, and maintain thereafter a 6-month supply of such drugs; and

"(B) that such 6-month supply required under subparagraph (A) be in addition to the average levels of inventory held by eligible entities over the previous year for the respective drugs.

"(2) INVENTORY MANAGEMENT.—Each eligible entity with a contract under this section for a reserve supply of eligible medical products shall manage and maintain inventory to ensure that such reserve supply of medical products are efficiently cycled to the commercial market.

"(3) ANNUAL AUDITS.—Not more than annually, the Secretary may request a physical audit count of the inventories of all eligible entities with a contract under this section to validate that each such entity is maintaining the appropriate amount of medical product reserve inventory.

"(4) REPORTING.—Each eligible entity with a contract under this section shall submit reports at such time and in such manner as the Secretary may require regarding—

"(A) current inventory levels of reserve medical products;

"(B) indicators of current inventory levels of reserve medical products relative to acceptable minimums; and

"(C) such other matters as the Secretary determines appropriate.

"(f) CONTRACT TERMS.—

"(1) IN GENERAL.—Subject to paragraph (2), a contract for a reserve supply of eligible medical products under this section shall (or, as specified below, may) include the following terms:

"(A) PAYMENT CONDITIONED ON ADEQUACY.—The contract shall provide that, except as provided in subparagraph (B), no payment under the contract shall be made until the entity demonstrates to the Secretary that the entity has acquired sufficient eligible medical products for purposes of maintaining a reserve amount of such portion of the total quantity of eligible medical products to be held in reserve under the contract as the Secretary determines to be acceptable for payment.

"(B) ADVANCE PAYMENTS.—

"(i) IN GENERAL.—A contract under this section may provide that, if the Secretary determines that an advance payment, partial payment for significant milestones, or payment to increase capacity is necessary to ensure success of the terms of the contract, the Secretary shall pay, in advance demonstrated acquisition and maintenance of reserve capacity, an

amount not to exceed 70 percent of the total contract amount to be paid to the eligible entity by the Secretary pursuant to the contract over the full period of the contract. The contract may also provide for an additional advance payments of 5 percent each for meeting the milestones specified in such contract, except that such payments shall not exceed 90 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.

"(ii) COST OF CAPITAL.—A contract under this section may provide for payments to compensate the contracting eligible entity for additional capital requirements related to the additional inventory to be maintained.

"(iii) TIMING.—The Secretary shall, to the extent practicable, make any determination under clause (i) to make an advance payment at the same time as the issuance of a solicitation.

"(iv) REPAYMENT.—If the Secretary makes an advance payment pursuant to clause (i), the contract shall provide that such advance payment is required to be repaid if there is a failure to perform by the eligible entity under the contract.

"(v) CONTRACT DURATION.—The contract shall be for a period not to exceed 3 years, except that, in first awarding the contract, the Secretary may provide for a longer duration, not to exceed 5 years, if the Secretary determines that complexities or other difficulties in performance under the contract justify such a period.

"(vi) STORAGE BY ELIGIBLE ENTITY.—The contract may provide that the eligible entity will provide storage for eligible medical products delivered to the ownership of private or commercial purchasers, for such period and under such terms and conditions as the Secretary may specify.

"(vii) SALES RIGHTS.—The contract shall provide that the eligible entity shall enter into contracts with private or commercial purchasers to purchase the addi-

tional quantities of such eligible medical products.

"(2) RIGHTS OF ELIGIBLE ENTITIES.—Nothing in this section shall be construed as affecting the rights of eligible entities under provisions of statute or regulation, including the Federal Acquisition Regulation) relating to the termination of contracts for the convenience of the Federal Government.

"(g) CONGRESSIONAL OVERSIGHT.—

"(1) INDEPENDENT EVALUATION AND REPORT.—Not later than 1 year after the date of enactment of this subpart and annually thereafter, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the appropriate congressional committees a report, concerning the program under this section.

"(2) CONTENTS OF REPORT.—The report under paragraph (1) shall review, assess, and provide recommendations, as appropriate, on the following:

"(A) The evaluation of the performance of entities under this section as measured against established milestones of a medical supply reserve utilizing a model that cycles inventory to private or commercial entities.

this section directly from the medical product manufacturer.

"(B) NOT AN AGENCY.—An eligible entity that enters into a contract under this section shall not be deemed to be a Federal agency for any purpose, including for any purpose under title 5, United States Code.

"(2) GENERIC DRUG.—The term 'generic drug' means a drug (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act) that is approved pursuant to section 505(j) of such Act.

"(3) PERSONAL PROTECTIVE EQUIPMENT.—The term 'personal protective equipment' means any device (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act) that is a face mask, filtering facepiece respirator, face shield, surgical mask, gown, other apparel, or glove that is intended for a medical purpose.

"(i) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $150,000,000 for each of fiscal years 2023 through 2025, to remain available until expended.

"(j) SUNSET .—The authority to award contracts under this section shall cease to be effective after 2027.".