

117TH CONGRESS
1ST SESSION

S. _____

To amend the Public Health Service Act to establish an Emergency Office of Manufacturing for Public Health, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Ms. WARREN introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Public Health Service Act to establish an Emergency Office of Manufacturing for Public Health, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Pandemic Emergency
5 Manufacturing Act of 2021”.

6 **SEC. 2. PUBLIC MANUFACTURING OF PHARMACEUTICALS.**

7 Part A of title III of the Public Health Service Act
8 (42 U.S.C. 241 et seq.) is amended by adding at the end
9 the following:

1 **“SEC. 310B. MANUFACTURING OF DRUGS, BIOLOGICAL**
2 **PRODUCTS, DEVICES, AND PERSONAL PRO-**
3 **TECTIVE EQUIPMENT.**

4 “(a) EMERGENCY OFFICE OF MANUFACTURING FOR
5 PUBLIC HEALTH.—

6 “(1) ESTABLISHMENT.—There is established
7 within the Department of Health and Human Serv-
8 ices an office to be known as the Emergency Office
9 of Manufacturing for Public Health (referred to in
10 this section as the ‘Office’).

11 “(2) PURPOSE.—The purposes of the Office
12 are—

13 “(A) to ensure an adequate supply of, and
14 increase access to, prescription drugs, biological
15 products, devices, and other supplies, including
16 personal protective equipment, necessary to, as
17 appropriate, diagnose, mitigate, prevent, or
18 treat COVID–19 and to mitigate the harm the
19 COVID–19 pandemic might otherwise cause for
20 the strategic national stockpile under section
21 319F–2, Federal, State, local, and Native
22 health programs, and the commercial market;

23 “(B) to address shortages in the strategic
24 national stockpile and commercial market of
25 prescription drugs, biological products, devices,

1 and personal protective equipment used to treat
2 conditions other than COVID–19; and

3 “(C) to provide prescription drugs, biologi-
4 cal products, devices, and personal protective
5 equipment necessary to diagnose, mitigate, pre-
6 vent, and treat COVID–19 and to mitigate the
7 harm the COVID–19 pandemic might otherwise
8 cause, to Federal, State, local, and Native
9 health programs, at no cost, and to consumers
10 in the commercial market and other inter-
11 national entities at cost.

12 “(3) PERSONNEL.—

13 “(A) DIRECTOR.—

14 “(i) IN GENERAL.—The Office shall
15 be headed by a Director, who shall be ap-
16 pointed by the President, not later than 15
17 days after the date of enactment of the
18 Pandemic Emergency Manufacturing Act
19 of 2021, by and with the advice and con-
20 sent of the Senate.

21 “(ii) ACTING DIRECTOR.—The Assist-
22 ant Secretary for Preparedness and Re-
23 sponse, if in compliance with subparagraph
24 (C), may serve as Director of the Office in
25 an acting capacity until the later of Senate

1 confirmation of a Director or 3 months
2 after date of enactment of the Pandemic
3 Emergency Manufacturing Act of 2021.

4 “(iii) COMPENSATION.—The Director
5 shall be compensated at the rate prescribed
6 for level III of the Executive Schedule
7 under section 5314 of title 5, United
8 States Code.

9 “(B) EMPLOYEES.—The Director of the
10 Office, in consultation with the Secretary, may
11 fix the number of, and appoint and direct, all
12 employees of the Office.

13 “(C) BANNED INDIVIDUALS.—

14 “(i) DRUG COMPANY LOBBYISTS.—No
15 former registered drug manufacturer lob-
16 byist—

17 “(I) may be appointed to the po-
18 sition of Director of the Office; or

19 “(II) may be employed by the Of-
20 fice during the 6-year period begin-
21 ning on the date on which the reg-
22 istered lobbyist terminates its reg-
23 istration in accordance with section
24 4(d) of the Lobbying Disclosure Act

1 of 1995 or the agent terminates its
2 status, as applicable.

3 “(ii) SENIOR EXECUTIVES OF LAW-
4 BREAKING COMPANIES.—No former senior
5 executive of a covered entity—

6 “(I) may be appointed to the po-
7 sition of Director of the Office; or

8 “(II) may be employed by the Of-
9 fice during the 6-year period begin-
10 ning on the later of—

11 “(aa) the date of the settle-
12 ment; and

13 “(bb) the date on which the
14 enforcement action has con-
15 cluded.

16 “(iii) COVERED ENTITY.—For pur-
17 poses of clause (ii), the term ‘covered enti-
18 ty’ means any entity that is—

19 “(I) a drug manufacturer; and

20 “(II)(aa) operating under Fed-
21 eral settlement, including a Federal
22 consent decree; or

23 “(bb) the subject of an enforce-
24 ment action in a court of the United
25 States or by an agency.

1 “(4) DUTIES.—

2 “(A) IN GENERAL.—The Office shall—

3 “(i) prepare and submit applications
4 for approval to the Food and Drug Admin-
5 istration, or enter into contracts for such
6 submission, for the manufacture of appli-
7 cable COVID–19 products and other appli-
8 cable drugs, biological products, and de-
9 vices when authorized under this section;

10 “(ii) obtain rights to manufacture ap-
11 plicable COVID–19 products and applica-
12 ble drugs, biological products, and devices
13 as authorized under this section;

14 “(iii) manufacture, or enter into con-
15 tracts with entities to manufacture, appli-
16 cable COVID–19 products and other appli-
17 cable drugs, biological products, and de-
18 vices as authorized under this section;

19 “(iv) determine a fair price for each
20 applicable drug, biological product, and de-
21 vice, in accordance with subparagraph
22 (B)(ii);

23 “(v) sell manufactured applicable
24 drugs, biological products, and devices at a
25 fair price, as authorized under this section;

1 “(vi) provide, at no cost, applicable
2 COVID–19 products to Federal, State,
3 local, and Native health programs, and
4 other domestic health care providers and
5 suppliers, as determined by the Secretary;

6 “(vii) sell, at-cost, applicable COVID–
7 19 products to other commercial entities
8 and international entities, in accordance
9 with subparagraph (B)(i); and

10 “(viii) manufacture, or enter into con-
11 tracts with entities to manufacture, active
12 pharmaceutical ingredients for use by the
13 Office or for sale to other entities.

14 “(B) PRICING DETERMINATIONS.—

15 “(i) AT-COST PRICE.—In determining
16 an at-cost price for an applicable COVID–
17 19 product under subparagraph (A)(vii)
18 the Office shall consider—

19 “(I) the cost to the Federal Gov-
20 ernment of manufacturing the appli-
21 cable COVID–19 product;

22 “(II) the administrative costs of
23 operating the Office; and

1 “(III) the cost to acquire or man-
2 ufacture applicable COVID–19 prod-
3 uct under this section.

4 “(ii) FAIR PRICE.—In determining a
5 fair price for an applicable drug, biological
6 product, or device under subparagraph
7 (A)(iv) the Office shall consider—

8 “(I) the impact of price on pa-
9 tient access to the applicable drug, bi-
10 ological product, or device;

11 “(II) the cost of the applicable
12 drug, biological product, or device to
13 Federal or State health care pro-
14 grams;

15 “(III) the cost to the Federal
16 Government of manufacturing the ap-
17 plicable drug, biological product, or
18 device;

19 “(IV) the administrative costs of
20 operating the Office;

21 “(V) the cost to acquire or manu-
22 facture the applicable drug, biological
23 product, or device under this section;
24 and

1 any invention in the United States or
2 territories of the United States, in-
3 cluding making, using, offering to sell
4 or selling, importing, or exporting
5 such invention, to reference or rely
6 upon clinical trial data submitted to a
7 regulatory authority or the grant of
8 marketing approval, and to access and
9 use otherwise confidential informa-
10 tion, including know-how, related to
11 the manufacture of an applicable
12 COVID-19 product or applicable
13 drug, biological product, or device.

14 “(II) NON-VOLUNTARY LICENS-
15 ING.—For any license that involves a
16 non-voluntary authorization to use
17 patented inventions, regulatory test
18 data, data, know-how or other intel-
19 lectual property rights, the license
20 shall provide for reasonable remunera-
21 tion to rights holders such as a rea-
22 sonable royalty on the sales of prod-
23 uct, a 1-time payment, or some com-
24 bination, provided that the combined
25 royalty payments to all rights holders

1 shall not exceed the percentage of
2 sales that is the average percent of all
3 royalty payments reported to the In-
4 ternal Revenue Service by companies
5 in the pharmaceutical and medicines
6 sector, North American Industry Clas-
7 sification System code 325410, pro-
8 vided that when products are distrib-
9 uted for free, the royalty shall be
10 based upon the cost of goods. When
11 there are multiple rights holders, the
12 allocation of the total royalty pay-
13 ments shall be determined by—

14 “(aa) agreement among the
15 rights holders;

16 “(bb) allocation by arbitra-
17 tion among the rights holders; or

18 “(cc) if neither item (aa)
19 nor (bb) applies, by the Office.

20 “(iii) **TRANSPARENCY.**—Subject to
21 clause (iv), the Secretary shall post any
22 contract agreement under subparagraph
23 (A) or license issued under clause (ii) on
24 the public internet website of the Depart-
25 ment of Health and Human Services, on

1 the date on which such agreement or li-
2 cense takes effect.

3 “(iv) PROTECTED INFORMATION.—In
4 carrying out this section, the Secretary
5 shall enforce applicable law concerning the
6 protection of confidential commercial infor-
7 mation and trade secrets.

8 “(D) ACTIVE PHARMACEUTICAL INGREDI-
9 ENTS.—

10 “(i) IN GENERAL.—The Office shall
11 manufacture, or enter into contracts with
12 entities to manufacture, an active pharma-
13 ceutical ingredient applicable to a drug or
14 biological product that is either an applica-
15 ble COVID–19 product or an applicable
16 drug or biological product if—

17 “(I) the Office determines that
18 such ingredient is not readily available
19 from existing suppliers or the existing
20 supply of such ingredient to the do-
21 mestic market is vulnerable to disrup-
22 tion;

23 “(II) the manufacture of such in-
24 gredient would improve the ability of
25 other entities to enter the market for

1 the manufacture of applicable
2 COVID–19 products or applicable
3 drugs, biological products, or devices,
4 or otherwise expand the manufacture
5 of applicable COVID–19 products or
6 applicable drugs, biological products,
7 or devices; or

8 “(III) the manufacture of such
9 ingredient is necessary for the Office
10 to carry out its duties under this sec-
11 tion.

12 “(ii) PRICE DETERMINATIONS.—In
13 determining the price at which to sell an
14 active pharmaceutical ingredient manufac-
15 tured in accordance with clause (i), the Of-
16 fice shall consider the cost to manufacture
17 the ingredient, the administrative costs of
18 the Office with respect to the ingredient,
19 and the impact of such price on market
20 competition for the ingredient.

21 “(E) PRIORITY.—In awarding contracts
22 under this paragraph, the Office shall prioritize
23 entities manufacturing applicable COVID–19
24 products and applicable drugs, biological prod-

1 ucts, and devices using components originating
2 and manufactured in the United States.

3 “(F) CONTRACT REQUIREMENTS.—All con-
4 tracts issued under this paragraph shall include
5 a requirement that the contract recipients rea-
6 sonably price products produced under the con-
7 tract.

8 “(b) MANUFACTURING OF PRODUCTS.—

9 “(1) IN GENERAL.—As soon as practicable
10 after the date of enactment of this section, but no
11 later than 1 month after such date of enactment, the
12 Office shall begin—

13 “(A) manufacturing, or entering into con-
14 tracts with entities for the manufacture of ap-
15 plicable COVID–19 products and applicable
16 drugs, biological products, and devices,
17 prioritizing drugs, biological products, devices
18 or personal protective equipment the manufac-
19 ture of which would provide the greatest public
20 health impact; and

21 “(B) constructing, or entering into con-
22 tracts to construct, manufacturing facilities, in-
23 cluding the construction of advanced manufac-
24 turing technology, RNA vaccines, DNA vac-
25 cines, recombinant protein vaccines, and other

1 therapeutics, viral vector-based vaccines, live at-
2 tenuated vaccines, inactivated vaccines, or other
3 therapeutics, after clinical data relating to such
4 products have demonstrated strong positive in-
5 dications of safety and efficacy, to ensure im-
6 mediate production at-scale upon Federal ap-
7 proval.

8 “(2) SUBMISSION OF APPLICATIONS.—For each
9 applicable COVID–19 product, and for each applica-
10 ble drug, biological product, or device that the Office
11 determines should be manufactured, as provided for
12 under this section, the Secretary shall—

13 “(A) submit an application under section
14 505(b), 505(j), or 515 of the Federal Food,
15 Drug, and Cosmetic Act or section 351(a) or
16 351(k) of this Act or submit a notification
17 under section 510(k) of the Federal Food,
18 Drug, and Cosmetic Act (or enter into a con-
19 tract with another entity to submit such an ap-
20 plication or notification);

21 “(B) request an emergency use authoriza-
22 tion of the product under section 564 of the
23 Federal Food, Drug, and Cosmetic Act (21
24 U.S.C. 360bbb–3) (or enter into a contract with

1 another entity to submit an application for such
2 use); or

3 “(C) obtain from the holder of an applica-
4 tion approved under subsection (c) or (j) of sec-
5 tion 505 or section 515 of the Federal Food,
6 Drug, and Cosmetic Act or subsection (a) or
7 (k) of section 351 of the Public Health Service
8 Act, or cleared under section 510(k) of the Fed-
9 eral Food, Drug, and Cosmetic Act, rights to
10 manufacture such applicable drug.

11 “(3) MANUFACTURING TIMELINES.—

12 “(A) PERSONAL PROTECTIVE EQUIP-
13 MENT.—Not later than 1 month after the date
14 of enactment of this section, the Secretary shall
15 begin the public manufacturing of personal pro-
16 tective equipment, including surgical masks,
17 surgical gowns, face shields, and N95 masks,
18 meeting the definition of applicable COVID–19
19 product and in accordance with this section.

20 “(B) COVID–19 DIAGNOSTIC TEST MATE-
21 RIALS.—Not later than 1 month after the date
22 of enactment of this section, the Secretary shall
23 begin the public manufacturing of materials
24 necessary for the development of COVID–19 di-
25 agnostic tests, including chemical reagents, test

1 swabs, and materials necessary to develop sero-
2 logical COVID–19 tests, meeting the definition
3 of applicable COVID–19 product and in accord-
4 ance with this section.

5 “(C) COVID–19 TREATMENT DRUGS.—As
6 soon as practicable after the date of enactment
7 of this section, the Secretary shall begin the
8 public manufacturing of drugs and biological
9 products in shortage, and any devices used to
10 administer such drugs and biological products,
11 that are used for treatment of severe COVID–
12 19 cases, including albuterol, drugs used to
13 intubate patients, antibiotics, and antivirals,
14 meeting the definition of applicable COVID–19
15 product and in accordance with this section.

16 “(4) PRIORITY MANUFACTURING.—The Office
17 shall prioritize the manufacturing of applicable
18 COVID–19 products and applicable drugs, biological
19 products, and devices that would have the greatest
20 impact on—

21 “(A) diagnosing, mitigating, preventing,
22 treating, or curing COVID–19;

23 “(B) limiting the harm the COVID–19
24 pandemic might otherwise cause to public
25 health and the economy;

1 “(C) addressing shortages of drugs, bio-
2 logical, products, and devices;

3 “(D) reducing the cost of combating
4 COVID–19 to Federal, State, local, and Native
5 health programs; and

6 “(E) alleviating demographic disparities in
7 COVID–19 outcomes or access to diagnosis,
8 mitigation, prevention, and treatment.

9 “(c) PROVISION OF PRODUCTS.—

10 “(1) PROVISION OF APPLICABLE COVID–19
11 PRODUCTS.—The Secretary shall provide applicable
12 COVID–19 products at no cost to Federal, State,
13 local, and Native health programs, and other domes-
14 tic health care providers and suppliers, including do-
15 mestic commercial health care providers, as deter-
16 mined by the Secretary, and sell at cost applicable
17 COVID–19 products to other commercial entities
18 and international entities. Amounts received from
19 the sale of such drugs shall be used for the activities
20 of the Office.

21 “(2) PROVISION OF APPLICABLE DRUGS, BIO-
22 LOGICAL PRODUCTS AND DEVICES.—The Secretary
23 shall sell applicable drugs, biological products, and
24 devices produced under this section at a fair price to
25 other entities. Amounts received from the sale of

1 such drugs shall be used to replenish the national
2 strategic stockpile under section 319F-2.

3 “(d) OVERSIGHT OF CONTRACTS.—In the case of ap-
4 plicable COVID-19 products and applicable drugs, bio-
5 logical products, and devices manufactured via contracts,
6 the Inspector General of the Department of Health and
7 Human Services shall conduct a review of not fewer than
8 1 of every 3 contracts entered into under this section, and
9 of the entities entering into such contracts, to ensure that
10 the Office is issuing contracts under fair and reasonable
11 terms and conditions, including facilitating the procure-
12 ment by the Federal Government of applicable COVID-
13 19 products and applicable drugs, biological products, and
14 medical devices at fair and reasonable prices. The Inspec-
15 tor General shall make each such review public and, in
16 cases where such a review identifies unreasonable prices,
17 submit recommendations to Congress on how the Office
18 should improve its contracting systems to ensure reason-
19 able pricing.

20 “(e) REPORTS TO CONGRESS.—The Director shall
21 prepare and submit to the President, the Committee on
22 Health, Education, Labor, and Pensions of the Senate,
23 and the Committee on Energy and Commerce of the
24 House of Representatives, not later than 1 month after
25 the date of enactment of the Pandemic Emergency Manu-

1 facturing Act of 2021 and monthly thereafter until 3
2 months after the public health emergency declared by the
3 Secretary under section 319 on January 31, 2020, with
4 respect to COVID–19 has concluded, that includes—

5 “(1) an assessment of the major supply chain
6 challenges facing hospitals, medical providers, the
7 Federal government, State, local, and tribal govern-
8 ments, and the private sector in procuring drugs, bi-
9 ological products, devices, and personal protective
10 equipment to combat and prevent the spread of
11 COVID–19; and

12 “(2) a description of the status of all drugs, bi-
13 ological products, devices, active pharmaceutical in-
14 gredients, and personal protective equipment for
15 which manufacturing has been authorized under this
16 section, including drugs, biological products, devices,
17 active pharmaceutical ingredients, and personal pro-
18 tective equipment being manufactured, drugs, bio-
19 logical products, devices, active pharmaceutical in-
20 gredients, and personal protective equipment for
21 which the Office has submitted an application for
22 approval or a notification for clearance or classifica-
23 tion to the Food and Drug Administration but has
24 not yet received approval, clearance, or classification,
25 and drugs, biological products, devices, active phar-

1 maceutical ingredients, and personal protective
2 equipment for which the Office has received ap-
3 proval, clearance, or classification from the Food
4 and Drug Administration but are not being manu-
5 factured.

6 “(f) DEFINITIONS.—In this section:

7 “(1) APPLICABLE DRUG, BIOLOGICAL PRODUCT,
8 OR DEVICE DEFINITION.—The term ‘applicable drug,
9 biological product, or device’ means a drug (as de-
10 fined in section 201(g) of the Federal Food, Drug,
11 and Cosmetic Act), biological product (as defined in
12 section 351(i) of the Public Health Service Act),
13 combination product (as described in section 503(g)
14 of the Federal Food, Drug, and Cosmetic Act), or
15 device (as defined in section 201(h) of the Federal
16 Food Drug and Cosmetic Act) for which an ap-
17 proved application under section 505 or 515 of the
18 Federal Food, Drug, and Cosmetic Act or section
19 351 of the Public Health Service Act, or clearance
20 under section 510(k) of the Federal Food, Drug,
21 and Cosmetic Act, is in effect, and—

22 “(A) is included in the drug shortage list
23 under section 506E of the Federal Food, Drug,
24 and Cosmetic Act; or

25 “(B) is vulnerable to shortage.

1 “(2) APPLICABLE COVID-19 PRODUCT DEFINI-
2 TION.—

3 “(A) IN GENERAL.—The term ‘applicable
4 COVID-19 product’ means a product that is
5 included on a list that the Secretary of Health
6 and Human Services, in consultation with the
7 Commissioner of Food and Drugs, the Assist-
8 ant Secretary for Preparedness and Response,
9 and the Director of the Centers for Disease
10 Control and Prevention, shall compile not later
11 than 2 weeks after the date of enactment of
12 this section and shall review and update, as
13 necessary, every 2 weeks of—

14 “(i) qualified pandemic or epidemic
15 products, as defined under section 319F-
16 3, that are—

17 “(I)(aa) drugs, biological prod-
18 ucts, and devices that are manufac-
19 tured, used, designed, developed,
20 modified, licensed or procured—

21 “(AA) to diagnose, mitigate,
22 prevent, treat, or cure COVID-
23 19; or

1 “(BB) to limit the harm the
2 COVID–19 pandemic might oth-
3 erwise cause;

4 “(bb) drugs, biological products,
5 and devices that are manufactured,
6 used, designed, developed, modified, li-
7 censed, or procured to diagnose, miti-
8 gate, prevent, treat, or cure a serious
9 or life-threatening disease or condition
10 caused by a product described in item
11 (aa); or

12 “(cc) drugs, biological products,
13 devices or technologies intended to en-
14 hance the use or effect of a drug, bio-
15 logical product, or device described in
16 item (aa) or (bb); and

17 “(ii) personal protective equipment,
18 including protective equipment for eyes,
19 face, head, and extremities, protective
20 clothing, respiratory devices, and protective
21 shields and barriers, used to protect people
22 from COVID–19 infection.

23 “(B) CONSULTATION.—In developing the
24 list described in subparagraph (A), the Sec-
25 retary shall consult with the Administrator of

1 the Federal Emergency Management Adminis-
2 tration and the Secretary of Defense to ensure
3 that, in instances where the President has en-
4 acted the Defense Production Act to produce
5 applicable COVID–19 products, the Office does
6 not replicate or overproduce products being de-
7 veloped under the Act.

8 “(3) NATIVE HEALTH PROGRAM.—The term
9 ‘Native health program’ shall include—

10 “(A) a program provided through the In-
11 dian Health Service;

12 “(B) any health program operated by—

13 “(i) an Indian tribe, or Tribal organi-
14 zation, as such terms are defined in section
15 4 of the Indian Self-Determination and
16 Education Assistance Act;

17 “(ii) an inter-tribal consortium, as de-
18 fined in section 501(a) of the Indian Self-
19 Determination and Education Assistance
20 Act; or

21 “(iii) an urban Indian organization, as
22 defined in section 4 of the Indian Health
23 Care Improvement Act; and

24 “(C) any health program provided through
25 a Native Hawaiian health care system, as de-

1 fined in section 12 of the Native Hawaiian
2 Health Care Improvement Act.

3 “(4) DOMESTIC HEALTH CARE PROVIDER.—The
4 term ‘domestic health care provider’ shall include the
5 direct support professional, home health, and per-
6 sonal care attendant workforce.

7 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
8 are authorized to be appropriated such sums as may be
9 necessary to carry out this section.”.