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S. 2740

To establish a strategic active pharmaceutical ingredient reserve to maintain a domestic supply of active pharmaceutical ingredients and key starting materials needed for the manufacturing of essential generic medicines, and to build a pipeline for domestic active pharmaceutical ingredient production.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 14, 2021

Mr. BROWN (for himself and Mr. CASSIDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To establish a strategic active pharmaceutical ingredient reserve to maintain a domestic supply of active pharmaceutical ingredients and key starting materials needed for the manufacturing of essential generic medicines, and to build a pipeline for domestic active pharmaceutical ingredient production.

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 “Promoting Readiness
5 and Ensuring Proper Active pharmaceutical ingredient

1 Reserves of Essential medicines Act of 2021” or the
2 “PREPARE Act”.

3 **SEC. 2. LISTING OF ESSENTIAL GENERIC MEDICINES.**

4 Part B of title III of the Public Health Service Act
5 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
6 tion 319M the following:

7 **“SEC. 319N. LISTING OF ESSENTIAL GENERIC MEDICINES.**

8 “(a) IN GENERAL.—The Secretary, in consultation
9 with the Commissioner of Food and Drugs, the Assistant
10 Secretary for Preparedness and Response, the Secretary
11 of Defense, Secretary of Homeland Security, and other
12 heads of agencies, as appropriate, shall establish and make
13 public a list of essential generic medicines determined, in
14 accordance with subsection (b), to be medically necessary
15 to have available at all times.

16 “(b) REQUIREMENTS.—

17 “(1) INITIAL LIST.—The initial list of essential
18 generic medicines under subsection (a) shall be the
19 generic medicines included on the list of essential
20 medicines, medical countermeasures, and critical in-
21 puts identified by the Commissioner of Food and
22 Drugs as published on October 30, 2020, in accord-
23 ance with section 3(c) of Executive Order 13944.

24 “(c) UPDATES.—

1 “(1) ANNUAL REVIEW.—Not less than once
2 each year, the Secretary, after consultation with the
3 Commissioner of Food and Drugs, the Assistant
4 Secretary for Preparedness and Response, the Sec-
5 retary of Defense, Secretary of Homeland Security,
6 and other heads of agencies, as appropriate, shall re-
7 view and update the list of essential generic medi-
8 cines required under subsection (a).

9 “(2) RATIONALE.—In carrying out the annual
10 review and update under paragraph (1), the Sec-
11 retary shall provide a rationale for each essential ge-
12 neric medicine added to, or removed from, the list
13 under subsection (a).

14 “(3) SPECIFIC POPULATIONS.—The Secretary
15 shall consider including on the list under subsection
16 (a), and, where appropriate, include on such list, es-
17 sential generic medicines that are essential to spe-
18 cific subpopulations, including pediatric populations,
19 in developing the list under such subsection.

20 “(4) THREAT ASSESSMENTS.—

21 “(A) IN GENERAL.—The Secretary, after
22 consultation with the Public Health Emergency
23 Medical Countermeasures Enterprise estab-
24 lished under section 2811–1, shall conduct reg-
25 ular threat assessments, and take such assess-

1 ments into consideration in updating the list in
2 accordance with paragraph (1).

3 “(B) THREAT ASSESSMENTS CONSIDER-
4 ATIONS.—Each threat assessment under this
5 paragraph shall include consideration of—

6 “(i) the lack of existing domestic ca-
7 pacity of essential generic medicines;

8 “(ii) the concentration of current sup-
9 ply of the essential generic medicine or ac-
10 tive pharmaceutical ingredients of the es-
11 sential generic medicine in one geo-
12 graphical region;

13 “(iii) whether there are less than 2
14 manufacturers of the essential generic
15 medicine or active pharmaceutical ingredi-
16 ents of the essential generic medicine; and

17 “(iv) the potential for increased de-
18 mand in a public health emergency.

19 “(5) DIRECTOR OF THE STRATEGIC ACTIVE
20 PHARMACEUTICAL INGREDIENTS RESERVE.—The
21 Secretary shall appoint a Director of the Strategic
22 Active Pharmaceutical Ingredients Reserve who has
23 experience in one or more of the following areas:
24 supply chain management, disaster response, phar-
25 maceutical or active pharmaceutical ingredient devel-

1 opment, or logistics. Such Director shall ensure a
2 sufficient supply of the active pharmaceutical ingre-
3 dients and critical components necessary to manu-
4 facture the essential generic medicines included on
5 the list under subsection (a) in an amount adequate
6 to serve the needs of patients living in the United
7 States and in the appropriate dosage forms.

8 “(d) APPEAL PROCESS.—The Secretary shall estab-
9 lish a process by which stakeholders may appeal a deter-
10 mination by the Secretary not to include an essential ge-
11 neric medicine on the list under subsection (a).

12 “(e) DEFINITIONS.—In this section:

13 “(1) DRUG.—The term ‘drug’ has the meaning
14 given such term in section 201(g) of the Federal
15 Food, Drug, and Cosmetic Act, and includes a bio-
16 logical product (as defined in section 351(i) of this
17 Act). Such term includes prescription and non-
18 prescription drugs, or active pharmaceutical ingredi-
19 ents of drugs.

20 “(2) ESSENTIAL GENERIC MEDICINE.—The
21 term ‘essential generic medicine’ means a drug for
22 which a generic is approved, that is medically nec-
23 essary to have available at all times because the
24 drug is—

1 “(A) commonly used to prevent, mitigate,
2 or treat a common disease or condition, or used
3 in a common procedure;

4 “(B) an antibiotic or antifungal used to
5 treat an infectious diseases;

6 “(C) necessary to prevent or mitigate a
7 public health emergency; or

8 “(D) life-supporting, life-sustaining, or in-
9 tended for use in the prevention or treatment of
10 a debilitating disease or condition.”.

11 **SEC. 3. ESTABLISHMENT OF THE STRATEGIC ACTIVE PHAR-**
12 **MACEUTICAL INGREDIENT RESERVE.**

13 Part B of title III of the Public Health Service Act
14 (42 U.S.C. 243 et seq.), as amended by section 2, is fur-
15 ther amended by inserting after section 319N the fol-
16 lowing:

17 **“SEC. 319N-1. STRATEGIC ACTIVE PHARMACEUTICAL IN-**
18 **GREDIENT RESERVE.**

19 “(a) STRATEGIC ACTIVE PHARMACEUTICAL INGRE-
20 DIENT RESERVE PLAN.—

21 “(1) IN GENERAL.—Not later than 90 days
22 after the date of enactment of the Promoting Readi-
23 ness and Ensuring Proper Active pharmaceutical in-
24 gredient Reserves of Essential medicines Act of
25 2021, the Secretary, in consultation with the Assist-

1 ant Secretary for Preparedness and Response, the
2 Director of the Centers for Disease Control and Pre-
3 vention, the Commissioner of Food and Drugs, and
4 the Director of the Biomedical Advanced Research
5 and Development Authority, shall prepare and sub-
6 mit to Congress a Strategic Active Pharmaceutical
7 Ingredient Reserve Plan (referred to in this section
8 as the ‘Plan’) in accordance with subsection (b),
9 which shall be used by the Secretary in establishing
10 and maintaining the Strategic Active Pharmaceutical
11 Ingredient Reserve described in subsection (c).

12 “(2) ANNUAL UPDATES.—The Secretary shall
13 update the plan annually and, by not later than
14 June 1 of each year, submit the updated plan to the
15 applicable committees of Congress.

16 “(3) NATIONAL SECURITY CONSIDERATIONS.—

17 “(A) SUBMISSIONS.—The Secretary shall
18 ensure that any submission of the plan (includ-
19 ing any update to the plan) to the applicable
20 committees of Congress is in a manner that
21 does not compromise national security.

22 “(B) EXEMPTION FROM DISCLOSURE.—In-
23 formation in the plan that, in the judgment of
24 the Secretary, would reveal public health
25 vulnerabilities shall be exempt from disclosure

1 under section 552(b)(3) of title 5, United
2 States Code.

3 “(b) PLAN REQUIREMENTS.—

4 “(1) IN GENERAL.—The Plan required under
5 subsection (a) shall—

6 “(A) detail the design, construction, and
7 filling of the storage and related facilities com-
8 prising the Strategic Active Pharmaceutical In-
9 gredient Reserve described in subsection (c) (re-
10 ferred to in this section as the ‘Reserve’);

11 “(B) detail the requirements for maintain-
12 ing the Reserve described in subsection (c), in-
13 cluding—

14 “(i) storage and testing requirements,
15 consistent with parts 210 and 211 of title
16 21, Code of Federal Regulations, or any
17 successor regulation; and

18 “(ii) any specific criteria agreed to by
19 the Secretary and the manufacturer of the
20 essential generic medicine using the active
21 pharmaceutical ingredient or key starting
22 material;

23 “(C) be designed to minimize the impact of
24 any interruption or reduction in imports of—

1 “(i) active pharmaceutical ingredients
2 and other key starting materials that the
3 Secretary determines are, or are likely to
4 become, dependent upon such imports for
5 a substantial portion of finished essential
6 generic medicines; and

7 “(ii) finished dosage forms of essential
8 generic medicines for which active pharma-
9 ceutical ingredients and other key starting
10 materials are not imported;

11 “(D) include provisions to strengthen do-
12 mestic capacity for active pharmaceutical ingre-
13 dient production, storage, and conversion; and

14 “(E) outline plans and processes for co-
15 ordinating and consulting, as appropriate, with
16 the Assistant Secretary for Preparedness and
17 Response regarding relevant issues of interest
18 pertaining to the maintenance and stocking of
19 the strategic national stockpile.

20 “(2) REQUIRED COMPONENTS.—

21 “(A) IN GENERAL.—The Plan shall include
22 the following:

23 “(i) Identification and prioritization of
24 the essential generic medicines included on

1 the most recent list under section
2 319N(a)—

3 “(I) that the Secretary deter-
4 mines are essential for health care
5 needs in the United States; and

6 “(II) for which the Secretary de-
7 termines that there is the greatest
8 need to maintain a reserve of the ac-
9 tive pharmaceutical ingredients and
10 key starting materials for the essen-
11 tial generic medicines—

12 “(aa) taking into account
13 factors including the extent to
14 which the United States is, or is
15 at risk of becoming, dependent
16 on foreign sources for a substan-
17 tial portion of the domestic need;
18 and

19 “(bb) giving special consid-
20 eration to the essential generic
21 medicines at risk of supply inter-
22 ruption as a result of the factors
23 described in section
24 319N(c)(4)(B).

1 “(ii) An evaluation of the utilization
2 levels of the essential generic medicines
3 identified under clause (i) to inform how
4 much of the active pharmaceutical ingredi-
5 ents of such medicines is required to cover
6 the projected health care needs for one
7 year of the United States population.

8 “(iii) A comprehensive assessment of
9 the essential generic medicines identified
10 under clause (i), including the existing
11 manufacturing bases for each such medi-
12 cine (including identification and location
13 of ownership of such facilities) and wheth-
14 er the active pharmaceutical ingredients of
15 such ingredients are manufactured domes-
16 tically or abroad, and whether finished dos-
17 age conversion steps for such essential ge-
18 neric medicines are performed domestically
19 or abroad.

20 “(iv) The types of facilities, equip-
21 ment, and technology required to appro-
22 priately store, track, test, and convert all
23 forms of active pharmaceutical ingredients
24 that are critical inputs of drugs that are
25 essential generic medicines, preliminary

1 proposed locations for such public and pri-
2 vately owned facilities in multiple locations
3 in the United States, the capacity required
4 of the facilities used, and the estimated
5 cost of acquisition and storage of the ac-
6 tive pharmaceutical ingredients and man-
7 agement and operation of the facilities.

8 “(v) An evaluation of the impact that
9 the establishment and ongoing mainte-
10 nance of the Reserve may have, including
11 on availability and pricing of active phar-
12 maceutical ingredients and finished drug
13 dosages.

14 “(vi) A distribution plan for the active
15 pharmaceutical ingredients held in the Re-
16 serve, which shall include—

17 “(I) protocols for the method of
18 conversion of active pharmaceutical
19 ingredients into finished drugs, in-
20 cluding conversion of key starting ma-
21 terials into active pharmaceutical in-
22 gredients and distribution from the
23 Reserve into the strategic national
24 stockpile and other government and

1 commercial pharmaceutical distribu-
2 tion networks; and

3 “(II) benchmarks for the Sec-
4 retary to initiate conversion of drug
5 products that are essential generic
6 medicines using the active pharma-
7 ceutical ingredients stored in the Re-
8 serve for transfer to the strategic na-
9 tional stockpile or other government
10 or commercial pharmaceutical dis-
11 tribution networks, based on changes
12 in the supply chain for the top essen-
13 tial generic medicines or a determina-
14 tion by the Secretary regarding a
15 threat to public health.

16 “(vii) A mechanism through which
17 private sector manufacturers of active
18 pharmaceutical ingredients or finished dos-
19 age forms may, through contracts with ex-
20 isting Reserve facilities, store and with-
21 draw such ingredients in the Reserve to
22 enhance resilience and reduce shortages
23 and disruptions in the supply chain.

24 “(viii) A mechanism through which
25 the Federal Government may purchase, via

1 manufacturing partners, reserve capacity
2 for finished drug manufacturing to convert
3 active pharmaceutical ingredients into fin-
4 ished drugs for essential generic medicines.

5 “(B) NUMBER OF DRUGS.—

6 “(i) IN GENERAL.—Pursuant to sub-
7 paragraph (A)(i), the Secretary shall en-
8 sure that for the first year after the date
9 of enactment of the Promoting Readiness
10 and Ensuring Proper Active pharma-
11 ceutical ingredient Reserves of Essential
12 medicines Act of 2021, the Plan includes
13 not less than 25 essential generic medi-
14 cines, and that 25 additional essential ge-
15 neric medicines are included in such Plan
16 for each year thereafter until the active
17 pharmaceutical ingredients necessary to
18 support the full list of essential generic
19 medicines identified under section 319N(a)
20 are covered.

21 “(ii) PRIORITIZATION.—The Secretary
22 shall prioritize essential generic medicines
23 needed immediately in the event of an
24 emergency.

1 “(3) QUANTITIES OF APIS AND KEY STARTING
2 MATERIALS.—

3 “(A) IN GENERAL.—To the maximum ex-
4 tent practicable, the Plan should include a plan
5 to ensure that, for each essential generic medi-
6 cine included in the Plan, the active pharma-
7 ceutical ingredients used in the production of
8 such medicine that are stored in the Reserve
9 are available in the minimum quantities as fol-
10 lows:

11 “(i) By the date that is 18 months
12 after the date of enactment of the Pro-
13 moting Readiness and Ensuring Proper
14 Active pharmaceutical ingredient Reserves
15 of Essential medicines Act of 2021, not
16 less than 10 percent of the total amount of
17 such ingredients needed to produce suffi-
18 cient quantities of the essential generic
19 medicines for the treatment of individuals
20 living in the United States.

21 “(ii) By the date that is 3 years after
22 such date of enactment, not less than 25
23 percent of the total amount of such ingre-
24 dients needed to produce sufficient quan-
25 tities of the essential generic medicines for

1 the treatment of individuals living in the
2 United States.

3 “(iii) By the date that is 5 years after
4 such date of enactment, not less than 50
5 percent of the total amount of such ingre-
6 dients needed to produce sufficient quan-
7 tities of the essential generic medicines for
8 the treatment of individuals living in the
9 United States.

10 “(iv) By the date that is 10 years
11 after such date of enactment, not less than
12 90 percent of the total amount of such in-
13 gredients needed to produce sufficient
14 quantities of the essential generic medi-
15 cines for the treatment of individuals living
16 in the United States.

17 “(B) CALCULATION OF QUANTITY OF
18 API.—In calculating the quantities of active
19 pharmaceutical ingredients needed for purposes
20 of subparagraph (A), the Secretary shall deter-
21 mine the quantity of each essential generic
22 medicine required to cover the projected health
23 care needs, over a 1-year period, of people living
24 in the United States, based on average annual
25 demand during the 3-year period preceding the

1 date of enactment of the Promoting Readiness
2 and Ensuring Proper Active pharmaceutical in-
3 gredient Reserves of Essential medicines Act of
4 2021.

5 “(c) ADMINISTERING THE STRATEGIC ACTIVE PHAR-
6 MACEUTICAL INGREDIENT RESERVE.—

7 “(1) IN GENERAL.—With respect to each active
8 pharmaceutical ingredient and key starting material
9 that is included in the Plan, the Secretary shall
10 place in storage, transport, track, and exchange
11 quantities of the substance that are—

12 “(A) produced in conformance with all
13 quality requirements under this Act and the
14 Federal Food, Drug, and Cosmetic Act, includ-
15 ing the associated regulations of such Acts;

16 “(B) stored in compliance with—

17 “(i) the requirements of parts 210
18 and 211 of title 21, Code of Federal Regu-
19 lations, or any successor regulation; and

20 “(C) any specific criteria agreed to by the
21 Secretary and the manufacturer of the essential
22 generic medicine using the active pharma-
23 ceutical ingredient or key starting material.

24 “(2) REQUIREMENTS.—To the greatest extent
25 practicable, in carrying out paragraph (1), the Sec-

1 retary shall acquire active pharmaceutical ingredi-
2 ents and key starting materials in a manner that
3 minimizes cost, minimizes vulnerability of the United
4 States to severe shortages or disruptions for essen-
5 tial generic medicines, minimizes the impact of ac-
6 quisition of such ingredients and materials to the
7 marketplace, gives preference to domestic manufac-
8 turers, and encourages competition in the market-
9 place.

10 “(3) DRAWDOWN OF THE RESERVE.—

11 “(A) IN GENERAL.—The Secretary may
12 distribute active pharmaceutical ingredients and
13 key starting materials in the Reserve in order
14 to initiate conversion of active pharmaceutical
15 ingredients and finished dosage form, in accord-
16 ance with the Plan developed under subsection
17 (b).

18 “(B) DEVIATIONS FROM PLAN.—In distrib-
19 uting active pharmaceutical ingredients and key
20 starting materials under subparagraph (A), the
21 Secretary, in consultation with the Commis-
22 sioner of Food and Drugs and the Assistant
23 Secretary for Preparedness and Response, may
24 deviate from the Plan developed under sub-
25 section (b) only after certifying that the dis-

1 tribution from the Reserve is required in re-
2 sponse to a significant drug supply interrup-
3 tion.

4 “(d) CONSULTATION.—

5 “(1) IN GENERAL.—In carrying out this sec-
6 tion, the Secretary shall consult with—

7 “(A) the Commissioner of Food and
8 Drugs, with respect to identifying essential ge-
9 neric medicines;

10 “(B) the Administrator of the Centers for
11 Medicare & Medicaid Services, with respect to
12 determining the volume of essential generic
13 medicines needed domestically; and

14 “(C) the Assistant Secretary for Prepared-
15 ness and Response, and, as appropriate, the Di-
16 rector of the Centers for Disease Control and
17 Prevention, regarding coordination with the
18 strategic national stockpile.

19 “(2) REPORTING BY FDA.—The Commissioner
20 of Food and Drugs shall provide to the Secretary
21 the information collected under section 510(j)(3) of
22 the Federal Food, Drug, and Cosmetic Act, for pur-
23 poses of carrying out this section.

24 “(e) CONTRACTING.—

1 “(1) IN GENERAL.—In carrying out this sec-
2 tion, the Secretary shall—

3 “(A) prioritize the purchase of active phar-
4 maceutical ingredients and other key starting
5 materials manufactured in the United States by
6 domestic manufacturers to the maximum extent
7 possible;

8 “(B) contract with domestic entities for
9 the—

10 “(i) distribution of active pharma-
11 ceutical ingredients and finished drug
12 products;

13 “(ii) storage, withdrawal, testing, and
14 conversion of active pharmaceutical ingre-
15 dients and other key starting materials;

16 “(iii) tracking and coordinating the
17 storage, testing, and sale of active pharma-
18 ceutical ingredients and other key starting
19 materials;

20 “(iv) sale of active pharmaceutical in-
21 gredients in advance of their expiration
22 dates; and

23 “(v) manufacturing, including contin-
24 uous manufacturing as appropriate, of an
25 active pharmaceutical ingredient or other

1 key starting material of an essential ge-
2 neric medicine that is anticipated to be in
3 shortage, as defined by the Secretary for
4 purposes of this section;

5 “(C) give preference to domestic nonprofit
6 and public-private partnerships, as appropriate;

7 “(D) ensure geographic diversity of the
8 physical storage of active pharmaceutical ingre-
9 dients and other key starting materials;

10 “(E) support domestic manufacturers of
11 active pharmaceuticals and other key starting
12 materials and facilitate long-term domestic ca-
13 pacity for essential generic medicines in the
14 United States; and

15 “(F) prioritize contracts that facilitate the
16 conversation of active pharmaceutical ingredi-
17 ents and other key starting materials into fin-
18 ished dosage form.

19 “(2) RULE OF CONSTRUCTION.—Nothing in
20 this subsection shall be construed to limit the Sec-
21 retary’s ability to enter into other types of contracts
22 to facilitate the implementation of this section.

23 “(f) REPORTS TO CONGRESS.—The Secretary shall
24 report to the applicable committees of Congress on supply
25 chain resiliency with respect to active pharmaceutical in-

1 ingredients for essential generic medicines, the status of the
2 Reserve, and other relevant information in a manner that
3 does not compromise national security.

4 “(g) DEFINITIONS.—In this section:

5 “(1) APPLICABLE COMMITTEES OF CON-
6 GRESS.—The term ‘applicable committees of Con-
7 gress’ means—

8 “(A) the Committee on Health, Education,
9 Labor, and Pensions and the Committee on In-
10 telligence of the Senate; and

11 “(B) the Committee on Energy and Com-
12 merce of the House of Representatives.

13 “(2) ESSENTIAL GENERIC MEDICINE.—The
14 term ‘essential generic medicine’ means a drug in-
15 cluded on the most current list under section
16 319N(a).

17 “(3) KEY STARTING MATERIAL.—The term ‘key
18 starting material’ means an active pharmaceutical
19 ingredient or critical input used in the manufac-
20 turing of an essential generic medicine, as well as in-
21 gredients or components that possess unique at-
22 tributes essential in assessing the safety and effec-
23 tiveness of such essential generic medicines, includ-
24 ing excipients and inactive ingredients.

1 “(h) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated to carry out this section
3 such sums as may be necessary.”.

4 **SEC. 4. WAIVER OF CERTAIN FDA ANDA REQUIREMENTS.**

5 Section 505(j) of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 355(j)) is amended by adding at the
7 end the following:

8 “(14) Notwithstanding any other provision of
9 this section, the holder of an approved application
10 under this subsection that changes the source of an
11 active pharmaceutical ingredient of the drug that is
12 the subject of such application to a source available
13 through the Strategic Active Pharmaceutical Ingred-
14 ient Reserve established under section 319N–1 of
15 the Public Health Service Act—

16 “(A) shall not be required to update the
17 approved application with respect to such
18 change before changing the source; and

19 “(B) shall inform the Secretary of the
20 change, through an update to the approved ap-
21 plication or other manner determined appro-
22 priate by the Secretary, prior to commercial
23 distribution of the drug.”.

1 **SEC. 5. GAO REPORT.**

2 By not later than 18 months after the date of enact-
3 ment of this Act, the Comptroller General of the United
4 States shall prepare and submit a report to Congress that
5 includes—

6 (1) an assessment of what is known about ac-
7 tive pharmaceutical ingredient manufacturing, in-
8 cluding—

9 (A) the time needed to develop and imple-
10 ment domestic manufacturing capabilities;

11 (B) projected costs of developing new man-
12 ufacturing capabilities for active pharmaceutical
13 ingredients not currently available domestically,
14 as of the date of the report; and

15 (C) projected costs of expanding existing
16 domestic capabilities and policies, as of the date
17 of the report, that may help establish or
18 strengthen domestic manufacturing capacity for
19 active pharmaceutical ingredients, excipients,
20 key starting materials, components, functional
21 ingredients, and finished dosage manufacturing
22 facilities; and

23 (2) an assessment of incentives already offered
24 or being considered for the development or improve-
25 ment of domestic capacity to manufacture active

1 pharmaceutical ingredients, their intermediates, and
2 their excipients, including—

3 (A) contractual arrangements for existing
4 domestic storage and manufacturing of active
5 pharmaceutical ingredients;

6 (B) guaranteed contracts for initial pur-
7 chase and replenishment of essential generic
8 medicines; and

9 (C) other policies designed to help
10 incentivize the relocation of manufacturing fa-
11 cilities to the United States or provide economic
12 incentives for domestic production.

○