U.S. Pharmaceutical Supply Chain Defense and Enhancement Act

U.S. Senator Elizabeth Warren (D-MA) and U.S. Senator Tina Smith (D-MN)

Section 2 – Listing of critical drugs

- The Department of Health and Human Services (HHS), in consultation with the Food and Drug Administration (FDA) and Department of Defense (DoD) shall develop a confidential list of drugs deemed to be crucial to public health or national security, and their requisite active pharmaceutical ingredients (APIs) and key starting materials.
    - HHS may consider the risk of shortages of a drug in developing this list.
    - The list shall be developed no later than 1 year after the bill is passed and will be updated every two years.
    - The list shall be submitted to the relevant Congressional committees in a confidential format.
- Interim list – 30 days after the passage of this bill, HHS shall establish an interim list of no less than 30 drugs based on the most recent list of essential medicines issued by the World Health Organization.
- Public comment – In establishing a critical drug list, the federal government shall solicit comments from the public on which drugs should be included.

Section 3 – Boosting domestic drug and active ingredient manufacturing capacity

- Contracts
    - The Biomedical Advanced Research and Development Authority (BARDA), shall be given $5 billion ($1 billion per year for each of fiscal years 2020-2024) to contract with companies and nonprofit entities headquartered and that utilize manufacturing establishments located in the United States to manufacture drugs, APIs, and key starting materials on the list developed by HHS, FDA, and DoD, using advanced manufacturing techniques.
    - To enter enter into these contracts, companies and non-profits must:
        - Develop and maintain a redundancy risk management and continuity of business plan that identifies and evaluates risks to the supply of the drug, API, or key ingredient that is produced. HHS is instructed to review each of these plans.
        - Commit to the implementation of a plan to ensure that the manufacturer can continue normal production of this drug, API, or key starting material in the case of an 18-month disruption.
        - Commit to maintaining a 3-month supply of APIs or key starting materials to mitigate the impact of a supply chain shortage or disruption.
        - Commit to selling the drugs, active pharmaceutical ingredients, and starting materials they manufacture at fair and reasonable prices.
    - HHS shall prioritize contracts that enhance the supply of generic drugs and drugs not currently manufactured in the United States, as well as their requisite APIs and starting materials.
    - The HHS Office of the Inspector General shall review at least 1 of every 3 contracts, and of the entities entering into such contracts, to ensure that contracts are being issued under fair and reasonable terms and conditions and issue a public report for each review.

- Federal Procurement of Domestically Manufactured Drugs
    - Between FY2024-2028, each of the DoD, HHS, the Bureau of Prisons (BOP), and the Department of Veterans Affairs (VA) shall be appropriated $1 billion per year to purchase drugs manufactured in the United States.
        - None of this funding may be used for any purpose not explicitly authorized by this bill.
        - Any unused funds will be reverted back to the general fund and shall be used by the National Institutes of Health to carry out biomedical research.

Section 4 – Supply chain transparency

- Domestic drug suppliers
    - Each domestic manufacturer of a drug procured by DoD, VA, BOP, or HHS, or domestic manufacturer of an active ingredient such a drug, shall submit an annual report to HHS that includes:
        - Whether any ingredient of such drug or API is sourced either wholly or in part from a foreign country.
        - 2 alternative sources of any API or key starting material that is procured from a single source.
        - An assessment of the resilience and capacity of these alternate sources.
- Foreign drug suppliers
    - Amends the Federal Food, Drug, and Cosmetics Act to require any foreign manufacturer that produces or modifies APIs that are then exported to the United States now required to register with HHS.
- Reports to Congress and the public
    - No later than one year after the passage of this bill, HHS shall submitted a classified report to Congress on the nation's reliance on imported drugs and APIs on the list HHS developed.
        - This report shall include:
            - The names of all brand and generic drugs that are:
                - not wholly produced in the United States
                - produced exclusively overseas
                - critical to public health or national security.
                - Procured in any quaintly by DoD for use by servicemembers or veterans
                - Procured by HHS for the Strategic National Stockpile
            - An assessment of the resiliency and capacity of alternative sources for these drugs.
        - HHS shall also release an unclassified, publically available summary of this report.
- Manufacturer compliance
    - Establishes penalties for manufacturers who fail to notify HHS of interruptions in the supply of drugs and APIs.
- Registry of active ingredients
    - $20 million shall be appropriated to HHS to establish an online registry of APIs using information reported by manufacturers

Section 5- Oversight of foreign pharmaceutical investment

- No later than one year after the passage of this bill, the Federal Trade Commission and the Committee on Foreign Investment in the United States shall conduct and submit to Congress, HHS, and FDA, a study on foreign investment in the pharmaceutical industry of the United States. This report shall detail:
    - How overreliance on foreign counties for pharmaceutical products impacts the United States' supply chain and domestic manufacturing capacity;
    - How foreign direct investment from abroad affects the nation's ability to produce drugs, as well as their key components;
    - How foreign direct investment in U.S. genome sequencing technologies affects domestic capacity to sequence or store DNA; and
    - The number of foreign investment transactions in the pharmaceutical industry and the sequencing or storage of DNA in the United States that CFIUS has reviewed in the past ten years.

Section 6 – Definitions

- Provides definitions of the terms "continuous manufacturing," "drug," and "starting material" for the purposes of this legislation.