TRANSPARENCY AND QUALITY IN PHARMACEUTICALS ACT

SECTION 1. SHORT TITLE.

This Act may be cited as the "Transparency and Quality In Pharmaceuticals Act" or the "TraQ Pharma Act."

SEC. 2. PURPOSE.

The purposes of this Act are to—

enable the Department of Defense to procure pharmaceuticals through the evaluation of the true country of origin of pharmaceuticals and their components; assess their relative level of quality and safety risk using an objective risk-categorization framework based on independently derived drug supply data; and integrating independent testing mechanisms to improve pharmaceutical supply chain transparency and protect servicemember health.

SEC. 3. EXPANSION OF PHARMACEUTICAL SUPPLY CHAIN QUALITY RISK SCORING PROGRAM.

(a) Expand effort to obtain data for DoD pharmaceutical supply chain transparency specific to individual National Drug Codes ("NDCs") which includes insights on true country of origin (location quality) and relative chemical quality and safety risks ("Drug Supply Data") –

(1) The Uniformed Services University of the Health Sciences shall continue the Pilot Study titled "Assessing the Security & Quality of the U.S. Military Health System Pharmaceutical Supply Chain" for a minimum of five (5) years following enactment in order to generate Drug Supply Data.

(2) This Pilot Study shall include, but is not limited to:

(A) Defining the DoD Essential Medicine list, to consist of not more than 100 medicines that do not have patent exclusivity and are deemed by the Department as essential for operational capabilities, pre-deployment, or the Military Health System, as guided by the initial two-year Pilot Study. To the extent practicable, the DoD Essential Medicines list shall be harmonized with the Defense-Relevant Generic Drug List established under section 887 of the National Defense Authorization Act for Fiscal Year 2025 (10 U.S.C. § 4865);

(B) Refreshing and expanding chemical testing data from the initial two-year Pilot Study to include all DoD Essential Medicines and creating NDC-specific categorizations of high-risk,

moderate-risk, or low-risk based on objective indicators for relative chemical quality and safety risk;

(C) Adding to the objective risk-categorization framework assessment of location of manufacturing, including flagging entities in China and other non-TAA-compliant countries, creating NDC-specific, objective categorizations of high-risk, moderate-risk, or low-risk based on independently derived indicators for true country of origin, where countries of concern, including China, are classified under the highest-risk category; and

(D) Making recommendations for the continuation of the scoring framework at the conclusion of the Pilot Study.

(b) Independent Testing.— The Drug Supply Data under this section shall be conducted by independent laboratories acceptable to USUHS that—

(1) are accredited under ISO 17025 standards; and

(2) are not registered as a Good Manufacturing Practice (GMP) facility to ensure no conflicts of interest.

(3) have experience developing and operating a published quality risk scoring framework applicable to individual NDCs.

(4) are duly licensed and demonstrate an ability to conduct ongoing post-market surveillance through procurement of pharmaceutical products from common wholesalers, and not directly from manufacturers, for this Act.

(c) Third-Party Audits. — The Secretary shall establish procedures for independent third-party audits of manufacturers or suppliers flagged as high-risk, or as necessary to verify the accuracy of Drug Supply Data provided under this Act.

SEC. 4. PROCUREMENT RESTRICTIONS BASED ON DRUG SUPPLY DATA.

(a) Revising procurement protocols -- In purchasing DoD Essential Medicines, DoD shall:

(1) Contract directly from pharmaceutical manufacturers using a procurement process that, in addition to price, shall prioritize procurement of products classified as low-risk and shall not procure products categorized as high-risk unless a waiver is granted under subsection (c); or

(2) Direct the prime vendor to utilize a procurement process in contracts with pharmaceutical manufacturers that, in addition to price, shall prioritize procurement of products classified as low-risk and shall not procure products categorized as high-risk unless a waiver is granted under subsection (c).

(b) Prohibition on Non-Compliant Pharmaceuticals.-- As part of the procurement process, the Department of Defense shall not procure any pharmaceutical product if Drug Supply Data indicates that--

(1) the country of origin of the product, its active pharmaceutical ingredient (API), or key starting materials is a non-TAA-designated country of concern; or

(2) the product has been classified as high-risk based on the objective risk-categorization framework.

(3) For purposes of this subsection, “country of origin” shall be defined as the country where the product’s last substantial transformation occurred, excluding final steps such as packaging, labeling, or minor formulation.

(c) Waiver Authority.--

(1) The Secretary may waive the prohibition under subsection (b) only in exceptional cases if—

(A) no compliant alternatives are available in sufficient quantity to meet Department of Defense requirements; and

(B) the waiver is reported to Congress with a justification based on national security needs.

(2) A waiver shall not be issued for reasons of cost alone.

(3) Approval from the Food and Drug Administration shall not be considered sufficient to override the origin (Sec 4(b)(1)) and quality risk (Sec 4(b)(2)) requirements established under this Act.

(d) Applicability.-- The requirements under subsection (a), (b) and (c) shall --

(1) apply to all pharmaceuticals and associated NDCs on the DoD Essential Medicines list, as defined in Sec 3(a)(2)(i)

(2) Phase-In according to the following--

(A) Not less than 10% of DoD Essential Medicines by the end of the first year following enactment;

(B) Not less than 40% of DoD Essential Medicines by the end of the second year following enactment;

(C) Not less than 100% of DoD Essential Medicines by the end of the third year following enactment;

(e) Data Management and Reporting.--The Secretary shall--

(1) maintain a database of Drug Supply Data accessible to relevant Department of Defense procurement officials; and

(2) submit an annual report to Congress detailing--

(A) compliance with contracting requirements; and

(B) any instances where non-compliant products were identified and the actions taken.

SEC. 5. FUNDING.

(a) Authorization of Appropriations.--To carry out this section, there are authorized to be appropriated $6,000,000 for the Uniformed Services University of the Health Sciences for each of fiscal years 2025 – 2029.

SEC. 6. RELATIONSHIP TO OTHER LAW.

Nothing in this Act shall be construed to override, modify, or weaken the requirements established under section 887 of the National Defense Authorization Act for Fiscal Year 2025 (10 U.S.C. § 4865). The framework established under this Act is intended to support the implementation, compliance verification, and enforcement of such section by providing objective data and independent testing mechanisms to assess pharmaceutical product origin and quality.

DEFINITIONS

“Objective risk-categorization framework” means a system developed in coordination with the Uniformed Services University of the Health Sciences to evaluate pharmaceutical products based on objective quality, safety, and location of manufacturing metrics including independently determined country of origin.