TWENTY-FIRST CONGRESS OF THE FEDERATED STATES OF MICRONESIA

FOURTH REGULAR SESSION, 2022 C.B. NO. 22-165

A BILL FOR AN ACT

To further amend title 54 of the Code of the Federated States of Micronesia (Annotated), as amended, by creating a new chapter 10 to establish the FSM Pharmaceutical Import Control Act of 2022, and for other purposes.

BE IT ENACTED BY THE CONGRESS OF THE FEDERATED STATES OF MICRONESIA:

Section 1. Title 54 of the Code of the Federated States of Micronesian (Annotated), as amended, is hereby further amended by creating a new chapter 10 entitled: "FSM Pharmaceutical Import Control Act of 2022".

Section 2. Chapter 10 of title 54 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new subchapter 1 entitled: "General Provisions".

Section 3. Chapter 10 of title 54 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1001 of subchapter 1 to read as follows:

"Section 1001. Short title. This Act may be referred to as the Pharmaceutical Import Control Act.".

Section 4. Chapter 10 of title 54 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1002 of subchapter 1 to read as follows:

"Section 1002. Statement of Policy. It is hereby declared as a policy of the Federated States of Micronesia: The enforcement of import controls on all pharmaceuticals is necessary to ensure acceptable standards of quality, safety and efficacy of pharmaceuticals entering the country; and ensure the practices of all persons, businesses, entities and establishments involved in the importation of pharmaceuticals into the FSM comply with the acceptable standards of quality, safety and efficacy."

Section 5. Chapter 10 of title 54 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1003 of subchapter 1 to read as follows:

"Section 1003. Definitions: For the purposes of this title, the following terms shall be given the meanings described herein:

(1) "Active Pharmaceutical Ingredient" (API) is the chemical substance contained in a pharmaceutical, which is responsible for its therapeutic effect. Some pharmaceuticals contain more than one active ingredient (combination product).

(2) "Assistant Secretary of Customs" means the Assistant Secretary for the FSM Customs and Tax Administration under the FSM Department of Finance and

Administration.

(3) "Authorized port of entry" means a port of entry designated by the Secretary of Justice from the ports-of-entry under Section 202 of Title 18 of the Code of the FSM where pharmaceuticals may be imported into the FSM.

(4) "Certificate of pharmaceutical product (CPP)" means a certificate issued by the authorized body of the exporting country that satisfies the pharmaceutical verification format standards to permit importation into the FSM as determined by the Secretary of Health.

(5) "Competent jurisdictions" means countries with stringent and operational regulatory system where medicines can be imported into the FSM as determined by the Secretary of Health.

(6) "Customs Administration" means the Customs and Tax Administration under the FSM Department of Finance and Administration.

(7) "Department of Health" means the Department of Health and Social Affairs.

(8) "Distribution" means the division and movement of pharmaceuticals from the port of entry to the Establishment or end user thereof, by means of various transport methods or storage.

(9) "Distributor" means an individual, company or legal entity distributing or seeking to distribute a

pharmaceutical.

(10) "Donation" means the act by which organizations, institutions, international development partners, non-government organizations and other legal entities provide pharmaceuticals to the FSM for free and for specific use, such as in the case of emergency or for humanitarian purposes.

(11) "Establishment" means an entity in the FSM that engages in the importation of pharmaceuticals and/or active pharmaceutical ingredients into the FSM, including but not limited to:

a. Wholesalers;

b. Distributors;

c. Pharmacies;

d. Importers;

e. Exporters;

f. Manufacturers; and

g. Warehouse operators.

(12) "Exportation" means the lawful process of sending medicines out of the FSM by, sea or air.

(13) "Exporter" means an individual, company or legal entity that exports pharmaceuticals.

(14) "FSM Approved Medicines List" means a list of pharmaceuticals determined by the Secretary of Health to meet the needs of the FSM population with pharmaceutical

registration approval for importation into the FSM.

(15) "Importation" means the lawful process of bringing medicines into the FSM, by sea or air.

(16) "Importer" means an individual, company or similar legal entity importing or seeking to import pharmaceuticals.

(17) "Inspect" or "Inspection" means an official examination, usually conducted on-site by the relevant authority to determine compliance to regulations, standards and practices by Establishments and/or any other entity engaged in the import of pharmaceuticals into the FSM at the ports of entry.

(18) "Manufacturer" means an individual, company or legal entity that engages in the operation of procuring supply, production, packaging, repackaging, labeling, relabeling, quality control, release, storage and distribution of active pharmaceutical ingredients and related controls.

(19) "Over-the-counter medicines (non-prescription medicines)" means medicines sold from licensed dealers without professional supervision and prescription that are suitable for self-medication for minor disease and symptoms.

(20) "Pharmaceutical" means any substance or medical product for human or veterinary use that is intended to

modify or explore physiological systems or pathological states for the benefit of the recipient. The term "pharmaceutical" includes any pharmaceutical product, drug, medicine, vaccine, biopharmaceuticals, blood and blood products, active pharmaceutical ingredients, and any other products with therapeutic effect.

(21) "Pharmaceutical Unit" means the Pharmaceutical Unit under the FSM Department of Health and Social Affairs.

(22) "Prescription" means an order mostly in written form by a licensed health care professional to a pharmacist or other therapist for a pharmaceutical or medicine to be provided to the health care professional's patient.

(23) "Procurement" means the process of acquiring pharmaceuticals, including those obtained by purchase or donation.

(24) "Secretary of Health" means the Secretary of Health and Social Affairs.

(25) "Wholesale" means all activities consisting of procuring, holding, or supplying pharmaceuticals for import or export.

(26) "Wholesaler" means an individual, company or similar legal entity engaged in the wholesale of pharmaceuticals."

Section 6. Chapter 10 of title 54 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by creating a new subchapter 2 entitled: "Scope of the Law".

Section 7. Chapter 10 of title 54 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1004 of subchapter 2 to read as follows:

"Section 1004. Scope of Law.

(1) Pharmaceutical Products.

All pharmaceuticals imported into the FSM shall be regulated under this Act. Any drug, medicine, or health supplement imported into the FSM with a therapeutic claim that is not scientifically verifiable shall be treated and regulated as a pharmaceutical under this Act.

(2) Pharmaceutical Activities.

All Establishment pharmaceutical activities related to the importation of pharmaceuticals into the FSM shall be regulated at the ports of entry under this Act.

(3) Exempt Pharmaceuticals.

The regulation of pharmaceuticals and pharmaceutical activities under this Act does not apply to natural or indigenous medicines native to the FSM and pharmaceuticals for personal use in accordance with Section 1304(3) of Title 41 of the Code of FSM.

(4) Establishment Requirements for Importation. Customs Administration shall only permit the import of pharmaceuticals into the FSM by Establishments licensed by the Pharmaceutical Unit with pharmaceutical product registration and approval from the Pharmaceutical Unit at authorized ports of entry. The Establishment shall demonstrate to the Customs Administration its compliance with Establishment licensure and all conditions on the pharmaceutical product registration implemented by the Pharmaceutical Unit pursuant to Chapter 13 of Title 41 of the Code of the FSM."

Section 8. Chapter 10 of title 54 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by creating a new subchapter 3 entitled: "Enforcement".

Section 9. Chapter 10 of title 54 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1005 of subchapter 3 to read as follows:

"Section 1005. Customs Administration Enforcement Authority.

(1) The Customs Administration shall have the authority to enforce Department of Health regulations on Establishments importing pharmaceuticals under Chapter 13 of the Title 41 of the Code of the FSM at all ports of entry.

(2) The Customs Administration shall inspect all pharmaceuticals at all ports of entry in order to implement and enforce this Act.

(3) The Assistant Secretary of Customs shall have the authority to deny entry and seize any pharmaceuticals at a port of entry:

(A) not in compliance with the import controls under Section 1006; and/or

(B) not at an authorized port of entry.

The Customs Administration shall not seize and/or deny entry of exempt pharmaceuticals under Section 1004(3)."

Section 10. Chapter 10 of title 54 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1006 of subchapter 4 to read as follows:

"Section 1006. Pharmaceutical Import Controls.

(1) The Assistant Secretary of Customs shall only permit the importation of pharmaceuticals by an Establishment with a valid license issued by the Pharmaceutical Unit under the following conditions:

(a) Pharmaceutical is on the FSM Approved Medicines List and from a competent jurisdiction as designated by the Secretary of Health; or

(b) Establishment has a valid pharmaceutical product registration approval from the Pharmaceutical

Unit for the specific pharmaceutical.

(2) The Assistant Secretary of Customs shall require all Establishments importing pharmaceuticals to present the required documentation as determined by the Secretary of Health, including but not limited to Establishment licensure and pharmaceutical registration, and certificate of pharmaceutical product ("CPP"), to the Customs Administration upon inspection at any port of entry.

(3) The Customs Administration, in coordination with the Pharmaceutical Unit, shall have the authority to deny the importation of substandard, unsafe pharmaceuticals, and/or falsified pharmaceuticals.

(4) The Customs Administration shall prohibit the import of any pharmaceutical and/or active pharmaceutical ingredients by any manufacturer."

Section 11. Chapter 10 of title 54 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1007 of subchapter 3 to read as follows:

"Section 1007. Entry of Pharmaceuticals for Public Health and Life-Saving Emergencies.

The Customs Administration shall permit the importation of a pharmaceutical not on the FSM Approved Medicines List, but from a competent jurisdiction only upon the

Secretary of Health signed certification that life-saving assistance or imminent peril to the country's public health, safety, or welfare requires the immediate entry of the pharmaceutical outside of the FSM Approved Medicines List and Pharmaceutical Unit product registration process in accordance with Section 1312 of Title 41 of the Code of the FSM."

Section 12. Chapter 10 of title 54 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by creating a new subchapter 4 entitled: "Administrative Citations".

Section 13. Chapter 10 of title 54 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1008 of subchapter 4 to read as follows:

"Section 1008. Administrative Citations.

The Secretary of Finance has the authority to issue administrative citations of $3,000 up to $15,000 upon a final finding that Establishment violated any provision of this Act in accordance with due process procedures under Chapter 1 of Title 17 of the Code of the FSM."

Section 14. This act shall become law upon approval by the President of the Federated States of Micronesia or upon its becoming law without such approval.

Date: 5/4/22 Introduced by: /s/ Ferny S. Perman
Ferny S. Perman