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, establish import controls on the importation of pharmaceuticals into the FSM, require all entities importing pharmaceuticals into the FSM to have a valid Pharmaceutical Unit license and pharmaceutical product registration approval in order to import pharmaceuticals, authorize the Secretary of Finance to fine any entity importing pharmaceuticals in violation of the Act, 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 under Section 202 of Title 18 of the Code of 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 and satisfy the pharmaceutical product registration approval criteria 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
1 similar legal entity engaged in the wholesale of
2 pharmaceuticals.”
3
4 Section 6. Chapter 10 of title 54 of the Code of the
5 Federated States of Micronesia (Annotated), as amended, is hereby
6 amended by creating a new subchapter 2 entitled: “Scope of the
7 Law”.
8
9 Section 7. Chapter 10 of title 54 of the Code of the
10 Federated States of Micronesia (Annotated), as amended, is hereby
11 amended by inserting a new section 1004 of subchapter 2 to read as
12 follows:
13
14 “Section 1004. Scope of Law.
15 (1) Pharmaceutical Products.
16 All pharmaceuticals imported into the FSM shall be
17 regulated under this Act. Any drug, medicine, or health
18 supplement imported into the FSM with a therapeutic claim
19 that is not scientifically verifiable shall be treated
20 and regulated as a pharmaceutical under this Act.
21
22 (2) Pharmaceutical Activities.
23 All Establishment pharmaceutical activities related to
24 the importation of pharmaceuticals into the FSM shall be
25 regulated at the ports of entry under this Act.
26
27 (3) Exempt Pharmaceuticals.
28 The regulation of pharmaceuticals and pharmaceutical
29 activities under this Act does not apply to natural or
30 indigenous medicines native to the FSM and
(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
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 3 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 product 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 deny the importation of expired pharmaceuticals, and/or pharmaceuticals with falsified CPP.

(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 only permit the importation of a pharmaceutical not on the FSM Approved
Medicines List or not registered as a pharmaceutical product with the Pharmaceutical Unit, if the pharmaceutical is from a competent jurisdiction and upon the Secretary of Health signed certification to Congress that life-saving assistance, or welfare requires the immediate entry of the pharmaceutical.”

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 Penalties”.

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 Penalties.
The Secretary of Finance has the authority to issue administrative penalties of $3,000 up to $15,000 upon a final finding that Establishment violated any provision of this Act. The Establishment shall have the right to request an administrative hearing 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.

June 21st, 2022

/s/ David W. Panuelo
David W. Panuelo
President
Federated States of Micronesia