TWENTY-SECOND CONGRESS OF THE FEDERATED STATES OF MICRONESIA

FOURTH REGULAR SESSION, 2022 CONGRESSIONAL BILL NO. 22-166 C.D.1

P.C. NO. 22-288 **PUBLIC LAW NO. 22-136**

AN ACT

To further amend title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, by creating a new chapter 13 to establish the FSM Safe Pharmaceutical Act of 2022, establish the Pharmaceutical Unit under the Department of Health, adopt criteria for the FSM Approved Medicines List and competent jurisdictions designation, establish the Pharmaceutical Unit licensure and pharmaceutical product registration process, and authorize the Secretary of Health to suspend or revoke any Pharmaceutical Unit license or product registration approval for cause, and for other purposes.

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

Section 1. Title 41 of the Code of the Federated States of Micronesian (Annotated), as amended, is hereby amended by creating a new chapter 13 entitled: "FSM Safe Pharmaceutical Act of 2022".

Section 2. Chapter 13 of title 41 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 13 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1301 of subchapter 1 to read as follows:

"Section 1301. Short title. This Act may be referred to as the Safe Pharmaceutical Act.".

Section 4. Chapter 13 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby

amended by inserting a new section 1302 of subchapter 1 to read as follows:

"Section 1302. Statement of Policy. It is hereby declared as a policy of the Federated States of Micronesia:

1. That all people have the right to access quality, safe and effective medicines;

2. The establishment and 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.

3. The national government and appropriate government departments shall, to the extent possible, cooperate with regulatory authorities in other countries as appropriate, to strengthen pharmaceutical import controls and align regulatory processes where needed to tackle public health emergencies, and address the proliferation of substandard, falsified and unlicensed pharmaceuticals entering the FSM."

Section 5. Chapter 13 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby

amended by inserting a new section 1303 of subchapter 1 to read as follows:

"Section 1303. 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) "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.

(3) "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.

(4) "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.

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

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

(7) "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.

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

(9) "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.

(10) "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.

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

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

(13) "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~~] and satisfy the pharmaceutical product registration approval criteria for importation into the FSM.

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

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

(16) "Inspectoral" 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.

(17) "Manufacturing" means all operations of procuring supply, production, packaging, repackaging, labeling, relabeling, quality control, release, storage and distribution of active pharmaceutical ingredients and

related controls.

(18) “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.

(19) “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 ingredient, and any other products with therapeutic effect.

(20) “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.

(21) “Procurement” means the process of acquiring pharmaceuticals, including those obtained by purchase and/or donation.

(22) “Quality assurance” means the comprehensive review of the pharmaceutical supply system and process based on scientifically accepted standards in the

industry to assess the quality of the pharmaceutical.

(23) "Sampling" means an operations designed to obtain a representative portion of a pharmaceutical product, based on an appropriate statistical procedure, for a defined purpose.

(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 13 of title 41 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 13 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1304 of subchapter 2 to read as follows:

"Section 1304. 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 under this Act. Only Establishments licensed by the Pharmaceutical Unit are eligible to import pharmaceuticals at authorized ports of entry in compliance with any Pharmaceutical Unit licensure, pharmaceutical product registration and approval process, and procurement, storage, record-keeping and disposal requirements under Section 1305.

(3) Exempt Pharmaceuticals and Activities.

(a) The regulation of pharmaceuticals and activities under this Act does not apply to [~~the importation of~~] natural or indigenous medicines native to the FSM.

(b) The regulation of pharmaceuticals and pharmaceutical activities under this Act does not apply to the importation of pharmaceuticals into the FSM for personal use subject to the following requirements:

(i) Pharmaceutical is an over-the-counter medicine that is not the treatment for a serious medical condition and there is no known significant health risk;

or

(ii) Pharmaceutical is prescribed by a licensed doctor under the following conditions:

(A) pharmaceutical is accompanied by a prescription from an FSM licensed doctor or prescription from a foreign country licensed doctor with certification that the pharmaceutical is a continuation of medical treatment performed by the foreign licensed doctor in the same foreign country where the doctor is licensed;

(B) the consumer of the prescribed pharmaceutical affirms in writing that the pharmaceutical is for personal use and will not be commercialized or distributed to other persons in the FSM; and

(C) the quantity on the pharmaceutical Prescription is not more than a three-month supply.

(4) Establishment Requirements. Establishments shall be licensed by the Pharmaceutical Unit in order to be eligible to import pharmaceuticals into the FSM. Establishments shall register any pharmaceutical it intends to import with the Pharmaceutical Unit and receive pharmaceutical product registration approval from the Pharmaceutical Unit before importing the pharmaceutical into the FSM."

Section 8. Chapter 13 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby

amended by creating a new subchapter 3 entitled: "Administration."

Section 9. Chapter 13 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1305 of subchapter 3 to read as follows:

"Section 1305. Pharmaceutical Unit.

(1) The Secretary of Health shall establish the Pharmaceutical Unit under the Department of Health to be headed by a coordinator, otherwise known as the Pharmaceutical Unit Coordinator, within 90 business days of enactment of this Act.

(2) The Pharmaceutical Unit shall have administrative, regulatory, inspectoral, and quality assurance functions.

(3) Within 90 business days of establishment of the Pharmaceutical Unit, the Pharmaceutical Unit shall adopt criteria for the FSM Approved Medicines List and standards for the competent jurisdiction designation, and submit to the Secretary of Health for approval. The Secretary of Health shall review and make a decision on the FSM Approved Medicines List criteria and competent jurisdiction designation standards proposed by the Pharmaceutical Unit within 30 business days. The Secretary of Health must approve the FSM Approved Medicines List criteria and competent jurisdiction

designation standards prior to regulation.

(4) Within 90 business days of establishment of the Pharmaceutical Unit, the Pharmaceutical Unit shall develop the Establishment licensure and pharmaceutical product registration process, and submit to the Secretary Health for approval. The Secretary of Health shall review and make a decision on the Establishment licensure and pharmaceutical product registration process proposed by the Pharmaceutical Unit within 30 business days. The Secretary of Health must approve the Establishment licensure and pharmaceutical product registration process prior to regulation.

(5) Upon compliance with subsection 4 of this Section, the Pharmaceutical Unit shall have the authority to implement the Establishment Licensure, and pharmaceutical product registration process, requirements and conditions under Section 1309 and Section 1310.

(6) The Pharmaceutical Unit Coordinator may call upon independent experts and/or technical partners to assist the Pharmaceutical Unit in development of criteria for the FSM Approved Medicines List and competent jurisdiction designations, Establishment licensure and pharmaceutical product registration process, and evaluation of pharmaceuticals for product registration purposes."

Section 10. Chapter 13 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by creating a new subchapter 4 entitled: "Regulation Authority."

Section 11. Chapter 13 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1306 of subchapter 4 to read as follows:

"Section 1306. Regulation through Rule-Making.

The Secretary of Health shall implement this Act by regulation in accordance with administrative rule-making procedures under Chapter 1 of Title 17 of the Code of the FSM."

Section 12. Chapter 13 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1307 of subchapter 4 to read as follows:

"Section 1307. Certificate of Pharmaceutical Product Requirements.

The Secretary of Health shall establish the Certificate for Pharmaceutical Product (CPP) form requirements in the World Health Organization recommended format or the equivalent and implement regulations accordingly."

Section 13. Chapter 13 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby

amended by inserting a new section 1308 of subchapter 4 to read as follows:

"Section 1308. FSM Approved Medicines List.

(1) The Secretary of Health shall establish the FSM Approved Medicines List and determine the medicines on the FSM Approved Medicines List. The Secretary of Health shall consider the Pharmaceutical Unit recommendations for pharmaceuticals to add, remove from, or modify on the FSM Approved Medicines List.

(2) The Secretary of Health shall review the FSM Approved Medicines List and the designation of competent jurisdictions every five years or upon the Secretary of Health certification to Congress that imminent peril to the public health, safety, or welfare requires immediate review and changes to the Approved Medicines List and/or competent jurisdiction designations. Upon review of the FSM Approved Medicines List and the competent jurisdiction designations, the Secretary of Health shall determine whether pharmaceuticals and jurisdictions will be added, removed, or modified, respectively.

(3) Only pharmaceuticals listed on the FSM Approved Medicines List from competent jurisdictions can be imported into the FSM by licensed Establishments without the specific pharmaceutical registration approval from the Pharmaceutical Unit.

(4) The Secretary of Health may add pharmaceuticals to the FSM Approved Medicines List upon certification of need by the States' health authorities and review of pharmaceutical."

Section 14. Chapter 13 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1309 of subchapter 4 to read as follows:

"Section 1309. Establishment licensing requirements.

(1) The Secretary of Health or his designee shall have the authority to regulate the licensure requirements for Establishments.

(2) All Establishments shall be licensed by the Pharmaceutical Unit in order to be eligible to import pharmaceuticals into the FSM [~~pharmaceuticals out of the FSM~~]. Establishments are prohibited from importing pharmaceuticals without a valid license from the Pharmaceutical Unit.

(3) All Establishments shall comply with the licensure standards and conditions set by the Secretary of Health or his designee including but not limited to unannounced random collection of a sample of the pharmaceutical at the authorized port of entry for quality assurance and testing purposes.

(4) The Secretary of Health, with input from the

Pharmaceutical Unit Coordinator, shall determine the fee and rules for Establishments to apply for licensure from the Pharmaceutical Unit."

Section 15. Chapter 13 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, as amended, is hereby amended by inserting a new section 1310 of subchapter 4 to read as follows:

"Section 1310. Pharmaceutical product registration system.

(1) The Secretary of Health or his designee shall have the authority to regulate the pharmaceutical product registration requirements. Pharmaceuticals registered in competent jurisdictions as determined by the Secretary of Health and designated on the FSM Approved Medicines List may be exempt from the pharmaceutical registration review requirements.

(2) The Secretary of Health, with input from the Pharmaceutical Unit Coordinator, shall establish the criteria and conditions for pharmaceutical product registration. The criteria and conditions for pharmaceutical product registration shall include but are not limited to:

(a) only licensed Establishments eligible to apply for pharmaceutical product registration with the Pharmaceutical Unit

(b) procurement, storage and disposal requirements for pharmaceuticals; and

(c) record-keeping requirements for pharmaceuticals.

(3) The Secretary of Health or his designee shall regulate the criteria and procedure for registration of new chemical compounds and/or variations to pharmaceuticals currently registered in the pharmaceutical product registration system.

(4) The Secretary of Health, with input from the Pharmaceutical Unit Coordinator, shall determine the fee and rules for Establishments to apply for pharmaceutical registration with the Pharmaceutical Unit."

Section 16. Chapter 13 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1311 of subchapter 4 to read as follows:

"Section 1311. Enforcement and Penalties.

(1) Suspension and Revocation of Establishment License.

The Secretary of Health shall have the authority to suspend or revoke for cause an Establishment license. The Establishment shall have the right to request review and/or administrative hearing on the license suspension or revocation in accordance with Chapter 1 of Title 17 of

the Code of the FSM.

(2) Suspension and Revocation of Approved Pharmaceutical Product Registration.

The Secretary of Health shall have the authority to suspend and/or revoke for cause any approved pharmaceutical product registration."

Section 17. Chapter 13 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1312 of subchapter 4 to read as follows:

"Section 1312. Entry of Pharmaceuticals for Public Health Emergency and Life Saving Assistance.

(1) The Secretary of Health shall establish and facilitate a streamlined process with the Assistant Secretary for Customs to permit licensed Establishments to import pharmaceuticals not on the FSM Approved Medicines List but from competent jurisdictions for public health and life-saving emergencies

(2) The Secretary of Health shall only permit licensed Establishments to import pharmaceuticals not on the FSM Approved Medicines List but from competent jurisdictions upon written certification to Congress that life-saving assistance or imminent peril to the public health, safety, or welfare requires the immediate entry of the pharmaceutical outside of the processes under Section

1307 and Section 1309 of this Act, respectively.

(3) The Pharmaceutical Unit shall conduct a review of any pharmaceutical imported under this Section in accordance with the established pharmaceutical registration criteria within 30 calendar days of the pharmaceutical importation into the FSM. If the pharmaceutical does not satisfy the pharmaceutical registration criteria, the Secretary of Health shall recall the pharmaceutical."

Section 18. Chapter 13 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1313 of subchapter 4 to read as follows:

"Section 1313: Donations.

The Secretary of Health shall only accept donations of pharmaceuticals on the FSM Approved Medicines List from competent jurisdictions and pharmaceuticals that will not expire for at least 1 year."

Section 19. Chapter 13 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by creating a new subchapter 5 entitled: "Confidentiality and Whistleblower Protections".

Section 20. Chapter 13 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1314 of subchapter 5 to read as

follows:

"Section 1314. Confidentiality of Records and Whistleblower Protections.

(1) The Department of Health shall keep confidential all information from any source on pharmaceutical activities regulated under this Act, except in response to an FSM department administrative order, FSM subpoena or court order, request from Congress pursuant to its oversight powers, or request from the information source for access to their own records in accordance with policy and procedures established by regulations and legislation.

(2) The Secretary of Health shall establish whistleblower protections under this Act by regulation, policy, and/or procedure."

Section 21. Chapter 13 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by creating a new subchapter 6 entitled: "Prohibited Pharmaceutical Activities."

Section 22. Chapter 13 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1315 of subchapter 6 to read as follows:

"Section 1315. Prohibited Pharmaceutical Activities.

(1) Establishments are prohibited from acting as an

internet pharmacy for the importation of pharmaceuticals outside the Pharmaceutical Unit product registration and review process.

(2) Establishments are prohibited from using the personal use exemption under Section 1304(3) for the importation of pharmaceuticals outside the Pharmaceutical Unit product registration process under Section 1310 of this Act, respectively.

(3) Establishments licensed by the Pharmaceutical Unit are prohibited from manufacturing pharmaceuticals in the FSM and importing pharmaceuticals and/or active pharmaceutical ingredients to manufacturer pharmaceuticals in the FSM."

Section 23. Chapter 13 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by creating a new subchapter 7 entitled: "Civil and Criminal Actions".

Section 24. Chapter 13 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1316 of subchapter 7 to read as follows:

"Section 1316. Civil and Criminal Actions.

"This Act shall not be construed to impede the FSM Department of Justice authority to enforce the nation's criminal or civil laws against any Establishment and/or

pharmaceutical activity."

Section 25. 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