STANDING COMMITTEE REPORT NO. 22-34

RE: H&SA/C.B. NO. 22-165

SUBJECT: FSM PHARMACEUTICAL IMPORT CONTROL ACT OF 2022

MAY 20, 2022

The Honorable Wesley W. Simina
Speaker, Twenty-Second Congress
Federated States of Micronesia
Fourth Regular Session, 2022

Dear Mr. Speaker:

Your Committee on Health and Social Affairs to which was referred C.B. NO. 22-165, entitled:

> "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.",

begs leave to report as follows:

The intent and purpose of this bill are expressed in its title.

The Committee on Health and Social Affairs held an hearing on C.B. NO. 22-165 and corresponding bill, C.B. NO. 22-166 on May 11, 2022. The purpose of C.B. NO. 22-165 is to establish and enforce pharmaceutical import controls at the ports of entry to help ensure the quality, safety, and efficacy of pharmaceuticals entering the country. C.B. NO. 22-165 declare this purpose as the national policy of the country.

C.B. NO. 22-165 intent is to authorize the Customs and Tax Administration with the authority to enforce the Pharmaceutical

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Unit licensure and pharmaceutical product registration requirements established by the Secretary of Health under C.B. NO. 22-166 at all ports of entry.

The Committee provides a bill summary of C.B. NO. 22-165 below:

1) C.B. NO. 22-165 authorizes the Customs and Tax Administration to regulate only the import of pharmaceuticals into the FSM. There is no regulation of natural or indigenous medicines natives to the FSM. Further, the bill provides for a personal use exemption on the condition that the person provides proof of a prescription from a licensed doctor, certifies that the pharmaceutical is for personal use, and the prescribed amount is limited to a 3-month supply. There is no prescription or certification requirements for over-the-counter pharmaceuticals.

2) C.B. NO. 22-165 directs the Customs and Tax Administration to enforce the Pharmaceutical Unit licensure and pharmaceutical product registration requirements on persons and entities importing pharmaceuticals at the ports of entry. In practice, the Customs and Tax Administration will check and verify the validity of the entities pharmaceutical unit license and require proof of pharmaceutical product registration and approval prior to allowing the pharmaceuticals to clear Customs.

3) C.B. NO. 22-165 gives the Customs and Tax Administration the authority to seize and/or deny the entry of pharmaceuticals where the importing entity does not have a valid Pharmaceutical Unit license and/or failed to obtain pharmaceutical product registration approval. Although, there is no requirement to register pharmaceutical products on the FSM Approved Medicines List from competent jurisdictions as determined by the Secretary of Health.

4) C.B. NO. 22-165 requires Customs to deny the entry of expired pharmaceuticals and/or pharmaceuticals with

falsified labeling or falsified certificate of pharmaceutical product documentation.

5) C.B. NO. 22-165 provides that pharmaceuticals for public health and life-saving emergencies can enter the FSM outside of the standard pharmaceutical product registration process even if the pharmaceutical is not on the FSM Approved Medicines List. However, the bill conditions that the pharmaceutical is only allowed to enter where the Secretary of Health signs a certification to Congress that the life-saving assistance or imminent peril to the country's public health, safety or welfare requires the immediate entry of the pharmaceutical.

6) The bill also provides the Secretary of Finance, as the Customs and Tax Administration is under the Department of Finance authority, with the power to issue fines of $3,000 up to $15,000 where an entity is found to have violated the pharmaceutical licensure and product registration requirements under the bill.

SUMMARY OF COMMITTEE ON HEALTH AND SOCIAL AFFAIRS MAY 11, 2022 HEARING:

H&SA Committee Members present at the May 11, 2022 hearing: Chairman Ferny S. Perman, Senator Florencio S. Harper, Senator Perpetua S. Konman, Senator Aren B. Palik, and Senator Joseph J. Urusemal.

Non-H&SA Committee Members present at the May 11, 2022 hearing: Speaker Wesley W. Simina.

The witnesses present at the May 11, 2022 H&SA Committee hearing were: Department of Health Secretary Marcus Samo, Department of Justice, Customs and Tax Administration, Revenue Administration Advisor with the Department of Finance and Administration, and former Department of Health Pharmacist.

Committee Chairman questioned the witnesses on the influx of substandard pharmaceuticals into the country and whether these pharmaceutical bills are necessary.

Secretary of Health testified that the pharmaceutical bills are important to strengthen the health of the country. Secretary of Health emphasized the need to regulate medicines entering the country and ensure that medicines used by the population are effective and good quality. Secretary of Health testified that the Department of Health has received anecdotal information based on complaints, comments, and observations from the population, but no actual data/statistics on substandard medicines. It is important that substandard medicines do not infiltrate the FSM because they can have a detrimental impact on our citizens.

Committee Chairman questioned the witnesses on how the Departments will implement the pharmaceutical bills and if there are regulations in place that can just be expanded. The Committee also raised the need for additional training and funding to implement the pharmaceutical bills.

The timeline for implementation was a point of contention for the Committee on C.B. NO. 22-165. The Committee highlighted the feasibility of the Customs and Tax Administration to develop and implement the necessary regulations to enforce C.B. NO. 22-165 at the ports of entry based on the Department of Health deadlines to develop the necessary regulations and procedures under C.B. NO. 22-166. C.B. NO. 22-166 requires the Secretary of Health to establish the Pharmaceutical Unit with the Pharmaceutical Unit Coordinator leading the unit within 3 months of the bill becoming law. Within 6 months after the bill is law, the Pharmaceutical Unit must have adopted the criteria for the FSM Approved Medicines List with competent jurisdiction designations (countries that meet pharmaceutical standards on safety and quality), and establish the licensure and pharmaceutical product registration process to submit to the Secretary of Health for review. The Secretary of Health has 30 business days from submission to review and make a decision on the recommended Approved Medicines List and competent

jurisdiction designation criteria, and the licensure and pharmaceutical product registration process. If the deadlines are adhered to under the bill, the Pharmaceutical Unit should be functioning in 7 to 8 months from enactment of the bill, but the requirement of Secretary of Health approval before the Pharmaceutical Unit can implement any processes' builds in some extra time if necessary for the Department of Health to establish the necessary processes.

The Committee raised personnel recruitment and skill training for Customs Officers per the increased port inspections expected under the pharmaceutical bill. The Committee also discussed the potential budgetary impact of the implementation of the pharmaceutical bill in practice based on the potential need to increase manpower at the ports of entry and hiring specialists with pharmaceutical expertise.

The Committee questioned the witnesses on the capability of the Department of Health, and Customs and Tax Administration on detection of substandard pharmaceuticals or falsity of medicine.

Secretary of Health testified that they will work with the Customs and Tax Administration current inspection system and understand that training will be necessary to handle the evaluation of pharmaceuticals entering the country. Secretary of Health testified that the Department of Health currently works with the Australian government through a partnership with the Australian Department of Health to test samples (droplets) of pharmaceuticals that enter the FSM. The FSM Department of Health collects the samples and mails the samples directly to the Australian Department of Health to conduct the testing. The Australian Department of Health reports the test results to the FSM Department of Health, who then notifies the hospital or entity where the samples collected of the test results. If the samples fails the test, the FSM Department of Health also asks the entity to no longer sell the pharmaceuticals that failed the test. According to the Department of Health, only a few sample collections have failed the sampling test. Secretary of Health also explained that the testing results can be uploaded to a database that other Pacific Island countries use to aid them in

their import controls of certain brands and quality of pharmaceuticals. Neighboring Pacific Islands also conduct random sample testing in partnership with countries that have established pharmaceutical testing regulations.

The Committee raised a question on whether C.B. NO. 22-165 will cover local medicines. C.B. NO. 22-165 explicitly states that the bill does not regulate medicines native or indigenous to the FSM. Persons in the FSM are free to make and use local medicines they have traditionally used to treat illness or ailments.

The Committee raised a question on whether the pharmaceutical bills address the rising costs of medicines and citizens ability to access affordable medicines. The Committee further expressed concern on the need to regulate the interstate sale of expired pharmaceuticals.

The Committee Chairman clarified the bill does not address affordable medicines directly but discussed the need to differentiate between generic and brand medicines as that may assist in the unreasonable prices of medicine, especially when persons may be paying more for a generic brand. Secretary of Health stated that citizens right to affordable medicines is based on the FSM National Medicines Policy.

The national government can regulate interstate commerce, the sale of goods and/or services between the states, including the sale of expired pharmaceuticals. However, the national government cannot regulate the sale of pharmaceuticals inside the states, as that is an area of state power. While the national government can regulate interstate commerce, in terms of regulating pharmaceuticals sold between states, the issue is enforcement authority and funding to support enforcement. Customs and Tax Administration only enforces regulations for the entry of goods that enter the country, not between the states. The states can enforce, but it is ultimately each state's decision if they will choose to enforce. The FSM Department of Health and appropriate national government departments should try to work with the states to encourage the adoption of state

pharmaceutical polices and regulations to ensure the safety and efficacy of medicines.

The Committee raised a question on how the Department of Health, and Customs and Tax Administration handle medicines that are donated.

Customs and Tax Administration testified that there is currently no tax on donated medicines and the donating countries or entities merely complete and provide the necessary paperwork for importation purposes. The rule is that all donated medicines cannot be expire for at least 1 year from the date of importation in order to be allowed into the country.

The Committee raised a question on whether organizations with subsection 501(c)(3) status will need to be registered with Customs and Tax Administration in order to be allowed to donate medicines. The Committee clarified that the current procedures in place that handled the import of COVID-19 vaccine donations can still apply. C.B. NO. 22-165 permits the entry of medicines in times of emergency or life-saving assistance under section 1007 outside the FSM Approved Medicines List.

The Committee also raised a question on the personal use exemption and whether personal use of prescribed medical marijuana would fall under the personal use exemption, namely for autistic children who medically benefit from medical marijuana. The Committee and Secretary of Health discussed this as a point for future discussion with the Department of Health. The Department of Health will determine whether medical marijuana meets the definition of pharmaceutical, especially since marijuana is illegal in this country. The Committee expressed the need to look into a medical marijuana distinction by law or regulation.

Customs and Tax Administration recommended the following changes to C.B. NO. 22-165:

1) Section 9, Page 9, line 1, delete “shall” and insert “may” Proposed change will read as follows:

The Customs Administration may inspect all pharmaceuticals at all ports of entry in order to implement and enforce this Act.

2) Section 13, Page 11, line 16 and line 18, delete "citations" and insert "penalties" (technical/stylistic) Proposed change will read as follows:
Administrative Penalties. The Secretary of Finance has the authority to issue administrative penalties of $3,000 to $15,000 upon a final finding that Establishment violated any provision of this Act . . .

Customs and Tax Administration explained the first recommended change is based on the fact that Customs has limited resources and manpower to inspect every container for pharmaceuticals. As a matter of practice, the Customs and Tax Administration does not inspect every container that enters the country, but rather deploys a risk management assessment to decide which containers, packages, baggage, among other items should be inspected. This allows Customs to deploy their limited resources in the most efficient way. Per the risk assessment, the Customs and Tax Administration inspects containers, packages, baggage among other items that are at high risk of bringing in illegal items, and goods that should be taxed or subject to additional regulation. The Customs and Tax Administration explained that in the case of pharmaceuticals, the Customs intelligence unit will likely evaluate the state hospital, with fairly standard pharmaceutical imports at a lower risk versus a business importer or individual seeking to bring in pharmaceuticals.

The Committee Chairman adjourned the hearing emphasizing the need to enact import controls on pharmaceuticals entering the country, and need of the World Health Organization continued support for the ongoing development and growth of pharmaceutical regulations in the country.

CONCLUSION

The Committee on Health and Social Affairs has reviewed C.B. NO. 22-165, and considered all testimony from the May 11, 2022 Public Hearing and feedback received from the Department of

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Health, Department of Justice, and the Customs and Tax Administration.

Your Committee would like to offer the following amendments to C.B. NO. 22-165 to read as follows:

1) Title, Page 1, after "2022," insert "establish import controls on the importation of pharmaceuticals into the FSM, require all persons or 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 person or entity importing pharmaceuticals in violation of the act"

2) Section 5, Page 2, lines 3-4, delete "from the ports of entry"

3) Section 5, Page 2, line 5, delete "where pharmaceuticals may be imported into the FSM."

4) Section 5, Page 4, line 25, delete "with pharmaceutical registration approval" and insert "and satisfy the pharmaceutical product registration approval criteria"

5) Section 9, Page 8, line 24, delete "the" before "Title 41"

6) Section 9, Page 9, line 10, insert "(4)" at the beginning of line

7) Section 9, Page 9, line 14, delete subchapter 4 and replace with "subchapter 3"

8) Section 10, Page 10, line 6, delete "pharmaceutical registration" and insert "pharmaceutical product registration"

9) Section 10, Page 10, line 6, between "pharmaceutical" and "registration", insert "product"

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10) Section 10, Page 10, lines 12-13, delete "substandard, unsafe pharmaceuticals, and/or falsified pharmaceuticals" and insert "expired pharmaceuticals, and/or pharmaceuticals with a falsified CPP"

11) Section 11, Pages 10, lines 21-25, delete lines 21-25

12) Section 11, Page 11, lines 1-7, delete lines 1-7 and insert "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."

13) Section 12, Page 11, line 11, delete "Citations" and insert "Penalties"

14) Section 13, Page 11, line 16, delete "Citations" and insert "Penalties"

15) Section 13, Page 11, line 18, delete "citations" and insert "penalties"

Your Committee supports C.B. NO. 22-165 as part of our national policy on supporting universal health coverage. Your Committee on Health and Social Affairs is in accord with the intent and purpose of C.B. NO. 22-165, and recommends passage on First Reading and that the bill is placed on the Calendar for Second and Final Reading in the form attached hereto, as C.B. NO. 22-165, C.D.1.

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Respectfully submitted,

/s/ Ferny S. Perman
Ferny S. Perman, chairman

/s/ Tiwiter Aritos
Tiwiter Aritos, vice chairman

/s/ Florencio S. Harper
Florencio Harper, member

Perpetua S. Konman, member

/s/ Esmond B. Moses
Esmond B. Moses, member

Aren B. Palik, member

Joseph J. Urusemal, member