STANDING COMMITTEE REPORT NO. 22-33

RE: H&SA/C.B. NO. 22-166

SUBJECT: FSM SAFE PHARMACEUTICAL ACT OF 2022

MAY 19, 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. 22-166, entitled:

> "A BILL FOR 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, 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. 22-166 and corresponding bill, C.B. NO. 22-165 on May 11, 2022. The purpose of C.B. NO. 22-166 is to establish the Pharmaceutical Unit licensure and pharmaceutical product registration requirements for the import of pharmaceuticals to help ensure the quality, safety, and efficacy of pharmaceuticals entering the country. C.B. NO. 22-166 declares this purpose as the national policy of the country.

C.B. NO. 22-166 intent is to form a Pharmaceutical Unit under the Department of Health that will establish the licensure and

pharmaceutical product registration process, and develop the criteria for the implementation of an FSM Approved Medicines List and designation of competent jurisdictions to ensure the country only imports quality, safe, and effective pharmaceuticals.

The Committee provides a bill summary of C.B. NO. 22-166 below:

1) C.B. NO. 22-166 declares that part of our nation's policy is the people's right to access quality, safe and effective medicines. Similar to C.B. NO. 22-166, the scope of the law is limited to persons or entities importing pharmaceuticals into the FSM.

   All persons or entities importing pharmaceuticals into the country must be licensed by the Pharmaceutical Unit. C.B. NO. 22-166 details that Pharmaceutical Unit licensed entities must register every pharmaceutical product they import into the country and receive approval from the Pharmaceutical Unit. Licensed persons or entities must comply with additional requirements that may be imposed as a condition of licensure by the Pharmaceutical Unit. The additional conditions may include requirements related to the procurement, storage, record-keeping and disposal of pharmaceuticals. The conditions align with the bill's intent and purpose to ensure the safety, quality and efficacy of pharmaceuticals imported into the country.

   C.B. NO. 22-166 prohibits manufacturing pharmaceuticals as a condition of Pharmaceutical Unit licensure.

2) The same exemptions to the C.B. NO. 22-165 bill apply to C.B. NO. 22-166: a) pharmaceuticals on the FSM Approved Medicines List from competent jurisdictions do not require pharmaceutical product registration approval; b) natural or indigenous medicines native to the FSM are not regulated; and c) pharmaceuticals for personal use up to 3-month supply do not require Pharmaceutical Unit license or product registration. Pharmaceuticals for personal use requires the person to show proof of their prescription from a licensed doctor and sign a certification that the

pharmaceutical is for personal use to clear Custom. There are no prescription or certification requirements for over-the-counter pharmaceuticals.

3) C.B. NO. 22-166 requires the Secretary of Health to implement the bill by regulation, including but not limited to:

   1) the department criteria for the FSM Approved Medicines List and competent jurisdictions designation; 2) the licensure and pharmaceutical product registration requirements; and 3) the Certificate for Pharmaceutical Product requirements.

   Under C.B. NO. 22-166, the Secretary of Health is required to review the FSM Approved Medicines List and competent jurisdictions designation every five years to ensure the unit systems are updated and correct. Pharmaceuticals can be added, removed, or modified with conditions on importation.

4) C.B. NO. 22-166 provides for the collection of licensure and pharmaceutical product registration fees by the Department of Health. The Secretary of Health will determine the fee amount with consideration from the Pharmaceutical Unit Coordinator.

5) C.B. NO. 22-166 gives the Secretary of Health the authority to revoke and suspend a license and/or pharmaceutical product registration approval for cause. The entity has the right to an administrative hearing and due process under Chapter 1 of Title 17 of the Code of the FSM.

6) Similar to C.B. NO. 22-165, C.B. No. 22-166 permits the entry of pharmaceuticals not on the FSM Approved Medicines List by licensed entities without pharmaceutical product registration for public health and life-saving emergencies. The Secretary must certify to Congress on the imminent peril to public health, safety, and/or welfare.

7) Donations of pharmaceuticals to the country are only accepted if it will not expire for 1 year or more, and the pharmaceuticals are on the FSM Approved Medicines List from competent jurisdictions.

8) C.B. NO. 22-166 requires the Secretary of Health to keep records confidential and establish whistleblower protections.

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. C.B. NO. 22-166 mandates at timeline for the Department of Health to complete certain procedures and regulations for the establishment and function of the Pharmaceutical Unit. The Committee also raised the need for additional training and funding to implement the pharmaceutical bills.

Secretary of Health testified that at this time additional funding is not necessary and the Department of Health can work with the current budget. However, the Department of Health may seek additional funding from Congress as the Pharmaceutical Unit develops. Secretary of Health testified that the current procedural deadlines in C.B. NO. 22-166 provide the department with the time to enact the different procedures and regulations to establish the Pharmaceutical Unit, adopt FSM Approved Medicines List and competent jurisdiction designation criteria, and the licensure and pharmaceutical product registration processes. The Secretary of Health testified that there are some operations in place that can be extended to pharmaceuticals but will still need the time to institute the regulations for pharmaceuticals.

The timeline for implementation was a point of contention for the Committee on C.B. NO. 22-166. The Committee highlighted the feasibility of the Department of Health to develop and implement the necessary regulations to enforce the bill under the current deadlines prescribed in 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 as a potential need for the proposed Pharmaceutical Unit. The Committee also discussed the potential budgetary impact of the implementation of the pharmaceutical bill in practice based on the need to hire specialists with pharmaceutical expertise for the newly formed pharmaceutical unit. Under C.B. NO. 22-166, the Pharmaceutical Unit can seek assistance from experts and technical partners on development and establishment of the Pharmaceutical Unit processes.

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 the proposed pharmaceutical bills will cover local medicines. C.B. NO. 22-166 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 especially when C.B. NO. 22-166 declares citizens have the right to affordable medicines as part of FSM National Policy. The Committee further expressed concern on access to affordable medicines and 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 point for further discussion on whether the Pharmaceutical Unit should have a coordinator position as the head of the department or an Assistant Secretary position. The Committee clarified that the coordinator position was proposed to aid in swift formation of the Pharmaceutical Unit in order to not go through the long assistant secretary position nomination, vetting, hiring, and appointment process. The coordinator position also takes into consideration the concerns on creating more bureaucracy and government expansion. The Committee clarified that this bill is just the first step as part of the formation and development of the Pharmaceutical Unit. If an assistant secretary position is necessary upon the formation and implementation of the Pharmaceutical Unit later on, the assistant secretary position can be added at that time. The priority is to have the Pharmaceutical Unit fully functioning as soon as possible.

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. 22-166 only adds that the donations must be made to the Department of Health and the Department of Health can only accept donated medicines from the FSM Approved Medicines List from competent jurisdictions under section 1313.

STANDING COMMITTEE REPORT NO. 22-33

RE: H&SA/C.B. NO. 22-166

SUBJECT: FSM SAFE PHARMACEUTICAL ACT OF 2022

MAY 19, 2022

C.B. NO. 22-166 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.

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. 22-166, and considered all testimony from the May 11, 2022 Public Hearing and feedback received from the Department of Health, Department of Justice, and the Customs and Tax Administration.

Your Committee would like to offer the following amendments to C.B. NO. 22-166 to read as follows:

1) Title, Page 1, after “2022,” insert “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 authorizes the Secretary of Health to suspend or revoke any

STANDING COMMITTEE REPORT NO. 22-33

RE: H&SA/C.B. NO. 22-166

SUBJECT: FSM SAFE PHARMACEUTICAL ACT OF 2022

MAY 19, 2022

Pharmaceutical Unit license or product registration approval for cause"

2) Section 4, Page 2, line 4, delete "," and insert "and"

3) Section 4, Page 2, line 4, delete "and affordable"

4) Section 5, Page 3, lines 9-10, delete "from the ports of entry"

5) Section 5, Page 3, lines 11-12, delete "where pharmaceuticals may be imported into the FSM."

6) Section 5, Page 5, line 7, delete "with pharmaceutical registration approval" and insert "and satisfy the pharmaceutical product registration approval criteria"

7) Section 7, Page 8, lines 13-14, delete "the importation of"

8) Section 7, Page 9, line 13, delete "(D)" and insert "(4)"

9) Section 9, Page 10, line 24, delete (1) and insert "(4)"

10) Section 9, Page 11, line 10, delete (1) and insert "(5)"

11) Section 9, Page 11, line 15, delete (1) and insert "(6)"

12) Section 14, Page 14, lines 12-13, delete "pharmaceuticals out of the FSM"

13) Section 18, Page 18, line 14, delete "." and insert "and pharmaceuticals that will not expire for at least 1 year."

Your Committee supports C.B. NO. 22-166 as part of our national policy on supporting universal health coverage. Your Committee

STANDING COMMITTEE REPORT NO. 22-33

RE: H&SA/C.B. NO. 22-166

SUBJECT: FSM SAFE PHARMACEUTICAL ACT OF 2022

MAY 19, 2022

on Health and Social Affairs is in accord with the intent and purpose of C.B. NO. 22-166, and recommends bill 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. 22-166, C.D.1.

Respectfully submitted,

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

Tiwiter Aritos, vice chairman

/s/ Florencio S. Harper
Florencio Harper, member

Perpetua S. Konman, member

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

/s/ Aren B. Palik
Aren B. Palik, member

Joseph J. Urusemal, member