

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

EIGHTEENTH CONGRESS
Third Regular Session



COMMITTEE REPORT No. 1304

Submitted by the **COMMITTEE ON GOOD GOVERNMENT AND PUBLIC ACCOUNTABILITY**
on **November 4, 2021**.

Re: **House Resolution No. 1396**

Informing the House of its Findings and Recommendations.

Sponsors: Representatives Michael Edgar Y. Aglipay, Deogracias Victor "DV" B. Savellano and Estrellita B. Suansing

Mr. Speaker:

The **Committee on Good Government and Public Accountability** to which was referred **House Resolution No. 1396**, entitled:

"A RESOLUTION DIRECTING THE HOUSE COMMITTEE ON GOOD GOVERNMENT AND PUBLIC ACCOUNTABILITY TO CONDUCT AN INQUIRY, IN AID OF LEGISLATION, ON THE QUESTIONABLE RECEIPT OF PRIVATE FUNDING BY THE FOOD AND DRUG ADMINISTRATION (FDA) AND OTHER GOVERNMENT AGENCIES AND INSTITUTIONS IN EXCHANGE FOR THE ISSUANCE OF SPECIFIC AND PRE-DEFINED POLICIES DIRECTED AGAINST A LEGITIMATE INDUSTRY UNDER PHILIPPINE LAWS AND IN COMPLETE DISREGARD OF THE RIGHTS AND WELFARE OF CONSUMERS,"

has considered the same and has the honor to submit to the House this attached report on its findings and recommendations.

Respectfully submitted:

A handwritten signature in black ink, appearing to be "M. Aglipay".

MICHAEL EDGAR Y. AGLIPAY

Chairperson, Committee on Good Government and Public Accountability

THE HONORABLE SPEAKER

House of Representatives

PREFATORY STATEMENT

House Resolution No. 1396, introduced by Representatives Deogracias Victor “DV” B. Savellano and Estrellita B. Suansing, entitled:

“A Resolution Directing the House Committee on Good Government and Public Accountability to Conduct an Inquiry, in Aid of Legislation, on the Questionable Receipt of Private Funding by the Food and Drug Administration (FDA) and Other Government Agencies and Institutions in Exchange for the Issuance of Specific and Pre-defined Policies Directed Against a Legitimate Industry under Philippine Laws and in Complete Disregard of the Rights and Welfare of Consumers,”

was referred to the Committee on Good Government and Public Accountability on 20 January 2021. Pursuant to Section 4, paragraph (2), Rule II of the Committee Rules, the Committee Members voted to take jurisdiction of the said Resolution on 16 March 2021 and undertook its initial meeting. On 09 June 2021, the second deliberation was held. After thorough discussion of all the relevant information and issues involved, the deliberation on House Resolution No. 1396 was terminated.

The Committee invited resource persons and officials from the concerned agencies and requested the submission of their respective position papers and pertinent supporting documents. The following resource persons were invited to participate in the public hearings:

From the Food and Drug Administration (**FDA**):

- Director General and Department of Health (**DOH**) Undersecretary Rolando Enrique Domingo; and
- Engr. Ana Rivera, Director for the Center for Cosmetics and Household;

From the Bureau of International Health Cooperation (**BIHC**), DOH:

- Dr. Maria Soledad Q. Antonio, Director IV; and
- Mr. Rodney Desmond Daniel M. Carza, Head, Policy and Technology, Health Promotion and Communication Service;

From the Civil Service Commission (**CSC**):

- Commissioner Aileen Lizada; and
- Assistant Commissioner Ariel Ronquillo;

From the Coalition of Asia Pacific Tobacco Harm Reduction Advocates:

- Ms. Janelle Fetalino.

STATEMENT OF FACTS

A. Background

The FDA is an agency under the DOH mandated to ensure the safety, efficacy and quality of health products, including food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro

diagnostic reagents, radiation-emitting devices or equipment, and household or urban hazardous substances, including pesticides and toys, or consumer products that affect health.¹

On 23 September 2003, the Republic of the Philippines, being a Member of the United Nations, was a signatory to the World Health Organization Framework Convention on Tobacco Control (**WHO-FCTC**). The Philippine Senate ratified the treaty on 06 June 2005.² The Philippines is one among 168 Signatories to the Convention. Currently, there are 182 Parties to the Convention whose citizens comprise more than 90% of the human population.³

A response to the increasing global concern for the ill effects of smoking, the WHO-FCTC is the first public health treaty negotiated under the guidance of the World Health Organization (**WHO**). It reaffirms that “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being xxx”.⁴ The WHO-FCTC expresses the concern of member-countries on various issues linked to tobacco use such as trade liberalization, global marketing, tobacco advertising, promotion and sponsorship, and the international movement of contraband and counterfeit cigarettes, among others.⁵ Utilizing this overall objective, the WHO-FCTC laid out a blueprint for tobacco control policies such as legislative, executive, administrative and other measures to be implemented by the Parties in their respective jurisdictions. Thus, the Parties to the international treaty are committed to enact new laws or amend existing ones in order to align with the WHO-FCTC.⁶

Since 2007, Bloomberg Philanthropies has supported the accelerated reduction of tobacco use in many countries, including the Philippines. Progress of this effort in the Philippines is thought to have begun soon after the ratification of the WHO-FCTC, and the grants program funded by the Bloomberg Initiative for the campaign is frequently mentioned. Despite considerable progress, there are significant challenges that must be addressed if the social, health and economic burden caused by the global tobacco epidemic is to be alleviated.

To implement the WHO-FCTC, the DOH developed the National Tobacco Control Strategy (**NTCS**) 2011-2016 which engages all relevant sectors of government, civil society, and non-governmental organizations to act within their social, cultural, occupational, and political networks and spheres of influence to control the use of tobacco.

In 2016, the FDA, through the DOH, submitted Terms of Reference to its developmental partners such as the WHO, the Asian Development Bank (**ADB**), and The International Union Against Tuberculosis and Lung Diseases (“The **Union**”), an international non-profit, non-government organization, to seek assistance and funding for capacity building of the agency.⁷

¹ The FDA website (<https://www.fda.gov.ph/about-fda/>).

² Pursuant to Senate Committee Report No. 12, submitted by the Committee on Foreign Relations on 22 February 2005, Senate, Republic of the Philippines.

³ The WHO-FCTC website (<https://fctc.who.int/who-fctc/overview/parties>).

⁴ Preamble, 1948 WHO Constitution

⁵ *Ibid.*

⁶ Addressing the tobacco epidemic in the Philippines: progress since ratification of the WHO FCTC, B. Bellew, M. Antonio, M. Limpin, L. Alzona, F. Trinidad, U. Dorotheo, R. Yapchiongco, R. Garcia, A. Anden, J. Alday, Public Health Action. 2013 Jun 21 (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4463107/>)

⁷ Presentation of FDA DG Domingo during the Committee meeting on March 16, 2021

On 13 December 2016, a grant agreement (the “**Agreement**”) was signed between Vital Strategies⁸ and the FDA. Under the said Agreement, Vital Strategies shall deliver a grants program for tobacco control with financial assistance from the Bloomberg Philanthropies⁹, and grant management from its agents.¹⁰

On February 2017, The Union supported a project of FDA entitled, “*Strengthening of the Regulatory Systems on Tobacco Control under the Food and Drug Administration*” (the “**Project**”). The overall objective of the Project was to enhance the regulatory capacity of the FDA. Under the project, The Union granted FDA US\$150,430 while the Philippine government’s estimated co-funding was US\$335,864. The project duration was from February 2017 to June 2020 with the following objectives: 1) To enable the FDA to hire manpower support in the implementation of the National Tobacco Control Program; 2) To enable the FDA to develop regulatory guidelines; 3) To enable the FDA to develop and implement an effective regulatory system for the implementation of existing laws and regulations; and 4) To capacitate the FDA-Field Regulatory Operations Office.¹¹

On 17 November 2017, Vital Strategies ceded its obligations to the FDA to The Union and assigned the latter as its agent in the administration, management, monitoring and evaluation of the grant.

On 30 June 2020, after two (2) requests for no-cost extension - January 2019 (12 months) and January 2020 (5 months) - the Project under the grant agreement was concluded.¹²

Meanwhile, the DOH mapped the NTCS 2017-2022, currently the country’s framework on tobacco control, in collaboration with other partner government agencies and civil society organizations. The NTCS 2017-2022 has the goal of improving the health of all Filipinos by reducing the prevalence of smoking and its associated health, social and economic costs, and the resulting inequalities. The Committee notes that the DOH likewise envisions a country with reduced morbidity and premature mortality rates caused by major non-communicable diseases by year 2030.

Towards this goal, several measures have been enacted, to wit: 1) Republic Act No. 9211, or the Tobacco Regulation Act of 2003; 2) Republic Act No. 9711, otherwise known as the “Food and Drug Administration Act of 2009” (or the “**FDA Act**”); 3) Republic Act No. 10351, or the Sin Tax Reform Law of 2012; 4) Republic Act No. 11346, increasing the excise tax on tobacco and imposing excise tax on Heated Tobacco Products (**HTPs**), among others, amending for the purpose National Internal Revenue Code of 1997 (the “**NIRC**”), as amended; and 5) Republic Act No. 11467, amending the provisions of the NIRC on tobacco, heated tobacco products (HTP) and vapor products. Further, Executive Order No. 26 (Series of 2017),¹³ as amended by Executive Order No. 106 (Series of 2020) were issued to address the serious and irreversible threat to public

⁸ Vital Strategies is an affiliate of The International Union Against Tuberculosis and Lung Disease (The Union) and continues to partner with The Union on many of its programs, including the Bloomberg Initiative to Reduce Tobacco Use. Vital Strategies is headquartered in New York, New York (See Annex 8, FDA-The Union Agreement).

⁹ *Ibid.*

¹⁰ Vital Strategies shall undertake to administer the funds awarded to the grantee and may engage one or more agents to assist in the administration and management of the grant award

¹¹ Presentation of DG Domingo during the Committee meeting on March 16, 2021

¹² FDA Submission: Chronology of Events

¹³ E.O. No. 26: “Providing for the Establishment of Smoke-Free Environments in Public and Enclosed Places”, signed on 16 May 2017.

health, prevent the initiation of non-smokers and the youth, and minimize health risks to both users and other parties exposed to emissions.¹⁴

On October 8, 2020, a public consultation via Zoom videoconferencing was held by the FDA on the crafting of regulations for HTPs, attended by stakeholders of the tobacco industry and Members of the House of Representatives namely Representatives Savellano, Suansing and Wes Gatchalian.

During the online hearing, various questions on matters not adequately explained by the FDA officials were raised. In particular, the matter on the FDA being a recipient of grants from foreign entities known for their stance against tobacco, such as The Union and the Bloomberg Philanthropies/Bloomberg Initiative (**Bloomberg**). Representatives Savellano and Suansing, authors of the subject Resolution, contended that said foreign entities may have exerted undue influence on the FDA when the latter designed and crafted the guidelines for the use of Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (**ENDS/ENNDS**) and HTPs, which in effect, undermined the country's sovereign power. The authors urged the body to review whether the actions of the FDA will make them liable for malfeasance, misfeasance and nonfeasance in office which are offenses punishable under existing laws. In addition, a query was raised on whether legislation is necessary to prevent a similar situation in the future. Hence, the filing of the instant House Resolution No. 1396.

The Committee took cognizance of House Resolution No. 1396, an in relation thereto, inquired into the acts of the FDA officials and circumstances attendant to the creation of the policies concerning the use of ENDS/ENNDS and HTPs to determine whether the grants coming from The Union and Bloomberg marred their capacity to craft fair, reasonable, and equitable rules and regulations for the benefit of the consumers, the tobacco industry, and the general public; and to determine whether or not there is a need to amend, alter, modify, repeal existing laws, or create new legislation.

B. Deliberation Proper

During the initial Committee hearing on 16 March 2021, Representative Savellano narrated that on 08 October 2020, Representative Suansing, Representative Gatchalian and himself participated in the public consultation conducted through virtual or online platform regarding the FDA's proposed guidelines to regulate ENDS/ENNDS and HTPs.

In said public hearing, Representative Savellano lamented that the FDA did not provide them an opportunity to raise their concerns, and that there was a clear lack of transparency, openness and effort to have a meaningful discussion. Representative Savellano also alleged that the FDA had been in receipt of funds from foreign private organizations, which had recommended to ban electronic cigarettes and HTPs in low and middle-income countries, like the Philippines. Further, he said that the DOH also received grants from Bloomberg from 2010 to 2012 for projects such as "*Moving to the next level in the Philippines - Complete implementation of the WHO Framework Convention on Tobacco Control*". He pointed out that while the project is laudable it, however, encourages the Local Government Units (**LGUs**) to actually pass local ordinances that mandates beyond what the current law provides. He then called on the Members to take a look at the FDA's predefined policies on e-cigarettes and HTPs, to ensure good governance.

¹⁴ E.O. No. 106: "Prohibiting the Manufacture, Distribution, Marketing and Sale of Unregistered and/or Adulterated Electronic Nicotine/Non-Nicotine Delivery Systems, Heated Tobacco Products and other Novel Tobacco Products, amending Executive Order No. 26 (s. 2017), signed on 26 February 2020.

In answer thereto, FDA Director General Domingo discussed the mandate of the agency. He asserted that President Rodrigo Roa Duterte instructed the FDA to regulate the ENDS, HTPs, and vapor products, and to formulate the regulatory framework to immediately put in operation R.A. No. 11467,¹⁵ amending and adding a new section to the NIRC.

The key points elucidated by Director General Domingo are as follows:

- In 2014, Administrative Order No. 2014-0008¹⁶ was issued by the DOH covering ENDS/ENNDS, classifying it as a pharmaceutical product to be regulated by the FDA.
- In 2016, the FDA and the DOH initiated extensive reviews on the existing regulatory framework. To accomplish their mandate, the FDA had to do major research programs on a daily basis on ENDS, ENNDs, HTPs and other vapor products. There was a need to hire additional staff to accomplish these objectives, however, they have a limited budget.
- Further, a proposal for funding from DOH was forwarded to its development partners such as the WHO, ADB, and non-government organization (**NGOs**), such as The Union.
- The Union is part of the Bloomberg Initiative, a program that gives grants to various governments to help their programs to reduce tobacco use. It co-manages the Bloomberg Initiative and its major objectives are to refine and optimize tobacco control programs to help smokers stop using tobacco and prevent children from smoking; support public sector efforts to implement effective policies; support efforts to educate communities about the harm of tobacco use; and develop a rigorous system to monitor the status of global tobacco use. The Union and Bloomberg are natural partners of the DOH and the FDA because they have the same goals insofar as tobacco use is concerned.
- The FDA has outlined the workplan for the development of the regulatory system in the Terms of Reference on its proposal to source funding for capacity building programs.
- In February 2017, The Union gave a grant to the FDA for its project entitled: *“Strengthening the Regulatory Systems of Tobacco Control under the Food and Drug Administration”* in the amount of US \$ 150,430, and co-funded by the Philippine government in the amount of \$ 335,864. The objectives of the project are to create the regulatory guidelines on HTPs and other vapor products, and to implement the same in consonance with Administrative Order No. 2014-0008.
- Majority of the fund, around PhP 3.5 Billion, was used for staffing or the hiring of Job Order personnel. The operation cost was spent to buy reagents and set up the Information Technology (IT) system. The unutilized amount of PhP 1.6 Million was already returned to The Union.
- The DOH works with its counterparts in other countries composed of private and public government institutions such as the WHO-FCTC, the United States Food and Drug Administration (**US FDA**), Medicines and Healthcare Products Regulatory Agency (**MHRA**) in Canada, The Union, Health Sciences Authority of Singapore, and other counterparts in Japan and Hongkong.
- Under Section 18 of the FDA Act and its Implementing Rules and Regulations, the FDA is allowed to accept grants, donations and all other endowments as long as

¹⁵ R.A. 11467: “An Act Amending Sections 109, 141, 142, 143, 144, 147, 152, 263, 263-A, 265, and 288-A, and Adding a New Section 290-A to R.A. No. 8424, as amended, otherwise known as the National Internal Revenue Code of 1997, and for other purposes”, also called the Sin Tax Law of 2020.

¹⁶ Administrative Order No. 2014-0008: Rules and Regulations on Electronic Nicotine Delivery System (ENDS) or Electronic Cigarettes, signed on 12 March 2014.

pertinent rules and regulations are followed. The fund is completely audited and that unutilized amount was returned to the grantor.

- The grant from The Union was not personally given nor used by any FDA official, rather it was directly issued to the Special Regulatory Fund (SRF)¹⁷ of the FDA, which manages the agency's income derived from the exercise of its regulatory functions and funds from grants and donations.
- As provided under the FDA Act, the FDA operated and managed the grant using the generally accepted accounting principles. To date, there have been no adverse findings from the Commission on Audit (**COA**) on any of disbursements and financial activities relative to the project.
- R.A. No. 11467, otherwise known as the Sin Tax Law of 2020, mandates the FDA to regulate the manufacture and sale of HTPs, including banning the sale to non-smokers or persons below twenty-one (21) years old. The Joint Memorandum Circular (JMC) No. 003-2020¹⁸, signed on 16 May 2017, was then issued as the rules and regulations implementing the provisions of R.A. Nos. 8424, 11346 and 11467 relating to HTPs and vapor products.
- On the creation and drafting of the administrative order on the regulations of vapor products and HTPs, the FDA followed the guidelines established by the DOH. The draft administrative order underwent review and clearance from the FDA Legal Services Support Center (LSSC). The public consultations held on April 8, 2020 and July 16, 2020 allowed stakeholders to submit comments and position papers through online posting. Due to operational constraints imposed by the Enhanced Community Quarantine (ECQ), in-person public consultation was precluded. Succeeding consultations were later done virtually. Announcements for the meetings were posted in the FDA website, and during these consultations, the FDA took time to clarify the issues and the major concerns of the stakeholders.
- The recent public hearing and consultations by FDA on the crafting of regulations for HTPs suffered technical problems relating connectivity.
- The online public consultations were done on 06 and 08 October 2020, but the FDA still accepted the inputs of stakeholders even up to the finalization of the administrative order. Finally, Administrative Order No. 2020-0055¹⁹ was signed on 01 December 2020.

As to the regulatory system, Director General Domingo assured the body that the FDA continuously monitors the results of scientific studies by international research groups and undertakes its own scientific evaluation of research findings. He assured the Committee that the regulations for the ENDS/ENNDS products are regularly updated based on the latest data.

In addition, upon query by Representative Savellano on the terms and conditions of the subject grant from The Union, Engr. Ana Trinidad Rivera, Director for Cosmetics Regulation and Research of the FDA stated that the release of funds is based on the terms of reference, work plan, regulations, and output that the FDA has developed. She also explained that during the hearing, there was a scheduled performance review of all regional offices of the FDA. She said that the FDA entertained all the recommendations it received from stakeholders and included them in the Regulatory Impact Analysis (**RIA**). Hence, all the concerns raised were included in the RIA submitted by the FDA.

¹⁷ Special Regulatory Fund (SRF) means the retained income, including grants, donations and all other endowments from local and external sources, accepted by the FDA in accordance with pertinent laws, rules and regulations deposited in an authorized government depository bank. (Section 5, (mm) Definition of Terms, IRR)

¹⁸ Implementing Rules and Regulations of the HTPs and Vapor Products as prescribed by RA Nos. 11346 and 11467.

¹⁹ Administrative Order No. 2020-0055: Regulation on Vapor Products and HTPs under the FDA.

Representative Savellano expressed concern that should a ban be implemented as a result of the FDA regulations; tobacco farmers would lose their livelihood. Director General Domingo said that the government is considering other sources of financial support for those affected by the country's development policy on tobacco control. He lamented that the government stands to lose because whatever benefit is gained from the tobacco industry in terms of livelihood and taxes, the same is used to finance the health needs of those who fall ill as a result of smoking. In addition, Director General Domingo stated that there is currently no policy to ban the use of tobacco products, rather the government's policy is regulation on the sale of tobacco products. He assured that the FDA takes into consideration the submissions of the stakeholders and health advocates, as well as the recommendations of the WHO, in order to obtain all the information necessary for the formulation of policies. He assured the Committee that the FDA tries to balance the interests of all concerned.²⁰

Upon query by Representative Suansing on the FDA's budgetary allocation, Director General Domingo said the FDA receives less than PhP 200 Million per year. In addition, the FDA is allowed to collect fees from its regulatory activities, such as licensing, marketing authorizations, product registration, inspection, and fines, and from these activities, the agency is able to collect approximately PhP 500 Million to PhP 600 Million a year. All of the agency's income becomes part of the SRF, which is used for the FDA's Maintenance and Other Operating Expenses (**MOOE**). He however clarified that FDA does not have a share in the income derived from the implementation of Republic Act No. 9502, otherwise known as the Universally-Accessible, Cheaper and Quality Medicines Act of 2008, citing that the FDA's SRF only consists of the income from its regulatory activities and grants. He explained that the amount the agency receives from the government only covers the expenditures for "Personnel Services".

Further, Director General Domingo stated that if there is a need for additional funds, the FDA requests the Department of Budget and Management (**DBM**) to allow it to use part of its income for MOOE expenditures, provided that these items are provided for in the National Expenditure Program (**NEP**).²¹

In reply to the query of Rep. Suansing, Director General Domingo stated that under Section 18, R.A. No. 9711, the agency is allowed to accept grants, donations, and all other endowments from local and external sources, in accordance with pertinent laws, rules and regulations. He elaborated that the agency has received grants from international organizations but none from local sources. He underscored that the only grants the FDA received during his incumbency came from the Japan International Cooperation Agency (JICA), which was used for the development of the agency's pharmacopoeia, and recently, from The Union.

Upon further query of Representative Suansing, Director General Domingo stated that he is not aware of any grant received from companies that apply for registration from the FDA. Representative Suansing asserted documents in her possession show that FDA received grants from Coca-Cola and Nestle companies at the time when the proposed bill on excise tax on sugar-sweetened beverages was being deliberated on by the Sixteenth Congress.²²

Asked how the FDA was able to request for donations from international sources, Director Rivera responded that in 2016, the FDA submitted applications for funding support to various international agencies, including the ADB, the WHO- Philippines Country Office; and that in 2019,

²⁰ See TSN: 16 March 2021/NGO/III-3.

²¹ See TSN: 16 March 2021/NGO/III-4-7.

²² See TSN: 16 March 2021/NGO/III-8-9.

the FDA also submitted a proposal to the Department of Science and Technology (**DOST**) for funding support for the establishment of laboratory facility where toxicology studies can be conducted on e-cigarette products. At the time, the FDA needed to undertake research programs on a daily basis, hence the need to hire additional staff. The FDA then submitted a proposal to the WHO, and then later, to other development partners of the DOH.²³

Representative Suansing asked if there was any commitment on the part of the FDA in exchange for receiving the grant from The Union and Bloomberg. Director General Domingo stated that the situation in 2016 was different, and that since then, the FDA has been able to generate more income. He discussed that because the DOH and the Department of Foreign Affairs (**DFA**) are partners of FDA in health advocacy, the agency can request foreign grants with the assistance of these departments. He added that there was no commitment on the part of the FDA other than the development of a regulatory system as provided in the Terms of Reference of the grant.²⁴

Noting the possible deleterious effect of the subject grant on the independence of government policy-making and regulation, Representative Suansing manifested the intent to file a bill prohibiting FDA from accepting grants from external sources.

Director General Domingo said that The Union and Bloomberg share the objective of optimizing tobacco control programs, help smokers stop using tobacco, and prevent children from starting to smoke. Both companies advocate the implementation of effective policies such as taxing the manufacturing and sale of cigarettes, preventing smuggling, altering the image of tobacco, protecting workers from exposure to secondhand smoke, and the education of the public about the harm of tobacco use. Director General Domingo also stated that his knowledge about Michael Bloomberg comes mostly from the news stories and during the time when Mr. Bloomberg was the Mayor of New York City. He also cited that the Bloomberg Philanthropies is a partner of the WHO and the DOH on health-related activities. The Union is one of the umbrella organizations of Bloomberg Foundation (Philanthropies).²⁵

On the query of Representative Rodante Marcoleta if there exists a mechanism in the FDA to determine the qualification of an entity before it accepts any grant or donation therefrom, the Committee notes the assertion of Director General Domingo that the BIHC of the DOH and the DFA undertake the vetting process of the grant submissions and recipients on the local grants and international grants, respectively. He discussed that the BIHC is the agency that reviews and checks all the qualifications of the possible partners before their offers are approved.²⁶

On this concern, Representative Marcoleta expressed the need for the Committee to ensure that Mr. Bloomberg has no connection with other industries that can compete with the electronic cigarettes, given the vast business network and influence that he can exert on the government. Pointing out however, determining whether these high-level organizations are not in competition or in competitive companies with the electronic cigarettes may be difficult.

Representative Marcoleta likewise raised equity considerations related to the ban on essential ingredients of electronic cigarettes and HTPs, citing that the promotion of tobacco products is not prohibited. He lamented the fact that the tobacco companies are registered with the National Tobacco Administration (**NTA**), the Bureau of Internal Revenue (**BIR**), and the

²³ See TSN: 16 March 2021/NGO/III-10.

²⁴ See TSN:16 March 2021/NGO/III-11.

²⁵ See TSN:16 March 2021/RDR/IV-2.

²⁶ See TSN: 16 March 2021/RDR/IV-1.

Bureau of Customs (**BOC**), but the electronic cigarettes sector is mandated to register with the FDA with an additional requirement of independent study, which costs millions of pesos. He then cautioned that the same may be a case of regulatory capture. He also underscored that while the FDA as a regulatory agency may be capable to undertake its mandated tasks, the motive behind the grant from The Union should be looked into.²⁷

Representative Marcoleta posited that even if the FDA can show that no conditions are attached to a grant from a foreign organization that may influence the policymaking function of the agency, there will always be doubt on the intention of the grant. Government agencies with regulatory authority should be totally impartial.

Meanwhile, Representative Rozzano Rufino Biazon asked about the possible effect on the mandate of the FDA to protect and promote the health of Filipinos should a law be passed prohibiting it from receiving grants. Director General Domingo replied that if a law shall prohibit the acceptance of grant, then the agency will undertake all its activities within the budget allowed on these activities and on its income. FDA may not be able to undertake other research activities like those relating to vaccines and other diseases such as cancer, citing that research activities are derived from the grants given to them. Director General Domingo also said that the primary goal of the FDA is to ensure the safety and quality of health products that are available in the market, particularly the new ones.

Representative Biazon asked whether the FDA indicated in its application for the grant that it was taking a policy direction towards banning or regulating the use of electronic cigarettes. Director of either to ban or to regulate electronic cigarettes in its application for the grant. Director General Domingo replied in the negative. Accordingly, the FDA in its application indicated that the agency intended to develop a regulatory framework for the new product. What was required of them was the submission of the agency's accomplishments and milestones to the FDA project: *Strengthening of the Regulatory Systems on Tobacco Control under the Food and Drug Administration*.

In addition, Rep. Biazon inquired if any FDA official has received personal benefit from the award of the grant, to which Director General Domingo replied in the negative, asserting that the fund was requested and received by the FDA as an institution. The utilization of the grant was also reviewed by the COA.²⁸

On whether the grant given by Bloomberg falls under the provision of Section 7 of R.A. No. 6713, otherwise known as the "*Code of Conduct and Ethical Standards for Public Officials and Employees*" pertaining to any "gift, gratuity, favor, entertainment, loan or anything of monetary value," Director General Domingo explained that the grant is not a gift, gratuity, favor, entertainment, or loan. He also stated that Bloomberg is not a client that needs to apply for registration with the FDA. He cited that the subject provision pertains to the individual public officer or employee who receives money for those purposes, and that the grant accrued to the funds of the FDA, not to any individual.²⁹

The Committee also noted the interpellation made by Rep. Biazon on the definition of political activity or propaganda as provided under *Batas Pambansa Bilang (BP) 39* or the Foreign Agents Registration Act. He pointed out that Bloomberg is not a foreign political party nor officially

²⁷ See TSN: 16 March 2021/RDR/IV-4.

²⁸ See TSN: 16 March 2021/RDR/IV-7.

²⁹ See TSN: 16 March 2021/RDR/IV-8.

representing foreign government, cases when registration is required. He asked if the agenda of The Union and Bloomberg is political in nature, to which Director General Domingo replied that he did not perceive any political motive behind the grant.³⁰

As to who shall ultimately benefit if the FDA shall be able to successfully regulate the use of products known medically and scientifically to cause disease, Director General Domingo said that both the tobacco product users and non-users, who are exposed to secondhand smoke shall benefit if the subject products are regulated.³¹

In contrast, if the said products are not regulated, Director General Domingo explained that the vendors can sell substandard and prohibited items that can be harmful to children and the public in general, while the manufacturers of the said substandard products stand to gain.

Representative Biazon then asked if the FDA's mandate is susceptible to the influence of the tobacco industry. Director General Domingo replied in the affirmative as he cited that it is a big industry in the country, hence the FDA strictly follows the prohibition of the CSC on the receipt of grants from the tobacco industry. Representative Biazon then manifested that the laws that have been cited in the subject resolution are not applicable to the issue raised against the FDA's receipt of the subject grants, citing that the jurisdiction of the Committee concerns acts of malfeasance, misfeasance and nonfeasance of public officials and employees. He urged the Committee to look into the laws that are alleged to have been violated by the FDA.³²

Representative Alfredo Garbin Jr. asserted that receiving a grant from international organization to finance the research and study on the formulation of national policy violated the Constitutional precept on the right to self-determination which is manifested in the independence of a government's acts and decisions from foreign interference.

Representative Jericho Jonas Nograles sought comment from Assistant Commissioner Ariel Ronquillo of the CSC on whether the act of the FDA in receiving the grant falls under the prohibition of R.A. No. 6713. Asst. Commissioner Ronquillo stated that no law was violated because the receipt of the grant was made pursuant to a law. Moreover, Asst. Commissioner Ronquillo noted that RA No. 6713 provides for exceptions such as the grant from international bodies for altruistic and humanitarian purposes. He stated that the Bloomberg/The Union grant falls under that exception because it concerns public health, hence, a valid receipt of a grant from a foreign grantor.³³

Further, Asst. Commissioner Ronquillo stated that there will be a violation of law if a donor shall directly interfere with the formulation of the government's regulatory policies, which was not the case in this instance.

Representative Nograles emphasized the need for the Committee to consider the FDA, as a regulatory body, should be allowed to receive grants from NGOs that are advocates against tobacco use. He further noted that in the instant case, The Union and Bloomberg are anti-tobacco.³⁴

³⁰ See TSN: 16 March 2021/RDR/IV-9.

³¹ See TSN: 16 March 2021/RDR/IV-10.

³² See TSN: 16 March 2021/RDR/IV-11.

³³ See TSN: 16 March 2021/RDR/IV-12.

³⁴ See TSN: 16 March 2021/RDR/IV-13.

Moreover, Representative Nograles noted that the FDA hired multiple Job Order personnel using the funds from the grant, which should be under the mandate of the CSC. He raised the concern that the FDA received money from a private organization that is anti-tobacco, where the said amount of money was utilized to hire job order personnel to conduct projects for tobacco control. He cautioned that this could cast doubt on the independence of the government from private interference. He also noted that the FDA has conducted consultations with other groups that are funded by The Union and Bloomberg. He observed that FDA/DOH did receive more than one grant from Bloomberg and that anti-tobacco regulation was issued after the receipt of grant on at least two (2) instances. At the first instance, the DOH received a grant of US\$ 192,000 from Bloomberg that coincided with the issuance of Administrative Order No. 2014-008 in 2014. The second instance is the grant received by the FDA in 2017.³⁵

It bears emphasis that Representative Nograles argued for the Committee to look into the provisions of the Constitution on the tenets of independence and freedom from foreign control, as well as the FDA Act, which allows the acceptance of grants from foreign entities, albeit subject to existing laws. He remarked that while The Union is not an applicant seeking a preferential right to conduct a regulated activity such as those who seek a license or registration from the FDA, it still must not exert influence against the registration of a particular product. He posed a concern whether Congress should allow the receipt of grants, not only for the FDA, but for all other government agencies.³⁶

Representative Jose Enrique Garcia asked about the objective of RA No. 9211, to which Director General Domingo stated that the law aims to decrease the burden of diseases caused by tobacco, thereby ensuring optimal health for all Filipinos. He added that smoking is the number one cause of preventable death and the government hopes that the use of tobacco and other harmful substances is lessened. Representative Garcia then asked on the country's yearly target for smoking prevalence, to which Director General Domingo said that by year 2020, the plan was to decrease the prevalence at less than 15%. He noted that the smoking prevalence was lessened at the time when the tax for the said products was increased. He underscored, however, that by the years 2018 to 2019, the prevalence rate again increased because cigarettes were sold at a cheaper price. He also stated that the government expects a decrease in smoking prevalence, which at this time is at 23%, way above the health targets of the country.

Representative Garcia queried on the acceptable rate of smoking prevalence, since he opined that even at the 10% prevalence rate, many can still fall ill or even die from the effects of smoking. Director General Domingo stated that the government intends that the rate to be as low as possible, and not want that the 10% to just succumb to death. What the FDA focuses on, is to prevent the next generation to get into the habit of smoking. He said that even in countries where smoking is prohibited, they still find it impossible to lower prevalence at 0%.

Inquiring into the objectives of the WHO-FCTC, which is to lower the prevalence and use of tobacco and smoking worldwide, Representative Garcia noted that these are similar with the objectives of R.A. No. 9211, which is to protect the health of the Filipino people. He then manifested that the country needs programs, campaigns, taxation policy, and effective monitoring, among others in order to achieve the objectives of the WHO-FCTC and RA No. 9211. Further, he asked if the grant given by The Union is in consonance with the goals of the WHO-FCTC and RA No. 9211, to which Director General Domingo replied in the affirmative, citing that

³⁵ *Ibid.*

³⁶ See TSN: 16 March 2021/RDR/IV-13-14.

the FDA and DOH collaborate with partner organizations that are aligned with their respective goals.

On interpellation by Representative Raneo Abu, as to the FDA's source of funds to pay for the services of its job orders, Director General Domingo said that almost all the new hires were paid using the grant. The job order personnel were tasked to undertake research on the publications of regulatory agencies from various countries, such as the USFDA, Health, Canada, RIVM, Netherlands and MHRA, Hongkong. They were supervised by the division chiefs for product registration and licensing division, respectively, including a project manager. Director Rivera said she is also one of the plantilla personnel who wrote the final draft of the policy framework.

The Committee noted that there was no instance when The Union funded official foreign travels of any FDA officer or personnel. Director Rivera cited that there was one instance when official/s travelled to Singapore, specifically to its Health Science Authority, but the expenses thereof were charged to the BIHC.

During the second Committee hearing, Representative Jericho Nograles urged the Committee to recommend that JMC No. 2010-001 on the Protection of the Bureaucracy Against Tobacco Industry Interference, be voided. He pointed out that the reason for the discrimination against the tobacco industry stems from the issuance of the said JMC No. 2010-001, purportedly between the CSC and the DOH. He then noted the submission of the CSC Commissioner Lizada to the Committee that the CSC did not issue any resolution authorizing any person to sign the subject JMC. Further, the CSC is a collegial body, hence, it needed to pass a resolution for the signing of any joint memorandum with any government agency. For the said reasons, Commissioner Lizada submitted that the subject JMC is *void ab initio*.

Representative Nograles observed that the Constitution provides for the mandate of the CSC, without mention of any role as policy implementor of the WHO. He proposed that the Committee Report should state that the CSC memorandum circular was without any basis, and that any resolution to that effect, therefore, should be considered as *void ab initio*. He averred that the objectivity of the CSC should be preserved and it should instead, focus on its constitutional mandate of instilling professionalism among government personnel.³⁷

Representative Savellano also observed that the subject JMC is often invoked to reject any and all forms of interaction between groups from the tobacco industry and the government, regardless of its nature. He cited for instance that the donation of a group from the tobacco industry of biohazard suits to the Department of National Defense (DND) was criticized for being violative of the JMC. He argued that the biohazard suits could very well help the government front liners at the time when the COVID-19 pandemic started. He then supported the position of Rep. Nograles for the revocation of the JMC.³⁸

Notably, Representative Suansing inquired on the model used by the FDA when it developed the draft guidelines for vapor products and HTPs. Director Rivera replied that the FDA considered RA No. 11467 in drafting the guidelines as provided for under the law and used as reference the regulatory framework of mature organizations, such as the European Union (EU), the USA, and Health Canada and the conditions and circumstances obtaining in the country. Representative Suansing then asked if the groups such as Health Justice Foundation, Inc. and

³⁷ See TSN: 09 June 2021/RTP/III-5-6.

³⁸ See TSN: 09 June 2021/RDR/V-1.

Action on Smoking and Health Philippines (**ASH**), and Framework Convention on Tobacco Control Alliance Philippines (**FCAP**) had contributed in the drafting of the guidelines in the regulations of ENDS/ENNDS and HTPs. Director Rivera replied that these groups participated in the FDA public hearings, however, their respective positions, which called for a total ban was not considered by the FDA. These groups' positions were also inconsistent with existing regulations such as Executive Order No. 106 and RA No. 11467. As to whether the FDA adopted any part of these groups' proposal, Director Rivera replied that the FDA mainly used the terms and concepts of their proposal which are consistent with the position of the WHO-FCTC and other international organizations.³⁹

Representative Sharon Garin also observed that whenever the DOH receives any donation from external sources, there would be a new issuance which is in support of the subject donation or grant, alluding to a strange coincidence of both events. Director Rivera said there hardly be any coincidence to speak of since the proceeds of the grant were received in 2018 and that Administrative Order No. 2020-0055⁴⁰ was issued on 01 December 2020. She noted that the order was the final issuance of the DOH relating to tobacco, and that the project, subject of the grant was terminated on June 2020. She cited that a similar order was issued in 2014⁴¹, but it was without any funding from private institutions.⁴²

For his part, Representative Savellano manifested that the issue is not whether or not a party is for or against the tobacco industry, because each has his own mandate and constituency to protect. He argued it is important to determine whether the FDA exercised fairness and acted in compliance with existing laws, citing that FDA's acceptance of grant from private institutions could destroy the tobacco industry. He added that it is his duty to protect the tobacco farmers of the Ilocos region who are his constituents.

Representative Savellano noted that based on previous communications as well as its public pronouncement, the FDA had conveyed that it will abide by the provisions of R.A. No. 11467, providing for an 18-month transitory period for concerned companies to comply with the requirements under the rules and regulations. He reminded the FDA that the agency is expected to enforce the regulation on vapor products and HTPs starting on 24 May 2022, observing that in the FDA's recent Circular No. 2021-010 dated 17 May 2021, the agency required the issuance of an FDA certification for vapor products and HTPs in the assessment and processing of excise tax collections of the BIR. He then argued that the said Circular contradicts FDA's pronouncement that it will not issue any regulation during the 18-month transitory period. Director Rivera explained that it was not the FDA that issued the subject regulations, rather, it was the BIR that requested the FDA to assist in the assessment of excise tax for the subject products.⁴³

Director Rivera pointed out that under the circular, the FDA certification requires industry players to file applications for each batch of vapor products of HTPs' refills and cartridges and important products must be processed per importer, per shipment, per batch, or lot number basis. Representative Savellano then inquired whether the industry players and importers have to go through a new set of applications for each of their products and refills, for every shipment and batch. He also asked whether the FDA imposes similar requirements on other products.

³⁹ See TSN: 09 June 2021/NGO/IV-4.

⁴⁰ DOH Administrative Order No. 2020-0055: Regulation on Vapor Products and HTPs under the FDA dated 01 December 2020.

⁴¹ DOH Administrative Order No. 2014-0008: Rules and Regulations on Electronic Nicotine Delivery System (ENDS) or Electronic Cigarettes, dated 12 March 2014.

⁴² See TSN: 09 June 2021/NGO/IV-9.

⁴³ See TSN: 09 June 2021/RDR/V-2.

In reply thereto, Director Rivera affirmed that FDA requires a batch declaration on other health and pharmaceutical products.⁴⁴

Representative Savellano asked whether or not the FDA consulted the Department of Trade and Industry (**DTI**) and coordinated with the BOC when it crafted Circular No. 2021-010. He noted that Section 4 of Executive Order No. 106 states: “The FDA and DTI are hereby directed to coordinate with the Bureau of Customs in the formulation of the guidelines, requirements, and procedures for the regulation of entry, importation of ENDS/ENNDS and HTPs and their components into the Philippine market.”

On this query, Director Rivera affirmed that the FDA coordinated with the BOC and the Department of Finance (**DOF**) regarding the issuance of the certification.

Representative Savellano also sought clarification whether the subject matter of ENDS/ENNDS and HTPs is included under the WHO-FCTC. Director Rivera read a portion of the WHO-FCTC Decision of the Conference of the Parties (**COP**) in 2014, which provides that the COP invites parties to consider prohibiting or regulating ENDS/ENNDS, including as tobacco products, medicinal products, consumer products or other categories as appropriate, considering a high level of protection for human health. She explained that in effect, the country has an option of either to ban or restrict ENDS/ENNDS, and other novel tobacco products.⁴⁵

The Committee Chairperson, Representative Michael Edgar Y. Aglipay, inquired with CSC Commissioner Aileen Lourdes A. Lizada, on her comments regarding CSC JMC No. 2010-01 on the Protection of the Bureaucracy Against Tobacco Industry Interference.

Commissioner Lizada stated that while the Commission has discussed the said JMC, it is still in the process of looking into other records in the Commission. In reply to Representative Aglipay, she stated that the CSC Charter provides that any act of the Commission is collegial in nature.⁴⁶

Representative Savellano then sought for the comment of Commissioner Lizada on the interpretation of the anti-tobacco organizations that because of said JMC, government cannot accept donations from the tobacco industry, and any interaction with the latter is prohibited.

Commissioner Lizada said several meetings have been held on the subject matter, and that she has requested for background information on what has transpired since the JMC was issued. In addition, she testified that her office is in the process of conducting a study and looking into the infirmities of the said JMC. Accordingly, the JMC provides what is an acceptable interaction between government officials and employees and the tobacco industry.⁴⁷

Relevant thereto, Rep. Savellano narrated that in 2011, the Department of Justice (**DOJ**) issued DOJ Opinion No. 28, Series of 2011, regarding Article 5.3 of the WHO-FCTC. “*Evidently, while stressing the fundamental and irreconcilable conflict between the interest of the tobacco industry and those of public health policy, thus, the need of any inter-action between the parties to the FCTC and those of the tobacco industry on matters to further the latter’s interest “to accountable and transparent”, the parties thereto, the Philippine government included, are not*

⁴⁴ See TSN: 09 June 2021/RDR/V-2.

⁴⁵ *Ibid.*

⁴⁶ See TSN: 09 June 2021/RDR/V-3.

⁴⁷ See TSN: 09 June 2021/RDR/V-4.

absolutely prohibited or precluded from entering into partnership with, or participating in activities of, those in the tobacco industry."⁴⁸

Notably, the issue in regard to the interaction of government personnel with those from the tobacco industry is highlighted by the donation of respirators to the DOH when the country experienced the initial surge of COVID-19 cases. Representative Rodriguez recalled that the DOH received 373 respirators donated by the Lucio Tan group which is identified with the tobacco industry. The DOH then wrote the CSC to seek guidance whether it is proper for the government to use the subject respirators, considering the prohibition provided for in the subject JMC. Representative Rodriguez then asked Commissioner Lizada what the reply was of the CSC. Commissioner Lizada responded that CSC addressed its reply to Director Alma Foronda of the DOH, stating that the use of the 373 respirators is allowed. Further, she relayed that in the exigency of service, it is best to allow the use of the subject respirators in order to respond to the pressing need of the people, and consider the acceptance of the equipment as an exemption from the coverage of the JMC. She then moved for the recall of the subject JMC for being defective.⁴⁹

Representative Rodriguez pointed out Commissioner Lizada's letter to the Committee, stating that DOH Secretary Duque was not authorized by a Collegial Board or the CSC to sign the JMC. Further, he said there is no record in the CSC showing that the Chairman was authorized to sign on behalf of the collegial body and the entire CSC. He lamented that the JMC is the cause of confusion why the DOH was unable to immediately dispatch the respirators.⁵⁰

Thereafter, Representative Rodriguez asked where the 373 respirators are being kept, to which Director Soledad Antonio, BIHC of the DOH, replied that upon receipt of the legal opinion from the CSC, the DOH pulled out the 373 respirators from the warehouse and are now being processed for donation to the hospitals in Metro Manila. Representative Rodriguez then noted that the letter signed by Director Antonio was dated 11 December 2020, but the respirators have not yet been dispatched up to the present time because of the stipulation in the JMC.

C. THE PARTIES

1) THE FOOD AND DRUG ADMINISTRATION (FDA)

The FDA was created under Republic Act 3720 in 1963, which was amended by Executive Order 175 in 1987, otherwise known as the "*Food, Drugs and Devices, and Cosmetics Act*". Subsequently, Republic Act No. 9711, otherwise known as "*The Food and Drug Administration Act of 2009*", was passed strengthening and rationalizing the regulatory capacity of the Bureau of Food and Drugs, now the FDA, and mandating changes in its organization.

The law outlines FDA's mandate to ensure the safety, efficacy or quality of health products which include food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents, radiation-emitting devices or equipment, and household/urban hazardous substances, including pesticides and toys, or consumer products that may have an effect on health.

It is the FDA's Vision to be "an internationally recognized center of regulatory excellence safeguarding the health of the Filipinos." Meanwhile, its Mission is to ensure safety, efficacy, purity

⁴⁸ See TSN: 09 June 2021/RDR/V-7

⁴⁹ See TSN: 09 June 2021/RDR/V-5.

⁵⁰ See TSN: 09 June 2021/RDR/V-6.

and quality of products regulated through effective implementation of the national regulatory framework consistent with international best practice.⁵¹

In the implementation of the project under the grant agreement, the FDA coordinated with other offices of the DOH, specifically the Disease Prevention and Control Bureau, the National Tobacco Control Program (**NTCP**), the Health Promotion and Communication Service, the Epidemiology Bureau, and the Legal Service. Also, FDA worked with other government agencies such as DTI, DOF, NGOs such as the ASH Philippines, professional groups, and civil society.⁵²

2) THE DEPARTMENT OF HEALTH (DOH), as the policy and regulatory agency in matters of public health, GOP

The DOH is the over-all technical authority on health as it is national body that formulates health policies and implements national programs pursuant thereto. The DOH has three (3) major roles in the health sector: (1) leadership in health; (2) enabler and capacity builder; and (3) administrator of specific services. Its mandate is to develop national plans, technical standards, and guidelines on health. Aside from being the regulator of all health services and products, the DOH is the provider of special tertiary health care services and technical assistance to health providers and stakeholders.⁵³

3) VITAL STRATEGIES; THE INTERNATIONAL UNION AGAINST TUBERCULOSIS AND LUNG DISEASE (THE UNION); BLOOMBERG PHILANTHROPIES; BLOOMBERG INITIATIVE:

In 2016, Vital Strategies was launched as a global health organization, to mark its cooperation with the World Lung Foundation (WLF) and the North American branch of The International Union Against Tuberculosis and Lung Disease (The Union North America). Vital Strategies is an affiliate of The Union. It continues to partner with The Union and Bloomberg Initiative on the agenda to reduce tobacco use.

As embodied in the Agreement, the Bloomberg Initiatives (BI) grants program as an important component of its agenda to reduce tobacco use. With funds from renowned philanthropist Michael R. Bloomberg, the grants program has supported the development and delivery of high-impact tobacco control interventions at the country level since 2016.

On 17 November 2017, Vital Strategies assigned The Union to be its agent in the management and monitoring and evaluation of the utilization of the funds under the grant. As its agent, The Union was explicitly authorized to administer and manage the grant with its scope being all function falling under specified clauses of the contract.⁵⁴

The Union co-manages the BI to Reduce Tobacco Use Grants Program in partnership with Tobacco-Free Kids. The program awards funds to projects delivering high-impact tobacco control interventions based on “MPOWER”, in low and middle-income countries. Priority is given to countries with the highest prevalence of tobacco use.⁵⁵

⁵¹ FDA Website (<https://www.fda.gov.ph/>).

⁵² FDA-The Union Agreement (Project Summary)

⁵³ DOH Website (<https://doh.gov.ph/about-us>).

⁵⁴ Annex 8, [Agent(s)] FDA- The Union Agreement

⁵⁵ FDA- The Union Agreement; Bloomberg Initiative

Bloomberg works in five (5) key areas: the arts, education, the environment, government innovation, and public health. Led by Mr. Michael Bloomberg, it includes his foundation, corporate, and personal philanthropy as well as Bloomberg Associates, a *pro bono* consultancy that works with mayors in cities around the world.⁵⁶

4) THE CIVIL SERVICE COMMISSION (CSC)

Republic Act No. 2260, or the Civil Service Act of 1959, as amended, conferred on the CSC the status of a department. The Constitution designates the CSC as a constitutional body.

On 24 September 1972, the CSC was reorganized under Presidential Decree No. 181, and again on 21 November 1986, through Executive Order No. 181. Under Executive Order No. 292, or the Administrative Code of 1987, the CSC is mandated to promote morale, efficiency, integrity, responsiveness, progressiveness, and courtesy in the Civil Service. It is also mandated to promulgate policies, standards and guidelines for the Civil Service and adopt plans and programs to promote economical, efficient and effective personnel administration in the government, among others.⁵⁷

D. THE AGREEMENT

The Agreement between Vital Strategies (Grantor) and the Food and Drug Administration (Grantee) was signed by both Parties on 17 December 2016. As stated therein, Vital Strategies undertook to deliver a grants *programme* for tobacco control with financial assistance from the Bloomberg Philanthropies, and assigned the management of the grant to its agent(s).

The Agreement has a term of twenty-four (24) months, however it underwent two (2) requests for extension, to allow the continuation of project deliverables and the commencement of new activities.

The Maximum Award of the grant was at US\$ 150,430 (One hundred fifty thousand four hundred and thirty US Dollars only).

Also, paragraph 3.2 provided that “the funds awarded shall be applied by the Grantee exclusively for provision of services as described in the Proposal Protocol, Budget and Work Plan with specified targets”.

In addition, paragraph 5.1 of the Agreement, on Monitoring and Evaluation, states, “The Grantee shall allow Vital Strategies’ or its agent(s)’ staff or consultants to verify, by examining the documents or by means of on-the-spot checks, the implementation of the Bloomberg Initiative project and conduct a full evaluation at the end of the project by an independent authority”.

E. THE PROJECT

The implementation of the project, entitled: “Strengthening of the Regulatory Systems on Tobacco Control under the Food and Drug Administration (FDA)” commenced on 1 February 2017, and was concluded on 30 June 2020.

⁵⁶ Bloomberg website (<https://www.bloomberg.org/about/>).

⁵⁷ CSC website (<http://www.csc.gov.ph/>).

The Project has the following goal: to contribute to the implementation of WHO-FCTC Articles 9, 10, 11 and 13.

Article 9 of the Agreement requires Parties to regulate the contents and emissions of tobacco products and the methods by which they are tested and measured.

Article 10 calls upon Parties to request manufacturers and importers to disclose to government authorities and the public information on the constituents and emissions of tobacco products. Partial guidelines were adopted at Conference of Parties (**COP**) 4 with amendments adopted at COP5 and COP6.

Article 11 requires each Parties, within three years of entry into force of the Convention for that Party, to adopt and implement effective measures to prohibit misleading tobacco packaging and labelling; ensure that tobacco product packages carry large health warnings and messages describing the harmful effects of tobacco use; ensure that such warnings cover 50% or more, but not less than 30%, of principal display areas and that they are in the Parties' principal language(s); and ensure that packages contain prescribes information on the tobacco products' constituents and emissions. Guidelines on implementation of Article 11 were adopted at COP3.

Article 13 requires Parties to undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship (a list of forms of tobacco advertising, promotion and sponsorship within the terms of the Convention, is provided in the appendix to the guidelines for implementation of Article 13, which were adopted at COP3). To be effective, the ban covered all types of tobacco advertising and promotion as well as any sponsorship conducted by the tobacco industry. The article also states that "*within the period of five years after entry into force of this Convention for that Party, each Party shall undertake appropriate legislative, executive, administrative and/or other measures and report accordingly in conformity with Article 21*". Further stated, "*a party that is not in a position to undertake a comprehensive ban due to its constitution or constitutional principles shall apply restrictions on all tobacco advertising, promotion and sponsorship*".⁵⁸

THE LAWS ON THE MATTER

The Committee noted the relevant laws, rules and regulations, including the international commitment that the country had become subject to as Party to the WHO-FCTC. It noted in particular, the provisions on financial resources that the WHO is authorized to make "available" to the Parties/member countries in order to facilitate easy compliance with their treaty obligations.

Sections 15 of Article II of the Philippine Constitution mandates: [Italics supplied]

xxx Section 1 5. State Policies: The State shall protect and promote the right to health of the people and instill health consciousness among them. xxx

Further, Section 16 of the same Article II, provides:

⁵⁸ FDA Submission; WHO-FCTC Philippines.

xxx Section 16: The State shall protect and advance the right of the people to a balanced and healthful ecology in accord with the rhythm and harmony of nature. xxx

In addition, Section 12, Article XIII of the same Constitution, states that:

xxx The State shall establish and maintain an effective food and drug regulatory system and undertake appropriate health manpower development and research responsive to the country's health needs and problems. xxx

The Committee also passed upon the laws creating the mandate of the Food and Drug Administration.

1. Section 3, Republic Act No. 9711 or the FDA Act of 2009⁵⁹, explicitly provides: [Italics supplied]

xxx Section 3: It is hereby declared a policy of the State to adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms, and initiatives that are aimed, directed and designed to:

a) protect and promote the right to health of the Filipino people; and

b) help establish and maintain an effective health product regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems.

xxx the State must enhance its regulatory capacity with regard to the inspection, licensing and monitoring of establishments, and the registration and monitoring of health products. xxx

2. Additionally, Section 18, RA No. 9711 provides: [Italics supplied]

xxx Section 18: All income that the FDA is allowed to retain under Section 31 of the Universally Accessible Cheaper and Quality Medicines Act of 2008 shall, any provision of law to the contrary notwithstanding, be deposited in an authorized government depository bank as a special regulatory fund. Any interest earned by such fund shall form part of the retained income. Such fund shall be used primarily for the acquisition of office and laboratory space xxx

The fund shall be allowed to accept grants, donations and all other endowments from local and external sources, in accordance with pertinent laws, rules and regulations. xxx

⁵⁹ RA No. 9711: "An Act Strengthening and Rationalizing the Regulatory Capacity of the Bureau of Food and Drugs (BFAD) by Establishing Adequate Testing Laboratories and Field Offices, Upgrading its Equipment, Augmenting its Human Resource Complement, Giving Authority to Retain its Income, Renaming it the Food and Drug Administration (FDA), amending Certain Sections of Republic Act No. 3720, as amended, and Appropriating Funds thereof".

In the same vein, the rules and regulations issued to implement the FDA Act (Department Circular No. 2011-0101, Section 2, General Powers and Functions, paragraph (x)) states:

xxx Section 2. General Powers and Functions: “The FDA shall have the following functions, powers and duties:

xxx

x. To accept grants, donations and other endowments from local and external sources in accordance with pertinent laws, rules and regulations;

xxx

Moreover, Section 5 of the same rules and regulations, declares that SRF shall be allowed to accept grants, donations and all other endowments from local and external sources in accordance with pertinent laws, rules and regulations.

In addition, Section 9 thereof, provides for the submission by the FDA of a report at the end of each fiscal year:

xxx Section 9. Reporting Requirement. At the end of any fiscal year, the FDA shall submit to the Secretary of Health, the Secretary of Budget and Management, and the Congressional Oversight Committee, created under Section 23 of the FDA Act of 2009, a report on collections and retained income as well as how the funds were utilized, including its accomplishments. Xxx

Meanwhile, the Committee took into consideration RA No. 7394, or the Consumer Act of the Philippines:

Article 2, Declaration of Basic Policy of RA No. 7394, states:

xxx Article 2. Declaration of Basic Policy: It is the policy of the State to protect the interests of the consumer, promote his general welfare and to establish standards of conduct for business and industry. Towards this end, the State shall implement measures to achieve the following:
a) protection against hazards to health and safety; xxx

In the same manner, the Committee reviewed the provisions of the WHO-FCTC, the Philippines being a State Party thereto.

A cursory reading of Articles 25 and 26, paragraphs 1 to 5, of Part VII on Scientific and Technical Cooperation and Communication of Information of the WHO-FCTC is instructive:

Article 25, Part VII on Scientific and Technical Cooperation and Communication of Information states:

xxx Article 25. Relations between the Conference of the Parties and intergovernmental organizations:

In order to provide technical and financial cooperation for achieving the objective of this Convention, the Conference of the Parties may request the cooperation of competent international and regional

intergovernmental organizations including financial and development institutions.

Moreover, Article 26 on Financial resources, of the same Part VII of the WHO-FCTC discusses the importance for Parties to obtain financial support to be able to uphold the provisions of the international treaty, particularly for developing countries and economies in transition, to wit:

xxx Article 26. Financial resources:

1. The Parties recognize the important role that financial resources play in achieving the objective of this Convention.

2. Each Party shall provide financial support in respect of its national activities intended to achieve the objective of the Convention, in accordance with its national plans, priorities and programmes.

3. Parties shall promote, as appropriate, the utilization of bilateral, regional, subregional and other multilateral channels to provide funding for the development and strengthening of WHO Framework Convention on Tobacco Control 24 multisectoral comprehensive tobacco control programmes of developing country Parties and Parties with economies in transition. Accordingly, economically viable alternatives to tobacco production, including crop diversification should be addressed and supported in the context of nationally developed strategies of sustainable development.

4. Parties represented in relevant regional and international intergovernmental organizations, and financial and development institutions shall encourage these entities to provide financial assistance for developing country Parties and for Parties with economies in transition to assist them in meeting their obligations under the Convention, without limiting the rights of participation within these organizations.

5. The Parties agree that: (a) to assist Parties in meeting their obligations under the Convention, all relevant potential and existing resources, financial, technical, or otherwise, both public and private that are available for tobacco control activities, should be mobilized and utilized for the benefit of all Parties, especially developing countries and countries with economies in transition; (b) the Secretariat shall advise developing country Parties and Parties with economies in transition, upon request, on available sources of funding to facilitate the implementation of their obligations under the Convention; xxx

Further, the Committee looked into the mandatory municipal laws of the Philippines, such as those embodied under the Code of Conduct and Ethical Standards for Public Officials and Employees⁶⁰; the Anti-Graft and Corrupt Practices Act⁶¹; and the Foreign Agents Act of 1979.⁶²

1. **Section 7 (d), Republic Act No. 6713, or the Code of Conduct and Ethical Standards for Public Officials and Employees:**

xxx Section 7. Prohibited Acts and Transactions. — *In addition to acts and omissions of public officials and employees now prescribed in the Constitution and existing laws, the following shall constitute prohibited acts and transactions of any public official and employee and are hereby declared to be unlawful:*

xxx

(d) Solicitation or acceptance of gifts. — *Public officials and employees shall not solicit or accept, directly or indirectly, any gift, gratuity, favor, entertainment, loan or anything of monetary value from any person in the course of their official duties or in connection with any operation being regulated by, or any transaction which may be affected by the functions of their office. As to gifts or grants from foreign governments, the Congress consents to: (i) The acceptance and retention by a public official or employee of a gift of nominal value tendered and received as a souvenir or mark of courtesy; (ii) The acceptance by a public official or employee of a gift in the nature of a scholarship or fellowship grant or medical treatment; xxx*

2. **Section 3 (e), Republic Act No. 3019, or the Anti-Graft and Corrupt Practices Act**
xxx Section 3. Corrupt practices of public officers. — *In addition to acts or omissions of public officers already penalized by existing law, the following shall constitute corrupt practices of any public officer and are hereby declared to be unlawful:*

(e) Causing any undue injury to any party, including the Government, or giving any private party any unwarranted benefits, advantage or preference in the discharge of his official administrative or judicial functions through manifest partiality, evident bad faith or gross inexcusable negligence. This provision shall apply to officers and employees of offices or government corporations charged with the grant of licenses or permits or other concessions. xxx

3. **Section 11, paragraphs 1(a), 1(c), and 3, of BP 39, or the Foreign Agents Act of 1979.**

Section 11 defines as unlawful certain acts that foreign agents can commit in the performance of their functions, to wit:

xxx Section 11. Unlawful Acts. (1) It shall be unlawful for any person within the Philippines who is a foreign agent:

(a) to transmit, convey, or otherwise furnish to any agency or official of the government for or in the interest of a foreign principal any political propaganda, or

⁶⁰ RA No. 6713: "An Act Establishing A Code of Conduct And Ethical Standards For Public Officials And Employees, To Uphold The Time-Honored Principle Of Public Office Being A Public Trust, Granting Incentives And Rewards For Exemplary Service, Enumerating Prohibited Acts And Transactions And Providing Penalties For Violations Thereof And For Other Purposes" was approved on 20 February 1989.

⁶¹ RA No. 3019: Anti-Graft and Corrupt Practices Act was approved on 17 August 1960.

⁶² BP 39: "An Act Regulating the Activities and Requiring the Registration of Foreign Agents in the Philippines" was approved on 07 September 1979.

to request from any agency or official for or in the interest of such foreign principal any information or advice pertaining to any political or public interests, policies or relations of foreign country or of a political party or pertaining to the foreign or domestic policies of the Philippines, unless the propaganda being issued or the request being made is prefaced or accompanied by a true and accurate statement to the effect that such person is registered as a foreign agent under this Act; xxx

b) xxx

c) to make, directly or indirectly, any contribution of money or other thing or value, or promise expressly or impliedly to make any such contribution, in connection with any convention, caucus or other process to select candidates for any political office. xxx

(3) It shall be unlawful for any public officer or employee or his spouse to act as a foreign agent. However, the government may employ any foreign agent: Provided, That the head of the employing agency certifies that such employment is required in the national interest. A certification issued under this paragraph shall be forwarded by the head of such agency to the Minister who shall cause the same to be filed along with the registration statement and other documents filed by such agent.

ISSUES

- 1) Whether or not the FDA officials, in requesting and receiving grant from The Union have committed malfeasance, misfeasance and nonfeasance in the performance of their duties with respect to the following laws:
 - a) Section 7 (d), RA No. 6713, or the Code of Conduct and Ethical Standards for Public Officials and Employees:**
 - b) Section 3 (e), RA No. 3019, or the Anti-Graft and Corrupt Practices Act**
 - c) Section 11, paragraphs 1(a), 1(c), and 3, of BP 39, or the Foreign Agents Act of 1979.****
- 2) Whether or not there is a need to review CSC JMC No. 2010-01.**
- 3) Whether or not there is a need to review existing laws, such as Section 18 of the FDA Act, to harmonize it with the other laws such as Section 7 (d) of RA No. 6713.**

DISCUSSION

The incidental issue and concern on sovereignty may be perfunctorily discussed, considering that investigations in aid of legislation are *sui generis*, and the jurisdiction to pass upon the constitutionality of any treaty or executive agreement, belongs to the courts of general jurisdiction, the Regional Trial Court. Also, under the terms of the Agreement, paragraph no. 13 provides for Applicable Laws governing Legal Disputes.

On the First Issue

Section 28, paragraph (t) of the Rules of the House of Representatives, as adopted, defines the jurisdiction of the Committee on Good Government and Public Accountability, to wit:

xxx Sec. 28 (t). Jurisdiction: All matters directly and principally relating to malfeasance, misfeasance and nonfeasance in office committed by officers and employees of the government and its political subdivisions and instrumentalities inclusive of investigations of any matter of public interest on its own initiative or upon order of the House. xxx

As it refers to a public official, **malfeasance** is defined as the intentional performance of an act that is wrong or illegal. Further, **misfeasance** denotes a legal act but performed in a wrongful manner, while **nonfeasance** means the failure to do what ought to be done.

Central to the discussion during the second meeting on 09 June 2021, were the manifestations and comments of Representative Rodriguez, who cited that the FDA may be held liable for soliciting and receiving the grant from The Union. These laws are the provisions of Section 7 (d) of RA No. 6713; Section 3 (e) of RA No. 3019; and Section 11, paragraphs (1) and (3) of BP 39. In addition, he proffered that the Committee should also look into whether or not sovereignty and the country's independence from foreign control and influence may likewise be a concern.

Along this line, Representative Marcoleta sought the comment of Director Rivera whether or not the FDA officials were in violation of any law in soliciting and accepting the grant from The Union, to infuse the financial resources to enhance their regulatory capacity.

Director Ana Rivera of the FDA stated that under Section 18, paragraph 2 of the FDA Act, the same provides that the agency can receive financial support from any local or international funding institution.⁶³

Section 18, paragraph (2) of the FDA Act, states: "*The fund shall be allowed to accept grants, donations and all other endowments from local and external sources, in accordance with pertinent laws, rules and regulations*".

The Committee noted the statement of Director Rivera as she cited that The Union, and its affiliate, Bloomberg Initiative are not subject of the regulatory power of the FDA. The same statement was echoed by Director General Domingo. Director Rivera also stated that the FDA had received financial support from the WHO, but that the same is not prohibited because the latter is an international organization with its work towards improving public health, to which the FDA is aligned in terms of policy and advocacy on tobacco control.⁶⁴

Similarly, the Committee looked into the FDA Act, which is the basis of the agency's mandate and jurisdiction. Indeed, a cursory reading of the FDA Act, Section 3, (b) thereof states that the FDA has mandate on the inspection, licensing and monitoring of *establishments*, and the registration and monitoring of *health products*.

Section 3, (b), FDA Act: "*help establish and maintain an effective health products regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems. Pursuant to this policy, the State must enhance its regulatory capacity and strengthen its capability with regard to the inspection, licensing and monitoring of establishments, and the registration and monitoring of health products*".

⁶³ See TSN: 09 June 2021/IPA/II-7.

⁶⁴ See TSN:09 June 2021/IPA/II-8.

Likewise, Section 4 of the FDA Act cites the objectives of the law and the jurisdiction of the FDA.

Section 4, FDA Act: This Act has the following objectives:

- a) *To enhance and strengthen the administrative and technical capacity of the FDA in the regulation of establishments and products under its jurisdiction;*
- b) *To ensure the FDA's monitoring and regulatory coverage over establishments and products under its jurisdiction;*
- c) *To provide coherence in the FDA's regulatory system for establishments and products under its jurisdiction."*

Relatedly, Section 1, Article III, of its IRR, provides that the FDA has full jurisdiction over the regulation of all health products.

On query of Representative Marcoleta as to why the FDA still needed to source fund from outside sources, Director Rivera admitted that since 2016, the budget allotted to the FDA was about PhP 4 Million per year, which could cover their operational expenses. However, there is no sufficient budget for them to conduct research and to hire personnel, hence the need to apply for grant. She also expressed that the FDA would be very grateful if Congress would appropriate more funds so that the agency can modernize its laboratory capability and fully implement the FDA Act.⁶⁵

Representative Marcoleta however rejoined that it was improper for the FDA to receive funds from an advocacy group because the latter is against the consumption and manufacture of tobacco, a legitimate industry in the country. He lamented that the case could be different if the FDA has received the grant from a *neutral organization*.

He also noted that the conditions imposed by the FDA in regulating the HTPs and other vape products, such as banning certain ingredients in e-cigarettes and requiring independent studies to back up the use of particular ingredients are very costly and could lead to a *de facto* ban.⁶⁶

Representative Marcoleta also asked the manner of disposing the funds coming from The Union, to which Director Rivera stated that under the terms and conditions of the proposal and the grant, it is stipulated that the fund shall be utilized solely for tobacco control. Further, Director Rivera pointed out that the fund was also used to hire most of the job order personnel needed to enhance FDA's research and regulatory capacity. She pointed out that the FDA has to determine the safety of more than fifteen thousand (15,000) flavors and the ingredients of e-cigarettes, as well as review the different emissions of the said products which could not be done with limited personnel support. Hence, the FDA needed to hire additional personnel to conduct review, research and make the necessary recommendations prior to the crafting of an administrative order (*i.e.*, Administrative Order No. 2020-0055).

The Committee also noted the testimony of Director Rivera that the Administrative Order was reviewed by the Policy and Planning Service and the Legal Service of the DOH, before it was indorsed to the Executive Committee. Upon indorsement, the administrative order went through another phase of critical review.⁶⁷

⁶⁵ See TSN:09 June 2021/IPA/II-9.

⁶⁶ *Ibid.*

⁶⁷ See TSN: 09 July 2021/IPA/II-10.

Representative Marcoleta also raised the concern on whether or not the FDA studied the contribution and impact of the tobacco industry on the economy, including the other sectors that rely on the said industry, and the revenue that have accrued to the national economy from taxes collected from the tobacco industry.

On this query, the Committee reviewed the National Tobacco Strategy and found that the same contains the facts and figures on tobacco use as a public health concern, such as the tobacco control policies, national capacity assessment for tobacco control, and the framework of the national tobacco strategy, among others.

The Committee noted the observation of Representative Marcoleta that in this kind of situation, the FDA and the DOH have to carefully execute a delicate balancing act, *i.e.* the Constitutional provisions enshrined in the general welfare clause, and the promotion and protection of people's right to health.

In addition, the Committee looked into Section 3 (e), of RA No. 3019, which describes the instances when public officers may be held liable.

In the case of *Alvarez vs. People*,⁶⁸ the Supreme Court ruled that there are two instances by which a public official may violate Section 3 (e) of Republic Act No. 3019 in the performance of the official's functions, namely:

- a) By causing undue injury to any party, including the Government;
- b) By giving any private party any unwarranted benefits, advantage or preference.

The accused may be charged under either mode or under both. Moreover, the use of the disjunctive term "or" connoted that either act qualifies as a violation of Section 3 (e) of R.A. No. 3019.

But as to how injury to any party can be adjudged, the Supreme Court has ruled earlier that proof of the extent of damage is not essential, it being sufficient that the injury suffered or the benefit received is perceived to be substantial enough and not merely negligible." (*Garcia vs. Sandiganbayan*, 720 SCRA 155, March 26, 2014).⁶⁹

The Committee noted the arguments of the authors of the Resolution and several Members who expressed disagreement over FDA's receipt of the grant from The Union and Bloomberg. Accordingly, the receipt of the grant, which was used to enhance its regulatory capacity may have unduly compromised its supposedly objective stance in the crafting and implementation of its regulatory framework on ENDS/ENNDS/ and HTPs. Moreover, the Members looked at the receipt of the grant as unfair because the fund shall inevitably discourage the use of tobacco and the said novel tobacco products, which is a legitimate industry in the country. It inevitably impacting negatively the livelihood of a sizable number of farmers and workers relying solely on their jobs for support.

However, while the FDA is allowed under the law to receive grants, the propriety of soliciting funding from an organization whose avowed policy is to ban or restrict the use of tobacco and novel tobacco products is questionable in as much as the FDA is in the process of issuing

⁶⁸ *Alvarez vs. People*, 653 SCRA 52, June 29, 2011; *Posadas vs. Sandiganbayan*, 701 SCRA 403, cited by Dabu, P.T. (2016). The Revised Penal Code, A Comprehensive Reviewer. Quezon City: Central Book Supply, Inc.

⁶⁹ *Garcia vs. Sandiganbayan*, 720 SCRA 155, March 26, 2014, *supra*

regulations on said products. At the very least, the FDA should have disclosed at the beginning of the public consultation the fact that it solicited and received a grant from The Union and Bloomberg Philanthropies. Public office is a public trust and a public servant is expected to exhibit, at all times, the highest degree of honesty and integrity and conduct themselves in such a manner as to be beyond reproach and suspicion, and free from any appearance of impropriety especially in the discharge of their official duties.

Moreover, as provided by law and in consonance with the WHO-FCTC, the FDA's policy is for strict regulation of novel tobacco products such as ENDS/ENNDS and HTPs, not to ban the use thereof.⁷⁰

A cursory reading of the WHO-FCTC outlines the duties of the Philippines, as party to the said treaty. Each of the provisions spell out in no unclear terms, the undertakings of the Philippines as Party thereto. It can be gleaned that upon the signing and ratification of the said international treaty, the DOH required to formulate the National Strategy for Tobacco for the period 2011-2016, then came up with the National Strategy covering the current period 2017-2022. As Party to the treaty, the Philippines is under obligation to strictly abide by the provisions thereof.

However, the Committee also note that under the same treaty, a State Party is expected to act "*in accordance with its national law*" or "*in accordance with its constitution or constitutional principles*" thus clearly still recognizing and putting prominence to the sovereign authority of each member state's governments.⁷¹

Because the FCTC is not a self-executing treaty, it needs the passage of domestic legislation in order to be enforceable within the jurisdiction of a member state. Such was the case with the use of Graphic Health Warnings for tobacco products within Philippine jurisdiction in 2014, which came into effect only after Congress passed R.A. No. 10643 or the Graphic Health Warnings Law, and not in 2005 when the FCTC treaty was ratified by the Philippine Senate.

On the issue of whether an act of a State is unconstitutional for being inimical to its sovereign power, the Committee shall defer consideration on whether or not to take jurisdiction over the said issue given that the mandate of the Committee is to settle only issues on malfeasance, misfeasance and nonfeasance of public officials and employees.

Section 2, of the Constitution, in no unclear terms, asserts: "*The Philippines renounces war, as an instrument of national policy; adopts the generally accepted principles of international law as part of the law of the land and adheres to the policy of peace, equality, justice, freedom, cooperation, and amity with all nations*".

Adoption of the generally accepted principles of international law is part of the law of the land. This portion of the declaration binds the Philippines, by reason of its membership in the family of nations, to enforce or observe within its jurisdiction generally accepted principles of international law, whether customary or by treaty provision, as part of the law of the land notwithstanding the fact that they are not embodied in statutory enactments. International law refers to the body of rules and principles which governs the relations of nations and their respective peoples in their intercourse with one another.⁷²

The transformation method requires that an international law be transformed into a domestic law through constitutional mechanism such as local legislation. It

⁷⁰ See TSN: 09 June 2021/IPA/II-1, *supra*

⁷¹ See Articles 5.3, 10, 11 (1), 12 (c), 13 (2), 13 (4), 14 (7), 15 (2), 15 (4.a, 4.c), 15 (6), and 26 (2) of the WHO Framework Convention on Tobacco Control (FCTC).

⁷² Philippine Constitutional Law, De Leon, 2012 edition.

*applies when, by mere constitutional declaration, international law is deemed to have the force of domestic law. Treaties become part of the law of the land through transformation pursuant to Article VII, Section 21. Thus, treaties or conventional international law must go through into municipal law that can be applied to domestic conflicts (Pharmaceutical and Health Care Association vs Duque III, 535 SCRA 265 [2007]).*⁷³

Meanwhile, Article II, Section 7, of the Constitution, provides: “The State shall pursue an independent foreign policy. In its relations with other states, the paramount consideration shall be national sovereignty, territorial integrity, national interest, and the right to self-determination”.

In addition, Article VII, Section 22 of the Constitution, states that based on the constitutional system, Congress, through legislation, and its upper chamber, the Senate, through its power to ratify treaties or international agreements, share with the President the responsibility of formulating the country’s foreign policy although the initiation of policies and the conduct thereof are primarily reposed in the President.

The Committee also looked into the concept of limitations on the exercise of sovereignty. Sovereignty has two (2) manifestations. The internal and external aspects are not absolutely true in practice because of the development of international relations and consequently, of international law. It is not therefore, correct to say that an independent state has a right to determine its conduct free from any restriction on the part of the other states. The free flow of information, investments, goods and services in the era of globalization also has impact on the sovereignty of states. It is no longer possible for a state to autonomously pursue its own goals without any restraint at all.⁷⁴

The independent action of a State may be curtailed by its own consent, such as by a treaty.

Sovereignty itself always resides in and remains, as a rule, to the government or its organs which cannot transgress constitutional restrictions. While sovereignty lies in the State and the State has absolute legal competence, the government must abide by and submit to the commands of the Constitution which is the expression of the sovereign will of the state itself.

Representative Rodriguez proffered that in the process of obtaining the grant, The Union and its affiliate must have had their own agent/s in the Philippines to facilitate the transaction. He then manifested that if indeed there have been agent/s that facilitated the transaction at the time, they should have first complied with *Batasan Pambansa Bilang 39* (BP 39), or the Foreign Agents Act of 1979.

Section 4 of BP 39 provides that foreign agents shall register with the Minister of Justice, now the DOJ, the personal information, compensation, nature of their activity, among others before they can obtain any information or advice from the Philippine government. Corollary thereto, Representative Rodriguez advanced that when the FDA received the grant from The Union and Bloomberg, the FDA officials became foreign agents of the latter. Unwittingly, The Union and Bloomberg had gotten advice and obtained information in the process of the award of the grant to the FDA, hence, he argued, the said entities may thus be considered foreign agents who are required to register their activity before the DOJ.

The Committee noted that, upon query by Representative Rodriguez whether the foreign agents had registered with the DOJ as required by the BP 39, Director Rivera stated that she is

⁷³ De Leon, citing Joaquin Bernas, SJ, *Constitutional Structure and Powers of Government*, Part (2005); An Introduction to International Law, 2002 Ed., p. 57; see *Mijares vs. Ranada*, 455 SCRA 397 (2005).

⁷⁴ *Ibid.*

not particularly privy to the matter although she pointed out that The Union and Bloomberg are recognized international development partners of the DOH.⁷⁵

This query on whether The Union and Bloomberg are registered with the DOJ, has not been further inquired into, nor has DOJ been invited to shed light or asked to submit a reply to this question of fact. Even granting that The Union or Bloomberg are not registered with the DOJ as required under the law, should their activities in line with the arts, education, the environment, government innovation, and public health be in the nature of “political activity” and can be interpreted as activities which seek to influence an agency or official of the Philippine Government with respect to the domestic or foreign policies of the country, or whether these activities are within the bounds of “political propaganda”, as is in Section 3, paragraphs (4) and (5) of the Foreign Agents Act of 1979?

Section 3, of the BP 39, the Foreign Agents Act of 1979, on the Definition of Terms, provides:

2) "*Foreign principal*" refers to the government of a foreign country or a foreign political party; a foreigner located within or outside the jurisdiction of the Republic of the Philippines; or a partnership, association, corporation, organization or other entity owned or controlled by foreigners.

(3) "*Foreign agent*" refers to any person who acts or agrees to act as political consultant, public relations counsel, publicity agent, information *representative*, or as *agent, servant, representative, or attorney for a foreign principal or for any domestic organization subsidized directly or indirectly in whole or in part by a foreign principal. The term "foreign agent" shall not include a duly accredited diplomatic or consular officer of a foreign country or officials of the United Nations and its agencies and of other international organizations recognized by the Republic of the Philippines while engaged in activities within the scope of their legitimate functions as such officers or a bona fide member or employee of a foreign press service or news organization while engaged in activities within the scope of his legitimate functions as such.*

(4) "*Political activity*" refers to **political propaganda** or any other activity which seeks in any reasonable degree to prevail upon, indoctrinate, convert, induce, persuade, or in any other way influence any agency or official of the Philippine Government, or any section of the public within the Philippines with respect to the domestic or foreign policies of the Philippines, or with respect to the political or public interests, policies, or relations of a foreign government or a foreign political party.

(5) "*Political propaganda*" refers to any oral, visual, graphic, written, pictorial, or other communication or expression:

(a) which seeks in any reasonable degree to prevail upon, indoctrinate, convert, induce, or in any other way influence a person or any section of the public within the Philippines with respect to the political or public interests, policies, or relations of a foreign government or a foreign political party or with respect to the foreign policies of the Philippines; or

⁷⁵ See TSN: 09 June 2021/IPA/II-2.

(b) which advocates, advises, instigates, or promotes social, political, or religious dissension, disorder, civil riot, or conflict involving the use of force, or the overthrow of the government of the Republic of the Philippines.

*(6) "Political consultant" refers to any person who engages in informing or advising any other person on the domestic or foreign policies of the Philippines or on the political or public interests, policies, or relations of a foreign government or of a **foreign** political party. xxx*

In addition, Section 4, of the same law provides the information required to be registered by a foreign agent.

xxx Section 4. Registration. Batas Pambansa Bilang 39: (1) Every person who is now a foreign agent shall, within thirty days after this Act takes effect, and every persons who shall hereafter become a foreign agent shall, within ten days thereafter, file with the Ministry of Justice, a true and a complete registration statement, under oath, which shall set forth

(a) The name, principal business address, and all other business and residence addresses in the Philippines or elsewhere, if any, of the registrant.

(b) The name of the foreign principal or other person/s or organization/s for which such person is acting as agent.

(c) A copy of the contract/s of employment, or in the absence thereof, a full statement of the terms and conditions, under which such person acts or agrees to act as agent.

(d) The date when such contract or each of such contracts was made, the date of commencement of activity thereunder and the period during which such contract or each of such contracts is to be in effect.

(e) The compensation to be paid, if any, and the form and manner of such compensation.

(f) The name of every foreign principal or other person or organization which contributed or which has promised to contribute to the compensation provided for such contract.

(g) A detailed statement of every activity which the registrant is performing or is assuming or purporting or has agreed to perform for himself or any other person than a foreign principal and which requires his registration.

(h) If the registrant be a partnership, association, or corporation, a true and complete copy of its charter, articles of incorporation, association, constitution, and by-laws and any other instruments relating to its organizations, powers and purposes.

(1) Such other statements, information or documents as the Ministry of Justice for purposes of this Act may from time to time require.

(2) The termination of the status of the foreign agent shall not relieve him from his obligation to file a registration statement in accordance with this Act for the period during which he was such an agent.

On the Second Issue

As regards CSC JMC No. 2010-01, the Committee expresses serious concern over the procedural infirmities surrounding its issuance and recommends that the CSC hastens its review thereof.

As revealed in the report submitted by CSC Commissioner Lizada on the “timeline of events regarding the CSC-DOH JMC No. 2010 and the [CSC] Grant from the Bloomberg Initiative and The Union” (the “OCL Report”), the issuance of subject JMC lacked the constitutional requirement for the decision-making process of the CSC to be collegial. According to the OCL Report, “based on the records and as borne out from the several Commission Meetings, indeed there was no Resolution authorizing Chair Duque to enter into the JMC and sign on behalf of the CSC”. The Committee cannot brush aside said finding considering that no less than the Constitution requires that decisions of the Commission be made by the body and not by individual members.

A commission is defined as “a board or committee officially appointed and empowered to perform certain acts or exercise certain jurisdiction of a public nature or relation. Noteworthy, the CSC is composed of a chairman and two (2) commissioners; the Commission on Election, a chairman and six (6) commissioners; and the COA, a chairman and two (2) commissioners. Clearly provided in Sec. 7 is that these three (3) constitutional commissions shall decide by a majority vote of all its members any case or matter brought before it; thus, the commissions are collegial bodies whose manner of working is characterized by a sharing of responsibility among the chairman and the commissioners of the commission.”⁷⁶

Thus, the absence of the constitutional requirement for collegial action in the signing and issuance of JMC No. 2010-01 renders the same void ab initio. It was the CSC, as a collegial body, which had the jurisdiction to decide and issue the joint memorandum and not the Chairman alone.

Furthermore, it bears emphasis that it is not the Constitutional function of the CSC to implement a DOH directive. The CSC is constitutionally mandated to promote morale, efficiency, integrity, responsiveness, progressiveness, and courtesy in the Civil Service; in short, it is tasked to oversee the integrity of government actions and processes. Verily, it is not responsible for setting public health policies with respect to tobacco control.

Aside from being potentially infringing of the Constitution, the Committee also finds that the cited examples on the wrongful interpretation of JMC No. 2010-01 deserve serious consideration. In our deliberations, it has come to the attention of this Committee that the JMC has been used as justification for rejecting life-saving donations from a legitimate industry and discriminating against tobacco companies and employees in the government’s national COVID-19 immunization program. It appears that the JMC has been improperly used as basis to discriminate against a legitimate industry.

JMC No. 2010-01 may have a noble objective of protecting the bureaucracy from tobacco industry interference, but if it is being implemented beyond what it provides, then Congress has

⁷⁶ *Rey Nathaniel C. Ifurung v. Hon. Conchita C. Carpio Morales*, G.R. No. 232131, 24 April 2018.

the obligation to intervene. It must not be sweepingly and blindly invoked to reject all forms of interaction with the tobacco industry, contrary to the State's avowed policy under RA No. 9211 to balance the interests of public health and tobacco farmers, workers, and stakeholders. State discrimination against a legitimate industry and the people who belong to it should never be permitted and tolerated.

It is apparent that the prohibitions contained in the JMC are already covered by existing laws such as RA No. 3019 and RA No. 6713. Thus, they are a mere duplication of the prohibited acts under these laws, except that they specifically and unnecessarily pertain to the tobacco industry. Even without JMC No. 2010-01, all public officials and employees must observe the same standards of personal conduct in the discharge and execution of their official duties under RA No. 6713 and must refrain from doing the acts and interactions prohibited therein.

Considering the foregoing, JMC No. 2010-01 should not be used as basis for refusing donations intended to benefit the public. As clarified by the DOJ in its Opinion No. 28, Series of 2011 dated 4 July 2011, the government is "not absolutely prohibited or precluded from entering into partnership with, or participating in activities of, those in the tobacco industry". The Committee posits that donations from the tobacco industry should be allowed subject to certain restrictions on communications in order to protect the government from any appearance of influence. Further, the Committee reminds the bureaucracy to avoid any discriminatory act that would result in the exclusion of legitimate industries and or entities on the basis of JMC No. 2010-01.

Hence, considering Commissioner Lizada's move to recall JMC No. 2010-01,⁷⁷ and the ongoing review initiated by CSC Chairperson Alicia dela Rosa-Bala and Commissioner Lizada, the Committee urges the CSC to hasten its review of JMC 2010-01.

On the Third Issue

Director General Domingo cited Section 18 of R.A. No. 9711 as the authority that FDA is allowed to accept grants, donations and all other endowments from local and external sources. However, the said authority is not without limitation as it is provided in the same provision that such acceptance should be in accordance with pertinent laws, rules and regulations.

Succinctly, R.A. No. 6713 is such law that may serve as a limitation to Section 18 of R.A. No. 9711. Section 7 (d) of RA No. 6713 prohibits public officials and employees from soliciting or accepting, directly or indirectly, gift, gratuity, favor, entertainment, loan or anything of monetary value from any person in the course of their official duties or in connection with any operation being regulated by, or any transaction which may be affected by the functions of said public officials and employees.

Director Rivera contended that in receiving the grant from The Union, FDA has merely abided by the FDA Law, which is a national statute like the Code of Conduct and Ethical Standards for Public Officials and Employees (RA No. 6713). On query of Representative Marcoleta on whether there is a need to harmonize both laws, Director Rivera affirmed the suggestion and welcomed any initiative to review both laws in order to reconcile their provisions.⁷⁸

The Union, which is a foreign organization, did not attach any conditions that may have influence on the policy-making function of the agency, but there will always be doubt on the intention of the grant. Government agencies with regulatory authority should be totally impartial.

⁷⁷ See TSN: 09 June 2021/RDR/V-5.

⁷⁸ *Ibid.*

Representative Sharon Garin also pointed out that a government regulatory agency that receives a grant from an international organization cannot go against the advocacy of such grantor. In the case of The Union which is an anti-tobacco organization, the FDA could have been influenced by the grantor to formulate a policy that is aligned with its advocacy. Director General Domingo said that the receipt of the grant is not illegal for as long as the grantor does not interfere with the formulation of policies by the grantee.

However, it was admitted during the course of the Committee hearing that the grant received from The Union was also used to hire Job Order personnel that conducted the research, study and review of data necessary for the crafting of the guidelines for the regulation of tobacco. Director Rivera even mentioned that the hiring of such personnel was in accord with the Terms of Reference agreed upon by the grantor. The research undertaken, and results of the study of these Job Order personnel were used by FDA in the formulation of its guidelines on the use of tobacco and other vapor products.

The Committee cannot discount the partiality of the study and findings of these Job Order personnel who were compensated using the grant from The Union.

The Committee also noted that RA No. 9711, or the FDA Act was signed on 18 August 2009, while RA No. 6713, the Code of Conduct and Ethical Standards was approved on 20 February 1989. *Statutory construction provides that as to conflict between two laws, the latter law governs.*

On the need to amend existing laws, such as the FDA Law, in order to harmonize it with existing laws, the Committee took note of the manifestation of the authors of the Resolution, particularly that of Representative Suansing. She proposed the possibility of filing a bill to amend the FDA Act, particularly prohibiting its capacity to receive donations, both local and foreign. The FDA Act may run in conflict with laws as discussed herein as to "solicitation and acceptance of gifts", in relation to the performance of government functions. The issues in relation to this proposal may be further reviewed.

FINDINGS AND CONCLUSION

The Committee considered and evaluated all the facts, statements of the resource persons and their respective legal standpoint, relevant laws and jurisprudence. After thorough and careful deliberation on House Resolution No. 1396, the Committee submits the following findings and conclusions:

1. While the FDA is allowed under the law to receive grants, the propriety of soliciting funding from an organization whose avowed policy is to ban or restrict the use of tobacco and novel tobacco products is questionable in as much as the FDA is in the process of issuing regulations on said products and as admitted, salaries of Job Order personnel involved in the development of said regulations came from said grant.

It was a judgement call on the part of FDA when it submitted the proposal to a private international organization, The Union, soliciting therein funding for the proposed project. Despite the noble intention, however, the Committee determined that the FDA failed to act judiciously when it did not consider the propriety of entering into such an arrangement. The fact that it failed to disclose said funding until questioned by members of Congress who were present at that time brings into question its fairness and objectivity. Therefore, officers and personnel of the FDA may be held

administratively liable for possible violation under Section 3 (e) of RA No. 3019 and Section 7 (d) of RA No. 6713.

2. The FDA should have been more circumspect in its acts, and should have exercised more caution and due diligence in the crafting and introduction of highly contentious policies, particularly those for which no groundwork has been laid out yet, such as in this case. The Committee finds that the tobacco industry may have been unwittingly disadvantaged during the formulation of the policies, rules and regulations concerning tobacco. Naturally, the stakeholders felt aggrieved when there was little opportunity for them to air their legitimate concerns and predicaments, especially since the implementation of the novel tobacco products is a first in the country. There were no ready standards, rules and procedures yet at the time of the issuance of the guidelines for vapor products and HTPs, hence the apparent confusion and dilemma that have been experienced by the stakeholders. The lack of clear guidelines and information characterized the discourse during the public hearings, which confusions became even more palpable when the consultations were conducted online.
3. On *Batas Pambansa Bilang 39*, or the Foreign Agents Registration Act, there is a dearth of information as to whether or not The Union and Bloomberg Initiative are duly compliant with the provisions of the said law. While the law may be antiquated and therefore, forgotten, it is a precept under Article 3 of the Civil Code of the Philippines, that ignorance of the law excuses no one from compliance therewith.

The Committee did not further put to task the FDA to submit any document to prove that The Union and Bloomberg have been duly registered. It accepted the averment that the FDA and the DOH regularly works with their foreign partners and counterparts in terms of mandate, jurisdiction, and advocacy.

The Committee takes the position that the activity of The Union and Bloomberg may not fall squarely under the nature and concept of what is indeed “political”, nor can they be considered as “political organizations”. However, ours is an increasingly complex world, characterized by rapid technological advancement and innovation, and populated by a widely diverse groups of people and cultures. The confluence of these factors fundamentally challenges and affects the previous ideologies and universal truths that have been the bedrock of civil societies for ages. Hence, it is difficult to accurately depict what is political, and what is not.

Failing to substantiate the statement through the submission of relevant records of registration with the Department of Justice, the Committee contends that the said foreign entities may be held liable under BP 39. Subsequently, the nature of the action/s of the officials of the Philippine government in relation to the activities of the grantors’ foreign agents may be further looked into.

4. Finally, the Committee finds that in order to accurately evaluate the current capacity of the FDA to conduct scientific research studies that are vital to decision-making, there may be a need to review the FDA Act on its fund sources for research and development purposes, and the necessity of filing legislation. The budgetary requirement of said research and development activities may also be looked into during the crafting of the General Appropriations Act.

RECOMMENDATIONS

1. The Committee recommends the review of the budgetary allocation to the FDA and similar agencies that are mandated to conduct research that shall be responsive to the country's health needs and problems.
2. The Committee recommends the review of the FDA Act on the receipt of grants and donations from local and international sources, as well as its IRR to reflect the realities that a grant may influence the grantee.
 - a. The Committee calls for an investigation by the into the funding received by the FDA and other government agencies from foreign private organizations, whether or not these were properly utilized and accounted for in accordance with appropriate government regulations, and whether or not these funds received under grants and such joint project agreements redounded to the personal benefit, either directly or indirectly, of the government officials directly dealing with these private organizations.
 - b. The Committee recommends the issuance of a policy prohibiting regulatory bodies and government agencies, including LGUs, from receiving monetary grants from foreign private organizations without proper registration and disclosure in exchange for allowing these donors to operate and interfere in the formulation and implementation of government policies.
3. The Committee recommends the review and possible amendment of BP 39, to better reflect new conditions obtaining due to passage of time. For example, a further clarification on the concept of "foreign agent", "political" or "political activity" may be required, in relation to the activities of philanthropic and influential organizations, such as Bloomberg.
4. The Committee urges the CSC to immediately resolve its ongoing review of JMC No. 2010-01 on the Protection of the Bureaucracy Against Tobacco Industry Interference.
5. The Committee urges DOH and FDA to adopt a policy of disclosure and transparency on the sources of funds, local and external, and any potential conflict of interest in case of external sources.
6. A copy of this Committee Report shall be furnished to the DOH, FDA, CSC, COA, and DBM for their information and appropriate action.