Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

EIGHTEENTH CONGRESS
Third Regular Session

COMMITTEE REPORT No._____

Submitted by the **COMMITTEE ON GOOD GOVERNMENT AND PUBLIC ACCOUNTABILITY** on _____.

Re: **House Resolution No. 1396** introduced by Representatives Deogracias Victor "DV" B. Savellano and Estrellita B. Suansing

Informing the House of its Findings and Recommendations.

Sponsors: Chairperson Michael Edgar Y. Aglipay and the members of the Committee on Good Government and Public Accountability.

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 PREDEFINED 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:

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 compose the list of resource persons, who were invited to participate in the public hearings, through physical attendance and Zoom video conference: From the Food and Drug Administration (**FDA**): Director General and Department of Health (**DOH**)Undersecretary Rolando Enrique Domingo; Engr. Ana Rivera, Director for the Center for Cosmetics and Household; Ms. Irene Florentino-Fariñas and Mr. Jekee Miraflor; from the Bureau of International Health Cooperation (**BIHC**), DOH: Director Maria Soledad Q. Antonio; 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; and 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 same on 06 June 2005.[2] Upon ratification of the WHO-FCTC, the Philippines became a Party thereto and was one among 168

[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.

Signatories to a legally binding international treaty, including the 182 Parties who later acceded thereto, covering more than 90% of the human population.[3]

Developed in response to the increasing global tobacco concern, the WHO-FCTC is the first public health treaty negotiated under the guidance of the World Health Organization (**WHO**). It reaffirmed the "right of all people to the highest standard of health" as stated in its Preamble to the 1946 Constitution. The WHO-FCTC focused in combating various issues in tobacco use such as trade liberalization, global marketing, tobacco advertising, promotion and sponsorship, and the international movement of contraband and counterfeit cigarettes, among others.[4] 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 mandated to enact new laws or amend existing ones in order to align with the WHO-FCTC.[5]

Since 2007, Bloomberg Philanthropies has supported the accelerated reduction of tobacco use in many countries, including the Philippines. Progress in the Philippines is discussed with particular emphasis on the period since ratification of the WHO-FCTC, and with particular focus on the grants program funded by the Bloomberg Initiative. Despite considerable progress, significant challenges are identified that must be addressed in future if the social, health and economic burden from the tobacco epidemic is to be alleviated.

To implement the WHO-FCTC, the Philippines, with the leadership of the DOH, established the National Tobacco Control Strategy (**NTCS**) 2011-2016, engaging 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.

In 2016, the FDA, through the DOH, has 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 (hereinafter referred as "The **Union**"), an international non- profit, non-government organization, to seek assistance and funding for capacity building of the agency.[6]

On 13 December 2016, a grant agreement (the "**Agreement**") was signed between Vital Strategies[7] and FDA. Under said Agreement, Vital Strategies shall deliver a grants program for tobacco control with financial assistance from the Bloomberg Philanthropies[8] and grant management from its agents.

On February 2017, The Union supported a project entitled, *"Strengthening of the Regulatory Systems on Tobacco Control under the Food and Drug Administration"* (the "**Project**"). Its overall objective was for the FDA to enhance its regulatory capacity for its tobacco control programs. Under the project, The Union granted FDA US$150,430 while the Philippine

[3] The WHO-FCTC website (https://fctc.who.int/who-fctc/overview/parties).
[4] *Ibid.*
5 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/)
[6] Presentation of FDA DG Domingo during the Committee meeting on March 16, 2021
[7] 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).
[8] *Ibid.*

government's estimated co-funding was US$335,864. The project duration was from February 2017 to June 2020 with the following objectives: 1) enable the FDA to hire manpower support in the implementation of the National Tobacco Control Program; 2) enable the FDA activities for the development of regulatory guidelines and the implementation of existing regulations; 3) enable the FDA to develop and implement the necessary regulatory system for the implementation of existing laws and regulations; and 4) capacitate the FDA-Field Regulatory Operations Office.[9]

On 17 November 2017, Vital Strategies ceded its obligations with 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 requests for no-cost extension - January 2019 (12 months) and January 2020 (5 months) - the Project under the grant agreement was concluded.[10]

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 DOH likewise envisions a country with reduced morbidity and premature mortality rates caused by major non-communicable diseases by year 2030.

Along this line, several measures have been issued, to wit: Republic Act No. 9211, or the Tobacco Regulation Act of 2003; Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009" (or the "**FDA Act**"); Republic Act No. 10351, or the Sin Tax Reform Law of 2012; 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 Republic Act No. 11467, amending and adding a new section to the NIRC. Further, executive issuances that included Executive Order No. 26 (Series of 2017),[11] as amended by Executive Order No. 106 (Series of 2020)[12].

On October 8, 2020, a public hearing and consultation meeting via zoom was undertaken 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 were raised to the FDA officials, who have not been able to properly clarify the issues raised. A particular issue was raised on the FDA being a recipient of a grant 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

[9] Presentation of DG Domingo during the Committee meeting on March 16, 2021
[10] FDA Submission: Chronology of Events
[11] E.O. No. 26: "Providing for the Establishment of Smoke-Free Environments in Public and Enclosed Places", signed on 16 May 2017.
[12] 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.

authors urged the body to review whether the actions of the FDA make them liable for malfeasance, misfeasance and nonfeasance in office thereby in violation of existing laws. In addition, concern 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 to look 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 grant coming from The Union and Bloomberg has 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 the need to amend, alter, modify, repeal existing laws, or create new legislation.

B. Deliberation Proper

During the initial meeting on 16 March 2021, Representative Deogracias Savellano narrated that on 08 October 2020, he was with Representative Estrellita Suansing and Representative Wes Gatchalian to participate in the public consultation regarding the FDAs proposed guidelines to regulate ENDS/ENNDS and HTPs, conducted through virtual or online platform.

In said public hearing, Representative Savellano lamented that the FDA did not provide them an opportunity to raise their concerns, there was a clear lack of transparency, openness and effort to have a meaningful discussion. Representative Savellano also raised issue 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 the same is a laudable project but encourages the Local Government Units (**LGUs**) to actually pass local ordinances to go 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.

In answer thereto, FDA Director General Domingo discussed the mandate of the agency. He said 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,[13] amending and adding a new section to the NIRC.

The key points elucidated by Director General Domingo are noted herein:

- In 2014, Administrative Order No. 2014-0008[14] 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. In order to realize their mandate, the FDA had to do major research programs on a daily basis. There was a need to hire additional staff to accomplish their objectives however, they have a limited budget.

[13] 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.

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

- Further, a proposal for funding from DOH was forwarded to its development partners such as 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 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 to prevent children from starting to smoke; support public sector efforts to implement effective policies; support efforts to educate communities about the harms of tobacco; 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 goal.
- The FDA has outlined the workplan for the development of the regulatory system in the Terms of Reference.
- 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, while the amount of $ 335,864 was co-funded by the Philippine government for the project. The objectives of the project is to create the regulatory guidelines 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, Framework Convention on Tobacco Control (**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 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 of the FDA, which manages their income in the exercise of their regulatory functions, including 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**).
- 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 21 years old. The Joint Memorandum Circular (JMC) No. 003-2020[15], signed on 16 May 2017, was then formulated as the Implementing Rules and Regulations on the use of HTPs and vapor products.
- On the creation and drafting of the administrative order, the FDA followed the guidelines established by the DOH. The same underwent review and clearance from the legal office. Public consultations have also been conducted, initially done on site. However, the hearing was later done through the internet applications.

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

Announcements for meeting were posted in their website. FDA took time to clarify the issues and the major concerns of the stakeholders which have been consolidated and considered.

- The recent public hearing and consultations by FDA on the crafting of regulations for HTPs had technical problems related to the online meetings.
- Public consultations were done on 06 and 08 October 2020, however they still accepted the inputs of stakeholders even up to the finalization of the administrative order. Finally, Administrative Order No. 2020-0055[16] was signed on 01 December 2020.

As to the regulatory system, Director General Domingo has assured that the FDA continuously updates the data and scientific studies coming from international research. They then undertake their own scientific evaluation and look into the strength of evidence for application to their own regulatory function. 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 they entertained all the recommendations at that time and collated them for inclusion to the Regulatory Impact Analysis (**RIA**). Hence, all the concerns raised were included in the RIA submitted by the FDA.

As a consequence of the FDA regulations, Representative Savellano expressed concern for the resulting livelihood of the tobacco farmers who rely on the industry, should a ban be implemented. Director General Domingo said that the government is reviewing other sources of funds to give financial support to 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 develop disease and those who die of ailments brought by smoking. In addition, Director General Domingo stated that there is no policy to ban on the use of said products, rather the government policy is for regulation. He assured that in the formulation of policies, FDA takes into consideration the stakeholders, health advocates, and the WHO recommendation, in order to obtain all the information in the creation of policies. He assured the Committee that they try to balance the interests of all concerned.[17]

Upon query by Representative Suansing on the FDA's budgetary allocation, Director General Domingo said FDA receives less than PhP 200 million per year. In addition, FDA is also allowed to collect fees from its regulatory activities, such as licensing, marketing authorizations, product registration, inspection, and fines, which total from PhP 500 million to PhP 600 million a year. The said amount, consisting of all their income then goes to the SRF, which is used for their Maintenance and Other Operating Expenses (**MOOE**). He however clarified that FDA does not have a share from the income derived from the implementation of the Universally-Accessible, Cheaper and Quality Medicines Act of 2008, citing that their SRF only consists of the income from their regulatory activities and from the grants. He explained that the amount they receive from the government can only cover the budget for "Personnel Services".

[16] Administrative Order No. 2020-0055: Regulation on Vapor Products and HTPs under the FDA.
[17] *See* TSN: 16 March 2021/NGO/III-3.

Further, Director General Domingo stated that if there is a need for additional fund, they then request the Department of Budget and Management (**DBM**) to allow them to use their income to fund their MOOE, with the requirement that the same is provided under the National Expenditure Program (**NEP**).[18]

Rep. Suansing then asked if the FDA is not prohibited to accept grants and donations, to which Director General Domingo said that under Section 18, RA 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 they do not have grants from local sources, rather the grants are given by international organizations. He underscored that the only grant that the FDA has received during his incumbency were those from Japan International Cooperation Agency (JICA), which was used for the development of their pharmacopoeia, and the recent grant from The Union.

Pointedly, Representative Suansing queried if the FDA has received grants from Coca-Cola and Nestle, to which Director General Domingo said that he is not aware of any grants coming from these companies, which apply for registration from the FDA. However, Representative Suansing stated that she has documents to show that FDA received grants from Coca- Cola and Nestle, during the 16th Congress, at the time that excise tax on sugar-sweetened beverages are being deliberated on.[19]

Asked how the FDA was able to request for donations from international sources, Director Rivera discussed that in 2016, they have submitted applications to various international agencies, including the ADB, the WHO- Philippines Country Office; and in 2019, they have also submitted a proposal to the Department of Science and Technology (**DOST**) for the analytical, toxicology, laboratory setting up of e-cigarettes. At the time, they needed to undertake research programs on a daily basis, hence the need to hire additional staff. They then submitted a proposal to the WHO, and then later, to other development partners of the DOH. [20]

Representative Suansing asked if there was any commitment on the part of the FDA in receiving the grant from The Union and Bloomberg. Director General Domingo stated that the situation in 2016 was different, while currently, the FDA has a bigger income. He discussed that DOH and the Department of Foreign Affairs (**DFA**), are FDA's partners pertaining to health advocacy, hence can request foreign grants with the assistance from 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. [21]

Thereafter, Representative Suansing manifested her intention to file a bill prohibiting the FDA from accepting grants.

In regard to The Union and Bloomberg, the same have the objective to optimize tobacco control programs, help smokers stop using tobacco, and prevent children from starting to smoke. Also, the goal is to implement effective policies, taxing cigarettes, preventing smuggling, altering the image of tobacco, and protecting workers from exposure to secondhand smoke, and to support advocate's efforts to educate communities about the harm of tobacco. As to the query on

[18] *See* TSN: 16 March 2021/NGO/III-4-7.
[19] *See* TSN: 16 March 2021/NGO/III-8-9.
[20] *See* TSN: 16 March 2021/NGO/III-10.
[21] *See* TSN:16 March 2021/NGO/III-11.

the background of Bloomberg, Director General Domingo said he learned about Michael Bloomberg from the news, during the time when he was the Mayor of New York City. He also cited that the Bloomberg Philanthropies is a usual partner of the WHO and the DOH on health-related activities. The Union is one of the umbrella organizations of Bloomberg Foundation (Philanthropies). [22]

The Committee further noted 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. Director General Domingo said that the BIHC of the DOH, for local grants, and the DFA, for international grants, undertake the vetting process of the grant submissions and recipients. He discussed that the BIHC is the agency that reviews and checks all the qualifications of the possible partners before the latter are approved. [23]

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 to the government. Although, he also pointed out the difficulty of determining whether these high-level organizations are not in competition or in competitive companies with the electronic cigarettes.

Representative Marcoleta likewise raised equity consideration related to the ban on essential ingredients of electronic cigarettes and HTPs, including its promotion, while the promotion on tobacco product itself is not banned. Also, he lamented that the tobacco companies are registered with the National Tobacco Administration (**NTA**), the Bureau of Internal Revenue (**BIR**), and the Bureau of Customs (**BOC**), however 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 argued that FDA as a regulatory agency may be capable to undertake its mandate, however, the motive behind the donation should be looked into. [24]

Representative Marcoleta posited that unless FDA can show that the grant from the foreign organization did not attach any conditions that may have influence on 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 queried on how the FDA shall be affected in case a law be passed prohibiting it to receive grants. Director General Domingo replied that if a law shall prohibit the acceptance of grant, then they cannot 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.

Representative Biazon inquired what is the FDA's primordial consideration in line with the Constitution, to which Director General Domingo stated that their primary goal is to protect and promote the health of every Filipino, and to ensure the safety and quality of products that are available in the market, particularly the new ones.

Moreover, Representative Biazon asked whether the FDA has indicated a policy direction 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 stated in its application that they need the

[22] *See* TSN:16 March 2021/RDR/IV-2.
[23] *See* TSN: 16 March 2021/RDR/IV-1.
[24] *See* TSN: 16 March 2021/RDR/IV-4.

funds to develop their regulatory framework. What was required of them was the submission of accomplishments and milestones in the program.

In addition, Rep. Biazon inquired if any FDA official has received personal benefit from the award of the grant, to which Director General Domingo said none because the fund was requested and received by the FDA as an institution. The utilization of the grant was also reviewed by the COA. [25]

Seeking for comment on whether the grant given by Bloomberg falls under the provision of Section 7 of R.A. No. 6713, pertaining to any "gift, gratuity, favor, entertainment, loan or anything of monetary value," Director General Domingo responded that the grant is not a gift, gratuity, favor, entertainment, or loan. He also stated that Bloomberg is not a client which needs to apply for registration with the FDA. Representative Biazon then interjected whether the grant is given to the FDA as an institution, or to any individual. He cited that the subject provision pertains to the individual public officer or employee who receives money for those purposes, to which Director General Domingo replied that the grant accrued to the funds of the FDA, not to any individual. [26]

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. He then pointed out that Bloomberg is not a foreign political party nor officially representing foreign government, cases when registration is required. He then asked if the agenda of the The Union and Bloomberg is political in nature, to which Director General Domingo replied that he did not perceive any political motive therewith. [27]

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 consumers and non-users, which can be exposed to secondhand smoke shall benefit if the subject products are regulated. [28]

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 products stand to gain.

Additionally, Representative Biazon then asked Director General Domingo whether he is familiar with tobacco politics, to which Director General Domingo affirmed. Representative Biazon then asked if the FDA's mandate is also threatened by the influence of the tobacco industry. Director General Domingo replied on the affirmative as he cited that it is a big industry in the country, hence they strictly follow 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 are not applicable to the issues surrounding the receipt of the subject grants, as he cited the mandate of the Committee on malfeasance, misfeasance and nonfeasance of public officials and employees. He urged the Committee to look into the subject provisions of laws that are alleged to have been violated by the FDA. [29]

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[25] *See* TSN: 16 March 2021/RDR/IV-7.
[26] *See* TSN: 16 March 2021/RDR/IV-8.
[27] *See* TSN: 16 March 2021/RDR/IV-9.
[28] *See* TSN: 16 March 2021/RDR/IV-10.
[29] *See* TSN: 16 March 2021/RDR/IV-11.

Representative Alfredo Garbin Jr. manifested that receiving 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 that is independent 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 RA No. 6713, or the Code of Conduct and Ethical Standards for Public Officials and Employees. Asst. Commissioner Ronquillo stated that no law was violated because the receipt of the grant was pursuant to a law. Moreover, Asst. Commissioner Ronquillo noted that RA No. 6713 provides for exceptions such as when the receipt of the grant from international bodies for altruistic and humanitarian purposes. He stated that the grant falls in that exception because it concerns public health, hence is a valid receipt of a grant from a foreign grantor. [30]

Further, Asst. Commissioner Ronquillo said there will be violation of law if the donor shall directly interfere with the formulation of the government's own regulatory policies, which was not the case herein.

For his part, Representative Nograles emphasized the need for the Committee to consider whether FDA, as a regulatory body should be allowed to receive grants from NGOs that are advocates against tobacco. He further noted that in the instant case, The Union and Bloomberg are anti-tobacco. [31]

Moreover, Representative Nograles noted that the FDA has hired multiple Job Order personnel using the funds from the grant, which should be under the mandate of the CSC. He raised 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 the same could be a constitutional violation on the independence of the government. He also noted that FDA has conducted consultations with other groups that are funded by The Union and Bloomberg. He cited his observation that every time an anti-tobacco regulation is issued by the FDA or the DOH, it coincides with grants coming from the Bloomberg, such as when Administrative Order No. 2014-008 was issued in 2014, he said DOH received $ 192,000. [32]

It bears emphasis to note that Representative Nograles argued for the Committee to look into the provisions of 1987 Constitution, which provides for 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 a client which seeks the approval of its license or registration with FDA, the former can still 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. [33]

Meanwhile, Representative Jose Enrique Garcia asked 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 it is their hope that the use of tobacco and other

[30] *See* TSN: 16 March 2021/RDR/IV-12.
[31] *See* TSN: 16 March 2021/RDR/IV-13.
[32] *Ibid*.
[33] *See* TSN: 16 March 2021/RDR/IV-13-14.

harmful substances shall be lessened. Representative Garcia then asked 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 said the smoking prevalence was lessened at the time when the tax for the said products was increased. However, he noted that by the years 2018 to 2019, the prevalence again increased because cigarettes were sold at a cheaper price. He also stated that they expect a decreased 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 a lot of people can still get disease causing death even at 10% prevalence. Director General Domingo stated that they wanted 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 to achieving the goals of the WHO-FCTC and RA No. 9211, to which Director General Domingo replied on the affirmative, citing that the FDA and DOH collaborate with partner organizations that are aligned with their respective goals.

Meanwhile, 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 travels abroad. Director Rivera cited that there was one travel to the Health Science Authority, Singapore but the expenses thereof came from the fund of the BIHC.

During the second Committee hearing, Representative Jericho Nograles urged the Committee to recommend that CSC JMC No. 2010-01 on the Protection of the Bureaucracy Against Tobacco Industry Interference, be struck down as void. He pointed out that the reason for the discrimination against the tobacco industry stems from the issuance of the Joint Memorandum Circular 2010-001 (**JMC**), purportedly between the CSC and the DOH. He then noted the submission of the CSC Commissioner Lizada to the Committee, citing that CSC did not issue any resolution authorizing any person to sign the subject Joint Memorandum Circular. 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, the Commissioner Lizada submitted that the subject JMC is *void ab initio*.

Representative Nograles observed that the 1987 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, or any resolution to that effect, therefore the same should be considered 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 the government personnel.[34]

Representative Savellano also observed that the subject JMC is often invoked to reject any and all forms of interaction of the groups from the tobacco industry with 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, and demanded for the latter to return the said biohazard suits 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 was starting to grip the nation. He then supported the position of Rep. Nograles, which called for the revocation of the JMC.[35]

Notably, Representative Suansing inquired on the model used by the FDA when it developed the draft guidelines for vapor products and HTPs. To which Director Rivera said that the FDA has considered RA No. 11467, as provided under the law and used as reference the regulatory framework of mature organizations, such as the European Union (**EU**), the USA, and Health Canada. However, Director Rivera said that they undertook to consider the conditions and circumstances in the country. Representative Suansing then asked if the groups such as Health Justice Foundation, Inc. and 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 have participated in their public hearings however, FDA did not consider their respective positions, as they called for a total ban. Likewise, there were inconsistencies with other existing regulations as stipulated in Executive Order No. 106 and RA No. 11467. As to whether the FDA had not adopted any part of their proposal, Director Rivera said that FDA has mainly used the terms and concepts of their proposal which are already consistent with the position of the WHO-FCTC and other international organizations. [36]

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. To which, Director Rivera replied that there hardly was coincidence as she cited that the funds have been received in 2018, and it took time for them before they released the Department Order. She added that Administrative Order No. 2020-0055[37], issued on 01 December 2020, was the final issuance of the DOH relating to tobacco, while the project, subject of the grant ended on June 2020. She cited that similar order was issued in 2014[38], however the same was formulated without any funding from relevant institutions. [39]

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[34] See TSN: 09 June 2021/RTP/III-5-6.
[35] See TSN: 09 June 2021/RDR/V-1.
[36] *See* TSN: 09 June 2021/NGO/IV-4.
[37] DOH Administrative Order No. 2020-0055: Regulation on Vapor Products and HTPs under the FDA dated 01 December 2020.
[38] DOH Administrative Order No. 2014-0008: Rules and Regulations on Electronic Nicotine Delivery System (ENDS) or Electronic Cigarettes, dated 12 March 2014.
[39] *See* TSN: 09 June 2021/NGO/IV-9.

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. FDA He added that it is his mandate to protect the tobacco farmers, his constituents in the Ilocos region.

Representative Savellano noted that based on previous communications as well as its public pronouncement, FDA has stated that it will abide by the provisions under R.A. No. 11467, providing for an 18-month transitory period for concerned companies to comply with the requirements under the Implementing Rules and Regulations (IRR). He said it is expected that the FDA shall enforce the regulation on vapor products and HTPs on 24 May 2022.

However, he observed that in FDA's recent Circular No. 2021-010 dated 17 May 2021, FDA now requires the issuance of FDA certification for vapor products and HTPs in the assessment and processing of excise tax collections with the BIR. He then argued that the said Circular contradicts FDA's initial pronouncement that it will not issue any regulation during the 18-month transitory period.

Director Rivera replied that it was not the FDA which issued the subject regulations, rather, it was the BIR that has requested them to assist in the assessment of excise tax for the subject products that arrive in our territory. She referred to the Revenue Regulation, directing the FDA to issue a certification, which shall be the basis for the assessment of excise tax. The role of the FDA relates to the determination of nicotine content. [40]

Under the circular, the FDA certification requires industry players to file applications for each batch of vapor products of HTPs' refills and cartridges. Further, important products must be processed on 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 application for each of their products and refills, for every shipment and batch. He also asked whether the FDA applies similar requirements to other products.

In reply thereto, Director Rivera affirmed that FDA requires batch declaration as it is with other health and pharmaceutical products. [41]

Further, Representative Savellano also raised concern on whether the FDA has consulted with the Department of Trade and Industry (**DTI**) and coordinated with the Bureau of Customs (**BOC**) when it crafted the Circular. He took note that under Section 4 of Executive Order No. 106, the same provides: "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." Hence, he alleged that the FDA has unilaterally issued additional requirements for importation of ENDS/ENNDS products and HTPs, which is in contrast to the provisions of E.O. No. 106.

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

[40] *See* TSN: 09 June 2021/RDR/V-2.
[41] *See* TSN: 09 June 2021/RDR/V-2.

Moreover, Rep. Savellano also sought clarification whether the subject matter of ENDS/ENDDS and HTPs are 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.[42]

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 they have discussed the said JMC, however they are 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. [43]

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 they have conducted several commission meetings on the subject matter, and that she has requested for background information on what has transpired at the time that it was issued. In addition, 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 those of the tobacco industry. [44]

Relevant thereto, Rep. Savellano narrated that in 2011, the Department of Justice (**DOJ**) issued DOJ Opinion No. 28, Series of 2010, regarding Article 5.3 of the WHO-FCTC. "Evidently, while in stressing the fundamental and reconcilable conflict between the interest of the tobacco industry and those of public health policy, does the need of any interaction between the parties, the FCTC and those in the tobacco industry on matters to further the latter's interest to be accountable and transparent. The parties, thereto, the Philippine government included, are not absolutely prohibited or precluded from entering into partnership, with or participating in activities of those in the tobacco industry."

Notably, the issue in regard to the interaction of government personnel with those from the tobacco industry was highlighted during this time of the COVID-19 health pandemic. Representative Rodriguez recalled that the DOH was in receipt of 373 respirators donated by the Lucio Tan group, identified with the tobacco industry. DOH then wrote the CSC to seek guidance whether it is proper for the government to use the subject respirators, considering what was provided for in the subject JMC. Representative Rodriguez then asked Commissioner Lizada what was the reply 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

[42] *Ibid*.
[43] *See* TSN: 09 June 2021/RDR/V-3.
[44] *See* TSN: 09 June 2021/RDR/V-4.

order to respond to the pressing need of the people, as an exemption from the coverage of the JMC. She then moved for the recall of the subject JMC for being defective. [45]

Representative Rodriguez pointed out Commissioner Lizada's letter of 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 that can be found in the CSC that authorized the Chairman 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. [46]

Thereafter, Representative Rodriguez asked where are the 373 respirators, to which Director Soledad Antonio, BIHC of the DOH, replied that upon receipt of the legal opinion from the CSC, the DOH has 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 their reliance to the JMC.

C. THE PARTIES

1) THE FOOD AND DRUG ADMINISTRATION (FDA)

The FDA is 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 embodying the mandate of the FDA to its present structure.

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.

Moreover, the FDA is also tasked to enforce the provisions of Republic Act No. 9211, or The Tobacco Regulation Act of 2003, among other laws. Together with other bureaus under the Health Regulation Team, the FDA Director-General, head of the agency, reports directly to the Office of the DOH Secretary.

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 and quality of products regulated through effective implementation of the national regulatory framework consistent with international best practice.[47]

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.[48]

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[45] *See* TSN: 09 June 2021/RDR/V-5.
[46] *See* TSN: 09 June 2021/RDR/V-6.
[47] FDA Website (https://www.fda.gov.ph/).
[48] *FDA-The Union Agreement (Project Summary)*

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

The DOH holds the over-all technical authority on health as it is national health policy-maker and regulatory institution. The DOH has three 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.[49]

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 the 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 International Union Against Tuberculosis and Lung Disease (The Union). It continues to partner with The Union and Bloomberg Initiative to Reduce Tobacco Use.

Moreover, Vital Strategies shall deliver the grants *programme* for tobacco control with financial assistance from Bloomberg Philanthropies, and grant management from its agent(s).

On 17 November 2017, Vital Strategies assigned The Union to be its agent in the management and monitoring and evaluation of the grant. As its agent, The Union is explicitly authorized to administer and manage the grant with its scope being all function falling under specified clauses of the contract.[50]

Meanwhile, Bloomberg Philanthropies works in five key areas: the arts, education, the environment, government innovation, and public health. Led by Michael Bloomberg, Bloomberg Philanthropies 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.[51]

As embodied in the Agreement, the Bloomberg Initiative (BI) grants program is an important component of the Bloomberg Initiative to reduce tobacco use. Since 2016, with funds from Michael R. Bloomberg, renowned philanthropist, the grants program supports the development and delivery of high-impact tobacco control interventions at the country level.

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.[52]

[49] DOH Website (https://doh.gov.ph/about-us).
[50] *Annex 8, [Agent(s)] FDA- The Union Agreement*
[51] Bloomberg website (https://www.bloomberg.org/about/).
[52] FDA- The Union Agreement; Bloomberg Initiative

4) THE CIVIL SERVICE COMMISSION (CSC)

Republic Act No. 2260, or the Civil Service Act of 1959, as amended, conferred CSC the status of a department. The 1973 Constitution elevated the CSC to 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. With Executive Order No. 292, or the Administrative Code of 1987, the CSC is constitutionally mandated to promote morale, efficiency, integrity, responsiveness, progressiveness, and courtesy in the Civil Service. As provided in the Administrative Code, the CSC is 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.[53]

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 shall deliver a grants *programme* for tobacco control with financial assistance from the Bloomberg Philanthropies, and grant management shall come from its agent(s).

The Agreement has a term of twenty-four (24) months, however it underwent two requests for extension, to continue with project deliverables and commence new activities.

The Maximum Award is at USD $150,430 (One hundred fifty thousand four hundred and thirty US Dollars only).

Also, it was provided under paragraph 3.2 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, thereof, Monitoring and Evaluation, of the Agreement 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)” (the Project) commenced on 1 February 2017, and was concluded on 30 June 2020.

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

Articles 9, 10, 11 and 13 of the WHO-FCTC are reproduced as follows:

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

[53] CSC website (http://www.csc.gov.ph/).

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 should cover all types of tobacco advertising and promotion as well as any sponsorship conducted by the tobacco industry. The comprehensive ban must be put into effect within five years of entry into force of the Convention for each Party, including of a cross-border advertising ban originating from the Party's territory. Parties that are not in a position to provide for a comprehensive ban due to their constitutional principles must apply restrictions.[54]

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 shall include in its discussion the Philippines' being Party to the said international treaty—in particular, the provisions on financial resources that the WHO has made "available" to help the Parties/Country Members gain access to funds in order to facilitate easy compliance to their obligations.

Sections 15 of Article II of the 1987 Constitution of the Republic of the Philippines, 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:

> ***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:

[54] FDA Submission; WHO-FCTC Philippines.

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.

The laws creating the mandate of the FDA, to wit:

1. Section 3, Republic Act No. 9711 or the FDA Act of 2009[55], 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 hereinafter 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

In the same vein, the Implementing Rules and Regulations of the FDA Act, embodied in Department Circular No. 2011-0101, Section 2, General Powers and Functions, paragraph (x) thereof states:

[55] 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".

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, under Section 5 of the same IRR, declares that the Special Regulatory Fund (**SRF**)[56] 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, states the reporting requirement that the FDA needed to accomplish at the end of a fiscal year, as follows:

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, of 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 by reason that the Philippines was 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 of the WHO-FCTC:

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

[56] A 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)

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 RA No. 6713, or the Code of Conduct and Ethical Standards for Public

Officials and Employees[57]; RA No. 3019, or the Anti-Graft and Corrupt Practices Act[58]; and BP 39, or the Foreign Agents Act of 1979.[59]

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 provides the unlawful 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 to request from any agency or official for or in the interest of such foreign principal

[57] 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.
[58] RA No. 3019: Anti-Graft and Corrupt Practices Act was approved on 17 August 1960.
[59] BP 39: "An Act Regulating the Activities and Requiring the Registration of Foreign Agents in the Philippines" was approved on 07 September 1979.

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 involving the laws hereinafter cited:***
   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*, 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.[60]

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.[61]

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".*

[60] *See* TSN: 09 June 2021/IPA/II-7.
[61] *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 said that they would be very grateful if Congress would appropriate a bigger fund so that they shall be able to modernize their laboratory capability and fully implement the FDA Act.[62]

Representative Marcoleta however rejoined that he still sees that it is improper for the FDA to receive funds from an advocacy group, which 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. [63]

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 discussed 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 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, 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).

In addition, Director Rivera emphasized that the Administrative Order was also 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. [64]

[62] *See* TSN:09 June 2021/IPA/II-9.
[63] *Ibid*.
[64] *See* TSN: 09 July 2021/IPA/II-10.

Representative Marcoleta also raised concern on whether the FDA has studied the contribution and impact of the tobacco industry in our economy, including the other sectors that rely on the said industry, and the taxes that have accrued to the national economy.

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 framework, among others.

The Committee noted the observation of Representative Marcoleta that in this kind of situation, the FDA and the DOH had 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*,[65] the Supreme Court ruled that there are two instances by which a public official violates Section 3 (e) of Republic Act No. 3019 in the performance of his 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 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).*[66]

The Committee well noted the arguments of the authors of the Resolution and several Members when they have decried foul 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/ENDDS/ and HTPs. Moreover, the Members look at the receipt of the grant as unfair because the fund shall inevitably counter the use of tobacco and the said novel tobacco products, which is a legitimate industry in the country-- a sizable number of farmers and workers rely on jobs thereon 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 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. The FDA should be reminded that a public office is a public trust. A

[65] *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.
[66] *Garcia vs. Sandiganbayan, 720 SCRA 155, March 26, 2014, supra*

public servant is expected to exhibit, at all times, the highest degree of honesty and integrity and should 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 to the WHO-FCTC, the FDA's policy is for strict regulation on noble tobacco products such as ENDS/ENDDS and HTPs, not to ban.[67]

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 was put to task 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, we also note that under the same treaty, several provisions have included a statement to the effect that the party's obligations stated therein should still be *"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.[68]

Moreover, the FCTC is not a self-executing treaty and necessitates 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 was mandated 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 to consider whether it shall take jurisdiction to settle the said issue given the mandate of the Committee to settle the issue on malfeasance, misfeasance and nonfeasance of public officials and employees.

Section 2, of the 1987 Constitution, in no unclear terms, asserts: *"The Philippines renounces was, 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 as 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 that they are not embodied in statutory enactments. International law refers to the body of rues and principles which governs the relations of nations and their respective peoples in their intercourse with one another.[69]

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

[67] See TSN: 09 June 2021/IPA/II-1, *supra*
[68] 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).
[69] Philippine Constitutional Law, De Leon, 2012 edition.

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]).[70]

Meanwhile, Section 7, of the 1987 Constitution, provides: "The State shall purse 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 1987 Constitution, states that based on the constitutional system, Congress, through legislation, and its upper chamber, the Senate, thru 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 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.[71]

The independent action of a state may be curtailed by its own consent, such as by 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 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 BP 39, or the Foreign Agents Act of 1979.

Section 4 of the 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 stated that when the FDA received the grant from The Union and Bloomberg, the FDA officials have become foreign agents of the latter. Unwittingly, The Union and Bloomberg had been getting advice and obtaining information in the process of the award of the grant to the FDA, hence he argued that the said entities are considered foreign agent who are required to register their activity before the DOJ.

The Committee noted that, upon query by Representative Rodriguez whether the foreign agents have registered with the DOJ as required by the BP 39, Director Rivera stated that she is not particularly privy on the matter although she pointed out that The Union and Bloomberg are recognized international development partners of the DOH.[72]

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[70] 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).
[71] *Ibid*.
[72] *See* TSN: 09 June 2021/IPA/II-2.

This query on whether The Union and Bloomberg are registered with the DOJ, has not been further inquired into, nor the DOJ been invited to shed light nor asked to submit reply on this question of fact. Even granting that they are not registered with the DOJ as required under the law, will their activities in line with the arts, education, the environment, government innovation, and public health be in the nature of “political activity” defined also as any other activity which seeks in any other way influence any agency or official of the Philippine Government, Philippines with respect to the domestic or foreign policies of the Philippines, or within the bounds of “political propaganda”, as provided 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*
>
> *(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 the subject 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 the CSC to hasten 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 collegial action on the part of the CSC. 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 commissioners; the COMELEC, a chairman and six commissioners; and the COA, a chairman and two commissioners. Clearly provided in Sec. 7 is that these three 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.[73]

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; it just so happened that the CSC Chairman at the time JMC No. 2010-01 was issued had come from the DOH.

Aside from being potentially infringing 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 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.

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

It is apparent that the prohibitions contained in the JMC are already covered in 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 prohibited acts and interactions 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,[74] 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.[75]

As correctly put by Representative Marcoleta, unless FDA can show that the grant from foreign organization did not attach any conditions that may have influence on the policy-making function of the agency, there will always be doubt on the intention of the grant. Government agencies with regulatory authority should be totally impartial.

Representative Sharon Garin also pointed out that a government regulatory agency who received grants from an international organization could not go against the advocacy of such grantor. In the case of The Union which is an anti-tobacco organization, FDA could have been influenced by the grantor and come-out with a policy aligned with its advocacy. Director General

[74] *See* TSN: 09 June 2021/RDR/V-5.
[75] *Ibid.*

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 has been 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, study and review of these Job Order personnel were used by FDA in the formulation of its guidelines regulating the tobacco use.

The Committee cannot discount the partiality of these research, study and review of 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 has 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 found and concluded as follows:

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, i.e. The Union to solicit 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. Coupled with 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 their stance, exercised more caution and due diligence in the crafting and introduction of highly contentious policies and particularly those for which no groundwork has been laid out yet, such as in this case. The Committee noted that the tobacco industry may have been unwittingly disadvantaged during the formulation of the policies, rules and regulations concerning tobacco. 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 are no ready standards, rules and procedures yet to lay as bases at the time, hence the apparent confusion and dilemma that have been experienced by the stakeholders. The lack of clear guidelines and information characterized the public hearings, which have later been confounded by the conduct of their consultations through online applications.

3. On the 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 have been duly compliant on the provisions of the said law. While the law may have been 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. What was merely provided was 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 has considered that activity of The Union and Bloomberg may not fall squarely under the nature and concept of what is indeed “political”, nor the organizations, 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 affect the previous ideologies and universal truths that have been the bedrock of civil societies for ages. Hence, it is difficult to run a schism between what is political, and what is not.

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

4. Finally, the Committee finds that the FDA Act may be looked into particularly as to the viability of fund source for research and development purposes in order to fully realize its mandate. The budgetary requirement of said research and development activities may also be looked into during the crafting of the General Appropriations Act.

RECOMMENDATION

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 COA to determine whether or not funding received by the FDA and other government agencies from foreign private organizations were properly utilized and accounted for in accordance with appropriate government regulations and did not redound 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 the 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. A copy of this Committee Report shall be furnished to the DOH, FDA, CSC, COA, and DBM for their information and appropriate action.